



MGBBase

MDS DATA DICTIONARY

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DISCLAIMER:

Note this document may be subject to change at every major release of MDS.

Please note that any data used is completely synthetic and purely for demonstrative purposes.

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MSBASE FOUNDATION LIMITED

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VERSION CONTROL

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| 1.1 | D. Stupar, R. More (MSBase) | Updated Pregnancy & Infant Outcomes Module (EUROCAT) | July 2025 | Revised |

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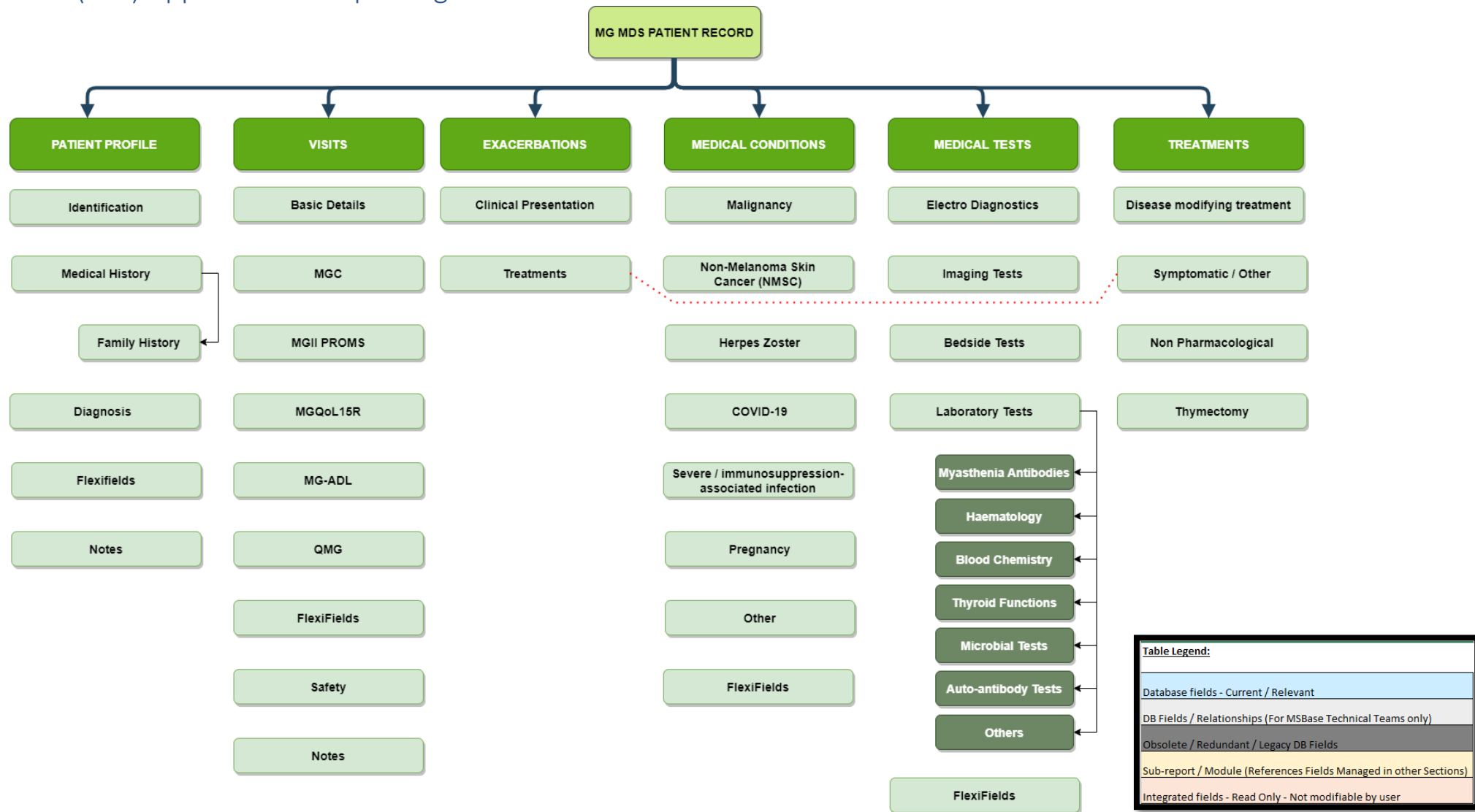
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MDS (MG) App Content Map & Legend



1. PATIENT PROFILE – Patient Identification

1.1 Description

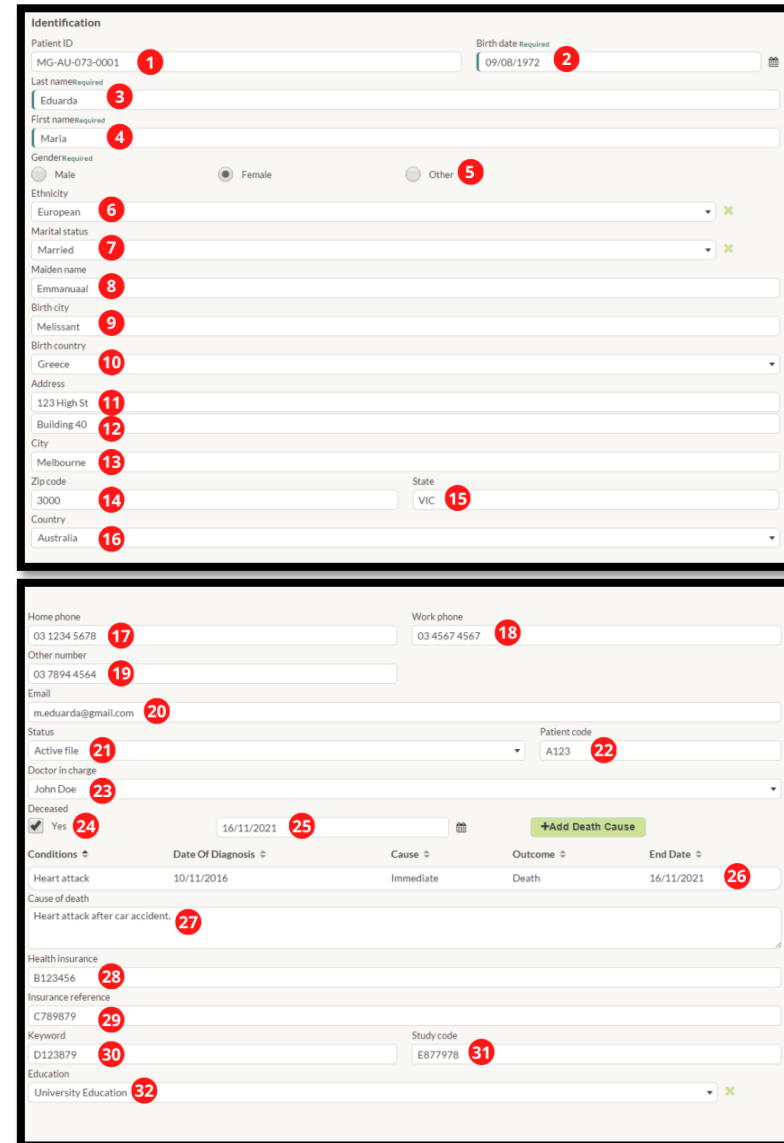
The Identification form captures basic demographic details, for example the Age and Sex and demographic details of the patient.

1.2 Rules and Constraints

- The minimum dataset consists of Last Name, First Name, Gender and Date of Birth.
- Patient cannot be saved unless mandatory fields are populated.
- Patient cannot be saved if there is another patient with the same identical minimum dataset.

1.3 Functions

- Add a patient – You can enter basic information about the patient, once saved, the patient now exists in MDS.
- Edit a patient – You can edit data about the patient.



The screenshot shows the 'Identification' form in MGBase. It is divided into two main sections. The top section contains fields for Patient ID (1), Birth date (2), Last name (3), First name (4), Gender (5), Ethnicity (6), Marital status (7), Maiden name (8), Birth city (9), Birth country (10), Address (11-13), Zip code (14), State (15), and Country (16). The bottom section contains Home phone (17), Work phone (18), Other number (19), Email (20), Status (21), Patient code (22), Doctor in charge (23), Deceased status (24), Date of death (25), a table of conditions (26), Cause of death (27), Health insurance (28), Insurance reference (29), Keyword (30), Study code (31), and University Education (32).

1.4 Patient Identification Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|---|--------------------------------|-----|--|-----------|--|---|------------------|---|
| 1.01 | Patient ID [Patient.GlobalCode] | String [nvarchar] | 100 | MG-CountryCode- CentreCode- PatientNumber, e.g. MG-XX-0000-0000 | Mandatory | | | Y | Read only. Unique, the ID for the patient. Patient Number is determined by current highest number + 1 |
| 1.02 | Birth Date [Patient.BirthDate] | Date [datetime] | | dd/mm/yyyy | Mandatory | Required Duplicate Check | Filtered Today less 100 years to Today | Y | Day set to 1 (Month precision) when sent to Registry |
| 1.03 | Last Name [Patient.LastName] | String [nvarchar] | 50 | | Mandatory | Required Duplicate Check Length | | N | |
| 1.04 | First name [Patient.FirstName] | String [nvarchar] | 50 | | Mandatory | Required Duplicate Check Length | | N | |
| 1.05 | Gender [Patient.Gender] | Radio [int] | | | Mandatory | Required Duplicate Check | Female [1]; Male [0], Other [2] | Y | Biological sex of patient |
| 1.06 | Ethnicity [Patient.EthnicOriginId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from Table EthnicOrigin African; Jewish; Middle-eastern; Admixed; Other; Indigenous; Asian; European; Hispanic; Inuit; Semite | Y | Ethnic origin |
| 1.07 | Marital status [Patient.MaritalStatusId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from Table MaritalStatus Married; De Facto; Separated; Divorced; Widowed; Single (never married) | N | |
| 1.08 | Maiden Name [Patient.MaidenName] | String [nvarchar] | 50 | | Yes | Length Available where Gender = Female | | N | |
| 1.09 | Birth City [Patient.BirthCity} | String [nvarchar] | 20 | | Yes | Length | | Y | Birth city of patient |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|---------------|
| 1.10 | Birth Country [Patient.BirthCountryId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table Country Afghanistan; Albania; Algeria; Andorra; Angola; Argentina; Armenia; Australia; Austria; Azerbaijan; Bahamas; Bahrain; Bangladesh; Barbados; Belarus; Belgium; Belize; Benin; Bermuda; Bhutan; Bolivia; Bosnia And Herzegovina; Botswana; Brazil; Brunei Darussalam; Bulgarie; Burkina Faso; Burundi; Cambodia; Cameroon; Canada; Cape Verde; Central African Republic; Chad; Chile; China; Colombia; Congo; Costa Rica; Cote D'Ivoire; Croatia; Cuba; Cyprus; Czech Republic; Denmark; Djibouti; Dominica; Dominican Republic; East Timor; Ecuador; Egypt; El Salvador; Equatorial Guinea; Eritrea; Estonia; Ethiopia; Finland; France; Gabon; Gambia; Georgia; Germany; Ghana; Gibraltar; Greece; Greenland; Grenada; Guadeloupe; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; Hong Kong; Hungary; Iceland; India; Indonesia; Iran; Iraq; Ireland; Israel; Italy; Jamaica; Japan; Jordan; Kazakhstan; Kenya; Kuwait; Kyrgyzstan; Laos; Latvia; Lebanon; Lesotho; Liberia; Libya; Liechtenstein; Lithuania; Luxembourg; Macedonia; Madagascar; Malawi; Malaysia; Maldives; Mali; Malta; Mauritania; Mauritius; Mexico; Moldova; Monaco; Mongolia; Morocco; Mozambique; Namibia; Nepal; Netherlands; New Caledonia; New Zealand; Nicaragua; Niger; Nigeria; North Korea; Norway; Oman; Pakistan; Palestine; Panama; | Y | Birth country |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|---------------|--|--------------------------------|-----|-------------|----------|------------------|---|------------------|----------------------|
| | | | | | | | Paraguay; Peru; Philippines; Poland; Portugal; Puerto Rico; Qatar; Romania; Russian Federation; Rwanda; Samoa; San Marino; Saudi Arabia; Senegal; Serbia; Seychelles; Sierra Leone; Singapore; Slovakia; Slovenia; Somalia; South Africa; South Korea; Spain; Sri Lanka; Sudan; Suriname; Swaziland; Sweden; Switzerland; Syria; "Taiwan; Republic Of China"; Tajikistan; Tanzania; Thailand; Togo; Tonga; Tunisia; Turkey; Turkmenistan; Uganda; Ukrainian Ssr; United Arab Emirates; United Kingdom; United States; Uruguay; Uzbekistan; Venezuela; Vietnam; Western Sahara; Yemen; Zaire; Zambia; Zimbabwe | | |
| 1.11, 1.12 | Address [Patient.Address_AddressLine1, Patient.Address_AddressLine2] | String [nvarchar] | 50 | | Yes | Length | | N | |
| 1.13 | City [Patient.Address_City] | String [nvarchar] | 50 | | Yes | Length | | N | |
| 1.14 | Zip Code [Patient.Address_ZipCode] | String [nvarchar] | 10 | | Yes | Length | | N | |
| 1.15 | State [Patient.Address_State] | String [nvarchar] | 20 | | Yes | Length | | N | |
| 1.16 | Country [Patient.AddressCountryId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table Country Afghanistan; Albania; Algeria; Andorra; Angola; Argentina; Armenia; Australia; Austria; Azerbaijan; Bahamas; Bahrain; Bangladesh; Barbados; Belarus; Belgium; Belize; Benin; Bermuda; Bhutan; Bolivia; Bosnia And Herzegowina; Botswana; | Y | Country of residence |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|-------|------|-----|-------------|----------|------------------|---|------------------|----------|
| | | | | | | | Brazil; Brunei Darussalam; Bulgarie; Burkina Faso; Burundi; Cambodia; Cameroon; Canada; Cape Verde; Central African Republic; Chad; Chile; China; Colombia; Congo; Costa Rica; Cote D'Ivoire; Croatia; Cuba; Cyprus; Czech Republic; Denmark; Djibouti; Dominica; Dominican Republic; East Timor; Ecuador; Egypt; El Salvador; Equatorial Guinea; Eritrea; Estonia; Ethiopia; Finland; France; Gabon; Gambia; Georgia; Germany; Ghana; Gibraltar; Greece; Greenland; Grenada; Guadeloupe; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; Hong Kong; Hungary; Iceland; India; Indonesia; Iran; Iraq; Ireland; Israel; Italy; Jamaica; Japan; Jordan; Kazakhstan; Kenya; Kuwait; Kyrgyzstan; Laos; Latvia; Lebanon; Lesotho; Liberia; Libya; Liechtenstein; Lithuania; Luxembourg; Macedonia; Madagascar; Malawi; Malaysia; Maldives; Mali; Malta; Mauritania; Mauritius; Mexico; Moldova; Monaco; Mongolia; Morocco; Mozambique; Namibia; Nepal; Netherlands; New Caledonia; New Zealand; Nicaragua; Niger; Nigeria; North Korea; Norway; Oman; Pakistan; Palestine; Panama; Paraguay; Peru; Philippines; Poland; Portugal; Puerto Rico; Qatar; Romania; Russian Federation; Rwanda; Samoa; San Marino; Saudi Arabia; Senegal; Serbia; Seychelles; Sierra Leone; Singapore; Slovakia; Slovenia; Somalia; South Africa; South Korea; Spain; Sri Lanka; Sudan; | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|--------------------------------|-----|-------------|----------|--|---|------------------|-------------------------|
| | | | | | | | Suriname; Swaziland; Sweden; Switzerland; Syria; "Taiwan; Republic Of China"; Tajikistan; Tanzania; Thailand; Togo; Tonga; Tunisia; Turkey; Turkmenistan; Uganda; Ukrainian Ssr; United Arab Emirates; United Kingdom; United States; Uruguay; Uzbekistan; Venezuela; Vietnam; Western Sahara; Yemen; Zaire; Zambia; Zimbabwe | | |
| 1.17 | Home Phone [Patient.HomePhone] | String [nvarchar] | 50 | | Yes | Length max 20 | | N | |
| 1.18 | Work Phone [Patient.WorkPhone] | String [nvarchar] | 50 | | Yes | Length max 20 | | N | |
| 1.19 | Other Number [Patient.OtherNumber] | String [nvarchar] | 50 | | Yes | Length max 20 | | N | |
| 1.20 | Email [Patient.Email] | String [nvarchar] | 100 | | Yes | Validity Length | | N | |
| 1.21 | Status [Patient.Status] | Dropdown [int] | | | Yes | | Active File [2]; Inactive File [1] | Y | Defaults to Active File |
| 1.22 | Patient Code [Patient.PatientCode] | String [nvarchar] | 50 | | Yes | Length | | N | |
| 1.23 | Doctor in charge [Patient.DoctorInCharge] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table User (Centre specific) | N | |
| 1.24 | Deceased [Patient.IsDeceased] | Checkbox [bit] | | | No | | No [0]; Yes [1] | Y | |
| 1.25 | Deceased Date [Patient.DateOfDeath] | Date [datetime] | | dd/mm/yyyy | Yes | Only available if Deceased = Yes Required if Deceased = Yes | Filtered ≥ Date of Birth and ≤ Today | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|------------------------------|-----|-------------|----------|---|--|------------------|---|
| 1.26 | Death Related Cause [FK__MedicalEv__Patie__09FE775D, Relationship 1 to Many, Patient.Id to MedicalEvent.PatientId] | Sub-Report [Relationship] | | | Yes | | | | Captured in Medical Events, aggregated in this view. |
| 1.27 | Cause of Death [Patient.CauseOfDeath] | String [nvarchar] | 50 | | Yes | Only available if Deceased = Yes Length | | Y | |
| 1.28 | Health Insurance [Patient.HealthInsurance] | String [nvarchar] | 20 | | Yes | Length | | N | |
| 1.29 | Insurance Reference [Patient.InsuranceReference] | String [nvarchar] | 20 | | Yes | Length | | N | |
| 1.30 | Keyword [Patient.Keyword] | String [nvarchar] | 50 | | Yes | Length | | N | |
| 1.31 | Study code [Patient.StudyCode] | String [nvarchar] | 20 | | Yes | Length | | N | |
| 1.32 | Education [Patient.Education] | Dropdown [nvarchar] | 20 | | Yes | | Lookup Values from table Education Primary school; Secondary school; University Education; Technical/ Trade College | Y | Education level |
| | [Patient.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [Patient.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [Patient.GlobalId] | Hidden [int] | | | Yes | | | Y | Unique patient id that is the used in the calculation of the Global Code. Used to track what the next id is for creating the Global Code (MSBase Patient ID). |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|------------------------------|-----|-------------|----------|------------------|----------------|------------------|---|
| | [Patient.Id] | Hidden [uniqueidentifier] | | | No | | | Y | Global unique id and assigned on creation |
| | [Patient.IMedFingerprint] | Hidden [nvarchar] | 50 | | Yes | | | Y | Populated when patient data is imported from iMed. Global unique iMed Patient ID |
| | [Patient.IsActive] | Hidden [bit] | | | No | | | Y | No longer used. |
| | [Patient.IsComplete] | Hidden [bit] | | | Yes | | | N | Calculated by – must have 1 visit in past 12 months with MGC and Modified Rankin scores. Must have a diagnosis. |
| | [Patient.IsDeleted] | Hidden [bit] | | | No | | | Y | Set when user deletes the record from Manage All patients. |
| | [Patient.IsEnrolled] | Hidden [bit] | | | No | | | N | Set to 1 when enrolled from Manage All Patients or Patient Details |
| | [Patient.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [Patient.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [Patient.RegistryId] | Hidden [uniqueidentifier] | | | Yes | | | N | Patient ID on registry, set when a patient is synced to registry. |
| | [Patient.RowVersion] | Hidden [bigint] | | | No | | | Y | System managed value to prevent conflicting edits to a record. |
| | [FK_Patient_EthnicOriginId, Relationship 1 to Many, | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|--------------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | EthnicOrigin.Id to Patient.EthnicOriginId] | | | | | | | | |
| | [FK_Patient_MaritalStatusId, Relationship 1 to Many, MaritalStatus.Id to Patient.MaritalStatusId] | Hidden [Relationship] | | | | | | | |
| | [FK_Patient_BirthCo__1EF99443, Relationship 1 to Many, Country.Id to Patient.BirthCountryId] | Hidden [Relationship] | | | | | | | |
| | [FK_Patient__Address__1E05700A, Relationship 1 to Many, Country.Id to Patient.AddressCountryId] | Hidden [Relationship] | | | | | | | |
| | [FK_Patient_EducationId, Relationship 1 to Many, Education.ID to Patient.EducationId] | Hidden [Relationship] | | | | | | | |
| | [FK_Paraclini__Patie__1B29035F, Relationship 1 to Many, Patient.Id to ParaclinicalTest.PatientId] | Hidden [Relationship] | | | | | | | |

2. PATIENT PROFILE – Medical History

Entry in the Clinic

Date Required 1

Referred by 2

History of other autoimmune diseases
 Unknown Yes No 3

Diseases and Medical conditions + Add new Delete 4

| Conditions | Date Of Diagnosis | Treatment Modality | Outcome | End Date |
|--------------|-------------------|--------------------|---------|------------|
| Heart attack | 10/11/2016 | | Death | 16/11/2021 |

Family Disease History +Add new Edit Delete 5 Family MG History ? Yes No 6

| MDS | Relationship | Name | MG | Medical Conditions |
|-----|--------------|------------|----|--|
| ✓ | Brother | Thomas May | ✓ | Myasthenia gravis (13/05/2004 - 14/11/2008) Skin cancer (28/08/1987 - 17/08/1995) |

Remarks 7

Save Cancel

2.1 Description

The Medical History captures information about the patient's medical history and family medical history.

- medical history for patient.
- Enter and Delete Medical Condition – You can add/edit Medical Event and Delete Medical Event.
- Enter and Delete Family History – You can add and remove family member disease history.

2.2 Rules and Constraints

- Medical History for family members does not need to be MS Related.

2.3 Functions

- Enter/Edit Data – You can add and modify diseases and medical conditions for patient and also access the family disease history (medical conditions) if applicable.

2.4 Medical History Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|--------------------------------|-----|-------------|----------|------------------|--|------------------|--|
| 2.01 | Date [PatientMedicalHistory.Date] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today | Y | Defaults to <today> Clinic entry/First Seen |
| 2.02 | Referred by [PatientMedicalHistory.ReferredById] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from Table CareProfessional (Centre specific) | N | |
| 2.03 | History of other autoimmune diseases [PatientMedicalHistory.HistoryOfOtherAutoimmuneDiseases] | Radio [bit] | | | Yes | | Unknown[NULL]; Yes[1]; No[0] | Y | Measure in months |
| 2.04 | Diseases and Medical conditions [FK__MedicalEv__Patie__09FE775D, Relationship 1 to Many, Patient.Id to MedicalEvent.PatientId] [FK__Covid19Event__Id__69279377, Relationship 1 to 1, MedicalEvent.Id to Covid19Event.Id] [FK__FlexiFieldEv__Id__7CA47C3F, Relationship 1 to 1, MedicalEvent.Id to FlexiFieldEvent.Id] [FK__HerpesEvent__Id__7F80E8EA, Relationship 1 to 1, MedicalEvent.Id to HerpesEvent.Id] [FK__Immunoinfect__Id__0169315C, Relationship 1 to 1, MedicalEvent.Id to ImmunoinfectionEvent.Id] [FK__MalignancyEv__Id__090A5324, Relationship 1 to 1, MedicalEvent.Id to MalignancyEvent.Id] [FK__NMSCEvent__Id__147C05D0, Relationship 1 to 1, MedicalEvent.Id to NMSCEvent.Id] [FK__OtherEvent__Id__1A34DF26, Relationship 1 to 1, MedicalEvent.Id to OtherEvent.Id] [FK__PregnancyEve__Id__320C68B7, | Sub-report [Relationships] | | | Yes | | | | Captured in Medical Events, aggregated in this view |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|------------------------------|---------------|-------------|----------|------------------|---------------------------|------------------|---|
| | Relationship 1 to 1, MedicalEvent.Id to PregnancyEvent.Id] | | | | | | | | |
| 2.05 | Family Disease History [FK__FamilyDis__Medic__78D3EB5B, Relationship 1 to Many, PatientMedicalHistory.Id to FamilyDiseaseHistory.MedicalHistoryId] [FK__FamilyDis__FAMIL__79C80F94, Relationship 1 to Many, FamilyDiseaseHistory.Id to FamilyDiseaseHistoryMedicalCondition.FamilyDiseaseHistoryId] | Sub-report | | | Yes | | | Y | |
| 2.06 | Family MG History [PatientMedicalHistory.IsFamilyMgHistory] | Radio [bit] | | | Yes | | No [0]; ? [NULL]; Yes [1] | Y | Defaults to ? Refer to Section Family History |
| 2.07 | Remarks [PatientMedicalHistory.Remarks] | Memo [text] | 2,147,483,647 | | Yes | | | N | |
| | [PatientMedicalHistory.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientMedicalHistory.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientMedicalHistory.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientMedicalHistory.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientMedicalHistory.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientMedicalHistory.RowVersion] | Hidden [bigint] | | | No | | | Y | System managed value to prevent conflicting edits to a record. |
| | [FK__PatientMe__Refer__24B26D99, Relationship 1 to Many, CareProfessional.Id to PatientMedicalHistory.ReferredById] | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|-----------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | [FK__PatientMedic__Id__25A691D2, Relationship 1 to 1 Patient.Id to PatientMedicalHistory.Id] | Hidden [Relationship] | | | | | | | |

3. PATIENT PROFILE - Medical History – Family History

3.1 Description

This Family History form is an important utility to capture familial medical conditions. A family member may already exist in MDS, in which case the family member may be selected from the drop-down list and their details will be pre-populated. However, in the likely scenario that the family member is not in MDS then this data may be entered manually.

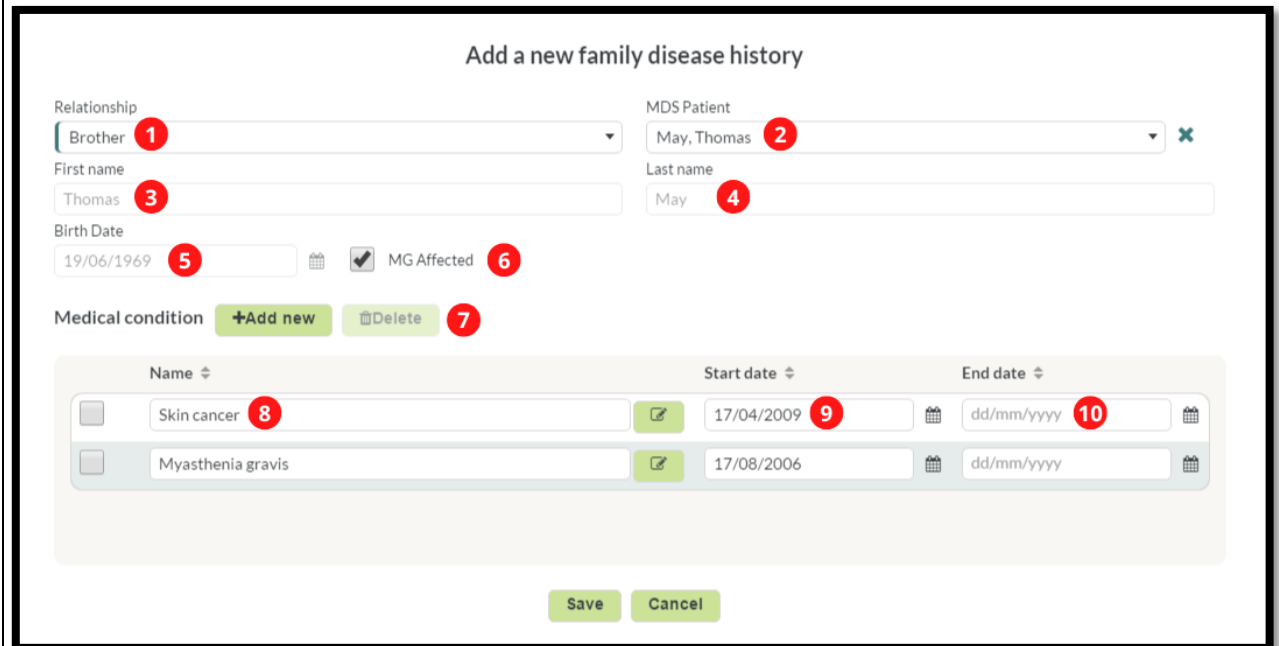
This screen will only appear when initiated from the Medical History page.

3.2 Rules and Constraints

- Relationship type is a mandatory field.

3.3 Functions

- Enter Data – User enters disease and medical history for patient.
- Enter, Edit and Delete Medical Condition – User able to add Medical Event and Delete Medical Event.
- Enter and Delete Family History – User able to add and remove family member disease history.



Add a new family disease history

Relationship: (1) MDS Patient: (2) ✕

First name: (3) Last name: (4)

Birth Date: (5) MG Affected (6)

Medical condition: (7)

| Name | Start date | End date |
|--|---|--|
| <input type="checkbox"/> Skin cancer (8) | <input type="text" value="17/04/2009"/> (9) | <input type="text" value="dd/mm/yyyy"/> (10) |
| <input type="checkbox"/> Myasthenia gravis | <input type="text" value="17/08/2006"/> | <input type="text" value="dd/mm/yyyy"/> |

3.4 Medical History – Family History Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|---|--------------------------------|-----|-------------|----------|------------------|--|------------------|--|
| 3.01 | Relationship [FamilyDiseaseHistory.FamilyRelationshipId] | Dropdown [uniqueidentifier] | | | No | Required | Lookup values from Table FamilyRelationshipType Brother; Children; Daughter; Distant; Dizygotic twin; Father; Monozygotic twin; Mother; Parents; Siblings; Sister; Son; Twins; Other | Y | |
| 3.02 | MDS Patient [FamilyDiseaseHistory.MdsPatientId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from Table Patient (Centre specific) | N | |
| 3.03 | First Name [FamilyDiseaseHistory.FirstName] | String [nvarchar] | 50 | | Yes | Length | | N | Read Only if MDS Patient selected Populates based on Patient selected |
| 3.04 | Last Name [FamilyDiseaseHistory.LastName] | String [nvarchar] | 50 | | Yes | Length | | N | Read Only if MDS Patient selected Populates based on Patient selected |
| 3.05 | Birth Date [FamilyDiseaseHistory.BirthDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered Today less 100 years to Today | Y | Read Only if MDS Patient selected Populates based on Patient selected |
| 3.06 | MG Affected [FamilyDiseaseHistory.MGAffected] | Checkbox [bit] | | | No | | Yes [1]; No [0] | Y | |
| 3.07 | Medical Condition [FK__FamilyDis__Medic__7BB05806, Relationship 1 to Many, MedicalCondition.Id to FamilyDiseaseHistoryMedicalCondition.MedicalConditionId] or [FK__FamilyDiseaseHistoryMedicalCondition__MeddraCondition, Relationship 1 to Many, 1_low_level_term.Ilt_code to FamilyDiseaseHistoryMedicalCondition.MeddraConditionId] | Sub Report [Relationship] | | | No | | Lookup values from table MedicalCondition or MedDRA LLT Please refer to the tab for the Table in the Db Schema file to see the selection options (and associated ids) available for this field. | Y | |
| | [FamilyDiseaseHistory.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | [FamilyDiseaseHistory.IsDeleted] | Hidden [bit] | | | No | | | Y | |
| | [FamilyDiseaseHistory.MedicalHistoryId] | Hidden [uniqueidentifier] | | | | | | Y | |
| | [FK__FamilyDis__Medic__78D3EB5B, Relationship 1 to Many, PatientMedicalHistory.Id to FamilyDiseaseHistory.MedicalHistoryId] | Hidden [Relationship] | | | | | | | |
| | [FK__FamilyDis__FamI__76EBA2E9, Relationship 1 to Many FamilyRelationshipType.Id to FamilyDiseaseHistory.FamilyRelationshipId] | Hidden [Relationship] | | | | | | | |
| | [FK__FamilyDis__MdsPa__77DFC722, Relationship 1 to Many Patient.Id to FamilyDiseaseHistory.MdsPatientId] | Hidden [Relationship] | | | | | | | |

Medical condition sub report

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|---|--|-----|-------------|------------------|------------------|--|------------------|----------|
| 3.08 | Name [FamilyDiseaseHistoryMedicalCondition.MedicalConditionId] or [FamilyDiseaseHistoryMedicalCondition.MeddraConditionId] | Selection Search [uniqueidentifier] or [bigint] | | | Yes or Yes | | Lookup values from table MedicalCondition or 1_low_level_term (MedDRA) Please refer to the tab for the Table in the Db Schema file to see the selection options (and associated ids) available for this field. | N | |
| 3.09 | Start date [FamilyDiseaseHistoryMedicalCondition.StartDate] | Date [datetime] | | dd/mm/yyyy | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|---|------------------------------|-----|-------------|----------|------------------|----------------|------------------|--------------------------------------|
| 3.10 | End date [FamilyDiseaseHistoryMedicalCondition.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | | N | |
| | [FamilyDiseaseHistoryMedicalCondition.CustomMedicalCondition] | Hidden [nvarchar] | 150 | | Yes | | | N | Set by iMed import |
| | [FamilyDiseaseHistoryMedicalCondition.FamilyDiseaseHistoryId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [FamilyDiseaseHistoryMedicalCondition.Id] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [FamilyDiseaseHistoryMedicalCondition.IsDeleted] | Hidden [bit] | | | No | | | N | Set when the user deletes the record |
| | [FK__FamilyDis__Medic__7BB05806, Relationship 1 to Many, MedicalCondition.Id to FamilyDiseaseHistoryMedicalCondition.MedicalConditionId] or [FK__FamilyDiseaseHistoryMedicalCondition_MeddraCondition, Relationship 1 to Many, 1_low_level_term.Ilt_code to FamilyDiseaseHistoryMedicalCondition.MeddraConditionId] | Hidden [Relationship] | | | | | | | |
| | [FK__FamilyDis__FAMIL__79C80F94, Relationship 1 to Many, FamilyDiseaseHistory.Id to FamilyDiseaseHistoryMedicalCondition.FamilyDiseaseHistoryId] | Hidden [Relationship] | | | | | | | |

4. PATIENT PROFILE – Diagnosis

4.1 Description

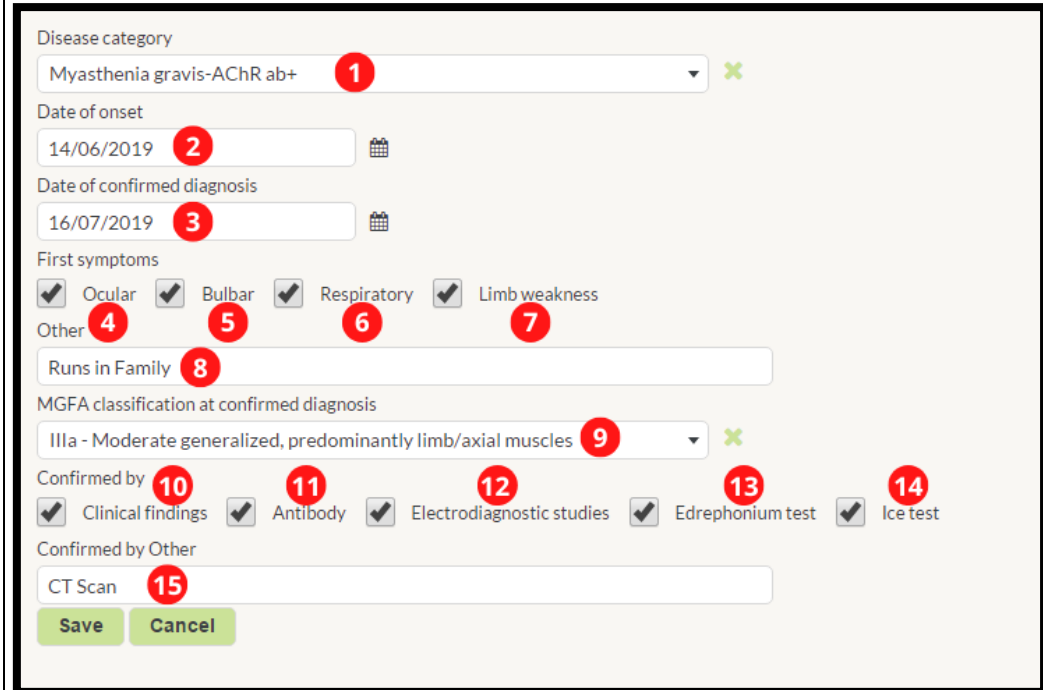
The diagnosis form allows the user to enter information about the MG diagnosis of the patient.

4.2 Rules and Constraints

- Date of confirmed diagnosis must occur after Date of onset

4.3 Functions

- Enter/edit Data – You can enter data about the patient's diagnosis.



The screenshot shows a diagnosis form with the following fields and callouts:

- 1: Disease category dropdown (Myasthenia gravis-AChR ab+)
- 2: Date of onset text input (14/06/2019)
- 3: Date of confirmed diagnosis text input (16/07/2019)
- 4: Ocular checkbox
- 5: Bulbar checkbox
- 6: Respiratory checkbox
- 7: Limb weakness checkbox
- 8: Other text input (Runs in Family)
- 9: MGFA classification at confirmed diagnosis dropdown (IIIa - Moderate generalized, predominantly limb/axial muscles)
- 10: Confirmed by text input (Clinical findings)
- 11: Antibody checkbox
- 12: Electrodiagnostic studies checkbox
- 13: Edrephonium test checkbox
- 14: Ice test checkbox
- 15: Confirmed by Other text input (CT Scan)

4.4 Diagnosis Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|--------------------------------|-----|-------------|----------|------------------|--|------------------|----------|
| 4.01 | Disease category [PatientDiagnosis.DiseaseCategoryId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from table DiseaseCategory Myasthenia gravis-AChR ab+; Myasthenia gravis-MuSKab+; Myasthenia gravis-other ab positive (specify); Myasthenia | y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|--------------------------------|-----|-------------|----------|------------------|--|------------------|----------|
| | | | | | | | gravis-seronegative; Myasthenia gravis- antibody status unknown; LEMS-VGCC ab+; LEMS-seronegative; LEMS- antibody status unknown; Congenital MG-known mutation (specify); Congenital MG- unknown mutation; Not myasthenia (diagnosis revised) | | |
| 4.02 | Date of onset [PatientDiagnosis.DateOfOnset] | Date [datetime] | | dd/mm/yyyy | Yes | | | Y | |
| 4.03 | Date of confirmed diagnosis [PatientDiagnosis.ConfirmedDiagnosisDate] | Date [datetime] | | dd/mm/yyyy | Yes | | | Y | |
| 4.04 | First Symptoms Ocular [PatientDiagnosis.FirstSymptomsOcular] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 4.05 | First Symptoms Bulbar [PatientDiagnosis.FirstSymptomsBulbar] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 4.06 | First Symptoms Respiratory [PatientDiagnosis.FirstSymptomsRespiratory] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 4.07 | First Symptoms Limb weakness [PatientDiagnosis.FirstSymptomsLimbWeakness] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 4.08 | First Symptoms Other [PatientDiagnosis.FirstSymptomsOther] | String [nvarchar] | 40 | | Yes | Length | | Y | |
| 4.09 | MGFA classification at confirmed diagnosis [PatientDiagnosis.MGFAClassificationAtDiagnosisId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from table MGFAClassificationAtDiagnosis CSR - No symptoms, no signs (except eye closure), no MG treatment 1 year; PR - No symptoms, no signs (except eye closure), no symptomatic MG therapy; I – Ocular; IIa - | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|-------------------|-----|-------------|----------|------------------|--|------------------|----------|
| | | | | | | | Mild generalized, predominantly limb/axial muscles; IIb - Mild generalized, predominantly oropharyngeal/respiratory muscles; IIIa - Moderate generalized, predominantly limb/axial muscles; IIIb - Moderate generalized, predominantly oropharyngeal/respiratory muscles; IVa - Severe generalized, predominantly limb/axial muscles; IVb - Severe generalized, predominantly oropharyngeal/respiratory muscles (feeding tube); V - Intubation; MM - No symptoms nor limitations, minor weakness found on exam; MM-0 - No symptoms, exam=MM, no MG treatment 1 year; MM-1 - No symptoms, exam=MM, some immunosuppression, no symptomatic therapy >1year; MM-2 - No symptoms, exam=MM, only MG treatment <120mg pyridostigmine/day; MM-3 - No symptoms, exam=MM, symptomatic and immunosuppression therapies in past year | | |
| 4.10 | Confirmed by Clinical Findings [PatientDiagnosis.ConfirmedByClinicalFindings] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|------------------------------|-----|-------------|----------|------------------|-------------------|------------------|--|
| 4.11 | Confirmed by Antibody [PatientDiagnosis.ConfirmedByAntibody] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 4.12 | Confirmed by Electrodiagnostic studies [PatientDiagnosis.ConfirmedByElectrodiagnosticStudies] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 4.13 | Confirmed by Edrephonium test [PatientDiagnosis.ConfirmedByEdrephoniumTest] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 4.14 | Confirmed by Ice test [PatientDiagnosis.ConfirmedByIceTest] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 4.15 | Confirmed By Other [PatientDiagnosis.ConfirmedByOther] | String [nvarchar] | 50 | | Yes | Length | | Y | |
| | [PatientDiagnosis.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientDiagnosis.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientDiagnosis.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientDiagnosis.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientDiagnosis.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientDiagnosis.RowVersion] | Hidden [bigint] | | | No | | | Y | System managed value to prevent conflicting edits to a record. |
| | [FK__PatientDiagn__Id__1FEDB87C, Relationship 1 to 1 Patient.Id to PatientDiagnosis.Id] | Hidden [Relationship] | | | | | | | |
| | [FK_PatientDiagnosis_DiseaseCategoryId, Relationship 1 to Many] | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|-----------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | DiseaseCategory.Id to PatientDiagnosis.DiseaseCategoryId] | | | | | | | | |
| | [FK_PatientDiagnosis_MGFAClassificationAtDiagnosisId, Relationship 1 to Many MGFAClassificationAtDiagnosis.Id to PatientDiagnosis.MGFAClassificationAtDiagnosisId] | Hidden [Relationship] | | | | | | | |

5. PATIENT PROFILE - Flexifields

5.1 Description

Flexifields that have been created can be found in the Patient Profile Flexifield section. By default, the Centre Flexifields will be shown.

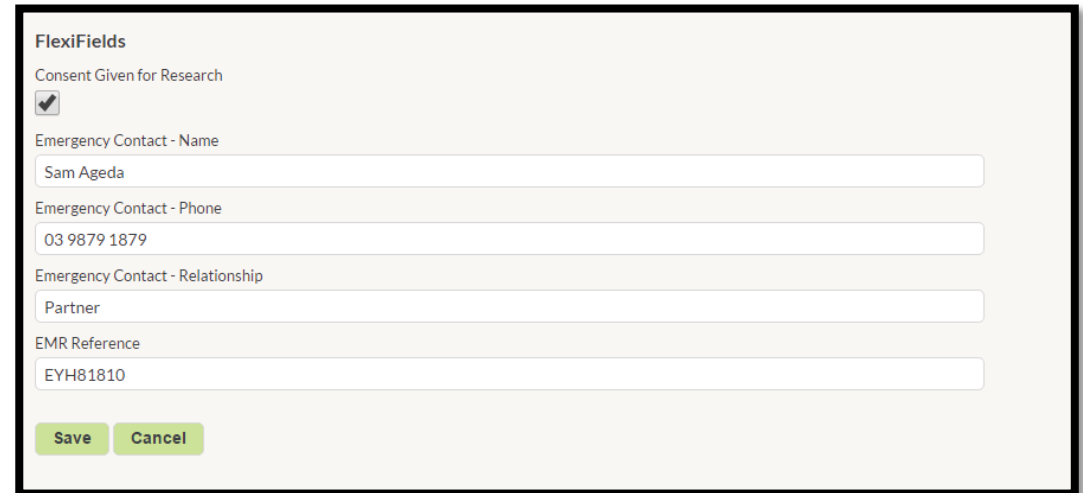
If the patient belongs to a sub-study where flexifields have been added, then they will also appear in this section as an additional tab. For further information refer to the User Guide.

5.2 Rules and Constraints

- Flexifields must be specified in the Preferences.
The types of flexifields that can be specified are:
 - Text
 - Numeric
 - Date
 - Text Area
 - Dropdown
 - Checkbox
 - Header

5.3 Functions

- Enter/Edit Data – You can enter data into Flexifields.



FlexiFields

Consent Given for Research

Emergency Contact - Name
Sam Ageda

Emergency Contact - Phone
03 9879 1879

Emergency Contact - Relationship
Partner

EMR Reference
EYH81810

5.4 Patient Flexifield Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|------------------------------|------|-------------|----------|------------------|---|------------------|--|
| | FlexiField Name [FlexiField.Name] | Field Label | | | | | | N | |
| | FlexiField Value [PatientFlexiField.Value] | String [nvarchar] | 1000 | | Yes | | Allowed values will depend on the type of flexifield. Dropdown lists comes from [FlexiFieldOption.Value] | N | |
| | [PatientFlexiField.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [PatientFlexiField.CreatedUtcDate] | Hidden [datetime] | | | No | | | N | |
| | [PatientFlexiField.FieldId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [PatientFlexiField.Id] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [PatientFlexiField.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [PatientFlexiField.ModifiedUtcDate] | Hidden [datetime] | | | No | | | N | |
| | [PatientFlexiField.PatientId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [PatientFlexiField.RowVersion] | Hidden [bigint] | | | No | | | N | System managed value to prevent conflicting edits to a record. |
| | [FK_PatientFI_Patie__21D600EE, Relationship 1 to 1 Patient.Id to PatientFlexiField.PatientId] | Hidden [Relationship] | | | | | | | |
| | [FK_PatientFI_Field__20E1DCB5, Relationship many to many FlexiField.Id to PatientFlexiField.FieldId] | Hidden [Relationship] | | | | | | | |

Notes:

- Table PatientFlexiField contains the value that is entered for flexifields from the Patient Profile Flexifields screen in MDS
- Table FlexiField contains the definition of the flexifields, i.e., Name and Data Type
- Table FlexiFieldOptions contains the values defined for flexifields where type is a dropdown

6. PATIENT PROFILE – Notes

6.1 Description

The Notes section allows the user to enter general notes about the patient, upload documents and provide links to WWW resources. **None of this data is sent to the MGBase Registry.**

6.2 Rules and Constraints

- Documents to be copied from origin directory to shared network location.

6.3 Functions

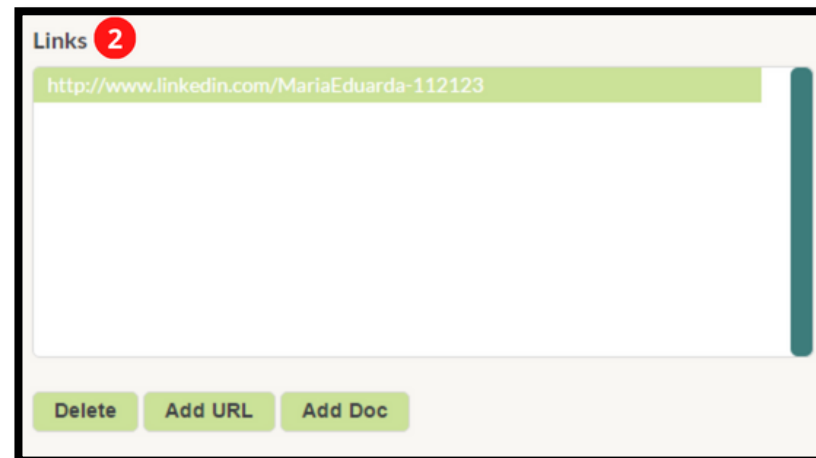
- Enter Data - User enters general notes about the patient.
- Add Link - User links to local document, this document is then copied to shared area so that other users have it available.
- Add URL - User links to WWW resources. The link is active, and no downloading of the site occurs.



Notes **1**

Working full time, contact after hours.

Save Cancel



Links **2**

<http://www.linkedin.com/MariaEduarda-112123>

Delete Add URL Add Doc

6.4 Notes Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|---------------|-------------|----------|------------------|------------------|------------------|--|
| 6.1 | Notes [Patient.Notes] | Text area [text] | 2,147,483,647 | | Yes | | | Y | |
| 6.2 | Links [PatientLink.Value] | String [nvarchar] | 100 | | No | | | N | Buttons on screen: Add URL Add Doc Delete |
| | [PatientLink.Id] | Hidden [uniqueidentifier] | | | No | | Url [0], Doc [1] | N | |
| | [PatientLink.LinkType] | Hidden [int] | | | No | | | N | |
| | [PatientLink.PatientId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [FK_PatientLi_Patie_22CA2527, Relationship 1 to many Patient.Id to PatientLink.PatientId] | Hidden [Relationship] | | | | | | | |

7. VISITS – Basic Details

7.1 Description

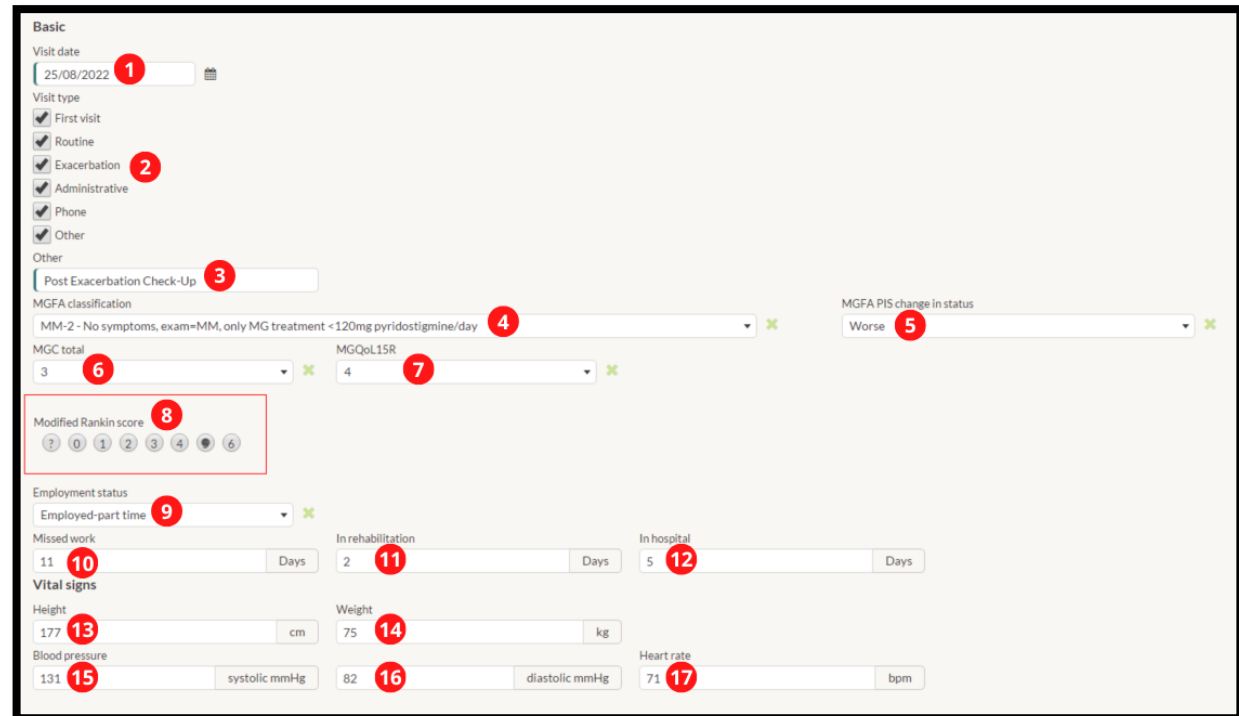
The Visits section captures the status of the patient on a specific date. A patient can have many Visits.

7.2 Rules and Constraints

- Visit date must be after date of birth, and prior to date of death. New Visit cannot be created if patient is marked as deceased.
- Visit Type is required
- MGC score is pulled through from MGC Tab (if score exists in that tab) but can be overwritten in the Basic tab by the clinician.
- **MGC** and **MRS** (Modified Rankin Score) are part of the minimum dataset and should be captured at bi-annual intervals at minimum.

7.3 Functions

- Create 1 or more visits
- Delete 1 or more visits
- Enter/edit data – You can enter/edit data about the visit



The screenshot shows the 'Basic' tab of the MGBase data entry form. The fields are numbered as follows:

- 1: Visit date (25/08/2022)
- 2: Visit type checkboxes (First visit, Routine, Exacerbation, Administrative, Phone, Other)
- 3: Other text field (Post Exacerbation Check-Up)
- 4: MGFA classification dropdown (MM-2 - No symptoms, exam=MM, only MG treatment <120mg pyridostigmine/day)
- 5: MGFA PIS change in status dropdown (Worse)
- 6: MGC total dropdown (3)
- 7: MGQoL15R dropdown (4)
- 8: Modified Rankin score (0-6) with a red box around the input area
- 9: Employment status dropdown (Employed-part time)
- 10: Missed work (11 Days)
- 11: In rehabilitation (2 Days)
- 12: In hospital (5 Days)
- 13: Height (177 cm)
- 14: Weight (75 kg)
- 15: Blood pressure - systolic (131 mm-Hg)
- 16: Blood pressure - diastolic (82 mm-Hg)
- 17: Heart rate (71 bpm)

7.4 Basic Details Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|--------------------------------|-----|-------------|----------|---|--|------------------|---|
| 7.01 | Visit Date [PatientVisit.DateOfVisit] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | | Y | Defaults to today's date |
| 7.02 | Visit Type [PatientVisitVisitType.VisitTypeId] | Checkbox [bit] | | | No | A visit type is required | Lookup values from table VisitType First visit; Routine; Exacerbation; Administrative; Phone; Other | Y | Displays as a list of checkboxes. Records saved in PatientVisitVisitType table based on types selected. |
| 7.03 | Other [PatientVisit.PurposeOther] | String [nvarchar] | 40 | | Yes | Required if Visit Type – Other selected | | N | |
| 7.04 | MGFA classification [PatientVisit.MGFAClassificationId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from table MGFAClassification CSR - No symptoms, no signs (except eye closure), no MG treatment 1 year; PR - No symptoms, no signs (except eye closure), no symptomatic MG therapy; MM-0 - No symptoms, exam=MM, no MG treatment 1 year; MM-1 - No symptoms, exam=MM, some immunosuppression, no symptomatic therapy >1year; MM-2 - No symptoms, exam=MM, only MG treatment <120mg pyridostigmine/day; MM-3 - No symptoms, exam=MM, symptomatic and immunosuppression therapies in past year; I – Ocular; IIa - Mild generalized, predominantly limb/axial muscles; IIb - Mild generalized, predominantly oropharyngeal/respiratory muscles; IIIa - Moderate generalized, predominantly limb/axial muscles; IIIb - Moderate generalized, predominantly oropharyngeal/respiratory muscles; IVa - Severe generalized, | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|---|--------------------------------|-----|-------------|----------|------------------|--|------------------|---|
| | | | | | | | predominantly limb/axial muscles; IVb - Severe generalized, predominantly oropharyngeal/respiratory muscles (feeding tube); V – Intubation; MM - No symptoms nor limitations, minor weakness found on exam | | |
| 7.05 | MGFA PIS change in status [PatientVisit.MGFAPISChangeStatus] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from table MGFAPISChangeStatus Improved; Unchanged; Worse; Exacerbation; Died of MG | Y | |
| 7.06 | MGC total [PatientVisitMGC.CalculatedScore] | Dropdown [int] | | | Yes | | Selection options 0 to 50 | Y | Selection on this screen will overwrite the calculated total. |
| 7.07 | MGQoL15R [PatientVisitMGQoL15R.CalculatedScore] | Dropdown [int] | | | Yes | | Selection options 0 to 30 | Y | Selection on this screen will overwrite the calculated total. |
| 7.08 | Modified Rankin score [PatientVisit.ModifiedRankinScore] | Radio [int] | | | Yes | | ?[NULL],0; 1; 2; 3; 4; 5; 6 | Y | |
| 7.09 | Employment Status [PatientVisit.EmploymentStatusId] | Dropdown [int] | | | Yes | | Lookup values from table EmploymentStatus Employed-part time; Employed-full time; Retired; Student; Unemployed; Home-maker | Y | |
| 7.10 | Days missed work [PatientVisit.DaysMissedWork] | Number [decimal] | | NNN.NN | Yes | | | Y | |
| 7.11 | Days in rehabilitation [PatientVisit.DaysRehabilitation] | Number [decimal] | | NNN.NN | Yes | | | Y | |
| 7.12 | Days in hospital [PatientVisit.DaysHospital] | Number [decimal] | | NNN.NN | Yes | | | Y | |
| | Vital signs | Section Header | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|------------------------------|-----|-------------|----------|------------------|----------------|------------------|--------------------------------------|
| 7.13 | Height (cm) [PatientVisit.Height] | Number [decimal] | | NNN | Yes | | | Y | |
| 7.14 | Weight (kg) [PatientVisit.Weight] | Number [decimal] | | NNNNNN | Yes | | | Y | |
| 7.15 | Blood Pressure – Systolic mmHg [PatientVisit.BloodPressureSystolic] | Number [int] | | NNN | Yes | | | Y | |
| 7.16 | Blood Pressure – Diastolic mmHg [PatientVisit.BloodPressureDiastolic] | Number [int] | | NNN | Yes | | | Y | |
| 7.17 | Heart rate (bpm) [PatientVisit.HeartRate] | Number [int] | | NNN | Yes | | | Y | |
| | [PatientVisit.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisit.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisit.ExaminedById] | Hidden [uniqueidentifier] | | | Yes | | | N | |
| | [PatientVisit.FirstVisit] | Hidden [bit] | | | No | | | Y | |
| | [PatientVisit.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisit.IsDeleted] | Hidden [bit] | | | No | | | Y | Set when the user deletes the record |
| | [PatientVisit.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisit.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|-----|-------------|----------|------------------|----------------|------------------|--|
| | [PatientVisit.RowVersion] | Hidden [bigint] | | | No | | | Y | System managed value to prevent conflicting edits to a record. |
| | [PatientVisit.PatientId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__PatientVi__Patie__2A6B46EF, Relationship 1 to Many, Patient.Id to PatientVisit.PatientId] | Hidden [Relationship] | | | | | | | |
| | [FK__PatientVi__Emplo__7E57BA87, Relationship 1 to Many, EmploymentStatus.Id to PatientVisit.EmploymentStatusId] | Hidden [Relationship] | | | | | | | |
| | [FK__PatientVi__Exami__297722B6, Relationship 1 to Many, User.Id to PatientVisit.ExaminedById] | Hidden [Relationship] | | | | | | | |
| | [FK__PatientVi__MGFAC__004002F9, Relationship 1 to Many, MGFAClassification.Id to PatientVisit.MGFAClassificationId] | Hidden [Relationship] | | | | | | | |
| | [FK__PatientVi__MGFAP__01342732, Relationship 1 to Many, MGFAPISChangeStatus.Id to PatientVisit.MGFAPISChangeStatusId] | Hidden [Relationship] | | | | | | | |
| | [FK__PatientVisit__Id__7D63964E, Relationship 1 to 1, PatientVisit.Id to PatientVisitMGC.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__PatientVisit__Id__7A8729A3, Relationship 1 to 1, | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|--------------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | PatientVisit.Id to PatientVisitMGQoL15R.Id] | | | | | | | | |
| | [FK__PatientVi__Patie__0504B816, Relationship 1 to Many, PatientVisit.Id to PatientVisitVisitType.PatientVisitId] | Hidden [Relationship] | | | | | | | |
| | [FK__PatientVi__Visit__05F8DC4F, Relationship 1 to Many, VisitType.Id to PatientVisitVisitType.VisitTypeId] | Hidden [Relationship] | | | | | | | |

8. VISITS – MGC

8.1 Description

This tab presents the MGC (Myasthenia Gravis Composite scale)

8.2 Functions

- This tab can be used to select a value for each of the relevant symptoms or impairments.
- The total is calculated based on all the selected values.
- The MGC total automatically pulls through to the Basic Visit tab for that specific Visit but can be overwritten by the clinician.

| MGC | | |
|--------------------|--|---|
| Ptosis | 1 (1) Between 11 - 45 seconds | X |
| Diplopia | 2 (3) Between 1-10 seconds | X |
| Eye Closure | 3 (0) Mild weakness (can be forced open with effort) | X |
| Talking | 4 (4) Constant slurring or nasal but can be understood | X |
| Chewing | 5 (2) Fatigue with solid food | X |
| Swallow | 6 (5) Frequent trouble swallowing e.g. necessitating change in diet | X |
| Breathing | 7 (2) Shortness of breath with exertion | X |
| Neck Weakness | 8 (1) Mild weakness | X |
| Shoulder Abduction | 9 (2) Mild weakness | X |
| Hip Flexion | 10 (4) Moderate weakness (ie ~50% weak) | X |
| TOTAL | 11 24 | X |

8.3 MGC Data Fields

Note: the value in () is the score for that option and value in [] is the identifier stored in the database for that option.

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|-------------------|-----|-------------|----------|------------------|--|------------------|----------|
| 8.01 | Ptosis [PatientVisitMGC.PtosisScore] | Dropdown [int] | | | Yes | | (0) Normal or >45 seconds[0]; (1) Between 11 - 45 seconds[1]; (2) Between 1-10 seconds[2] (3) Immediate[3] | Y | |
| 8.02 | Diplopia [PatientVisitMGC.DiplopiaScore] | Dropdown [int] | | | Yes | | (0) Normal or >45 seconds[0]; (1) Between 11 - 45 seconds[1]; (3) Between 1-10 seconds[2]; (4) Immediate [3] | Y | |
| 8.03 | Eye Closure [PatientVisitMGC.EyeClosureScore] | Dropdown [int] | | | Yes | | (0) Normal[0]; (0) Mild weakness (can be forced open with effort)[1]; (1) Moderate weakness (can be forced open easily)[2]; (2) Severe weakness (unable to keep eyes closed)[3] | Y | |
| 8.04 | Talking [PatientVisitMGC.TalkingScore] | Dropdown [int] | | | Yes | | (0) Normal[0]; (2) Intermittant slurring or nasal speech[1]; (4) Constant slurring or nasal but can be understood[2]; (6) Difficult to understand speech[3] | Y | |
| 8.05 | Chewing [PatientVisitMGC.ChewingScore] | Dropdown [int] | | | Yes | | (0) Normal[0]; (2) Fatigue with solid food[1]; (4) Fatigue with soft food[2]; (6) Gastric tube[3] | Y | |
| 8.06 | Swallow [PatientVisitMGC.SwallowScore] | Dropdown [int] | | | Yes | | (0) Normal[0]; (2) Rare episode of choking or trouble swallowing[1]; (5) Frequent trouble swallowing e.g. | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| | | | | | | | necessitating change in diet[2]; (6) Gastric tube[3]" | | |
| 8.07 | Breathing [PatientVisitMGC.BreathingScore] | Dropdown [int] | | | Yes | | (0) Normal[0]; (2) Shortness of breath with exertion[1] (4) Shortness of breath at rest[2]; (9) Ventilator dependence[3] | Y | |
| 8.08 | Neck Weakness [PatientVisitMGC.NeckWeaknessScore] | Dropdown [int] | | | Yes | | (0) Normal[0]; (1) Mild weakness[1]; (3) Moderate weakness (ie ~50% weak)[2]; (4) Severe weakness[3] | Y | |
| 8.09 | Shoulder Abduction [PatientVisitMGC.ShoulderAbductionScore] | Dropdown [int] | | | Yes | | (0) Normal[0]; (2) Mild weakness[1]; (4) Moderate weakness (ie ~50% weak)[2]; (4) Severe weakness[3] | Y | |
| 8.10 | Hip Flexion [PatientVisitMGC.HipFlexionScore] | Dropdown [int] | | | Yes | | (0) Normal[0]; (2) Mild weakness[1]; (4) Moderate weakness (ie ~50% weak)[2]; (4) Severe weakness[3] | Y | |
| 8.11 | TOTAL [PatientVisitMGC.CalculatedScore] | Dropdown [int] | | | Yes | | 0 to 50 | Y | Calculated but can be manually overridden. |
| | [PatientVisitMGC.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMGC.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisitMGC.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|-----|-------------|----------|------------------|----------------|------------------|--|
| | [PatientVisitMGC.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMGC.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisitMGC.RowVersion] | Hidden [bigint] | | | No | | | Y | System managed value to prevent conflicting edits to a record. |
| | [FK__PatientVisit__Id__7D63964E, Relationship 1 to 1, PatientVisit.Id to PatientVisitMGC.Id] | Hidden [Relationship] | | | | | | | |

9. VISITS – MGII PROMS

9.1 Description

This tab presents the MGII PROMS (Myasthenia Gravis Impairment Index, Patient Reported Outcome Measures) tab with relevant questions and values which can be selected and filled.

9.2 Rules and Constraints

- The total is calculated based on all selected responses (values) from all the sections.
- MGII PROMS is not mandatory but if used, ideally should be completed at least annually.

9.3 Functions

- Each section can be completed separately (Eyes | Eating | Speaking and Breathing | Generalised Symptoms)
- Clinician is able to navigate between any of the sections in order to complete selected questions pertaining to the patient record.

MGII PROMS

Eyes | Eating | Speaking and Breathing | Generalised Symptoms

Eyes

Double vision
 Double vision during the day
 Have you experienced episodes of double vision? If yes, at what time do they occur (on average)?

(1) Episodes only in the evenings **1** ✕

Double vision with activities
 Have you experienced double vision with activities such as reading, driving, watching TV or using a computer? If yes, how long does it take (on average) before the double vision occurs?

(2) After less than 1 hour, but not immediately **2** ✕

Severity of double vision
 Have you experienced double vision? If yes, how severe has it been (at your worst)?

(1) Mild: It doesn't affect my daily activities **3** ✕

Eyelids

Eyelid drooping throughout the day
 Have you experienced drooping of your eyelid(s)? If yes, when does it occur (on average)?

(2) Drooping starts in the afternoons **4** ✕

Eyelid drooping with activities
 Have you experienced drooping of your eyelid(s) with activities such as reading, driving, watching TV or using a computer? If yes, how long does it take (on average) before the drooping occurs?

(1) After more than 1 hour **5** ✕

Severity of eyelid drooping
 Have you experienced drooping of your eyelids? If yes, how severe has it been (at your worst)?

(2) It affects my vision, but no need to lift my eyelid **6** ✕

TOTAL 9

Eyes | **Eating** | Speaking and Breathing | Generalised Symptoms

Eating

Problems eating

Difficulty swallowing
 Have you had difficulty swallowing? How difficult has it been?

(4) Unable to swallow or using a feeding tube **7** ✕

Chewing different types of food
 Have you experienced chewing? How severe has it been (at your worst)?

(2) Difficulty chewing soft foods (e.g: hard boiled egg) **8** ✕

Chewing tiredness/fatigue
 At your worst, how long does it take to develop fatigue or tiredness in your jaw?

(1) Difficulty chewing at the end of the meal **9** ✕

TOTAL 23

Eyes **Eating** **Speaking and Breathing** **Generalised Symptoms**

Speaking and Breathing
Please answer regarding the past 2 weeks

Voice changes during the day
Have you experienced episodes of nasal, hoarse or weak voice? When do they occur (on average)?

(1) Voice changes only in the evenings **10** ✕

Voice changes with prolonged conversation
How long can you talk (on average)? How severe has it been (at your worst)?

(1) Voice changes after more than 30 minutes **11** ✕

Severity of voice changes
At your worst, how severe have your voice changes been? (Nasal, hoarse, weak voice)

(1) Mild changes: my voice is mostly clear **12** ✕

Speech clarity during day
Have you experienced difficulty pronouncing words or slurred speech? When does it occur on average?

(0) No episodes of slurred speech **13** ✕

Speech clarity with prolonged conversation
How long can you talk (on average), before developing slurred speech? (Normal conversation, with pauses for other speakers)

(1) Slurred speech after 30 minutes **14** ✕

Severity of speech changes
At your worst, how severe have your speech changes been? (Slurring, difficulty pronouncing words)

(0) No episodes of slurred speech **15** ✕

Difficulty breathing
Have you experienced shortness of breath that is caused by myasthenia? (i.e. not caused by asthma, or other lung/heart disease) If yes, when has it occurred (at your worst)?

(3) At rest or when lying on my back **16** ✕

TOTAL 23

Eyes **Eating** **Speaking and Breathing** **Generalised Symptoms**

Generalised Symptoms
Please answer regarding the past 2 weeks

Overall physical tiredness
Have you experienced overall physical tiredness caused by myasthenia gravis? (i.e. not by sleeplessness, depression or other medical conditions)

(0) No physical tiredness **17** ✕

Arm weakness severity
Have you experienced weakness in your arms? If yes, how severe has it been (at your worst)?

(1) Mild weakness (e.g. difficulty lifting heavy objects) **18** ✕

Arm weakness with prolonged use
Have you experienced weakness in your arms after prolonged use? When does it happen (on average)?

(0) No arm weakness **19** ✕

Leg weakness severity
Have you experienced weakness in your legs? If yes, how severe has it been (at your worst)?

(0) No leg weakness **20** ✕

Leg weakness with prolonged use
Have you experienced weakness in your legs after prolonged use? When does it happen (on average)?

(2) Weakness when walking less than 10 blocks at my own pace **21** ✕

Neck weakness
Have you experienced weakness in your neck? When does it happen (on average)?

(2) Weakness starting in the afternoons **22** ✕

TOTAL 28

9.4 MGII PROMS Data Fields

Note: the value in () is the score for that option and value in [] is the identifier stored in the database for that option.

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|---|-------------------|-----|-------------|----------|------------------|--|------------------|----------|
| | Eyes | Heading | | | | | | | |
| | Double Vision | Sub-Heading | | | | | | | |
| 9.01 | Double vision during the day [PatientVisitMgiiProms.DoubleVisionDay] | Dropdown [int] | | | Yes | | (0) No Double Vision[0]; (1) Episodes only in the evenings[1]; (2) Episodes starting in the afternoons[2]; (3) Constant or present most of the day[3] | Y | |
| 9.02 | Double vision with activities [PatientVisitMgiiProms.DoubleVisionActivities] | Dropdown [int] | | | Yes | | (0) No Double Vision[0]; (1) After more than 1 hour[1]; (2) After less than 1 hour, but not immediately[2]; (3) Constant double vision or it starts immediately[3] | Y | |
| 9.03 | Severity of double vision [PatientVisitMgiiProms.DoubleVisionSeverity] | Dropdown [int] | | | Yes | | (0) No Double Vision[0]; (1) Mild: It doesn't affect my daily activities[1]; (2) It affects my activities, but no need to cover one eye[2]; (3) I need to cover one eye to be able to function[3] | Y | |
| | Eyelids | Sub-Heading | | | | | | | |
| 9.04 | Eyelid drooping throughout the day [PatientVisitMgiiProms.EyeLidDroopingDay] | Dropdown [int] | | | Yes | | (0) No Eyelid Drooping[0]; (1) Only in the evenings[1]; (2) Drooping starts in the afternoons[2]; (3) Constant drooping or present most of the day[3] | Y | |
| 9.05 | Eyelid drooping with activities [PatientVisitMgiiProms.EyeLidDroopingActivities] | Dropdown [int] | | | Yes | | (0) No Eyelid Drooping[0]; (1) After more than 1 hour[1]; (2) After less than 1 hour, but not immediately[2]; (3) Constant drooping or it starts immediately[3] | Y | |
| 9.06 | Severity of eyelid drooping [PatientVisitMgiiProms.EyeLidDroopingSeverity] | Dropdown [int] | | | Yes | | (0) No Eyelid Drooping[0]; (1) Mild: It doesn't affect my vision[1]; (2) It affects my vision, but no need to lift my eyelid[2]; | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|-------------------|-----|-------------|----------|------------------|--|------------------|----------|
| | | | | | | | (3) I need to lift my eyelid or tilt my head to be able to see[3] | | |
| | Eating | Heading | | | | | | | |
| | Problems eating | Sub-Heading | | | | | | | |
| 9.07 | Difficulty swallowing [PatientVisitMgiiProms.DifficultySwallowing] | Dropdown [int] | | | Yes | | (0) No swallowing problems[0]; (1) Occasional episodes of choking/coughing with food or liquids[1]; (2) Liquids return through my nose, but no problems with solid food[2]; (3) Difficulty swallowing hard food, requiring a change in diet[3]; (4) Unable to swallow or using a feeding tube[4] | Y | |
| 9.08 | Chewing different types of food [PatientVisitMgiiProms.ChewingDifferentFoods] | Dropdown [int] | | | Yes | | (0) No chewing difficulty[0]; (1) Difficulty chewing hard foods (e.g: steak, raw carrots)[1]; (2) Difficulty chewing soft foods (e.g: hard boiled egg)[2]; (3) Unable to chew (eating only liquids or feeding tube)[3] | Y | |
| 9.09 | Chewing tiredness/fatigue [PatientVisitMgiiProms.ChewingFatigue] | Dropdown [int] | | | Yes | | (0) No chewing difficulty[0]; (1) Difficulty chewing at the end of the meal[1]; (2) Difficulty chewing from the beginning of the meal[2]; (3) Unable to chew (eating only liquids or feeding tube)[3] | Y | |
| | Speaking and Breathing | Heading | | | | | | | |
| | Please answer regarding the past 2 weeks | Sub-Heading | | | | | | | |
| 9.10 | Voice changes during the day [PatientVisitMgiiProms.VoiceChangesDay] | Dropdown [int] | | | Yes | | (0) No voice changes[0]; (1) Voice changes only in the evenings[1]; (2) Voice changes starting in the afternoons[2]; (3) Constant voice changes or present most of the day[3] | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|---|-------------------|-----|-------------|----------|------------------|--|------------------|----------|
| 9.11 | Voice changes with prolonged conversation [PatientVisitMgiiProms.VoiceChangesConversation] | Dropdown [int] | | | Yes | | (0) No voice changes[0]; (1) Voice changes after more than 30 minutes[1]; (2) Voice changes after less than 30 minutes, but not immediately[2]; (3) Constant voice changes or they start immediately (less than 1 minute)[3] | Y | |
| 9.12 | Severity of voice changes [PatientVisitMgiiProms.VoiceChangesSeverity] | Dropdown [int] | | | Yes | | (0) No voice changes[0]; (1) Mild changes: my voice is mostly clear[1]; (2) Moderate changes: it can be hard to understand me[2]; (3) Severe changes: it is impossible to understand me[3] | Y | |
| 9.13 | Speech clarity during day [PatientVisitMgiiProms.SpeechClarityDay] | Dropdown [int] | | | Yes | | (0) No episodes of slurred speech[0]; (1) Slurred speech only in the evenings[1]; (2) Slurred speech starting in the afternoons[2]; (3) Constant slurring, or present most of the day[3] | Y | |
| 9.14 | Speech clarity with prolonged conversation [PatientVisitMgiiProms.SpeechClarityConversation] | Dropdown [int] | | | Yes | | (0) No episodes of slurred speech[0]; (1) Slurred speech after 30 minutes[1]; (2) Slurred speech after less than 30 minutes, but not immediately[2]; (3) Constant slurring, or it starts immediately (less than 1 minute)[3] | Y | |
| 9.15 | Severity of speech changes [PatientVisitMgiiProms.SpeechChangesSeverity] | Dropdown [int] | | | Yes | | (0) No episodes of slurred speech[0]; (1) Mild slurring: it is easy to understand me[1]; (2) Moderate slurring: there are some difficulties understanding me[2]; (3) Severe slurring: it is impossible to understand me[3] | Y | |
| 9.16 | Difficulty breathing [PatientVisitMgiiProms.BreathingDifficulty] | Dropdown [int] | | | Yes | | (0) No shortness of breath (except for strenuous exercise)[0]; (1) With moderate effort (e.g. walking several blocks at my own pace)[1]; (2) With minimal effort (e.g. getting dressed, walking inside the house)[2];(3) At rest or when | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|-------------------|-----|-------------|----------|------------------|---|------------------|----------|
| | | | | | | | lying on my back[3]; (4) Requiring assisted ventilation[4] | | |
| | Generalised Symptoms | Heading | | | | | | | |
| | Please answer regarding the past 2 weeks | Sub-Heading | | | | | | | |
| 9.17 | Overall physical tiredness [PatientVisitMgiiProms.OverallPhysicalTiredness] | Dropdown [int] | | | Yes | | (0) No physical tiredness[0]; (1) Overall physical tiredness in the evenings[1]; (2) Overall physical tiredness starting in the afternoons[2]; (3) Constant physical tiredness, or present most of the day[3] | Y | |
| 9.18 | Arm weakness severity [PatientVisitMgiiProms.ArmWeaknessSeverity] | Dropdown [int] | | | Yes | | (0) No arm weakness[0]; (1) Mild weakness (e.g: difficulty lifting heavy objects)[1]; (2) Moderate weakness (e.g: difficulty lifting arms above the shoulders, but I can do it)[2]; (3) Severe weakness (e.g: unable to lift arms above the shoulders)[3] | Y | |
| 9.19 | Arm weakness with prolonged use [PatientVisitMgiiProms.ArmWeaknessProlongedUse] | Dropdown [int] | | | Yes | | (0) No arm weakness[0]; (1) Weakness when keeping my arms up for too long (e.g. washing or drying my hair)[1]; (2) Weakness with prolonged activities at shoulder level (e.g: organizing objects on a shelf, holding a phone to the ear)[2]; (3) Weakness with minimal effort (e.g: desk work, chopping vegetables)[3] | Y | |
| 9.20 | Leg weakness severity [PatientVisitMgiiProms.LegWeaknessSeverity] | Dropdown [int] | | | Yes | | (0) No leg weakness[0]; (1) Mild weakness (e.g: difficulty standing from a squat or from tying my shoes)[1]; (2) Moderate weakness (e.g: difficulty standing from a chair, I need to push up with my arms)[2]; (3) Severe weakness (e.g: unable to stand from a chair without assistance)[3] | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------|--|------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| 9.21 | Leg weakness with prolonged use [PatientVisitMgiiProms.LegWeaknessProlongedUse] | Dropdown [int] | | | Yes | | (0) No leg weakness[0]; (1) Weakness when walking more than 10 blocks at my own pace[1]; (2) Weakness when walking less than 10 blocks at my own pace[2]; (3) Constant weakness or with minimal effort (standing, walking inside the house)[3] | Y | |
| 9.22 | Neck weakness [PatientVisitMgiiProms.NeckWeakness] | Dropdown [int] | | | Yes | | (0) No neck weakness[0]; (1) Weakness only in the evenings[1]; (2) Weakness starting in the afternoons[2]; (3) Constant weakness or present most of the day[3] | Y | |
| 9.23 | Total [PatientVisitMgiiProms.CalculatedScore] | String [int] | | | Yes | | | Y | Read only Calculated based on selected responses |
| | [PatientVisitMgiiProms.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMgiiProms.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisitMgiiProms.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMgiiProms.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMgiiProms.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisitMgiiProms.RowVersion] | Hidden [bigint] | | | No | | | Y | System managed value to prevent conflicting edits to a record. |
| | [FK__PatientVisit__Id__77AABCF8, Relationship 1 to 1, PatientVisit.Id to PatientVisitMgiiProms.Id] | Hidden [Relationship] | | | | | | | |

10. VISITS – MGQoL15R

10.1 Description

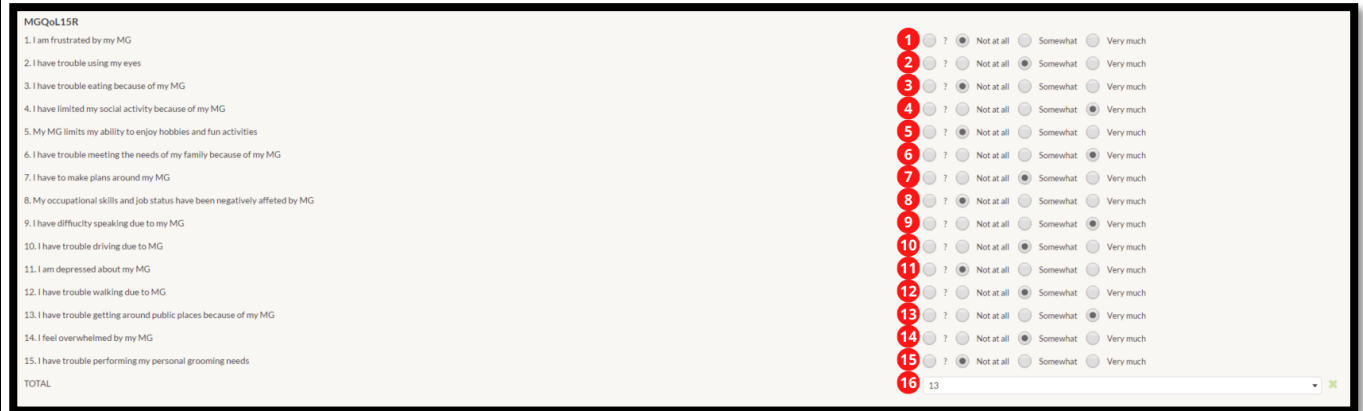
This tab presents a survey designed to assess aspects of life related to myasthenia gravis. There is appropriate correlation between the 15 item MG-QOL 15 and other MG-specific scales (MGC, MG-ADL, and MG-MMT). The MG-QOL 15 can be completed by the patient or administered by the physician or trained clinic personnel or study coordinator.

10.2 Rules and Constraints

- There are 15 items, however the total is calculated based on all selected / filled responses (values).
- MGQoL15R is not mandatory but if used, ideally should be completed at least annually.
- Once saved, the total is pulled through to the Visit Basic screen for the same date.

10.3 Functions

- Each question has a radio button selection making it easy to complete quickly.)



MGQoL15R

| | | | |
|--|---|---|--|
| 1. I am frustrated by my MG | <input type="radio"/> Not at all | <input type="radio"/> Somewhat | <input type="radio"/> Very much |
| 2. I have trouble using my eyes | <input type="radio"/> Not at all | <input checked="" type="radio"/> Somewhat | <input type="radio"/> Very much |
| 3. I have trouble eating because of my MG | <input type="radio"/> Not at all | <input type="radio"/> Somewhat | <input type="radio"/> Very much |
| 4. I have limited my social activity because of my MG | <input type="radio"/> Not at all | <input type="radio"/> Somewhat | <input checked="" type="radio"/> Very much |
| 5. My MG limits my ability to enjoy hobbies and fun activities | <input type="radio"/> Not at all | <input type="radio"/> Somewhat | <input type="radio"/> Very much |
| 6. I have trouble meeting the needs of my family because of my MG | <input type="radio"/> Not at all | <input type="radio"/> Somewhat | <input checked="" type="radio"/> Very much |
| 7. I have to make plans around my MG | <input type="radio"/> Not at all | <input checked="" type="radio"/> Somewhat | <input type="radio"/> Very much |
| 8. My occupational skills and job status have been negatively affected by MG | <input type="radio"/> Not at all | <input type="radio"/> Somewhat | <input type="radio"/> Very much |
| 9. I have difficulty speaking due to my MG | <input type="radio"/> Not at all | <input type="radio"/> Somewhat | <input checked="" type="radio"/> Very much |
| 10. I have trouble driving due to MG | <input type="radio"/> Not at all | <input checked="" type="radio"/> Somewhat | <input type="radio"/> Very much |
| 11. I am depressed about my MG | <input checked="" type="radio"/> Not at all | <input type="radio"/> Somewhat | <input type="radio"/> Very much |
| 12. I have trouble walking due to MG | <input type="radio"/> Not at all | <input checked="" type="radio"/> Somewhat | <input type="radio"/> Very much |
| 13. I have trouble getting around public places because of my MG | <input type="radio"/> Not at all | <input type="radio"/> Somewhat | <input checked="" type="radio"/> Very much |
| 14. I feel overwhelmed by my MG | <input type="radio"/> Not at all | <input checked="" type="radio"/> Somewhat | <input type="radio"/> Very much |
| 15. I have trouble performing my personal grooming needs | <input checked="" type="radio"/> Not at all | <input type="radio"/> Somewhat | <input type="radio"/> Very much |
| TOTAL | 13 | | |

10.4 MGQoL15R Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|----------------|-----|-------------|----------|------------------|---|------------------|--|
| 10.01 | MGQoL15R01 [PatientVisitMGQoL15R.Q1] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 1. I am frustrated by my MG |
| 10.02 | MGQoL15R02 [PatientVisitMGQoL15R.Q2] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 2. I have trouble using my eyes |
| 10.03 | MGQoL15R03 [PatientVisitMGQoL15R.Q3] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 3. I have trouble eating because of my MG |
| 10.04 | MGQoL15R04 [PatientVisitMGQoL15R.Q4] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 4. I have limited my social activity because of my MG |
| 10.05 | MGQoL15R05 [PatientVisitMGQoL15R.Q5] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 5. My MG limits my ability to enjoy hobbies and fun activities |
| 10.06 | MGQoL15R06 [PatientVisitMGQoL15R.Q6] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 6. I have trouble meeting the needs of my family because of my MG |
| 10.07 | MGQoL15R07 [PatientVisitMGQoL15R.Q7] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 7. I have to make plans around my MG |
| 10.08 | MGQoL15R08 [PatientVisitMGQoL15R.Q8] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 8. My occupational skills and job status have been negatively affected by MG |
| 10.09 | MGQoL15R09 [PatientVisitMGQoL15R.Q9] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 9. I have difficulty speaking due to my MG |
| 10.10 | MGQoL15R10 [PatientVisitMGQoL15R.Q10] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 10. I have trouble driving due to MG |
| 10.11 | MGQoL15R11 [PatientVisitMGQoL15R.Q11] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 11. I am depressed about my MG |
| 10.12 | MGQoL15R12 [PatientVisitMGQoL15R.Q12] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 12. I have trouble walking due to MG |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| 10.13 | MGQoL15R13 [PatientVisitMGQoL15R.Q13] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 13. I have trouble getting around public places because of my MG |
| 10.14 | MGQoL15R14 [PatientVisitMGQoL15R.Q14] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 14. I feel overwhelmed by my MG |
| 10.15 | MGQoL15R15 [PatientVisitMGQoL15R.Q15] | Radio [int] | | | Yes | | ?[NULL]; Not at all[0]; Somewhat[1]; Very Much[2] | Y | 15. I have trouble performing my personal grooming needs |
| 10.16 | Total [PatientVisitMGQoL15R.CalculatedScore] | Dropdown [int] | | | Yes | | 0 to 30 | Y | Calculated but can be manually overridden. |
| | [PatientVisitMGQoL15R.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMGQoL15R.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisitMGQoL15R.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMGQoL15R.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMGQoL15R.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisitMGQoL15R.RowVersion] | Hidden [bigint] | | | No | | | Y | System managed value to prevent conflicting edits to a record. |
| | [FK__PatientVisit__Id__7A8729A3, Relationship 1 to 1, PatientVisit.Id to PatientVisitMGQoL15R.Id] | Hidden [Relationship] | | | | | | | |

11. VISITS – MG-ADL

11.1 Description

This tab presents the Myasthenia Gravis – Activities of Daily Living Survey and profile. Quick to complete (<10 minutes)

11.2 Rules and Constraints

- There are 8 items, however the total is calculated based on all selected / filled responses (values).
- MG-ADL is not mandatory but if used, ideally should be completed at least annually.
- Total is auto-calculated and read-only on the MG-ADL Tab

11.3 Functions

Each question has a drop-down box making it easy to complete quickly.



| Item | Response | Number | Status |
|---|--|--------|--------|
| Talking | (1) Intermittent slurring or nasal speech | 1 | ✗ |
| Chewing | (2) Fatigue with soft food | 2 | ✗ |
| Swallowing | (2) Frequent choking necessitating changes in diet | 3 | ✗ |
| Breathing | (1) Shortness of breath with exertion | 4 | ✗ |
| Impairment of ability to brush teeth or comb hair | (2) Rest periods needed | 5 | ✗ |
| Impairment of ability to arise from chair | (0) None | 6 | ✗ |
| Double Vision | (2) Daily, but not constant | 7 | ✗ |
| Eyelid Droop | (1) Occurs, but not daily | 8 | ✗ |
| TOTAL | 11 | 9 | |

11.3 MG-ADL Data Fields

Note: the value in () is the score for that option and value in [] is the identifier stored in the database for that option.

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|-------------------|-----|-------------|----------|------------------|---|------------------|----------|
| 11.01 | Talking [PatientVisitMGADL.Talking] | Dropdown [int] | | | Yes | | (0) Normal[0]; (1) Intermittent slurring or nasal speech[1]; (2) Constant slurring or nasal, but can be understood[2]; (3) Difficult to understand speech[3] | Y | |
| 11.02 | Chewing [PatientVisitMGADL.Chewing] | Dropdown [int] | | | Yes | | (0) Normal[0]; (1) Fatigue with solid food[1]; (2) Fatigue with soft food[2]; (3) Gastric tube[3] | Y | |
| 11.03 | Swallowing [PatientVisitMGADL.Swallowing] | Dropdown [int] | | | Yes | | (0) Normal[0]; (1) Rare episode of choking[1]; (2) Frequent choking necessitating changes in diet[2]; (3) Gastric tube[3] | Y | |
| 11.04 | Breathing [PatientVisitMGADL.Breathing] | Dropdown [int] | | | Yes | | (0) Normal[0]; (1) Shortness of breath with exertion[1]; (2) Shortness of breath at rest[2]; (3) Ventilator dependence[3] | Y | |
| 11.05 | Impairment of ability to brush teeth or comb hair [PatientVisitMGADL.BrushCombImpairment] | Dropdown [int] | | | Yes | | (0) None[0]; (1) Extra effort, but no rest periods needed[1]; (2) Rest periods needed[2]; (3) Cannot do one of these functions[3] | Y | |
| 11.06 | Impairment of ability to arise from chair [PatientVisitMGADL.AriseImpairment] | Dropdown [int] | | | Yes | | (0) None[0]; (1) Mild, sometimes uses arms[1]; (2) Moderate, always uses | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| | | | | | | | arms[2]; (3) Severe, requires assistance[3] | | |
| 11.07 | Double Vision [PatientVisitMGADL.DoubleVision] | Dropdown [int] | | | Yes | | (0) None[0]; (1) Occurs, but not daily[1]; (2) Daily, but not constant[2]; (3) Constant[3] | Y | |
| 11.08 | Eyelid Droop [PatientVisitMGADL.EyelidDroop] | Dropdown [int] | | | Yes | | (0) None[0]; (1) Occurs, but not daily[1]; (2) Daily, but not constant[2]; (3) Constant[3] | Y | |
| 11.09 | TOTAL [PatientVisitMGADL.CalculatedScore] | String [int] | | | Yes | | | Y | Read only Calculated based on selected responses |
| | [PatientVisitMGADL.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMGADL.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisitMGADL.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMGADL.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitMGADL.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisitMGADL.RowVersion] | Hidden [bigint] | | | No | | | Y | System managed value to prevent conflicting edits to a record. |
| | [FK__PatientVisit__Id__08D548FA, Relationship 1 to 1, | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | PatientVisit.Id to PatientVisitMGADL.Id] | | | | | | | | |

12. VISITS – QMG

12.1 Description

This tab presents the Quantitative Myasthenia Gravis score. The QMG score has several items that measure endurance or fatigability, taking into account the fluctuating nature of the disease.

12.2 Rules and Constraints

- There are 13 items, however the total is calculated based on all selected / filled responses (values).
- QMG is not mandatory but if used, ideally should be completed at least annually.

12.3 Functions

Each question has a dropdown value that can be selected making it easy to complete quickly.)

| QMG | |
|---|--|
| Double vision- lateral gaze (sec) | (0) No diplopia in 60 seconds 1 x |
| Ptosis-upward gaze (sec) | (1) Ptosis between 11-59 seconds 2 x |
| Facial muscles (eye closure) | (0) Normal lid closure 3 x |
| Swallowing water (1/2 cup) | (2) Severe coughing 4 x |
| Speech following counting aloud from 1-50 (onset of dysarthria) | (1) Dysarthria at count between 30-49 5 x |
| Right arm outstretched-90 degrees, sitting (sec) | (0) Right arm outstretched for 240 seconds 6 x |
| Left arm outstretched- 90 degrees, sitting (sec) | (2) Left arm outstretched between 10-89 seconds 7 x |
| Forced vital capacity | (1) 65-79% 8 x |
| Right hand grip (kg) | (1) Male 15-44 kg, Female 10-29 kg 9 x |
| Left hand grip (kg) | (1) (1) Male 15-34 kg, Female 10-24 kg 10 x |
| Head, lifted 45% supine (sec) | (0) 120 seconds 11 x |
| Right leg outstretched- 45-50%, supine (sec) | (1) 31-99 seconds 12 x |
| Left leg outstretched- 45-50%, supine (sec) | (0) 100 seconds 13 x |
| TOTAL | 10 14 |

12.3 QMG Data Fields

Note: the value in () is the score for that option and value in [] is the identifier stored in the database for that option.

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|-------------------|-----|-------------|----------|------------------|--|------------------|----------|
| 12.01 | Double vision- lateral gaze (sec) [PatientVisitQMG.DoubleVisionLateralGaze] | Dropdown [int] | | | Yes | | (0) No diplopia in 60 seconds[0]; (1) Diplopia between 11-59 seconds[1]; (2) Diplopia between 1-10 seconds[2]; (3) Spontaneous Diplopia[3] | Y | |
| 12.02 | Ptosis-upward gaze (sec) [PatientVisitQMG.PtosisUpwardGaze] | Dropdown [int] | | | Yes | | (0) No Ptosis in 60 seconds[0]; (1) Ptosis between 11-59 seconds[1]; (2) Ptosis between 1-10 seconds[2]; (3) Spontaneous Ptosis[3] | Y | |
| 12.03 | Facial muscles (eye closure) [PatientVisitQMG.FacialMuscles] | Dropdown [int] | | | Yes | | (0) Normal lid closure[0]; (1) Complete, weak, some resistance[1]; (2) Complete, without resistance[2]; (3) Incomplete lid closure[3] | Y | |
| 12.04 | Swallowing water (1/2 cup) [PatientVisitQMG.SwallowingWater] | Dropdown [int] | | | Yes | | (0) Normal[0]; (1) Minimal coughing or throat clearing[1]; (2) Severe coughing[2]; (3) Cannot swallow (test not attempted)[3] | Y | |
| 12.05 | Speech following counting aloud from 1-50 (onset of dysarthria) [PatientVisitQMG.SpeechFollowingCounting Aloud] | Dropdown [int] | | | Yes | | (0) None at count to 50[0]; (1) Dysarthria at count between 30-49[1]; (2) Dysarthria at count between 10-29[2]; (3) Dysarthria before count to 9[3] | Y | |
| 12.06 | Right arm outstretched-90 degrees, sitting (sec) [PatientVisitQMG.RightArmOutstretched] | Dropdown [int] | | | Yes | | (0) Right arm outstretched for 240 seconds[0]; (1) Right arm outstretched between 90-239 seconds[1]; (2) Right arm outstretched between 10-89 seconds[2]; (3) Right arm outstretched between 1-9 seconds[3] | Y | |
| 12.07 | Left arm outstretched- 90 degrees, sitting (sec) [PatientVisitQMG.LeftArmOutstretched] | Dropdown [int] | | | Yes | | (0) Left arm outstretched for 240 seconds[0]; (1) Left arm outstretched between 90-239 seconds[1]; (2) Left arm outstretched between 10-89 seconds[2]; (3) Left arm outstretched between 1-9 seconds[3] | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| 12.08 | Forced vital capacity [PatientVisitQMG.ForcedVitalCapacity] | Dropdown [int] | | | Yes | | (0) >=80%[0]; (1) 65-79%[1]; (2) 50-64%[2]; (3) <50%[3] | Y | |
| 12.09 | Right hand grip (kg) [PatientVisitQMG.RightHandGrip] | Dropdown [int] | | | Yes | | (0) Male >=45 kg, Female >=30 kg[0]; (1) Male 15-44 kg, Female 10-29 kg[2]; (2) Male 5-14 kg, Female 5-9 kg[4]; (3) Male or Female 0-4 kg[6] | Y | |
| 12.10 | Left hand grip (kg) [PatientVisitQMG.LeftHandGrip] | Dropdown [int] | | | Yes | | (0) Male >=35 kg, Female >=25 kg[0]; (1) Male 15-34 kg, Female 10-24 kg[2]; (2) Male 5-14 kg, Female 5-9 kg[4]; (3) Male or Female 0-4 kg[6] | Y | |
| 12.11 | Head, lifted 45% supine (sec) [PatientVisitQMG.HeadLifted45] | Dropdown [int] | | | Yes | | (0) 120 seconds[0]; (1) 30-119 seconds[1]; (2) 1-29 seconds[2]; (3) 0 seconds[3] | Y | |
| 12.12 | Right leg outstretched- 45-50%, supine (sec) [PatientVisitQMG.RightLegOutstretched] | Dropdown [int] | | | Yes | | (0) 100 seconds[0]; (1) 31-99 seconds[1]; (2) 1-30 seconds[2]; (3) 0 seconds[3] | Y | |
| 12.13 | Left leg outstretched- 45-50%, supine (sec) [PatientVisitQMG.LeftLegOutstretched] | Dropdown [int] | | | Yes | | (0) 100 seconds[0]; (1) 31-99 seconds[1]; (2) 1-30 seconds[2]; (3) 0 seconds[3] | Y | |
| 12.14 | TOTAL [PatientVisitQMG.CalculatedScore] | String [int] | | | Yes | | | Y | Read only Calculated based on selected responses |
| | [PatientVisitQMG.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitQMG.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|------------------------------|-----|-------------|----------|------------------|----------------|------------------|--|
| | [PatientVisitQMG.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitQMG.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientVisitQMG.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientVisitQMG.RowVersion] | Hidden [bigint] | | | No | | | Y | System managed value to prevent conflicting edits to a record. |
| | [FK_PatientVisit_Id_0BB1B5A5, Relationship 1 to 1, PatientVisit.Id to PatientVisitQMG.Id] | Hidden [Relationship] | | | | | | | |

13. VISIT - Flexifields

13.1 Description

Centre specified Flexifields for Visits are in this section.

13.2 Rules and Constraints

- Flexifields must be specified in the Preferences.

13.3 Functions

- Enter/Edit Data – You can enter/edit data for flexifields.

FlexiFields

01 - Administrative

02 - Schedule Next Visit

03 - Preferred Time for Next Visit

04 - Patient Well-being

05 - Mood of Patient (Self-Assessed)

06 - Mood of Patient (Comments)

13.4 Visit Flexifields Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Comments |
|-----|---|------------------------------|------|-----------------------------|----------|--|
| | FlexiField Name [FlexiField.Name] | Field Label | | Centres / User-specified | | Allowed values will depend on the type of flexifield. Dropdown lists comes from [FlexiFieldOption.Value] These values are not sent through to the Registry |
| | FlexiField Value [PatientVisitFlexiField.Value] | String [nvarchar] | 1000 | <i>Various (Depending)</i> | Yes | Allowed values will depend on the type of flexifield. Dropdown lists comes from [FlexiFieldOption.Value] These values are not sent through to the Registry |
| | [PatientVisitFlexiField.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | |
| | [PatientVisitFlexiField.CreatedUtcDate] | Hidden [datetime] | | | No | |
| | [PatientVisitFlexiField.FieldId] | Hidden [uniqueidentifier] | | | No | |
| | [PatientVisitFlexiField.Id] | Hidden [uniqueidentifier] | | | No | |
| | [PatientVisitFlexiField.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | |
| | [PatientVisitFlexiField.ModifiedUtcDate] | Hidden [datetime] | | | No | |
| | [PatientVisitFlexiField.PatientVisitId] | Hidden [uniqueidentifier] | | | No | |
| | [PatientVisitFlexiField.RowVersion] | Hidden [bigint] | | | No | System managed value to prevent conflicting edits to a record. |
| | [FK__PatientVi__Patie__2C538F61, Relationship Many to Many PatientVisit.Id to PatientVisitFlexiField.PatientVisitId] | Hidden [Relationship] | | | | |
| | [FK__PatientVi__Field__2B5F6B28, Relationship many to many FlexiField.Id to PatientVisitFlexiField.FieldId] | Hidden [Relationship] | | | | |

Notes:

- Table PatientVisitFlexiField contains the value that is entered for flexifields from the Visit Flexifields screen in MDS
- Table FlexiField contains the definition of the flexifields, i.e. Name and Data Type
- Table FlexiFieldOption contains the values defined for flexifields where type is a dropdown

14. VISIT - Safety

14.1 Description

The safety page allows the user to report changes in the medical conditions of the patient, such as malignancies, adverse reactions, or events.

14.2 Functions

- Enter/Edit Safety data – You can add/edit the safety data
- View/Add/Delete Medical conditions – You can add/edit the Medical Conditions of the patient.

Safety

Has the patient developed a malignancy (excluding NMSC) since the last visit? 1 ? Yes No

Has the patient developed a non-melanoma skin cancer (NMSC) since their last visit? 2 ? Yes No

Has the patient developed herpes zoster (shingles) since last visit? 3 ? Yes No

Has the patient developed an immunosuppression-associated or severe infection since last visit? 4 ? Yes No

Has the patient developed any other significant medical condition since last visit? 5 ? Yes No

Diseases and Medical conditions + Add new Delete

| Conditions | Date Of Diagnosis | Treatment Modality | Outcome | End Date |
|---|-------------------|--------------------|---------|------------|
| <input type="checkbox"/> 6 Heart attack | 10/11/2016 | | Death | 16/11/2021 |

14.3 Safety Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|----------------|-----|-------------|----------|------------------|---------------------------|------------------|---|
| 14.01 | Malignancy Developed [PatientVisit.Safety_Malig] | Radio [bit] | | | Yes | | No[0]; ?[NULL]; Yes[1] | Y | Has the patient developed a malignancy (excluding NMSC) since the last visit ? Defaults to ? |
| 14.02 | Non-Melanoma Cancer Developed [PatientVisit.Safety_Nonmal] | Radio [bit] | | | Yes | | No[0]; ?[NULL]; Yes[1] | Y | Has the patient developed a non-melanoma skin cancer (NMSC) since the last visit ? Defaults to ? |
| 14.03 | Herpes Zoster Developed [PatientVisit.Safety_Herpes] | Radio [bit] | | | Yes | | No[0]; ?[NULL]; Yes[1] | Y | Has the patient developed a herpes zoster (shingles) since the last visit ? Defaults to ? |
| 14.04 | Immunosuppression Developed [PatientVisit.Safety_Immuno] | Radio [bit] | | | Yes | | No[0]; ?[NULL]; Yes[1] | Y | Has the patient developed an immunosuppression-associated or severe infection since the last visit ? Defaults to ? |
| 14.05 | Other Significant Condition Developed [PatientVisit.Safety_Other] | Radio [bit] | | | Yes | | No[0]; ?[NULL]; Yes[1] | Y | Has the patient developed any other significant medical condition since the last visit ? Defaults to ? |
| 14.06 | Disease and Medical conditions | Sub- Report | | | Yes | | | | Captured in Medical Events, aggregated in this view |

15. VISIT – Reproductive Health

15.1 Description

The reproductive health tab under the “Visit” module allows for clinicians to capture summary data around reproductive health. Note that it is preferable for detailed data around pregnancy to be captured in the Pregnancy module, however this tab allows for a summary as an alternative to save the clinician time.

15.2 Rules and constraints

- Certain fields such as capturing numeric values (totals) are only enabled when “Yes” has been selected for the related question.

15.2 Functions

- Enter/Edit Reproductive summary data
- View/Add/Delete Pregnancy, Menopause and Pregnancy complications summary data.

Basic MGC MGII PROMS MGQoL15R MG-ADL QMG Safety Reproductive Health FlexiFields Notes

Note for Clinician
There are two options for entering patient data related to reproductive health, pregnancy and neonatal outcomes:

1. Enter detailed data by creating or editing a Patient Pregnancy Record. The Patient Pregnancy Record (Form) is captured on a record-per-pregnancy basis. Please check whether a pre-existing pregnancy record is already captured, and update accordingly.
2. Enter summary data here. Choosing this option only requires you to complete the form below.
Note: To avoid duplication, please add each pregnancy only once, using either Option 1 or Option 2

New Pregnancy Form **1**

Pregnancy

Has the patient been pregnant before? Yes No Unknown **2**

Is the patient currently pregnant? Yes No Unknown **3**

Menopause

Has the patient undergone Menopause? Yes No Unknown **4**

Last menstrual period **5**

Summary Reproductive History

It is preferable to complete a Pregnancy record at a detailed level instead, and to update any pre-existing records with the additional outcomes data. Note - this is summary information and if completed, does not need to be captured at an individual Pregnancy record as well.

How many times has the patient been pregnant? (excluding the current) **6**

How many infants in total have been born? **7**

Has the patient had any multiple gestation pregnancies? (Twins etc.) Yes No **8**

Has the patient reported any of the following complications, relating to previous pregnancies?

Pregnancy Complications

Spontaneous abortions (Pregnancy loss < 20 weeks) Yes No Unknown **9**

If 'Yes', how many pregnancies were affected by this? **10**

Neonatal death (Pregnancy loss > 20 weeks) Yes No Unknown **11**

If 'Yes', how many pregnancies were affected by this? **12**

Live births with major/minor congenital abnormality? Yes No Unknown **13**

If 'Yes', how many pregnancies were affected by this? **14**

If 'Yes', what was the nature of the congenital abnormality? + **15**

Has the patient reported any of the following during past pregnancies? + **16**

Were any of the congenital abnormalities medically verified? Yes No Unknown **17**

Were the congenital abnormalities reported to a pharmaceutical company through local pharmacovigilance channels? Yes No Unknown **18**

Was the patient (mother) born with any congenital malformations? Yes No Unknown **19**

If 'Yes', what type of congenital malformations? + **20**

Save **Cancel**

15.3 Reproductive Health Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--------------------------------|-----------------|-----|-------------|----------|------------------------------|------------------------|------------------|---|
| 15.01 | New Pregnancy Form Button | Button | | | | | | N | Button allows user to Opt to enter detailed data for a Pregnancy record |
| 15.02 | Prior Pregnancy | Radio [bit] | | | Yes | | Yes; No; Unknown; NULL | Y | |
| 15.03 | Current Pregnancy Status | Radio [bit] | | | Yes | | Yes; No; Unknown; NULL | Y | |
| 15.04 | Menopause Status | Radio [bit] | | | Yes | | Yes; No; Unknown; NULL | Y | "Has patient undergone Menopause?" |
| 15.05 | Menopause – LMP Date | Date [datetime] | | dd/mm/yyyy | No | Enabled if Menopause = "Yes" | | Y | Last menstrual period |
| 15.06 | No of past pregnancies | Number | | | Yes | | | Y | "How many times has patient been pregnant" |
| 15.07 | Total Infants Born | Number | | | Yes | | | Y | "How many infants born in total?" (Live births) |
| 15.08 | Multiple gestation pregnancies | Radio [bit] | | | Yes | | Yes; No; NULL | Y | "Has patient had any multiple gestation pregnancies?" |
| 15.09 | Spontaneous abortions status | Radio [bit] | | | Yes | | Yes; No; Unknown; NULL | Y | (Pregnancy loss <20 weeks) |
| 15.10 | Spontaneous abortions total | Number | | | Yes | Enabled only if 15.09 = Yes | | Y | "If "Yes" how many pregnancies affected?" |
| 15.11 | Neonatal death status | Radio [bit] | | | Yes | | Yes; No; Unknown; NULL | Y | (Pregnancy loss >20 weeks) |
| 15.12 | Neonatal death total | Number | | | Yes | Enabled only if 15.11 = Yes | | Y | "If "Yes" how many pregnancies affected?" |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|-------------|-----|-------------|----------|--|--|------------------|--|
| 15.13 | Live births w/ MMCA | Radio [bit] | | | Yes | | Yes; No; Unknown; NULL | Y | "Live births with major / minor congenital abnormality?" |
| 15.14 | Live births MMCA Total | Number | | | Yes | Enabled only if 15.13 = Yes | | Y | "If "Yes" how many pregnancies affected?" |
| 15.15 | Congenital abnormality selection | Dropdown | | | Yes | Enabled only if 15.3 = Yes and 15.14 has a numerical value | Reference list <Congenital Abnormalities> | Y | (Ability to add multiple) |
| 15.16 | Patient reported Maternal complications | Dropdown | | | Yes | | Reference list: <Maternal Complications> | Y | (Ability to add multiple) |
| 15.17 | MMCA medical verification status | Radio [bit] | | | Yes | | Yes; No; Unknown; NULL | Y | "Were any of the congenital abnormalities medically verified?" |
| 15.18 | MMCA reported pharmacovigilance | Radio [bit] | | | Yes | | Yes; No; Unknown; NULL | Y | "Were congenital abnormalities reported through local pharmacovigilance channels?" |
| 15.19 | Mother congenital malformations | Radio [bit] | | | Yes | | Yes; No; Unknown; NULL | Y | "Was the patient (Mother) born with any congenital malformations?" |
| 15.20 | Mother congenital malformations type | Dropdown | | | Yes | Enabled only if 15.19 = Yes | Reference list <Congenital Abnormalities> | Y | (Ability to add multiple) |

VISIT - Notes

Description

Visit specific Notes section where the user can upload documents and refer to URL.

Rules and Constraints

- Documents are not stored within MDS, they are linked to a drive location.

Functions

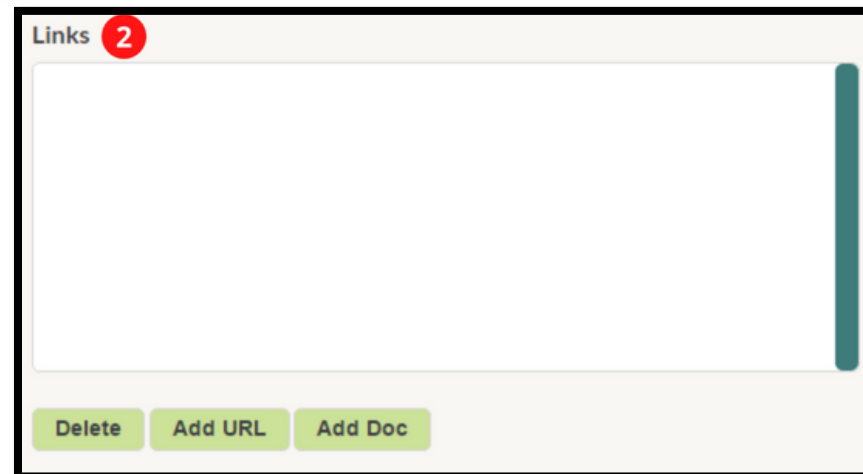
- Enter Data – You can enter notes about the visit.
- Add Link – You can link to a local document.
- Add URL – You can link to WWW resources.



Notes **1**

Make booking for next appointment.

Save Cancel



Links **2**

Delete Add URL Add Doc

Notes Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|---------------|-------------|----------|------------------|----------------|------------------|--|
| | Notes [PatientVisit.Notes] | Text area [text] | 2,147,483,647 | | Yes | | | N | |
| | Links [PatientVisitLink.Value] | String [nvarchar] | 100 | | Yes | | | N | Buttons on screen: <ul style="list-style-type: none"> • Add URL • Add Doc • Delete |
| | [PatientVisitLink.Id] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [PatientVisitLink.LinkType] | Hidden [int] | | | No | | | N | |
| | [PatientVisitLink.PatientVisitId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [FK__PatientVi__Patie__2D47B39A, Relationship 1 to many PatientVisit.Id to PatientVisitLink.PatientVisitId] | Hidden [Relationship] | | | | | | | |

16.Exacerbations

Exacerbation

It is recommended to create a Visit (with outcome data) as well as an Exacerbation entry

Onset date: 14/10/2014 1 Duration: 18 2 Days

Symptoms

Ocular 3 Bulbar 4 Respiratory 5 Limb weakness 6

Other: 7

Worst MGC during exacerbation: 8 Estimated Documented 9

Treatment site: Ambulatory 10

ADL impact: Yes No Not known 11

This patient has a DMT in progress if you wish to record dose changes please do so via the Treatment menu

| Treatment | Starting on | Ending on | Dose | Unit | Period | Route |
|---|-------------|------------|------------|---------------|-----------------|----------------|
| Salbutamol 12 | 14/10/2014 | 20/08/2020 | 100 | mcg | /3 Hour | SC |
| IVIG | 14/10/2014 | 16/08/2017 | 400 | mg | Monthly | IV |
| Select an option | dd/mm/yyyy | dd/mm/yyyy | Enter dose | Select a unit | Select a period | Select a route |
| Select an option | dd/mm/yyyy | dd/mm/yyyy | Enter dose | Select a unit | Select a period | Select a route |

Remarks 13
First Exacerbation in a While.

16.1 Description

This section captures the date and details of Exacerbation events.

16.2 Rules and Constraints

- The only medication that can be linked to an exacerbation is typically a corticosteroid. Note, there are symptomatic treatments that have been “classified” in the treatment preferences as Corticosteroids, to be available for selection under exacerbations, even though they are not necessarily Corticosteroids.
- Should a patient have an existing DMT (Disease Modifying Therapy) in progress, this will be flagged in orange text on the exacerbation record. Should the clinician need to change dosage information, this needs to be done via the Treatments menu.

16.3 Functions

- Add/Delete Exacerbation – You can Add/Delete Exacerbation for patient.
- Add/Delete Corticosteroid – You can Add/Delete Corticosteroid (or Variable dosing) schedule.

16.4 Exacerbation Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| 16.01 | Date of Onset [PatientExacerbation.OnsetDate] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Date of Death | Y | Defaults to "today" |
| 16.02 | Duration (days) [PatientExacerbation.Duration] | Number [decimal] | | NNN.N | Yes | | Min value = 0 Max value = 999.9 | Y | |
| 16.03 | Symptoms – Ocular [PatientExacerbation.SymptomsOcular] | Checkbox [bit] | | | No | | True[1]; False[0] | Y | |
| 16.04 | Symptoms -Bulbar [PatientExacerbation.SymptomsBulbar] | Checkbox [bit] | | | No | | True[1]; False[0] | Y | |
| 16.05 | Symptoms -Respiratory [PatientExacerbation.SymptomsRespiratory] | Checkbox [bit] | | | No | | True[1]; False[0] | Y | |
| 16.06 | Symptoms -Limb Weakness [PatientExacerbation.SymptomsLimbWeakness] | Checkbox [bit] | | | No | | True[1]; False[0] | Y | |
| 16.07 | Symptoms -Other [PatientExacerbation.SymptomsOther] | String [nvarchar] | 50 | | Yes | | | Y | |
| 16.08 | Worst MGC during exacerbation [PatientExacerbation.WorstMGC] | Dropdown [int] | | | Yes | | 0 to 50 | Y | |
| 16.09 | Worst MGC Type [PatientExacerbation.WorstMGCType] | Radio [int] | | | Yes | | Estimated[1]; Documented[2] | Y | Becomes visible when Worst MGC during exacerbation is not NULL |
| 16.10 | Treatment Site [PatientExacerbation.TreatmentSiteId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from table TreatmentSite Not treated; Ambulatory; Hospital-ward; Hospital- HDU/ICU; Not known | Y | |
| 16.11 | ADL Impact [PatientExacerbation.ADLImpact] | Radio [bit] | | | Yes | | No[0]; Not known [NULL]; Yes[1] | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|------------------------------|------|-------------|----------|------------------|----------------|------------------|---|
| 16.12 | Treatment [FK_DMTreatment_ExacerbationId, Relationship 1 to Many, PatientExacerbation.Id to DMTreatment.ExacerbationId] or [FK__Symptomat__Relap__3F6663D5, Relationship 1 to Many, PatientExacerbation.Id to SymptomaticTreatment.ExacerbationId] | Sub Form [Relationship] | | | | | | Y | List filtered to treatments where flagged for exacerbation |
| 16.13 | Remarks [PatientExacerbation.Remarks] | Memo [nvarchar] | 1000 | | Yes | | | N | |
| | [PatientExacerbation.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientExacerbation.CreatedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientExacerbation.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientExacerbation.IsDeleted] | Hidden [bit] | | | No | | | Y | Set when the user deletes the record |
| | [PatientExacerbation.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientExacerbation.ModifiedUtcDate] | Hidden [datetime] | | | No | | | Y | |
| | [PatientExacerbation.PatientId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PatientExacerbation.RowVersion] | Hidden [bigint] | | | Yes | | | Y | System managed value to prevent conflicting edits to a record. |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|--------------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | [FK__PatientRe__Patie__269AB60B, Relationship 1 to Many, Patient.Id to PatientExacerbation.PatientId] | Hidden [Relationship] | | | | | | | |
| | [FK__PatientEx__Treat__02284B6B, Relationship 1 to Many, TreatmentSite.Id to PatientExacerbation.TreatmentSiteId] | Hidden [Relationship] | | | | | | | |

Notes:

Treatments module under Exacerbation Section is a sub-report and is the same data captured in the Treatments Table (Refer to Section 36 Disease Specific Treatments)

17. MEDICAL CONDITIONS – Malignancy

17.1 Description

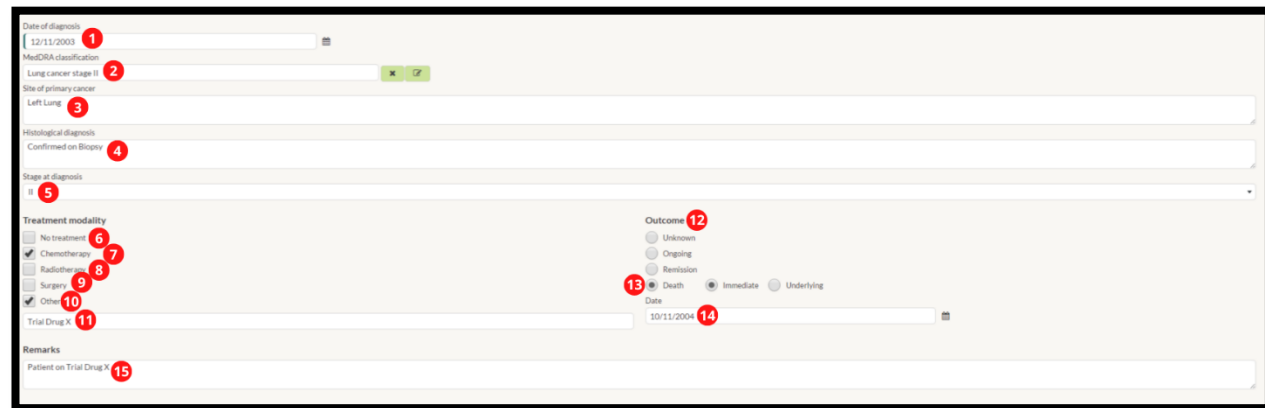
The Malignancy section allows you to record occurrences and details of malignancy.

17.2 Rules and Constraints

- Date of event must be after date of birth and prior to date of death.

17.3 Functions

- Add/Delete Malignancy – You can add/delete malignancy event.
- Add/Edit – You can add/edit details of the malignancy.



17.4 Malignancy Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|------------------------------|---------------|-------------|----------|------------------|---|------------------|---|
| 17.01 | Date of diagnosis [MedicalEvent.DateOfEvent] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Date of Death | Y | Defaults to Today's date or Date of Death |
| 17.02 | MedDRA Classification [MalignancyEvent.MeddraConditionId] | Selection Window [bigint] | | | Yes | | MedDRA LLT | Y | MedDRA LLT code stored in db field |
| 17.03 | Site of primary cancer [MalignancyEvent.PrimarySite] | Memo [text] | 2,147,483,647 | | Yes | | | Y | |
| 17.04 | Histological diagnosis [MalignancyEvent.HistoDiagnosis] | Memo [text] | 2,147,483,647 | | Yes | | | Y | |
| 17.05 | Stage at diagnosis [MalignancyEvent.StageDiag] | Dropdown [int] | | | Yes | | I[1]; II[2]; III[3]; IV[4] | Y | |
| 17.06 | Treatment – No Treatment [MalignancyEvent.IsNoTreatment] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 17.07 | Treatment – Chemotherapy [MalignancyEvent.IsChemotherapy] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 17.08 | Treatment – Radiotherapy [MalignancyEvent.IsRadiotherapy] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 17.09 | Treatment – Surgery [MalignancyEvent.IsSurgery] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 17.10 | Treatment – Other [MalignancyEvent.IsOther] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 17.11 | Treatment Modality Other [MalignancyEvent.TreatmentOther] | String [nvarchar] | 100 | | Yes | Length | | Y | Only available if Treatment – Other = True |
| 17.12 | Outcome [MalignancyEvent.EventOutcome] | Radio [int] | | | Yes | | Death[3]; Ongoing[1]; Remission[2]; Unknown[NULL] | Y | Note: If Death selected, Patient Identification and Medical History will automatically update with the relevant data. |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|------------------------------|---------------|-------------|----------|------------------|---|------------------|---|
| 17.13 | Death Outcome [MalignancyEvent.DeathReason] | Radio [int] | | | Yes | | Immediate[1]; Underlying[2] | Y | Visible when Outcome = Death |
| 17.14 | Outcome End Date [MalignancyEvent.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered between Date of Diagnosis (for Remission) or Date of Birth (for Death) and Today's date or ≤ Date of Death | Y | Only available if Outcome = Remission or Death |
| 17.15 | Remarks [MalignancyEvent.Remarks] | Memo [text] | 2,147,483,647 | | Yes | | | N | |
| | [MalignancyEvent.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK_MalignancyEvent_MeddraCondition, Relationship 1 to Many, 1_low_level_term.llt_code to MalignancyEvent.MeddraConditionId] | Hidden [Relationship] | | | | | | | |
| | [FK_MalignancyEv_Id__090A5324, Relationship 1 to 1, MedicalEvent.Id to MalignancyEvent.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Condition is stored in Table MedicalEvent, fields Type and Title

18. MEDICAL CONDITIONS - NMSC (Non-Melanoma Skin Cancer)

18.1 Description

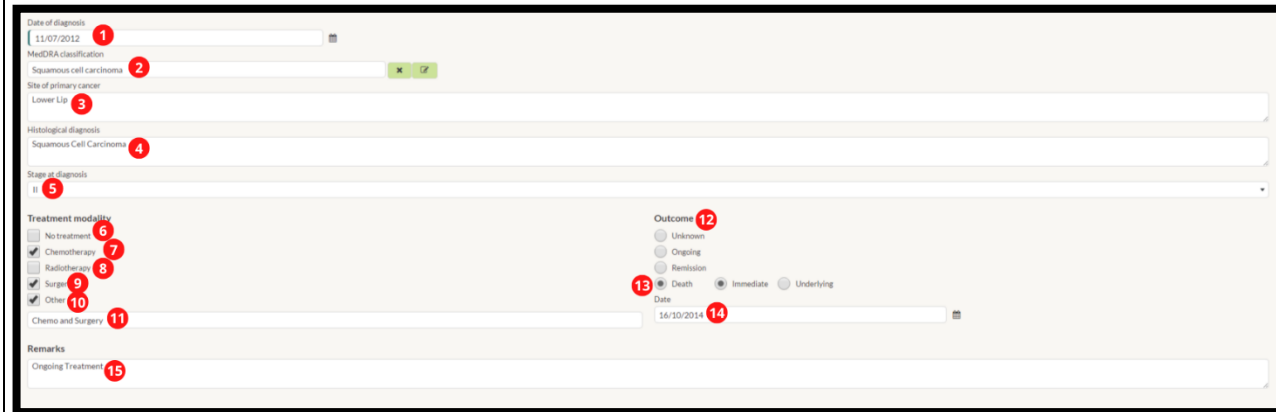
The NMSC section allows the user to record occurrences and details of NMSC.

18.2 Rules and Constraints

- Date of event must be after date of birth and prior to date of death.

18.3 Functions

- Add/Delete NMSC – You can add/delete NMSC event
- Add/Edit – You can add/edit details of the NMSC.



The screenshot shows a data entry form for a Non-Melanoma Skin Cancer (NMSC) event. The form includes the following fields and options:

- 1** Date of diagnosis: 11/07/2012
- 2** MedDRA classification: Squamous cell carcinoma
- 3** Site of primary cancer: Lower Lip
- 4** Histological diagnosis: Squamous Cell Carcinoma
- 5** Stage at diagnosis: II
- 6** Treatment modality: No treatment
- 7** Chemotherapy
- 8** Radiotherapy
- 9** Surgery
- 10** Other
- 11** Chemo and Surgery
- 12** Outcome: Unknown, Ongoing, Remission, Death, Immediate, Underlying
- 13** Date: 16/10/2014
- 14** Date: 16/10/2014
- 15** Remarks: Ongoing Treatment

18.4 NMSC Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|------------------------------|---------------|-------------|----------|------------------|---|------------------|---|
| 18.01 | Date of diagnosis [MedicalEvent.DateOfEvent] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Date of Death | Y | Defaults to Today's date or Date of Death |
| 18.02 | MedDRA Classification [NMSCEvent.MeddraConditionId] | Selection Window [bigint] | | | Yes | | MedDRA LLT | Y | MedDRA LLT code stored in db field |
| 18.03 | Site of primary cancer [NMSCEvent.PrimarySite] | Memo [text] | 2,147,483,647 | | Yes | | | Y | |
| 18.04 | Histological diagnosis [NMSCEvent.HistoDiagnosis] | Memo [text] | 2,147,483,647 | | Yes | | | Y | |
| 18.05 | Stage at Diagnosis [NMSCEvent.StageDiag] | Dropdown [int] | | | Yes | | I[1]; II[2]; III[3]; IV[4] | Y | |
| 18.06 | Treatment – No Treatment [NMSCEvent.IsNoTreatment] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 18.07 | Treatment – Chemotherapy [NMSCEvent.IsChemotherapy] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 18.08 | Treatment – Radiotherapy [NMSCEvent.IsRadiotherapy] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 18.09 | Treatment – Surgery [NMSCEvent.IsSurgery] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 18.10 | Treatment – Other [NMSCEvent.IsOther] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 18.11 | Treatment Modality Other [NMSCEvent.TreatmentOther] | String [nvarchar] | 100 | | Yes | Length | | Y | Only available if Treatment – Other = True |
| 18.12 | Outcome [NMSCEvent.EventOutcome] | Radio [int] | | | Yes | | Death[3]; Ongoing[1]; Remission[2]; Unknown[NULL] | Y | Note: If Death selected, Patient Identification and Medical History will automatically update with the relevant data. |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|------------------------------|---------------|-------------|----------|------------------|---|------------------|--|
| 18.13 | Death Outcome [NMSCEvent.DeathReason] | Radio [int] | | | Yes | | Immediate[1]; Underlying[2] | Y | Visible when Outcome = Death |
| 18.14 | Outcome Date [NMSCEvent.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered between Date of Diagnosis (for Remission) or Date of Birth (for Death) and Today's date or ≤ Date of Death | Y | Only available if Outcome = Remission or Death |
| 18.15 | Remarks [NMSCEvent.Remarks] | Memo [text] | 2,147,483,647 | | Yes | | | N | |
| | [NMSCEvent.Id] | Hidden [uniqueidentifier] | | | | | | Y | |
| | [FK_NMSCEvent_MeddraCondition, Relationship 1 to Many, 1_low_level_term.Ilt_code to NMSCEvent.MeddraConditionId] | Hidden [Relationship] | | | | | | | |
| | [FK__NMSCEvent__Id__147C05D0, Relationship 1 to 1, MedicalEvent.Id to NMSCEvent.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Condition is stored in Table MedicalEvent, fields Type and Title

19. MEDICAL CONDITIONS – Herpes Zoster

19.1 Description

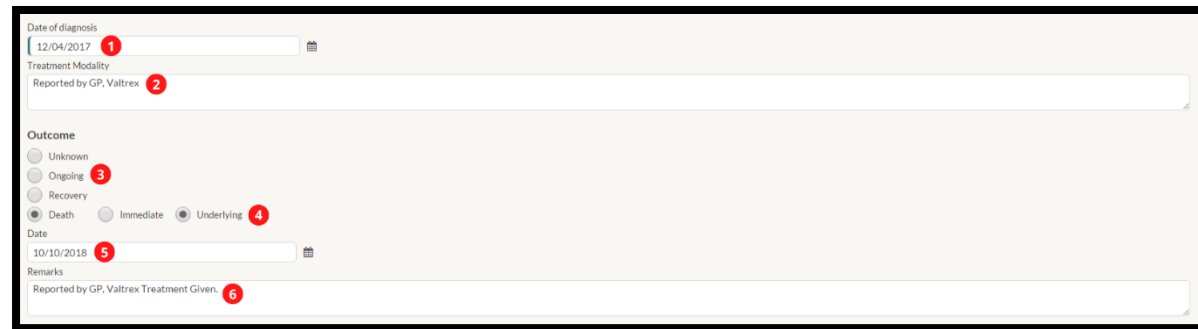
The Herpes Zoster section allows the user to record occurrences and details of Herpes Zoster.

19.2 Rules and Constraints

- Date of event must be after date of birth and prior to date of death.

19.3 Functions

- Add/Delete Herpes Zoster – You can add/delete Herpes Zoster event.
- Add/Edit – You can add/edit details of the Herpes Zoster.



The screenshot shows a form for recording a Herpes Zoster event. It includes the following fields and options:

- Date of diagnosis:** 12/04/2017 (1)
- Treatment Modality:** Reported by GP, Valtrex (2)
- Outcome:** Radio buttons for Unknown, Ongoing (3), Recovery, Death, Immediate, and Underlying (4). The "Underlying" option is selected.
- Date:** 10/10/2018 (5)
- Remarks:** Reported by GP, Valtrex Treatment Given (6)

19.4 Herpes Zoster Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|------------------------------|---------------|-------------|----------|------------------|---|------------------|---|
| 19.01 | Date of diagnosis [MedicalEvent.DateOfEvent] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Date of Death | Y | Defaults to Today's date |
| 19.02 | Treatment Modality [HerpesEvent.TreatmentModality] | Memo [text] | 2,147,483,647 | | Yes | | | Y | |
| 19.03 | Outcome [HerpesEvent.EventOutcome] | Radio [int] | | | Yes | | Death[3]; Ongoing[1]; Recovery[2]; Unknown[NULL] | Y | Note: If Death selected, Patient Identification and Medical History will automatically update with the relevant data. |
| 19.04 | Death Outcome [HerpesEvent.DeathReason] | Radio [int] | | | Yes | | Immediate[1]; Underlying[2] | Y | |
| 19.05 | Outcome Date [HerpesEvent.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Between Date of Birth and Today's date or ≤ Date of Death | Y | Only available if Outcome = Recovery or Death |
| 19.06 | Remarks [HerpesEvent.Remarks] | Memo [text] | 2,147,483,647 | | Yes | | | N | |
| | [HerpesEvent.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__HerpesEvent__Id__7F80E8EA, Relationship 1 to 1, MedicalEvent.Id to HerpesEvent.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Condition is stored in Table MedicalEvent, fields Type and Title

20. MEDICAL CONDITIONS – COVID-19

Medical condition

Date of onset

Diagnosis Confirmed? Yes No **3** **4** Was DMT ceased / delayed during this infection? Yes No **5**

Diagnosis Confirmed By

PCR Positive Negative Not Done **6**

Serology Positive Negative Not Done **7**

Typical Chest Imaging Finding Positive Negative Not Done **8**

Symptoms

Symptomatic? Yes No **9**

Fever Yes No **10**

Fatigue Yes No **11**

Dry Cough Yes No **12**

Sore Throat Yes No **13**

Anosmia Yes No **14**

Pain Yes No **15**

Pneumonia Yes No **16**

Diarrhoea Yes No **17**

Other Medical Conditions

Pregnancy Yes No **18**
 (†) Please capture all relevant Pregnancy data in the Pregnancy module

Current Smoker Yes No **19**

Obesity Yes No **20**

Other Medical Conditions? (Comorbidities?) Yes No **21**

CVS Incl. Hypertension Yes No **22**

Diabetes Yes No **23**

Chronic Lung Disease Yes No **24**

Renal Disease Yes No **25**

Liver Disease Yes No **26**

Malignancy Yes No **27**

Active In Remission **28**

Lab Tests

Pathology Test Conducted? Yes No **29**

Has a pathology test been done during this illness?

Lymphocyte Count
 22/12/2020 g/dL

White Cell Count
 22/12/2020 g/dL

CD19 B Cell Count
 22/12/2020 g/dL

COVID-19 Severity Indicator

Mild **39**

Moderate

Severe

Life threatening

Hospital Related Incidents

Hospital Admission? Yes No **40**

Date of Admission **41**

Date of Discharge **42**

ICU Admission? Yes No **43**

Date of Admission **44**

Date of Discharge **45**

Was Ventilation Required? Yes No **46**

Invasive Non-Invasive **47**

Was ECMO Required? Yes No **48**

COVID-19 Outcome

Unknown

Ongoing

Recovery **49**

Death

Date **50**

Remarks

Moderate Covid-19

20.1 Description

- The COVID-19 section allows the user to record occurrences and details of the COVID-19 (SARS-CoV-2) infection.

20.2 Rules and Constraints

- Date of event must be after date of birth and prior to date of death.
- Date of Diagnosis can only be entered once “Diagnosis confirmed?” = “Yes”
- If “Was DMT ceased / delayed during this infection?” = “Yes” the message “Please update the following DMTs in the treatment section” (and will display any active or ongoing DMTs)
- Symptoms can only be selected if “Symptomatic?” = “Yes”
- Comorbidities can only be selected if “Other Medical Conditions?” (Comorbidities) = “Yes”
- Pathology Test Data can only be entered, if “Pathology Test Conducted?” = “Yes”

20.3 Functions

- Add/Delete COVID-19 infection event
- Add/Edit – You can add/edit details of the COVID-19 infection event

20.4 COVID-19 Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|------------------------------|-----|-------------|----------|--|---------------------------------------|------------------|--|
| 20.01 | Medical Condition [Covid19Event.MeddraConditionId] or [Covid19Event.MedicalConditionId] [uniqueidentifier] | Selection Window [bigint] | | | | Mandatory | MedDRA Conditions List | Y | Defaults to COVID-19 MedDRA Condition ID |
| 20.02 | Date of Onset [MedicalEvent.DateOfEvent] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today | Y | Defaults to Today's date or Date of Death |
| 20.03 | Diagnosis Confirmed? [Covid19Event.IsDiagnosisConfirmed] | Radio [bit] | | | No | | Yes[1]; No[0] | Y | |
| 20.04 | Date Confirmed [Covid19Event.DiagnosisConfirmedDate] | Date [datetime] | | dd/mm/yyyy | Yes | Mandatory if Diagnosis Confirmed? = Yes | Filtered ≥ Date of Birth and ≤ Today | Y | Available if Diagnosis Confirmed? = Yes |
| 20.05 | DMT ceased / delayed? [Covid19Event.WasDmtDelayed] | Radio [bit] | | | Yes | | Yes[1]; No[0] | Y | Note: If Yes, a list of DMTs will be displayed |
| 20.06 | Confirmed By – PCR [Covid19Event.ConfirmedByPcr] | Radio [int] | | | Yes | At least 1 confirmation must be selected if Diagnosis Confirmed? = Yes | Positive[1]; Negative[2]; Not Done[3] | Y | Visible if Diagnosis Confirmed? = Yes |
| 20.07 | Confirmed By – Serology [Covid19Event.ConfirmedBySerology] | Radio [int] | | | Yes | At least 1 confirmation must be selected if Diagnosis Confirmed? = Yes | Positive[1]; Negative[2]; Not Done[3] | Y | Visible if Diagnosis Confirmed? = Yes |
| 20.08 | Confirmed By – Chest Imaging [Covid19Event.ConfirmedByChestImaging] | Radio [int] | | | Yes | At least 1 confirmation must be selected if Diagnosis Confirmed? = Yes | Positive[1]; Negative[2]; Not Done[3] | Y | Visible if Diagnosis Confirmed? = Yes |
| 20.09 | Symptomatic? [Covid19Event.IsSymptomatic] | Radio [int] | | | No | | Yes[1]; No[0] | Y | |
| 20.10 | S – Fever [Covid19Event.SymptomsFever] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | Available when Symptomatic? = Yes |
| 20.11 | S – Fatigue [Covid19Event.SymptomsFatigue] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | Available when Symptomatic? = Yes |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|----------------|-----|-------------|----------|--|----------------|------------------|--|
| 20.12 | S – Dry Cough [Covid19Event.SymptomsDryCough] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | Available when Symptomatic? = Yes |
| 20.13 | S – Sore Throat [Covid19Event.SymptomsSoreThroat] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | Available when Symptomatic? = Yes |
| 20.14 | S – Anosmia [Covid19Event.SymptomsAnosmia] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | Available when Symptomatic? = Yes |
| 20.15 | S – Pain [Covid19Event.SymptomsPain] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | Available when Symptomatic? = Yes |
| 20.16 | S – Pneumonia [Covid19Event.SymptomsPneumonia] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | Available when Symptomatic? = Yes |
| 20.17 | S – Diarrhoea [Covid19Event.SymptomsDiarrhoea] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | Available when Symptomatic? = Yes |
| 20.18 | Other MC – Pregnancy [Covid19Event.OtherConditionsPregnancy] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | |
| 20.19 | Other MC – Current Smoker [Covid19Event.OtherConditionsCurrentSmoker] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | |
| 20.20 | Other MC – Obesity [Covid19Event.OtherConditionsObesity] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | |
| 20.21 | Other MC – Comorbidities [Covid19Event.OtherConditionsOther] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | |
| 20.22 | Comorbidities – CVS Incl. [Covid19Event.OtherConditionsCvs] | Radio [int] | | | Yes | At least 1 condition must be selected if Other Medical Conditions (Comorbidities)? = Yes | Yes[1]; No[0] | Y | Available if Other Medical Conditions (Comorbidities)? = Yes |
| 20.23 | Comorbidities – Diabetes [Covid19Event.OtherConditionsDiabetes] | Radio [int] | | | Yes | At least 1 condition must be selected if Other Medical Conditions (Comorbidities)? = Yes | Yes[1]; No[0] | Y | Available if Other Medical Conditions (Comorbidities)? = Yes |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|------------------------------|-----|-------------|----------|--|----------------------------|------------------|--|
| 20.24 | Comorbidities – Chronic Lung Disease [Covid19Event.OtherConditionsLungDisease] | Radio [int] | | | Yes | At least 1 condition must be selected if Other Medical Conditions (Comorbidities)? = Yes | Yes[1]; No[0] | Y | Available if Other Medical Conditions (Comorbidities)? = Yes |
| 20.25 | Comorbidities – Renal Disease [Covid19Event.OtherConditionsRenalDisease] | Radio [int] | | | Yes | At least 1 condition must be selected if Other Medical Conditions (Comorbidities)? = Yes | Yes[1]; No[0] | Y | Available if Other Medical Conditions (Comorbidities)? = Yes |
| 20.26 | Comorbidities – Liver Disease [Covid19Event.OtherConditionsLiverDisease] | Radio [int] | | | Yes | At least 1 condition must be selected if Other Medical Conditions (Comorbidities)? = Yes | Yes[1]; No[0] | Y | Available if Other Medical Conditions (Comorbidities)? = Yes |
| 20.27 | Comorbidities – Malignancy [Covid19Event.OtherConditionsMalignancy] | Radio [int] | | | Yes | At least 1 condition must be selected if Other Medical Conditions (Comorbidities)? = Yes | Yes[1]; No[0] | Y | Available if Other Medical Conditions (Comorbidities)? = Yes |
| 20.28 | Comorbidities – Malignancy Type [Covid19Event.OtherConditionsMalignancyType] | Radio [int] | | | Yes | Mandatory if Malignancy = Yes | Active[1]; In Remission[2] | Y | Available if Malignancy (Comorbidities)? = Yes |
| 20.29 | Pathology Test Conducted? [Covid19Event.PathologyTestConducted] | Radio [int] | | | Yes | | Yes[1]; No[0] | Y | |
| 20.30 | Lymphocyte – Date | Date | | | | | | Y | Available if Pathology Test Conducted? = Yes A Medical Test record, type Lab – Haematology, is created on save when data is complete. |
| 20.31 | Lymphocyte – Value | String | | | | Mandatory if Lymphocyte – Date is not NULL | | Y | Available if Pathology Test Conducted? = Yes |
| 20.32 | Lymphocyte – Unit | Dropdown | | | | Mandatory if Lymphocyte – Date is not NULL | | Y | Available if Pathology Test Conducted? = Yes |
| | [Covid19Event.LymphocyteTestResultId] | Hidden [uniqueidentifier] | | | Yes | | | Y | |
| 20.33 | White Cell – Date | | | | | | | Y | Available if Pathology Test Conducted? = Yes A Medical Test record, type Lab – |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|------------------------------|-----|-------------|----------|--|-------------------|------------------|---|
| | | | | | | | | | Haematology, is created on save when data is complete. |
| 20.34 | White Cell – Value | | | | | Mandatory if White Cell – Date is not NULL | | Y | Available if Pathology Test Conducted? = Yes |
| 20.35 | White Cell – Unit | | | | | Mandatory if White Cell – Date is not NULL | | Y | Available if Pathology Test Conducted? = Yes |
| | [Covid19Event.WhiteCellCountTestResultId] | Hidden [uniqueidentifier] | | | Yes | | | Y | |
| 20.36 | CD19B Cell – Date | | | | | | | Y | Pathology Test Conducted? = Yes A Medical Test record, type Lab – Haematology, is created on save when data is complete. |
| 20.37 | CD19B Cell – Value | | | | | Mandatory if CD19B Cell – Date is not NULL | | Y | Available if Pathology Test Conducted? = Yes |
| 20.38 | CD19B Cell – Unit | | | | | Mandatory if CD19B Cell – Date is not NULL | | Y | Available if Pathology Test Conducted? = Yes |
| | [Covid19Event.CD19BCellTestResultId] | Hidden [uniqueidentifier] | | | Yes | | | Y | |
| 20.39 | COVID-19 Severity – Mild [Covid19Event.IsMild] | Checkbox [int] | | | No | | True[1]; False[0] | Y | |
| 20.39 | COVID-19 Severity – Moderate [Covid19Event.IsModerate] | Checkbox [int] | | | No | | True[1]; False[0] | Y | |
| 20.39 | COVID-19 Severity – Severe [Covid19Event.IsSevere] | Checkbox [int] | | | No | | True[1]; False[0] | Y | |
| 20.39 | COVID-19 Severity – Life threatening [Covid19Event.IsLifeThreatening] | Checkbox [int] | | | No | | True[1]; False[0] | Y | |
| 20.40 | Hospital Admission? [Covid19Event.HospitalAdmission] | Radio [bit] | | | Yes | | Yes[1]; No[0] | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|------------------------------|---------------|-------------|----------|---|--|------------------|--|
| 20.41 | HA – Date of Admission [Covid19Event.DateOfHospitalAdmission] | Date [datetime] | | | Yes | Mandatory if Hospital Admission? = Yes | Filtered ≥ Date of Birth and ≤ Today | Y | Available if Hospital Admission? = Yes |
| 20.42 | HA – Date of Discharge [Covid19Event.DateOfHospitalDischarge] | Date [datetime] | | | Yes | | Filtered ≥ Date of Birth and ≤ Today | Y | Available if Hospital Admission? = Yes |
| 20.43 | ICU Admission? [Covid19Event.IcuAdmission] | Radio [bit] | | | Yes | | Yes[1]; No[0] | Y | |
| 20.44 | ICU – Date of Admission [Covid19Event.DateOfIcuAdmission] | Date [datetime] | | | Yes | Mandatory if ICU Admission? = Yes | Filtered ≥ Date of Birth and ≤ Today | Y | Available if ICU Admission? = Yes |
| 20.45 | ICU – Date of Discharge [Covid19Event.DateOfIcuDischarge] | Date [datetime] | | | Yes | | Filtered ≥ Date of Birth and ≤ Today | Y | Available if ICU Admission? = Yes |
| 20.46 | Was Ventilation Required? [Covid19Event.WasVentilationRequired] | Radio [bit] | | | Yes | | Yes[1]; No[0] | Y | |
| 20.47 | Ventilation Type [Covid19Event.VentilationType] | Radio [bit] | | | Yes | | Invasive[1]; Non-Invasive[2] | Y | Available if Was Ventilation Required? = Yes |
| 20.48 | ECMO Required? [Covid19Event.WasEcmoRequired] | Radio [bit] | | | Yes | | Yes[1]; No[0] | Y | |
| 20.49 | COVID-19 Outcome [Covid19Event.EventOutcome] | Radio [int] | | | Yes | | Unknown[NULL]; Ongoing[1]; Recovery[2]; Death[3] | Y | |
| 20.50 | Outcome End Date [Covid19Event.EndDate] | Date [datetime] | | | Yes | Mandatory if Recovery or Death selected | Max date = Today | Y | Available if Recovery or Death selected |
| 20.51 | Remarks [Covid19Event.Remarks] | Memo [text] | 2,147,483,647 | | Yes | | | N | |
| | [Covid19Event.DeathReason] | Hidden [int] | | | Yes | | | Y | No longer used |
| | [Covid19Event.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|--------------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | [FK__Covid19Event__Id__69279377, Relationship 1 to 1, MedicalEvent.Id to Covid19Event.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__Covid19Event_MeddraCondition, Relationship 1 to Many, 1_low_level_term.Ilt_code to COVID19Event.MeddraConditionId] | Hidden [Relationship] | | | | | | | |
| | [FK__Covid19Ev__Medic__68336F3E, Relationship 1 to Many, MedicalCondition.Id to COVID19Event.MedicalConditionId] | Hidden [Relationship] | | | | | | | |
| | [FK__Covid19Ev__CD19B__6CF8245B, Relationship 1 to 1, LaboratoryTestMeasureResult.Id to COVID19Event.CD19BCellTestResultId] | Hidden [Relationship] | | | | | | | |
| | [FK__Covid19Ev__Lymph__6C040022, Relationship 1 to 1, LaboratoryTestMeasureResult.Id to COVID19Event.LymphocyteTestResultId] | Hidden [Relationship] | | | | | | | |
| | [FK__Covid19Ev__White__6B0FDBE9, Relationship 1 to 1, LaboratoryTestMeasureResult.Id to COVID19Event.WhiteCellCountTestResultId] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Condition is stored in Table MedicalEvent, fields Type and Title

21. MEDICAL CONDITIONS

– Immuno-suppression-associated

21.1 Description

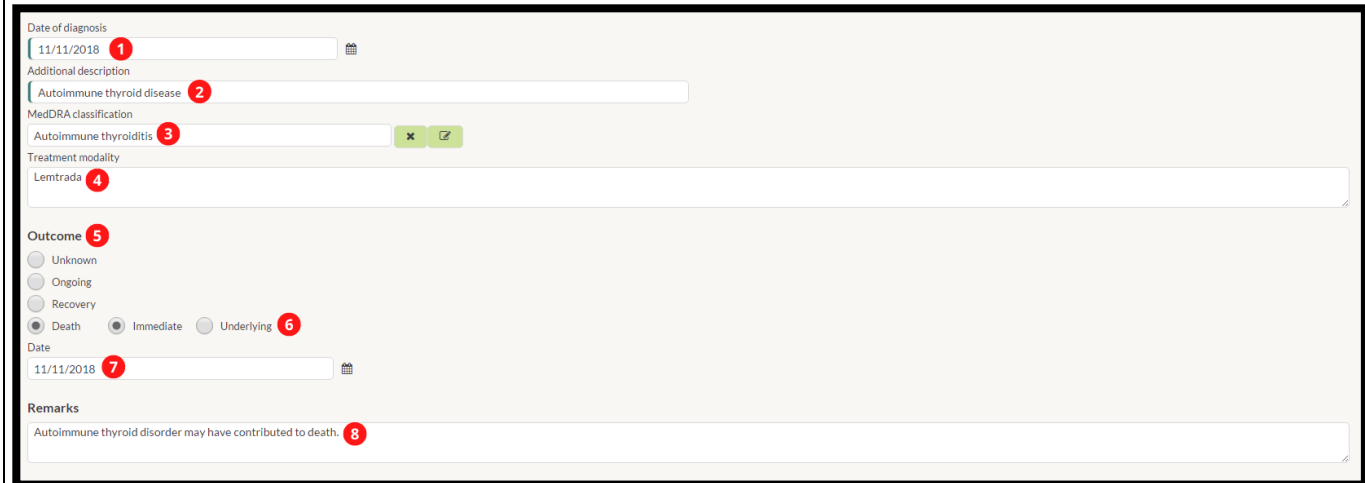
The Immuno-Suppression Associated section allows the user to record occurrences and details of infection.

21.2 Rules and Constraints

- Date of event must be after date of birth and prior to date of death.

21.3 Functions

- Add/Delete Immuno-Suppression Associated – You can add/delete Immuno-Suppression Associated event
- Add/Edit – You can add/edit details of the Immuno-Suppression Associated event.



The screenshot displays a data entry form for medical conditions. The form includes the following fields and options:

- Date of diagnosis:** A date picker field containing "11/11/2018" (marked with a red 1).
- Additional description:** A text input field containing "Autoimmune thyroid disease" (marked with a red 2).
- MedDRA classification:** A dropdown menu showing "Autoimmune thyroiditis" (marked with a red 3), with "x" and "edit" icons to the right.
- Treatment modality:** A text input field containing "Lemtrada" (marked with a red 4).
- Outcome:** A section with radio button options: "Unknown", "Ongoing", "Recovery", "Death", "Immediate", and "Underlying" (marked with a red 5). The "Immediate" option is selected (marked with a red 6).
- Date:** A date picker field containing "11/11/2018" (marked with a red 7).
- Remarks:** A text input field containing "Autoimmune thyroid disorder may have contributed to death." (marked with a red 8).

21.4 Immuno-suppression-associated Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|------------------------------|---------------|-------------|----------|-------------------------------|---|------------------|--|
| 21.01 | Date of Diagnosis [MedicalEvent.DateOfEvent] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today or Date of Death | Y | |
| 21.02 | Additional Description [ImmunoinfectionEvent.InfectionName] | String [nvarchar] | 100 | | Yes | Mandatory Length | | Y | |
| 21.03 | MedDRA classification [ImmunoinfectionEvent.MeddraConditionId] | Selection Window [bigint] | | | Yes | | | Y | MedDRA Condition selection window |
| 21.04 | Treatment Modality [ImmunoinfectionEvent.TreatmentModality] | Memo [text] | 2,147,483,647 | | Yes | Maximum length 500 characters | | Y | |
| 21.05 | Outcome [ImmunoinfectionEvent.EventOutcome] | Radio [int] | | | Yes | | Death[3]; Ongoing[1]; Recovery[2]; Unknown[NULL] | Y | |
| 21.06 | Death Outcome [ImmunoinfectionEvent.DeathReason] | Radio [int] | | | Yes | | Immediate[1]; Underlying[2] | Y | Visible if Outcome = Death |
| 21.07 | Outcome Date [ImmunoinfectionEvent.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | For Death: Filtered ≥ Date of Birth and ≤ Today For Recovery: Filtered ≥ Date of Diagnosis and ≤ Today | Y | Available if Outcome = Recovery or Death |
| 21.08 | Remarks [ImmunoinfectionEvent.Remarks] | Memo [text] | 2,147,483,647 | | Yes | | | N | |
| | [ImmunoinfectionEvent.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__Immunoinfect__Id__0169315C, Relationship 1 to 1, MedicalEvent.Id to ImmunoinfectionEvent.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__ImmunoinfectionEvent_MeddraCondition, Relationship 1 to Many, | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | 1_low_level_term.lit_code to ImmunoInfectionEvent.MeddraConditionId] | | | | | | | | |

Notes:

- Type of Medical Condition is stored in Table MedicalEvent, fields Type and Title

22. MEDICAL CONDITIONS – Pregnancy & Infant Outcomes(a)

22.1 Pregnancy Description

The Pregnancy section allows the user to record occurrences and details of pregnancy, more accurate detailed capture of maternal and neonatal outcomes, including the use of EUROCAT classification criteria for neonatal complication as well as detailed breastfeeding data capture.

Pregnancy
Infant Outcomes 1

Please use this form to provide information on current or past pregnancy events

Substance Use

Did patient smoke during this pregnancy? Yes No Unknown 1

Did patient consume alcohol during this Pregnancy? Yes No Unknown 2

If yes, was alcohol consumed during the first trimester? Yes No Unknown 4

4 or more times a week 3

2-4 times a month 5

Pregnancy

Last menstrual period (LMP; pregnancy start date) 6

Estimated delivery date 7

ART Method 8

Maternal Ethnicity 9

Was the patient (mother) born with any congenital malformations? Yes No Unknown 10

If yes, select relevant congenital abnormality:

+ 11

Outcome #1

Pregnancy end date 12

Gestation period

Weight Units 13

14 grams

Infant Length 15

16 cm

Head Circumference 17

18 cm

Breastfeeding 19

Sex 20

Breastfeeding start date 21

Exclusive breastfeeding end date 22

All breastfeeding end date 23

Obstetric / Maternal Complications + 24

Delivery Method 25

Outcome 26

APGAR Score 27

1 minute Abnormal Normal Unknown 27

10 minute Abnormal Normal Unknown 28

Add Outcome 29

Consent for Infant Outcome Data 30

Does the patient consent to the data capture for the Infant, as part of centre ethics approval?

Yes No

22.2 Rules and Constraints

- Pregnancy screen is only enabled and visible if patient is female
- Entering date for “Last menstrual period” will automatically calculate a delivery date 40 weeks one and enter this into “Estimated delivery date”. Conversely, entering date for “Estimated delivery date” will reverse calculate a “Last menstrual period” date (minus 40 weeks from EDD)
- Once Pregnancy end date has been captured, the calculation of the Gestation period, based on the difference between the “Estimated delivery date” and the “Pregnancy end date”, is displayed on the screen
- Birth weight <2500 Grams will display alert message: “Low birth weight entered. Are you sure?”
- Birth weight >4300 Grams will display alert message: “Heavy birth weight entered. Are you sure?”
- Birth weight <6 Pounds or >9 Pounds 7 Ounces will display the same alert message.
- If “Breastfeeding” = “Yes” This will expand a section for further detail to be captured around breastfeeding dates.
- Up to 3 Outcomes can be captured. If more Outcomes are required, they will need to be added as a separate Pregnancy record.
- If any Outcome = a “live birth” then the clinician will be able to enter associated Infant outcome data, upon recording agreement in terms of maternal consent
- Validation: A “live” birth is only considered live if one of the following Outcomes is selected:
 - Term delivery healthy (≥ 37 weeks)
 - Pre-term delivery healthy (< 37 weeks)
 - Term delivery with congenital abnormality (≥ 37 weeks)
 - Pre-term delivery with congenital abnormality (< 37 weeks)

22.3 Functions

Add/Edit / Delete Pregnancy – You can add/edit / delete Pregnancy event.

22.4 Pregnancy Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|----------|--|-----------------------------|-----|-------------|----------|---|--|------------------|--|
| | <u>Substance User Section</u> | | | | | | | | |
| 22.01.01 | Smoking Status during Pregnancy | Radio [int] | | | Yes | | Yes; No; Unknown; NULL | Y | |
| 22.01.02 | Alcohol consumed during Pregnancy | Radio [int] | | | Yes | | Yes; No; Unknown; NULL | Y | |
| 22.01.03 | Alcohol consumed during Pregnancy frequency | Dropdown [uniqueidentifier] | | | Yes | Conditionally enabled if 20.01.02 = Yes | Never Monthly or less 2-4 times a month 2-3 times a week 4 times or more a week | | |
| 22.01.04 | Alcohol consumed during first trimester | Radio [int] | | | Yes | | Yes; No; Unknown; NULL | Y | |
| 22.01.05 | Alcohol consumed during FirstTrim frequency | Dropdown [uniqueidentifier] | | | Yes | Conditionally enabled if 20.01.04 = Yes | Never Monthly or less 2-4 times a month 2-3 times a week 4 times or more a week | Y | |
| | <u>Pregnancy details section</u> | | | | | | | | |
| 22.01.06 | Last menstrual period (LMP; pregnancy start date) | Date [datetime] | | dd/mm/yyyy | | Calcs EDD | | Y | |
| 22.01.07 | Estimated delivery date [PregnancyEvent.EstimatedDeliveryDate] | Date [datetime] | | dd/mm/yyyy | Yes | Calcs LMP | Filtered ≥ Date of Birth | Y | |
| 22.01.08 | ART Method [PregnancyEvent.IVFMethoId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table PregnancyRefData where Discriminator = IVFMethod None; IVF; IUI; Ovulation Drugs; Other | Y | |
| 22.01.09 | Maternal Ethnicity [PregnancyEvent.MaternalEthnicityId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup values from Table EthnicOrigin African; Jewish; Middle-eastern; Admixed; Other; Indigenous; Asian; European; Hispanic; Inuit; Semite | Y | |
| 22.01.10 | Mother congenital malformations | Radio [int] | | | Yes | | Yes; No; Unknown; NULL | Y | |
| 22.01.11 | Mother congenital abnormalities (MedDRA) | MedDRA Selector [bigint] | | | Yes | | | Y | MedDRA Condition selection window. LLT Stored |
| | <u>Outcome Section</u> | | | | | | | | |
| 22.01.12 | Pregnancy End Date [PregnancyChildEvent.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered ≥ Last menstrual period | Y | Gestation auto calculation displays adjacent to this field for information |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|----------|---|--------------------------------|-----|-------------|----------|----------------------------------|---|------------------|---|
| 22.01.13 | Weight Units [PregnancyChildEvent.BirthWeightUnit] | Dropdown [int] | | | No | | Grams; Pounds/Ounces | Y | |
| 22.01.14 | Grams [PregnancyChildEvent.BirthWeight] | Number [decimal] | | | No | | | Y | Visible when Weight Units = Grams |
| 22.01.14 | Pounds [PregnancyChildEvent.BirthWeightLbs] | Number [decimal] | | | Yes | | | Y | Visible when Weight Units = Pounds / Ounces |
| 22.01.14 | Ounces [PregnancyChildEvent.BirthWeightOz] | Number [decimal] | | | Yes | | | Y | Visible when Weight Units = Pounds / Ounces |
| 22.01.15 | Infant Length Unit | Dropdown [int] | | | | | Centimetres; Inches | Y | |
| 22.01.16 | Infant Length Value | Number [decimal] | | | | | | Y | Entered in centimetres or inches |
| 22.01.17 | Head Circumference Unit | Dropdown [int] | | | | | Centimetres; Inches | | |
| 22.01.18 | Head Circumference Value | Number [decimal] | | | | | | | Entered in centimetres or inches |
| 22.01.19 | Breastfeeding [PregnancyChildEvent.Breastfeeding] | Dropdown [bit] | | | No | | Yes;No | Y | |
| 22.01.20 | Sex [PregnancyChildEvent.SexId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table PregnancyRefData where Discriminator = PregnancySex Male; Female, Indeterminate | Y | |
| 22.01.21 | Breastfeeding start date [PregnancyChildBreastFeedingEvent.StartDate] | Date [datetime] | | dd/mm/yyyy | No | Mandatory if Breastfeeding = Yes | Filtered ≥ Pregnancy End Date | Y | Visible when Breastfeeding = Yes |
| 22.01.22 | Exclusive breastfeeding end date [PregnancyChildBreastFeedingEvent.NonExStartDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered ≥ Pregnancy End Date | Y | Visible when Breastfeeding = Yes |
| 22.01.23 | All breastfeeding end date [PregnancyChildBreastFeedingEvent.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered ≥ Pregnancy End Date | Y | Visible when Breastfeeding = Yes |
| 22.01.24 | Obstetric / Maternal Complications [PregnancyObstetricMaternalComplicationEvent.ObstetricMaternalComplicationId] | Dropdown [uniqueidentifier] | | | No | | Lookup Values from table PregnancyRefData where Discriminator = PregnancyObstetricMaternalComplication Please refer to the tab for the Table in the Db Schema file to see the selection options | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|------------|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| | | | | | | | (and associated ids) available for this field. | | |
| 22.01.25 | Delivery Method [PregnancyChildEvent.DeliveryMethodId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table PregnancyRefData where Discriminator = PregnancyDeliveryMethod Vaginal Delivery; Vaginal Delivery Assisted; Elective Caesarian; Emergency Caesarian | Y | |
| 22.01.26a | Outcome [PregnancyChildEvent.OutcomeId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table PregnancyRefData where Discriminator = PregnancyOutcome Ongoing; Term delivery healthy (>=37 weeks); Pre-term delivery healthy (<37 weeks); Term delivery with congenital abnormality (>=37 weeks); Pre-term delivery with congenital abnormality (<37 weeks); Miscarriage (< 20 weeks); Miscarriage (>= 20 weeks); Ectopic pregnancy; Elective Termination; Neonatal death (>20 weeks) | Y | |
| 22.01.26-b | Congenital Abnormality [PregnancyChildCongenitalAbnormalityEvent.PregnancyCongenitalAbnormalityId] | Dropdown [uniqueidentifier] | | | No | | Lookup Values from table PregnancyRefData where Discriminator = PregnancyCongenitalAbnormality Please refer to the tab for the Table in the Db Schema file to see the selection options (and associated ids) available for this field. | Y | Visible when Outcome = Term delivery with congenital abnormality (>=37 weeks) or Pre-term delivery with congenital abnormality (<37 weeks) |
| 22.01.26-c | Reason for Termination/Miscarriage [PregnancyChildEvent.TerminationReasonId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table PregnancyRefData where Discriminator = PregnancyTerminationReason Unknown; Maternal Medical; Non-medical DMT Exposure; Cardiac Malformation; Down's Syndrome; Other chromosomal abnormality; Gastroschisis; Limb shortening defect; Neural tube defect; Unviable foetus; Other | Y | Visible when Outcome = Miscarriage (< 20 weeks) or Miscarriage (>= 20 weeks) or Elective Termination |
| 22.01.27 | APGAR score – 1 Minute | Radio [int] | | | Yes | | Abnormal; Normal; Unknown; NULL | Y | |
| 22.01.28 | APGAR score – 10 Minute | Radio [int] | | | Yes | | Abnormal; Normal; Unknown; NULL | Y | |
| 22.01.29 | Add Outcome Button – Feature allowing additional outcomes to be added | | | | | | | | |
| 22.01.30 | Consent for Infant Outcome Data | Radio [int] | | | Yes | See Comments | Yes; No; NULL | Y | Consent must = "Yes" to enable Infant Outcome Data to be captured |

22. MEDICAL CONDITIONS – Pregnancy & Infant Outcomes(b)

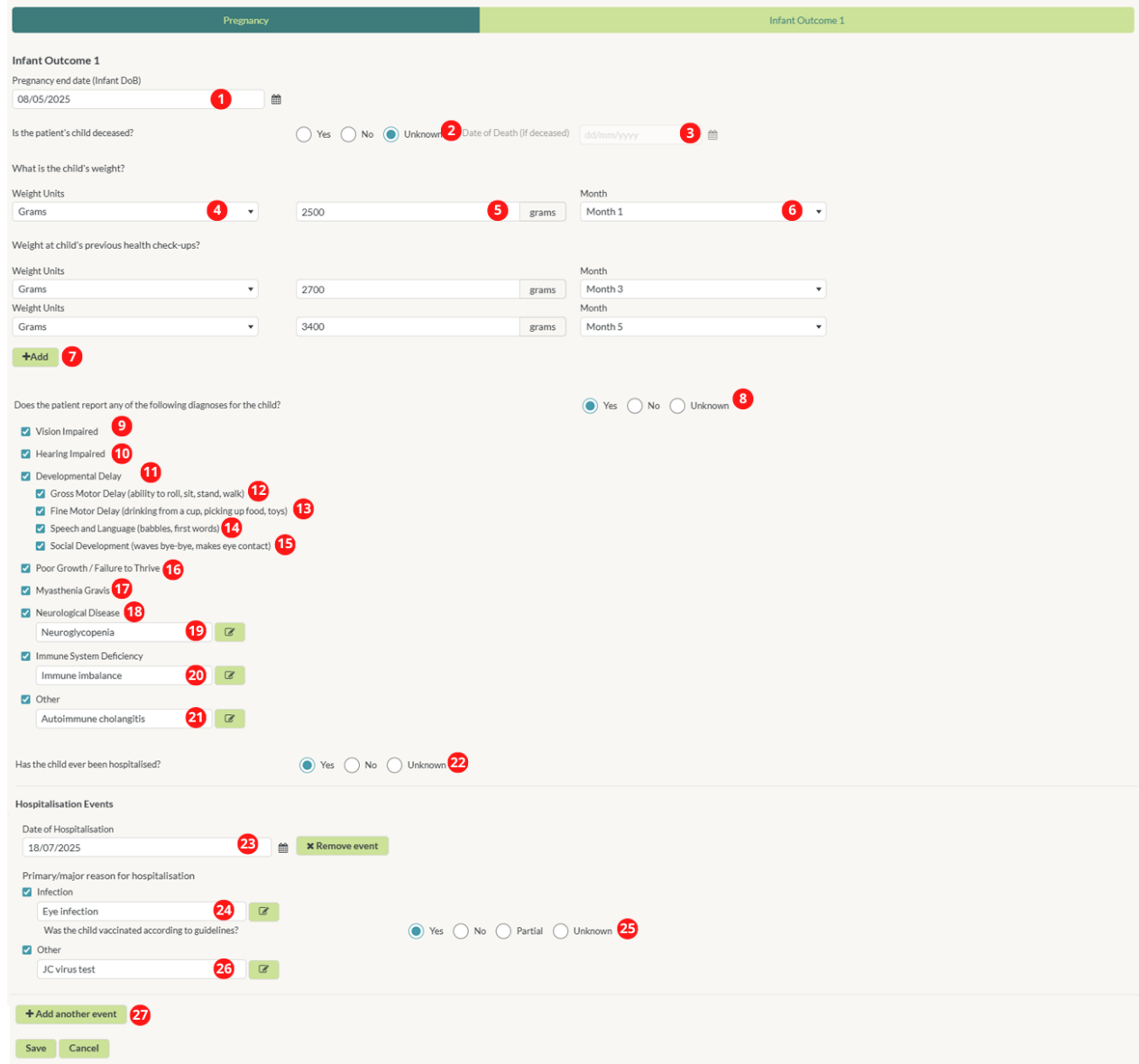
22.2 Infant Outcome Module

The Infant Outcome section allows for the collection of infant outcome data, which is only enabled upon maternal consent. This section captures infant birth data including elements such as weight intervals, developmental delays, hospitalisation events including MedDRA coded diagnosis and vaccination status

- Rules and Constraints

- Infant data can only be captured for live births. Refer section 20.1
- Consent must be set to “Yes” to enable the capture of Infant Outcome Data
- Pregnancy end date (Infant Date of Birth) is automatically linked to the associated pregnancy end date for the relevant infant in the Pregnancy screen

Retracting consent deletes all infant outcome data previously captured (User is alerted via message prompt)



The screenshot displays the 'Infant Outcome 1' form in the MGBase system. The form is divided into two main sections: 'Pregnancy' (top, dark green header) and 'Infant Outcome 1' (bottom, light green header). The form contains the following fields and controls, each marked with a red number:

- 1:** Pregnancy end date (Infant DoB) text input field.
- 2:** Radio button for 'Unknown' in the 'Is the patient's child deceased?' section.
- 3:** Date of Death (if deceased) text input field.
- 4:** Weight Units dropdown menu (set to Grams).
- 5:** Weight value text input field (set to 2500).
- 6:** Month dropdown menu (set to Month 1).
- 7:** '+Add' button for adding previous health check-ups.
- 8:** Radio button for 'Yes' in the 'Does the patient report any of the following diagnoses for the child?' section.
- 9-15:** Checked checkboxes for various developmental delays: Vision Impaired, Hearing Impaired, Developmental Delay, Gross Motor Delay, Fine Motor Delay, Speech and Language, and Social Development.
- 16-21:** Checked checkboxes for various medical conditions: Poor Growth / Failure to Thrive, Myasthenia Gravis, Neurological Disease (with Neuroglycopenia sub-field), Immune System Deficiency (with Immune imbalance sub-field), and Other (with Autoimmune cholangitis sub-field).
- 22:** Radio button for 'Yes' in the 'Has the child ever been hospitalised?' section.
- 23:** Date of Hospitalisation text input field.
- 24:** Checked checkbox for 'Infection' (with Eye infection sub-field).
- 25:** Radio button for 'Yes' in the 'Was the child vaccinated according to guidelines?' section.
- 26:** Checked checkbox for 'Other' (with JC virus test sub-field).
- 27:** '+Add another event' button.

At the bottom of the form, there are 'Save' and 'Cancel' buttons.

| Ref | Field | Type | Len | Data Format | Nullable | Validation/ check | Allowed Values | Sent to Registry | Comments | |
|----------|--|------------------|-----|-------------|----------|---|--|------------------|--|--|
| | <u>Infant Outcome Data</u> | | | | | | | | | |
| 22.02.01 | Pregnancy end date (Infant DoB) | Date [datetime] | | dd/mm/yyyy | | | | Y | Aligned with Outcome 20.01.12 – updating this field also updates 20.01.12 | |
| 22.02.02 | Infant deceased status | Radio [int] | | | Yes | | Yes; No; Unknown; NULL | Y | | |
| 22.02.03 | Infant deceased date (Date of Death) | Date [datetime] | | dd/mm/yyyy | | Only enabled if deceased status = "Yes" | | Y | | |
| 22.02.04 | Infant weight units | Dropdown [int] | | | No | | Grams; Pounds/Ounces | Y | Ability to select metric/imperial units | |
| 22.02.05 | Infant weight value | Number [decimal] | | | Yes | | | Y | | |
| 22.02.06 | Infant weight month | Dropdown [int] | | | | | Picklist of values ranging from [Month 1 – Month 18] | Yes | | |
| 22.02.07 | <i>"Add" Button enables user to add additional records of Infant Weight at previous health check-ups up to 18 months</i> | | | | | | | | Y | Ability to record up to 18 months of infant weight intervals |
| | <u>Infant Diagnostic Data</u> | | | | | | | | | |
| 22.02.08 | Patient reported diagnosis on behalf of infant | Radio [int] | | | Yes | | Yes; No; Unknown; NULL | Y | If "Yes" is selected, this enables further details to be captured around any diagnosis details | |
| 22.02.09 | Vision Impaired | Checkbox | | | | | Checked / Unchecked [True / False] | Y | | |
| 22.02.10 | Hearing Impaired | Checkbox | | | | | Checked / Unchecked [True / False] | Y | | |
| 22.02.11 | Developmental Delay | Checkbox | | | | Yes | Checked / Unchecked [True / False] | Y | Must be set to "True" (Checked) to enable fields below: 20.02.12 – 20.02.15) | |
| 22.02.12 | Developmental Delay – Gross Motor Delay | Checkbox | | | | Yes | Checked / Unchecked [True / False] | Y | Conditionally enabled if 20.02.11 is set to "True" | |
| 22.02.13 | Developmental Delay – Fine Motor Delay | Checkbox | | | | Yes | Checked / Unchecked [True / False] | Y | Conditionally enabled if 20.02.11 is set to "True" | |
| 22.02.14 | Developmental Delay – Speech and Language | Checkbox | | | | Yes | Checked / Unchecked [True / False] | Y | Conditionally enabled if 20.02.11 is set to "True" | |
| 22.02.15 | Developmental Delay – Social Development | Checkbox | | | | Yes | Checked / Unchecked [True / False] | Y | Conditionally enabled if 20.02.11 is set to "True" | |
| 22.02.16 | Poor growth -failure to thrive | Checkbox | | | | Yes | Checked / Unchecked [True / False] | | | |

| | | | | | | | | | |
|----------|---|--------------------------|--|------------|-----|--------------------|---|---|---|
| 22.02.17 | Myasthenia Gravis | Checkbox | | | | Yes | Checked / Unchecked [True / False] | | |
| 22.02.19 | Neurological Disease | MedDRA Selector [bigint] | | | Yes | | [Relevant MedDRA Term as selected by Clinician] | Y | MedDRA Condition selection window. LLT Stored |
| 22.02.20 | Immune System Deficiency | MedDRA Selector [bigint] | | | Yes | | [Relevant MedDRA Term as selected by Clinician] | Y | MedDRA Condition selection window. LLT Stored |
| 22.02.21 | Other | MedDRA Selector [bigint] | | | Yes | | [Relevant MedDRA Term as selected by Clinician] | Y | MedDRA Condition selection window. LLT Stored |
| 22.02.22 | Infant Hospitalisation status | Radio [int] | | | Yes | | Yes; No; Unknown; NULL | Y | If "Yes" is selected, this enables further details to be captured around any hospitalisation events |
| | <u>Hospitalisation Events</u> | | | | | | | | <i>(Section only enabled if 20.02.21 is set to "Yes")</i> |
| 22.02.23 | Date of hospitalisation | Date [datetime] | | dd/mm/yyyy | | | | Y | |
| 22.02.24 | Infection | MedDRA Selector [bigint] | | | Yes | Enabled if Checked | | Y | MedDRA Condition selection window. LLT Stored |
| 22.02.25 | Infant vaccination status | Radio [int] | | | Yes | | Yes; No; Partial; Unknown; NULL | Y | |
| 22.02.26 | Other | MedDRA Selector [bigint] | | | Yes | Enabled if Checked | | Y | MedDRA Condition selection window. LLT Stored |
| 22.02.27 | Add Event Button – Feature allowing additional hospitalisation events to be added | | | | | | | | |

23. MEDICAL CONDITIONS - Other Events

23.1 Description

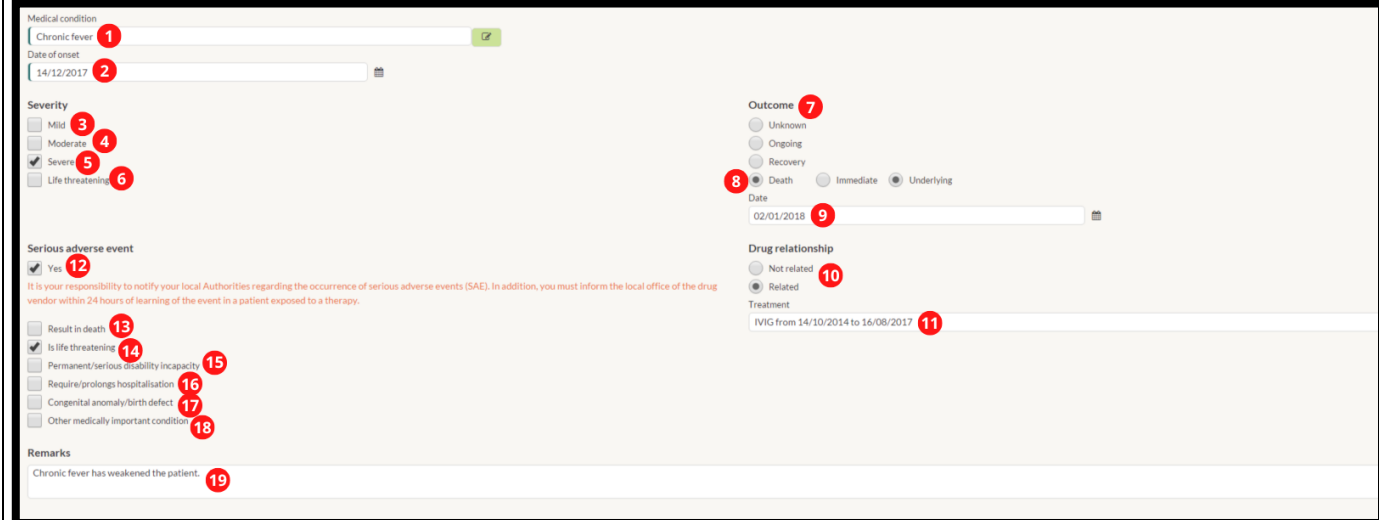
This section captures other medical events.

23.2 Rules and Constraints

- Medical Conditions can be selected from existing MedDRA terms. OR
- Medical Conditions can be selected from the list of reference data terms.
- The start date of the related treatment must occur on or before the date of the adverse condition.

23.3 Functions

- Add/Delete Other Events – You can add/delete Other Events
- Add/Edit – You can add/edit details of the Other Events



Medical condition

Chronic fever **1**

Date of onset

14/12/2017 **2**

Severity

Mild **3**

Moderate **4**

Severe **5**

Life threatening **6**

Serious adverse event

Yes **12**

It is your responsibility to notify your local Authorities regarding the occurrence of serious adverse events (SAE). In addition, you must inform the local office of the drug vendor within 24 hours of learning of the event in a patient exposed to a therapy.

Result in death **13**

Is life threatening **14**

Permanent/serious disability/incapacity **15**

Require/prolongs hospitalisation **16**

Congenital anomaly/birth defect **17**

Other medically important condition **18**

Remarks

Chronic fever has weakened the patient. **19**

Outcome **7**

Unknown

Ongoing

Recovery

Death **8**

Immediate

Underlying

Date

02/01/2018 **9**

Drug relationship

Not related

Related **10**

Treatment

IVIG from 14/10/2014 to 16/08/2017 **11**

23.4 Other Events Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|--|-----|-------------|----------|------------------|---|------------------|---|
| 23.01 | Medical Condition [OtherEvent.MeddraConditionId] or [OtherEvent.MedicalConditionId] | Selection Window [bigint] or [uniqueidentifier] | | | Yes | Mandatory | MedDRA LLT or Centre Medical Conditions Lookup values from Table MedicalCondition Please refer to the tab for the Table in the Db Schema file to see the selection options (and associated ids) available for this field. | Y | |
| 23.02 | Date of Onset [MedicalEvent.DateOfEvent] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth Max date = Today or Date of Death | Y | Defaults to Today |
| 23.03 | Severity – Mild [OtherEvent.IsMild] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 23.04 | Severity – Moderate [OtherEvent.IsModerate] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 23.05 | Severity – Severe [OtherEvent.IsSevere] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 23.06 | Severity – Life threatening [OtherEvent.IsLifeThreatening] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |
| 23.07 | Outcome [OtherEvent.EventOutcome] | Radio [int] | | | Yes | | Unknown[NULL]; Ongoing[1]; Recovery[2]; Death[3] | Y | |
| 23.08 | Death Outcome [OtherEvent.DeathReason] | Radio [int] | | | Yes | | Immediate[1]; Underlying[2] | Y | Visible if Outcome = Death |
| 23.09 | Outcome End Date [OtherEvent.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered ≥ Date of Onset or Date of Birth (if Outcome = Death) and ≤ Today or Date of Death | Y | Available if Outcome = Recovery or Death |
| 23.10 | Drug Relationship [OtherEvent.DrugRelationship] | Radio [bit] | | | No | | Not Related[0]; Related[1] | Y | |
| 23.11 | Treatment [OtherEvent.Treatment] | Dropdown [uniqueidentifier] | | | Yes | | [List MS Specific Treatments or Symptomatic Treatments assigned to that patient] | Y | Available if Drug Relationship = Related |
| 23.12 | Serious Adverse Event [OtherEvent.IsSerious] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|------------------------------|---------------|-------------|----------|------------------|-------------------|------------------|--|
| 23.13 | Result in death [OtherEvent.ResultsInDeath] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | Available if Serious Adverse Event = Yes |
| 23.14 | Is life threatening [OtherEvent.IsSeriouslyLifeThreatening] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | Available if Serious Adverse Event = Yes |
| 23.15 | Permanent/serious disability incapacity [OtherEvent.IsPermanent] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | Available if Serious Adverse Event = Yes |
| 23.16 | Require/prolongs hospitalisation [OtherEvent.ProlongsHospitalisation] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | Available if Serious Adverse Event = Yes |
| 23.17 | Congenital anomaly/birth defect [OtherEvent.IsCongenital] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | Available if Serious Adverse Event = Yes |
| 23.18 | Other medically important condition [OtherEvent.IsOther] | Checkbox [bit] | | | No | | False[0]; True[1] | Y | Available if Serious Adverse Event = Yes |
| 23.19 | Remarks [OtherEvent.Remarks] | Memo [text] | 2,147,483,647 | | Yes | | | N | |
| | [OtherEvent.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [OtherEvent.TreatmentOther] | Hidden [nvarchar] | | | Yes | | | Y | No longer used |
| | [FK__OtherEvent__Id__1A34DF26, Relationship 1 to 1, MedicalEvent.Id to OtherEvent.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__OtherEvent__MeddraCondition, Relationship 1 to Many, 1_low_level_term.llt_code to OtherEvent.MeddraConditionId] | Hidden [Relationship] | | | | | | | |
| | [FK__OtherEven__Medic__1940BAED, Relationship 1 to Many, MedicalCondition.Id to OtherEvent.MedicalConditionId] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Condition is stored in Table MedicalEvent, fields Type and Title

24. MEDICAL CONDITIONS – Flexifields

24.1 Description


User specified Flexifields for Medical Conditions are in this section.

24.2 Rules and Constraints

Flexifields must be specified in the Preferences.

24.3 Functions

- Enter/Delete Data – You can enter/delete Flexifield data.

FlexiFields
Date of diagnosis
 

24.4 Medical Condition Flexifield Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|------|-------------|----------|------------------|---|------------------|-------------------|
| | Date of diagnosis [MedicalEvent.DateOfEvent] | Date [datetime] | | | No | | | | Defaults to Today |
| | FlexiField Name [FlexiField.Name] | Field Label | | | | | | N | |
| | FlexiField Value [MedicalEventFlexiField.Value] | String [nvarchar] | 1000 | | Yes | | Allowed values will depend on the type of flexifield. Dropdown lists comes from [FlexiFieldOption.Value] | N | |
| | [MedicalEventFlexiField.FieldId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [MedicalEventFlexiField.Id] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [MedicalEventFlexiField.MedicalEventId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [FlexiFieldEvent.Id] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [FK_FlexiFieldEv__Id__7CA47C3F, Relationship 1 to 1 MedicalEvent.Id to FlexiFieldEvent.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__MedicalEv__Field__OAF29B96, Relationship many to many FlexiField.Id to MedicalEventFlexiField.FieldId] | Hidden [Relationship] | | | | | | | |

Notes:

- Table MedicalEventFlexiField contains the value that is entered for flexifields from the Medical Events Flexifields screen in MDS



- Table FlexiField contains the definition of the flexifields, i.e. Name and Data Type
- Table FlexiFieldOptions contains the values defined for flexifields where type is a dropdown
- Type of Medical Condition is stored in Table MedicalEvent, fields Type and Title

25. MEDICAL TESTS – Electro Diagnostics

25.1 Description

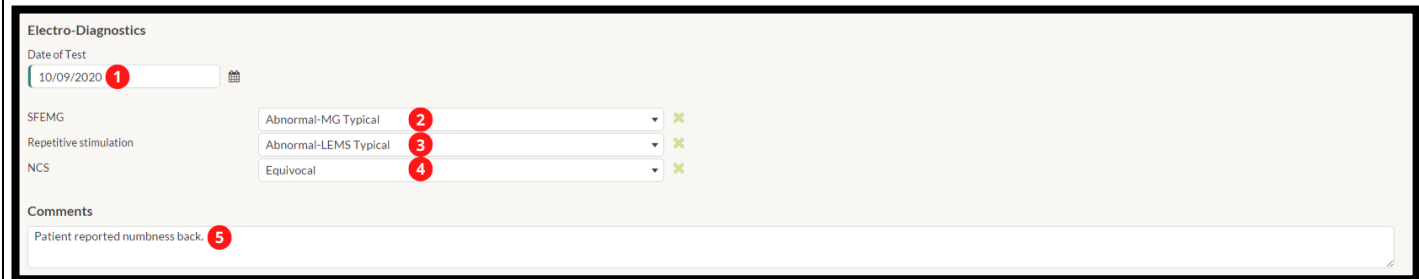
- This section provides details on the results of an Electro Diagnostics test.

25.2 Rules and Constraints

- Date of test field mandatory

25.3 Functions

- Add/Delete – You can add/delete Electro Diagnostic event details for a patient.



Electro-Diagnostics

Date of Test
10/09/2020

SFEMG
Abnormal-MG Typical

Repetitive stimulation
Abnormal-LEMS Typical

NCS
Equivocal

Comments
Patient reported numbness back.

25.4 Electro Diagnostics Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|------------------------------|-----|-------------|----------|------------------|--|------------------|-------------------|
| 25.01 | Date of Test [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | | Y | Defaults to Today |
| 25.02 | SFEMG [ElectroDiagnosticTest.SFEMG] | Dropdown [int] | | | Yes | | Normal[0]; Abnormal-LEMS Typical[1]; Equivocal[2]; Not Tested/Unknown[3]; Abnormal-MG Typical[4] | Y | |
| 25.03 | Repetitive stimulation [ElectroDiagnosticTest.RepetitiveStimulation] | Dropdown [int] | | | Yes | | Normal[0]; Abnormal-LEMS Typical[1]; Equivocal[2]; Not Tested/Unknown[3]; Abnormal-MG Typical[4] | Y | |
| 25.04 | NCS [ElectroDiagnosticTest.NCS] | Dropdown [int] | | | Yes | | Normal[0]; Abnormal-LEMS Typical[1]; Equivocal[2]; Not Tested/Unknown[3]; Abnormal-MG Typical[4] | Y | |
| 25.05 | Comments [ElectroDiagnosticTest.Comments] | Memo [nvarchar] | 200 | | Yes | Length | | N | |
| | [ElectroDiagnosticTest.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__ElectroDiagn__Id__2A363CC5, Relationship 1 to 1 ParaclinicalTest.Id to ElectroDiagnosticTest.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

26. MEDICAL TESTS - Imaging

26.1 Description

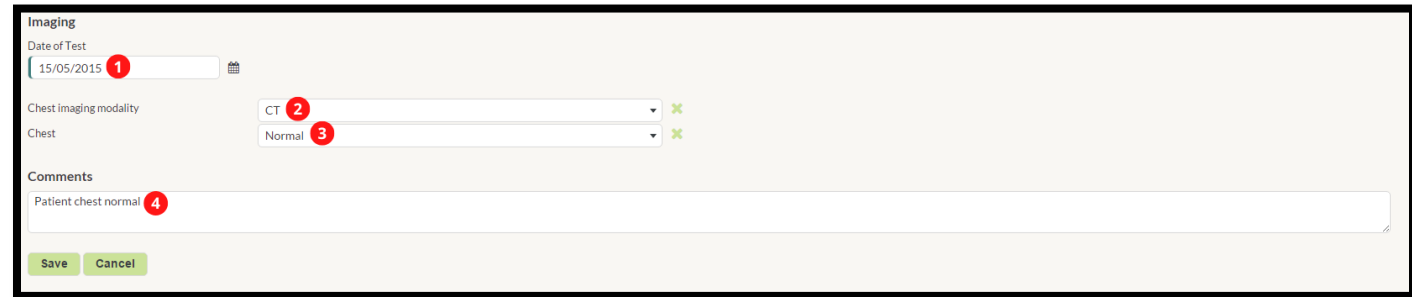
- This section provides details on the results of an imaging test.

26.2 Rules and Constraints

- Date of test field mandatory.

26.3 Functions

- Add/Delete – You can add/delete imaging test details for a patient.



The screenshot shows the 'Imaging' form in the MGBase software. It contains the following fields and elements:

- Date of Test:** A date input field containing '15/05/2015', marked with a red '1' and a calendar icon.
- Chest imaging modality:** A dropdown menu with 'CT' selected, marked with a red '2' and a green 'x' icon.
- Chest:** A dropdown menu with 'Normal' selected, marked with a red '3' and a green 'x' icon.
- Comments:** A text area containing 'Patient chest normal', marked with a red '4'.
- Buttons:** 'Save' and 'Cancel' buttons at the bottom left.

26.4 Imaging Test Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|-------------------|
| 26.01 | Date of Test [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | | Y | Defaults to Today |
| 26.02 | Chest imaging modality [ImagingTest.ChestImagingModalityId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table ChestImagingModality CXR; CT; MRI; Other | Y | |
| 26.03 | Chest [ImagingTest.ChestImagingResultId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table ChestImagingResult Normal; Mass -suggestive of thymoma; Thymic enlargement suggestive of hyperplasia; Other significant finding (comment); Not done/unknown | Y | |
| 26.04 | Comments [ImagingTest.Comments] | Memo [nvarchar] | 200 | | Yes | Length | | N | |
| | [ImagingTest.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__ImagingTest__Id__2FEF161B, Relationship 1 to 1 ParaclinicalTest.Id to ImagingTest.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__ImagingTe__Chest__30E33A54, Relationship 1 to many ChestImagingModality.Id to ImagingTest.ChestImagingModalityId] | Hidden [Relationship] | | | | | | | |
| | [FK__ImagingTe__Chest__31D75E8D, Relationship 1 to many ChestImagingResult.Id to ImagingTest.ChestImagingResultId] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

27. MEDICAL TESTS - Bedside

27.1 Description

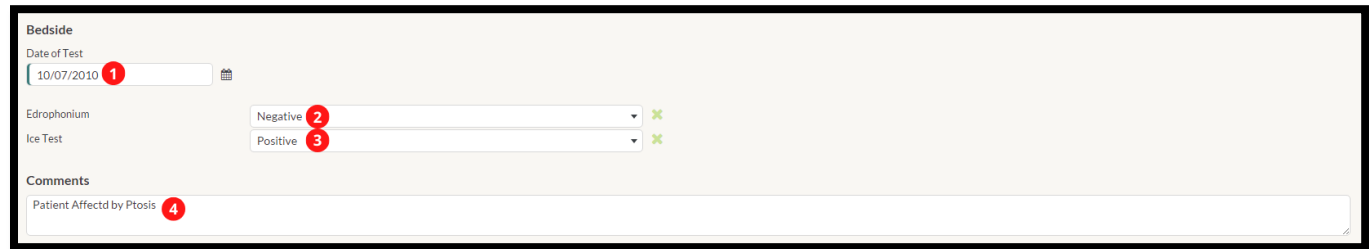
- This section provides details on the results of a bedside test.

27.2 Rules and Constraints

- Date of test field mandatory

27.3 Functions

Add/Delete – You can add/delete bedside test details for a patient.



The screenshot shows the 'Bedside' form in the MGBase software. It contains the following fields and elements:

- Date of Test:** A date input field containing '10/07/2010', marked with a red circle '1' and a calendar icon.
- Edrophonium:** A dropdown menu with 'Negative' selected, marked with a red circle '2' and a green 'x' icon.
- Ice Test:** A dropdown menu with 'Positive' selected, marked with a red circle '3' and a green 'x' icon.
- Comments:** A text area containing the text 'Patient Affectd by Ptosis', marked with a red circle '4'.

27.4 Bedside Test Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|------------------------------|-----|-------------|----------|------------------|---|------------------|-------------------|
| 27.01 | Date of Test [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | | Y | Defaults to Today |
| 27.02 | Edrophonium [BedsideTest.Edrophonium] | Dropdown [int] | | | Yes | | Positive[0]; Negative[1]; Equivocal[2]; Not Tested / Unknown[3] | Y | |
| 27.03 | Ice Test [BedsideTest.IceTest] | Dropdown [int] | | | Yes | | Positive[0]; Negative[1]; Equivocal[2]; Not Tested / Unknown[3] | Y | |
| 27.04 | Comments [BedsideTest.Comments] | Memo [nvarchar] | 200 | | Yes | Length | | N | |
| | [BedsideTest.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK_BedsideTest_Id__2D12A970, Relationship 1 to 1 ParaclinicalTest.Id to BedsideTest.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

28. MEDICAL TESTS - Laboratory Tests – Myasthenia Antibodies

28.1 Description

The Myasthenia Antibodies section, part of the broader Laboratory Tests, enables the user to enter data from exams and comment where the test value is abnormal.

28.2 Rules and Constraints

- Date of test field mandatory

28.3 Functions

- Add/Delete Lab test – You can add/delete Lab test details for a patient.
- Add/Delete Lab test Calendar Event – You can add/delete Calendar Event.

| Myasthenia Antibodies | Haematology | Blood Chemistry | Thyroid Tests | Microbial Tests | Auto-antibody Tests |
|--|----------------|-------------------|------------------------------|------------------------------------|---------------------|
| Date: 03/09/2022 61 | | | | | |
| | Unit | Negative/Positive | | Comments | |
| AChR antibodies method unspecified | 28.2 1 | nmol/L 2 | Positive 3 | AChR antibodies method unspecified | 4 |
| AChR antibodies RIA | 34.6 5 | 10e9/L 6 | Negative 7 | AChR antibodies RIA | 8 |
| AChR antibodies ELISA | 27.7 9 | % 10 | Positive 11 | AChR antibodies ELISA | 12 |
| AChR antibodies CBA | 13.3 13 | g/L 14 | Negative 15 | AChR antibodies CBA | 16 |
| MuSK antibodies method unspecified | 8.7 17 | umol/L 18 | Positive 19 | MuSK antibodies method unspecified | 20 |
| MuSK antibodies RIA | 18.2 21 | umol/L 22 | Negative 21 | MuSK antibodies RIA | 24 |
| MuSK antibodies ELISA | 31.8 25 | g/L 26 | Equivocal 25 | MuSK antibodies ELISA | 28 |
| MuSK antibodies CBA | 16.5 29 | umol/L 30 | Negative 29 | MuSK antibodies CBA | 32 |
| Lrp4 antibodies method unspecified | 13.5 33 | % 34 | Equivocal 33 | Lrp4 antibodies method unspecified | 36 |
| Lrp4 antibodies CBA | 12.4 37 | umol/L 38 | Not Tested/Unknown 37 | Lrp4 antibodies CBA | 40 |
| Titin antibodies | 2.7 41 | 10e9/L 42 | Negative 41 | Titin antibodies | 44 |
| Ryanodine Receptor antibodies | 14.8 45 | umol/L 46 | Not Tested/Unknown 45 | Ryanodine Receptor antibodies | 48 |
| Skeletal muscle antibodies | 11.2 53 | U/L 50 | Equivocal 49 | Skeletal muscle antibodies | 52 |
| VGCC antibodies | 16.5 57 | g/dL 54 | Equivocal 53 | VGCC antibodies | 56 |
| Other antibodies | 17.2 61 | % 58 | Positive 57 | Other antibodies | 60 |
| Lab performing test: Dorevitch Pathology 62 | | | | | |

28.4 Laboratory Tests – Myasthenia Antibodies Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|--------|-----|-------------|----------|------------------|---|------------------|--|
| 28.01 | AChR antibodies method unspecified count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.02 | AChR antibodies method unspecified unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.03 | AChR antibodies method unspecified Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.04 | AChR antibodies method unspecified comments | String | 100 | | Yes | | | N | |
| 28.05 | AChR antibodies RIA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.06 | AChR antibodies RIA unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.07 | AChR antibodies RIA Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.08 | AChR antibodies RIA comments | String | 100 | | Yes | | | N | |
| 28.09 | AChR antibodies ELISA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.10 | AChR antibodies ELISA unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|--------|-----|-------------|----------|------------------|---|------------------|--|
| 28.11 | AChR antibodies ELISA Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.12 | AChR antibodies ELISA comments | String | 100 | | Yes | | | N | |
| 28.13 | AChR antibodies CBA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.14 | AChR antibodies CBA unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.15 | AChR antibodies CBA Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.16 | AChR antibodies CBA comments | String | 100 | | Yes | | | N | |
| 28.17 | MuSK antibodies method unspecified count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.18 | MuSK antibodies method unspecified unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.19 | MuSK antibodies method unspecified Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.20 | MuSK antibodies method unspecified comments | String | 100 | | Yes | | | N | |
| 28.21 | MuSK antibodies RIA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.22 | MuSK antibodies RIA unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|--------|-----|-------------|----------|------------------|---|------------------|--|
| | | | | | | | ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | | |
| 28.23 | MuSK antibodies RIA Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.24 | MuSK antibodies RIA comments | String | 100 | | Yes | | | N | |
| 28.25 | MuSK antibodies ELISA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.26 | MuSK antibodies ELISA unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.27 | MuSK antibodies ELISA Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.28 | MuSK antibodies ELISA comments | String | 100 | | Yes | | | N | |
| 28.29 | MuSK antibodies CBA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.30 | MuSK antibodies CBA unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.31 | MuSK antibodies CBA Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.32 | MuSK antibodies CBA comments | String | 100 | | Yes | | | N | |
| 28.33 | Lrp4 antibodies method unspecified count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|--------|-----|-------------|----------|------------------|---|------------------|--|
| 28.34 | Lrp4 antibodies method unspecified unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.35 | Lrp4 antibodies method unspecified Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.36 | Lrp4 antibodies method unspecified comments | String | 100 | | Yes | | | N | |
| 28.37 | Lrp4 antibodies CBA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.38 | Lrp4 antibodies CBA unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.39 | Lrp4 antibodies CBA Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.40 | Lrp4 antibodies CBA comments | String | 100 | | Yes | | | N | |
| 28.41 | Titin antibodies count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.42 | Titin antibodies unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.43 | Titin antibodies Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.44 | Titin antibodies comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|--------|-----|-------------|----------|------------------|---|------------------|--|
| 28.45 | Ryanodine Receptor antibodies count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.46 | Ryanodine Receptor antibodies unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.47 | Ryanodine Receptor antibodies Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.48 | Ryanodine Receptor antibodies comments | String | 100 | | Yes | | | N | |
| 28.49 | Skeletal muscle antibodies count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.50 | Skeletal muscle antibodies unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.51 | Skeletal muscle antibodies Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.52 | Skeletal muscle antibodies comments | String | 100 | | Yes | | | N | |
| 28.53 | VGCC antibodies count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.54 | VGCC antibodies unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.55 | VGCC antibodies Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----------------------------------|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| 28.56 | VGCC antibodies comments | String | 100 | | Yes | | | N | |
| 28.57 | Other antibodies count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 6. See section below for database table information. |
| 28.58 | Other antibodies unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 28.59 | Other antibodies Negative/Positive | Select | | | Yes | | Negative; Positive; Equivocal; Not Tested/Unknown | Y | |
| 28.60 | Other antibodies comments | String | 100 | | Yes | | | N | |
| 28.61 | Date [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today or Date of Death | Y | Defaults to Today |
| 28.62 | Lab performing test [LaboratoryTest.LabPerformingTest] | Memo [nvarchar] | 500 | | Yes | Length | | N | |
| Database Table Information | | | | | | | | | |
| | Test Name [LaboratoryTestMeasureResult.TypeId] | Label [uniqueidentifier] | | | No | | Lookup Values from table LaboratoryTestType where Category = 6 | Y | |
| | Value [LaboratoryTestMeasureResult.Value] | Number [decimal] | | NNNNNN.NN | Yes | Format | | Y | |
| | Unit [LaboratoryTestMeasureResult.UnitId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| | Result [LaboratoryTestMeasureResult.Result] | Number [int] | | | Yes | | Normal: Negative[0]; Positive[1] Negative/Positive: Negative[0]; Positive[1]; Equivocal[2]; | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|-----|-------------|----------|------------------|--|------------------|----------|
| | | | | | | | Not Tested/Unknown[3] or Not Detected[0]; Detected[1] or Non Reactive[0]; Reactive[1] or Negative[0]; Positive[1]; Indeterminate[2] or No[0]; Yes[1] | | |
| | Comments [LaboratoryTestMeasureResult.Comments] | String [nvarchar] | 100 | | Yes | Length | | N | |
| | [LaboratoryTestMeasureResult.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__Laborator__Labor__035179CE, Relationship 1 to 1 LaboratoryTest.Id to LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__TypeI__04459E07, Relationship 1 to Many LaboratoryTestType.Id to LaboratoryTestMeasureResult.TypeId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__UnitI__0539C240, Relationship 1 to Many LaboratoryTestUnit.Id to LaboratoryTestMeasureResult.UnitId] | Hidden [Relationship] | | | | | | | |
| | [FK__LaboratoryTe__Id__025D5595, Relationship 1 to 1 ParaclinicalTest.Id to LaboratoryTest.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

29. MEDICAL TESTS - Laboratory Tests – Haematology

29.1 Description

The haematology section, part of the broader Laboratory Tests, enables the user to enter data from exams and comment where the test value is abnormal.

29.2 Rules and Constraints

- Date of test field mandatory

29.3 Functions

- Add/Delete Lab test – You can add/delete Lab test details for a patient.
- Add/Delete Lab test Calendar Event – You can add/delete Calendar Event
- Once a Unit has been selected, that same Unit will be pre-filled for future tests of the same type, until the type is changed.

| Myasthenia Antibodies | Haematology | Blood Chemistry | Thyroid Tests | Microbial Tests | Auto-antibody Tests |
|---|---|---|---------------|---|---------------------|
| Date: 03/09/2022 62 | | | | | |
| | Unit | Normal | | Comments | |
| White cell count | 42.2 1 g/dL 2 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 3 | | White cell count 4 | |
| Red cell count | 7.5 5 g/dL 6 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 7 | | Red cell count 8 | |
| Lymphocyte Count | 18.3 9 g/dL 10 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 11 | | Lymphocyte Count 12 | |
| Lymphocyte Count lower limit | 31.5 13 | | | | |
| T cell count | 27.6 14 umol/L 15 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 16 | | T cell count 17 | |
| CD4 T cell count | 16.2 18 % 19 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 20 | | CD4 T cell count 21 | |
| CD8 T cell count | 9.7 22 % 23 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 24 | | CD8 T cell count 25 | |
| CD19 B cell count | 8.3 26 U/L 27 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 28 | | CD19 B cell count 29 | |
| NK cell count | 17.4 30 umol/L 31 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 32 | | NK cell count 33 | |
| Neutrophil count | 41.2 34 10e9/L 35 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 36 | | Neutrophil count 37 | |
| Monocyte count | 12.1 38 umol/L 39 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 40 | | Monocyte count 41 | |
| Eosinophil count | 16.7 42 U/L 43 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 44 | | Eosinophil count 45 | |
| Basophil count | 21.3 46 % 47 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 48 | | Basophil count 49 | |
| Platelet count | 32.1 50 mmol/L 51 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 52 | | Platelet count 53 | |
| Haemoglobin count | 6.5 54 % 55 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 56 | | Haemoglobin count 57 | |
| Erythrocyte Sedimentation Rate | 19.7 58 g/dL 59 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 60 | | Erythrocyte Sedimentation Rate 61 | |

29.4 Laboratory Tests – Haematology Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 29.01 | White cell count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.02 | White cell count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.03 | White cell count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.04 | White cell count comments | String | 100 | | Yes | | | N | |
| 29.05 | Red cell count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.06 | Red cell count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.07 | Red cell count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.08 | Red cell count comments | String | 100 | | Yes | | | N | |
| 29.09 | Lymphocyte Count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.10 | Lymphocyte Count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|------------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| | | | | | | | ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | | |
| 29.11 | Lymphocyte Count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.12 | Lymphocyte Count comments | String | 100 | | Yes | | | N | |
| 29.13 | Lymphocyte Count lower limit | Number | | NNNNNN.NN | Yes | | | Y | |
| 29.14 | T cell count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.15 | T cell count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.16 | T cell count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.17 | T cell count comments | String | 100 | | Yes | | | N | |
| 29.18 | CD4 T cell count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.19 | CD4 T cell count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.20 | CD4 T cell count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.21 | CD4 T cell count comments | String | 100 | | Yes | | | N | |
| 29.22 | CD8 T cell count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|----------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| | | | | | | | | | section below for database table information. |
| 29.23 | CD8 T cell count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.24 | CD8 T cell count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.25 | CD8 T cell count comments | String | 100 | | Yes | | | N | |
| 29.26 | CD19 B cell count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.27 | CD19 B cell count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.28 | CD19 B cell count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.29 | CD19 B cell count comments | String | 100 | | Yes | | | N | |
| 29.30 | NK cell count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.31 | NK cell count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.32 | NK cell count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.33 | NK cell count comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 29.34 | Neutrophil count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.35 | Neutrophil count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.36 | Neutrophil count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.37 | Neutrophil count comments | String | 100 | | Yes | | | N | |
| 29.38 | Monocyte count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.39 | Monocyte count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.40 | Monocyte count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.41 | Monocyte count comments | String | 100 | | Yes | | | N | |
| 29.42 | Eosinophil count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.43 | Eosinophil count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.44 | Eosinophil count normal | Checkbox | | | Yes | | Positive; Negative | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 29.45 | Eosinophil count comments | String | 100 | | Yes | | | N | |
| 29.46 | Basophil count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.47 | Basophil count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.48 | Basophil count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.49 | Basophil count comments | String | 100 | | Yes | | | N | |
| 29.50 | Platelet count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.51 | Platelet count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.52 | Platelet count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.53 | Platelet count comments | String | 100 | | Yes | | | N | |
| 29.54 | Haemoglobin count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 0. See section below for database table information. |
| 29.55 | Haemoglobin count unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----------------------------------|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|-------------------|
| 29.56 | Haemoglobin count normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.57 | Haemoglobin count comments | String | 100 | | Yes | | | N | |
| 29.58 | Erythrocyte Sedimentation Rate count | Number | | NNNNNN.NN | Yes | | | Y | |
| 29.59 | Erythrocyte Sedimentation Rate unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 29.60 | Erythrocyte Sedimentation Rate normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 29.61 | Erythrocyte Sedimentation Rate comments | String | 100 | | Yes | | | N | |
| 29.62 | Date [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today or Date of Death | Y | Defaults to Today |
| Database Table Information | | | | | | | | | |
| | Test Name [LaboratoryTestMeasureResult.TypeId] | Label [uniqueidentifier] | | | No | | Lookup Values from table LaboratoryTestType where Category = 0 | Y | |
| | Value [LaboratoryTestMeasureResult.Value] | Number [decimal] | | NNNNNN.NN | Yes | Format | | Y | |
| | Unit [LaboratoryTestMeasureResult.UnitId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| | Result [LaboratoryTestMeasureResult.Result] | Number [int] | | | Yes | | Normal: Negative[0]; Positive[1] Negative/Positive: Negative[0]; Positive[1]; Equivocal[2]; Not Tested/Unknown[3] or Not Detected[0]; Detected[1] or Non Reactive[0]; Reactive[1] or Negative[0]; Positive[1]; | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|-----|-------------|----------|------------------|-----------------------------------|------------------|----------|
| | | | | | | | Indeterminate[2] or No[0]; Yes[1] | | |
| | Comments [LaboratoryTestMeasureResult.Comments] | String [nvarchar] | 100 | | Yes | Length | | N | |
| | [LaboratoryTestMeasureResult.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__Laborator__Labor__035179CE, Relationship 1 to 1 LaboratoryTest.Id to LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__TypeI__04459E07, Relationship 1 to Many LaboratoryTestType.Id to LaboratoryTestMeasureResult.TypeId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__UnitI__0539C240, Relationship 1 to Many LaboratoryTestUnit.Id to LaboratoryTestMeasureResult.UnitId] | Hidden [Relationship] | | | | | | | |
| | [FK__LaboratoryTe__Id__025D5595, Relationship 1 to 1 ParaclinicalTest.Id to LaboratoryTest.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

30. MEDICAL TESTS - Laboratory Tests – Blood Chemistry

30.1 Description

The Blood Chemistry section, part of the broader Laboratory Tests, enables the user to enter data from exams and comment where the test value is abnormal.

30.2 Rules and Constraints

- Date of test field mandatory

30.3 Functions

- Add/Delete Lab test – You can add/delete Lab test details for a patient.
- Add/Delete Lab test Calendar Event – You can add/delete Calendar Event.

| Myasthenia Antibodies | Haematology | Blood Chemistry | Thyroid Tests | Microbial Tests | Auto-antibody Tests |
|---|-------------|---|---|--|---|
| Date: 03/09/2022 97 | | | | | |
| | Unit | Normal | | | Comments |
| Creatine Kinase | 9.8 | 1 % | 2 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 3 | Creatine Kinase 4 |
| Sodium | 11.6 | 5 g/dL | 6 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 7 | Sodium 8 |
| Potassium | 17.5 | 9 U/L | 10 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 11 | Potassium 12 |
| Urea | 12.3 | 13 U/L | 14 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 15 | Urea 16 |
| Uric Acid | 17.6 | 17 mmol/L | 18 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 19 | Uric Acid 20 |
| Creatinine | 21.5 | 21 umol/L | 22 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 23 | Creatinine 24 |
| eGFR | 27.6 | 25 g/dL | 26 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 25 | eGFR 28 |
| Total Protein | 25.2 | 29 mmol/L | 30 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 29 | Total Protein 32 |
| Albumin | 12.2 | 33 10e9/L | 34 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 33 | Albumin 36 |
| Calcium | 15.6 | 37 % | 38 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 37 | Calcium 40 |
| AST | 27.7 | 41 10e9/L | 42 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 41 | AST 44 |
| ALT | 15.7 | 45 mmol/L | 46 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 45 | ALT 48 |
| Gamma-GT | 23.2 | 53 g/dL | 50 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 49 | Gamma-GT 52 |
| Bilirubin | 12.4 | 57 U/L | 54 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 53 | Bilirubin 56 |
| Alkaline Phosphatase | 21.6 | 61 10e9/L | 62 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 63 | Alkaline Phosphatase 64 |
| Amylase | 11.2 | 65 g/dL | 66 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 67 | Amylase 68 |
| Lipase | 19.6 | 69 U/L | 70 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 71 | Lipase 72 |
| CRP | 13.4 | 73 umol/L | 74 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 75 | CRP 76 |
| ACE | 18.5 | 77 g/L | 78 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 79 | ACE 80 |
| Immunoglobulin Total | 6.7 | 81 mmol/L | 82 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 83 | Immunoglobulin Total 84 |
| Immunoglobulin G | 9.7 | 85 U/L | 86 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 87 | Immunoglobulin G 88 |
| Immunoglobulin M | 15.4 | 89 mmol/L | 90 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 91 | Immunoglobulin M 92 |
| Immunoglobulin A | 12.6 | 93 % | 94 <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative | 95 | Immunoglobulin A 96 |

30.4 Laboratory Tests – Blood Chemistry Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 30.01 | Creatine Kinase count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.02 | Creatine Kinase unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.03 | Creatine Kinase normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.04 | Creatine Kinase comments | String | 100 | | Yes | | | N | |
| 30.05 | Sodium count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.06 | Sodium unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.07 | Sodium normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.08 | Sodium comments | String | 100 | | Yes | | | N | |
| 30.09 | Potassium count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.10 | Potassium unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.11 | Potassium normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.12 | Potassium comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 30.13 | Urea count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.14 | Urea unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.15 | Urea normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.16 | Urea comments | String | 100 | | Yes | | | N | |
| 30.17 | Uric Acid count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.18 | Uric Acid unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.19 | Uric Acid normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.20 | Uric Acid comments | String | 100 | | Yes | | | N | |
| 30.21 | Creatinine count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.22 | Creatinine unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.23 | Creatinine normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.24 | Creatinine comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 30.25 | eGFR count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.26 | eGFR unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.27 | eGFR normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.28 | eGFR comments | String | 100 | | Yes | | | N | |
| 30.29 | Total Protein count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.30 | Total Protein unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.31 | Total Protein normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.32 | Total Protein comments | String | 100 | | Yes | | | N | |
| 30.33 | Albumin count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.34 | Albumin unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.35 | Albumin normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.36 | Albumin comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 30.37 | Calcium count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.38 | Calcium unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.39 | Calcium normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.40 | Calcium comments | String | 100 | | Yes | | | N | |
| 30.41 | AST count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.42 | AST unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.43 | AST normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.44 | AST comments | String | 100 | | Yes | | | N | |
| 30.45 | ALT count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.46 | ALT unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.47 | ALT normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.48 | ALT comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|-------------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 30.49 | Gamma-GT count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.50 | Gamma-GT unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.51 | Gamma-GT normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.52 | Gamma-GT comments | String | 100 | | Yes | | | N | |
| 30.53 | Bilirubin count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.54 | Bilirubin unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.55 | Bilirubin normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.56 | Bilirubin comments | String | 100 | | Yes | | | N | |
| 30.57 | Alkaline Phosphatase count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.58 | Alkaline Phosphatase unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.59 | Alkaline Phosphatase normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.60 | Alkaline Phosphatase comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 30.61 | Amylase count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.62 | Amylase unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.63 | Amylase normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.64 | Amylase comments | String | 100 | | Yes | | | N | |
| 30.65 | Lipase count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.66 | Lipase unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.67 | Lipase normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.68 | Lipase comments | String | 100 | | Yes | | | N | |
| 30.69 | CRP count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.70 | CRP unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.71 | CRP normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.72 | CRP comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|-------------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 30.73 | ACE count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.74 | ACE unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.75 | ACE normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.76 | ACE comments | String | 100 | | Yes | | | N | |
| 30.77 | Immunoglobulin Total count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.78 | Immunoglobulin Total unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.79 | Immunoglobulin Total normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.80 | Immunoglobulin Total comments | String | 100 | | Yes | | | N | |
| 30.81 | Immunoglobulin G count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.82 | Immunoglobulin G unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.83 | Immunoglobulin G normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.84 | Immunoglobulin G comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|--|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| 30.85 | Immunoglobulin M count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.86 | Immunoglobulin M unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.87 | Immunoglobulin M normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 30.88 | Immunoglobulin M comments | String | 100 | | Yes | | | N | |
| 30.89 | Immunoglobulin A count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 1. See section below for database table information. |
| 30.90 | Immunoglobulin A unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 30.91 | Immunoglobulin A normal | Select | | | Yes | | Yes; No | Y | |
| 30.92 | Immunoglobulin A comments | String | 100 | | Yes | | | N | |
| 30.93 | Date [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today or Date of Death | Y | Defaults to Today |
| <u>Database Table Information</u> | | | | | | | | | |
| | Test Name [LaboratoryTestMeasureResult.TypeId] | Label [uniqueidentifier] | | | No | | Lookup Values from table LaboratoryTestType where Category = 1 | Y | |
| | Value [LaboratoryTestMeasureResult.Value] | Number [decimal] | | NNNNNN.NN | Yes | Format | | Y | |
| | Unit [LaboratoryTestMeasureResult.UnitId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table LaboratoryTestUnit | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|-----|-------------|----------|------------------|---|------------------|----------|
| | | | | | | | ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | | |
| | Result [LaboratoryTestMeasureResult.Result] | Number [int] | | | Yes | | Normal: Negative[0]; Positive[1] Negative/Positive: Negative[0]; Positive[1]; Equivocal[2]; Not Tested/Unknown[3] or Not Detected[0]; Detected[1] or Non Reactive[0]; Reactive[1] or Negative[0]; Positive[1]; Indeterminate[2] or No[0]; Yes[1] | Y | |
| | Comments [LaboratoryTestMeasureResult.Comments] | String [nvarchar] | 100 | | Yes | Length | | N | |
| | [LaboratoryTestMeasureResult.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__Laborator__Labor__035179CE, Relationship 1 to 1 LaboratoryTest.Id to LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__TypeI__04459E07, Relationship 1 to Many LaboratoryTestType.Id to LaboratoryTestMeasureResult.TypeId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__UnitI__0539C240, Relationship 1 to Many LaboratoryTestUnit.Id to LaboratoryTestMeasureResult.UnitId] | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|--------------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | [FK__LaboratoryTe__Id__025D5595, Relationship 1 to 1 ParaclinicalTest.Id to LaboratoryTest.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

31. MEDICAL TESTS - Laboratory Tests – Thyroid Function

31.1 Description

The Thyroid Function section, part of the broader Laboratory Tests, enables the user to enter data from exams and comment where the test value is abnormal.

31.2 Rules and Constraints

- Date of test field mandatory

31.3 Functions

- Add/Delete Lab test – You can add/delete Lab test details for a patient.
- Add/Delete Lab test Calendar Event – You can add/delete Calendar Event.

| Myasthenia Antibodies | Haematology | Blood Chemistry | Thyroid Tests | Microbial Tests | Auto-antibody Tests | Others |
|--|--|--|--|---|---------------------|----------|
| Date: 09/05/2008 25 | | | | | | |
| | Value | Unit | Normal | Positive | Negative | Comments |
| TSH | 12.6 1 | % 2 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 3 | TSH 4 | | |
| T3 | 16.5 5 | U/L 6 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 7 | T3 8 | | |
| T4 | 14.3 9 | g/dL 10 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 11 | T4 12 | | |
| Anti-microsomal antibodies | 18.8 13 | umol/L 14 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 15 | Anti-microsomal antibodies 16 | | |
| Anti-thyroglobulin antibodies | 19.2 17 | 10e9/L 18 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative 19 | Anti-thyroglobulin antibodies 20 | | |
| TSH receptor antibody | 16.4 21 | mmol/L 22 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative 23 | TSH receptor antibody 24 | | |

31.4 Laboratory Tests – Thyroid Function Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 31.01 | TSH count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 2. See section below for database table information. |
| 31.02 | TSH unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 31.03 | TSH normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 31.04 | TSH comments | String | 100 | | Yes | | | N | |
| 31.05 | T3 count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 2. See section below for database table information. |
| 31.06 | T3 unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 31.07 | T3 normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 31.08 | T3 comments | String | 100 | | Yes | | | N | |
| 31.09 | T4 count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 2. See section below for database table information. |
| 31.10 | T4 unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 31.11 | T4 normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 31.12 | T4 comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|----------|-----|-------------|----------|------------------|---|------------------|--|
| 31.13 | Anti-microsomal antibodies count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 2. See section below for database table information. |
| 31.14 | Anti-microsomal antibodies unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 31.15 | Anti-microsomal antibodies normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 31.16 | Anti-microsomal antibodies comments | String | 100 | | Yes | | | N | |
| 31.17 | Anti-thyroglobulin antibodies count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 2. See section below for database table information. |
| 31.18 | Anti-thyroglobulin antibodies unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 31.19 | Anti-thyroglobulin antibodies normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 31.20 | Anti-thyroglobulin antibodies comments | String | 100 | | Yes | | | N | |
| 31.21 | TSH receptor antibody count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 2. See section below for database table information. |
| 31.22 | TSH receptor antibody unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 31.23 | TSH receptor antibody normal | Checkbox | | | Yes | | Positive; Negative | Y | |
| 31.24 | TSH receptor antibody comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----------------------------------|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|-------------------|
| 31.25 | Date [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today or Date of Death | Y | Defaults to Today |
| Database Table Information | | | | | | | | | |
| | Test Name [LaboratoryTestMeasureResult.TypeId] | Label [uniqueidentifier] | | | No | | Lookup Values from table LaboratoryTestType where Category = 2 | Y | |
| | Value [LaboratoryTestMeasureResult.Value] | Number [decimal] | | NNNNNN.NN | Yes | Format | | Y | |
| | Unit [LaboratoryTestMeasureResult.UnitId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| | Result [LaboratoryTestMeasureResult.Result] | Number [int] | | | Yes | | Normal: Negative[0]; Positive[1] Negative/Positive: Negative[0]; Positive[1]; Equivocal[2]; Not Tested/Unknown[3] or Not Detected[0]; Detected[1] or Non Reactive[0]; Reactive[1] or Negative[0]; Positive[1]; Indeterminate[2] or No[0]; Yes[1] | Y | |
| | Comments [LaboratoryTestMeasureResult.Comments] | String [nvarchar] | 100 | | Yes | Length | | N | |
| | [LaboratoryTestMeasureResult.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK_Laborator__Labor__035179CE, Relationship 1 to 1 LaboratoryTest.Id to | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|-----------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | LaboratoryTestMeasureResult.LaboratoryTestId] | | | | | | | | |
| | [FK__Laborator__TypeI__04459E07, Relationship 1 to Many LaboratoryTestType.Id to LaboratoryTestMeasureResult.TypeId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__UnitI__0539C240, Relationship 1 to Many LaboratoryTestUnit.Id to LaboratoryTestMeasureResult.UnitId] | Hidden [Relationship] | | | | | | | |
| | [FK__LaboratoryTe__Id__025D5595, Relationship 1 to 1 ParaclinicalTest.Id to LaboratoryTest.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

32. MEDICAL TESTS - Laboratory Tests – Microbial Tests

32.1 Description

The Microbial Tests section, part of the broader Laboratory Tests, enables the user to enter data from exams and comment where the test value is abnormal.

32.2 Rules and Constraints

- Date of test field mandatory

32.3 Functions

- Add/Delete Lab test – You can add/delete Lab test details for a patient.
- Add/Delete Lab test Calendar Event – You can add/delete Calendar Event.

| Myasthenia Antibodies | Haematology | Blood Chemistry | Thyroid Tests | Microbial Tests | Auto-antibody Tests | Others |
|---|---|--|---|-----------------|---------------------|--------|
| Date: 09/05/2008 50 | | | | | | |
| | Unit | Negative/Positive | | Comments | | |
| HBV core antigen | 12.2 1 | ? 2 | <input checked="" type="checkbox"/> Detected <input type="checkbox"/> Not Detected | | | 3 |
| HBV surface antigen | 14.6 5 | % 6 | <input checked="" type="checkbox"/> Detected <input checked="" type="checkbox"/> Not Detected | | | 7 |
| HBV core antibody | 9.3 9 | g/dL 10 | <input checked="" type="checkbox"/> Detected <input type="checkbox"/> Not Detected | | | 11 |
| HBV surface antibody | 7.2 13 | U/L 14 | <input checked="" type="checkbox"/> Detected <input checked="" type="checkbox"/> Not Detected | | | 15 |
| Anti-HCV antibody | 8.5 17 | g/L 18 | <input checked="" type="checkbox"/> Detected <input type="checkbox"/> Not Detected | | | 19 |
| HIV antibody | 9.2 21 | umol/L 22 | <input checked="" type="checkbox"/> Detected <input checked="" type="checkbox"/> Not Detected | | | 23 |
| Syphilis Serology | 9.5 25 | mmol/L 26 | <input checked="" type="checkbox"/> Reactive <input type="checkbox"/> Non Reactive | | | 27 |
| VZV antibody | 12.1 29 | 10e9/L 30 | <input checked="" type="checkbox"/> Detected <input checked="" type="checkbox"/> Not Detected | | | 31 |
| CMV antibody | 13.7 33 | 10e12/L 34 | <input checked="" type="checkbox"/> Detected <input type="checkbox"/> Not Detected | | | 35 |
| Tuberculosis IGRA (Quantiferon Gold) | 21.6 37 | nmol/L 38 | <input type="checkbox"/> Positive <input checked="" type="checkbox"/> Negative <input type="checkbox"/> Indeterminate | | | 39 |
| Mantoux Test | 14.6 41 | pmol/L 42 | <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input checked="" type="checkbox"/> Indeterminate | | | 43 |
| Anti JC Virus antibody in plasma | 17.5 45 | L/L 46 | <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate | | | 47 |
| JCV Index | 12.2 49 | | | | | 48 |

32.4 Laboratory Tests – Microbial Tests Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---------------------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 32.01 | HBV core antigen count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 3. See section below for database table information. |
| 32.02 | HBV core antigen Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.03 | HBV core antigen Negative/Positive | Checkbox | | | Yes | | Detected; Not Detected | Y | |
| 32.04 | HBV core antigen Comments | String | 100 | | Yes | | | N | |
| 32.05 | HBV surface antigen count | Number | | NNNNNN.NN | Yes | | | Y | |
| 32.06 | HBV surface antigen Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.07 | HBV surface antigen Negative/Positive | Checkbox | | | Yes | | Detected; Not Detected | Y | |
| 32.08 | HBV surface antigen Comments | String | 100 | | Yes | | | N | |
| 32.09 | HBV core antibody count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 3. See section below for database table information. |
| 32.10 | HBV core antibody Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.11 | HBV core antibody Negative/Positive | Checkbox | | | Yes | | Detected; Not Detected | Y | |
| 32.12 | HBV core antibody Comments | String | 100 | | Yes | | | N | |
| 32.13 | HBV surface antibody count | Number | | NNNNNN.NN | Yes | | | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|----------|-----|-------------|----------|------------------|---|------------------|--|
| 32.14 | HBV surface antibody Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.15 | HBV surface antibody Negative/Positive | Checkbox | | | Yes | | Detected; Not Detected | Y | |
| 32.16 | HBV surface antibody Comments | String | 100 | | Yes | | | N | |
| 32.17 | Anti HCV antibody count | Number | | NNNNNN.NN | Yes | | | Y | |
| 32.18 | Anti HCV antibody Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.19 | Anti HCV antibody Negative/Positive | Checkbox | | | Yes | | Detected; Not Detected | Y | |
| 32.20 | Anti HCV antibody Comments | String | 100 | | Yes | | | N | |
| 32.21 | HIV antibody count | Number | | NNNNNN.NN | Yes | | | Y | |
| 32.22 | HIV antibody Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.23 | HIV antibody Negative/Positive | Checkbox | | | Yes | | Detected; Not Detected | Y | |
| 32.24 | HIV antibody Comments | String | 100 | | Yes | | | N | |
| 32.25 | Syphilis Serology count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 3. See section below for database table information. |
| 32.26 | Syphilis Serology Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.27 | Syphilis Serology Negative/Positive | Checkbox | | | Yes | | Reactive; Not Reactive | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|----------|-----|-------------|----------|------------------|---|------------------|----------|
| 32.28 | Syphilis Serology comments | String | 100 | | Yes | | | N | |
| 32.29 | VZV antibody count | Number | | NNNNNN.NN | Yes | | | Y | |
| 32.30 | VZV antibody Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.31 | VZV antibody Negative/Positive | Checkbox | | | Yes | | Detected; Not Detected | Y | |
| 32.32 | VZV antibody Comments | String | 100 | | Yes | | | N | |
| 32.33 | CMV antibody count | Number | | NNNNNN.NN | Yes | | | Y | |
| 32.34 | CMV antibody Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.35 | CMV antibody Negative/Positive | Checkbox | | | Yes | | Detected; Not Detected | Y | |
| 32.36 | CMV antibody Comments | String | 100 | | Yes | | | N | |
| 32.37 | Tuberculosis IGRA (Quantiferon Gold) count | Number | | NNNNNN.NN | Yes | | | Y | |
| 32.38 | Tuberculosis IGRA (Quantiferon Gold) Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.39 | Tuberculosis IGRA (Quantiferon Gold) Negative/Positive | Checkbox | | | Yes | | Positive; Negative; Indeterminate | Y | |
| 32.40 | Tuberculosis IGRA (Quantiferon Gold) Comments | String | 100 | | Yes | | | N | |
| 32.41 | Mantoux Test count | Number | | NNNNNN.NN | Yes | | | Y | |
| 32.42 | Mantoux Test Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----------------------------------|--|--------------------------------|-----|-------------|----------|------------------|---|------------------|--|
| | | | | | | | ?, %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | | |
| 32.43 | Mantoux Test Negative/Positive | Checkbox | | | Yes | | Positive; Negative; Indeterminate | Y | |
| 32.44 | Mantoux Test Comments | String | 100 | | Yes | | | N | |
| 32.45 | Anti JC Virus antibody in plasma count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 3. See section below for database table information. |
| 32.46 | Anti JC Virus antibody in plasma Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?, %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 32.47 | Anti JC Virus antibody in plasma Negative/Positive | Checkbox | | | Yes | | Positive; Negative; Indeterminate | Y | |
| 32.48 | Anti JC Virus antibody in plasma Comments | String | 100 | | Yes | | | N | |
| 32.49 | JCV Index count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 3. See section below for database table information. |
| 32.50 | Date [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today or Date of Death | Y | Defaults to Today |
| Database Table Information | | | | | | | | | |
| | Test Name [LaboratoryTestMeasureResult.TypeId] | Label [uniqueidentifier] | | | No | | Lookup Values from table LaboratoryTestType where Category = 3 | Y | |
| | Value [LaboratoryTestMeasureResult.Value] | Number [decimal] | | NNNNNN.NN | Yes | Format | | Y | |
| | Unit [LaboratoryTestMeasureResult.UnitId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table LaboratoryTestUnit ?, %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|-----|-------------|----------|------------------|---|------------------|----------|
| | Result [LaboratoryTestMeasureResult.Result] | Number [int] | | | Yes | | Normal: Negative[0]; Positive[1] Negative/Positive: Negative[0]; Positive[1]; Equivocal[2]; Not Tested/Unknown[3] or Not Detected[0]; Detected[1] or Non Reactive[0]; Reactive[1] or Negative[0]; Positive[1]; Indeterminate[2] or No[0]; Yes[1] | Y | |
| | Comments [LaboratoryTestMeasureResult.Comments] | String [nvarchar] | 100 | | Yes | Length | | N | |
| | [LaboratoryTestMeasureResult.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__Laborator__Labor__035179CE, Relationship 1 to 1 LaboratoryTest.Id to LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__TypeI__04459E07, Relationship 1 to Many LaboratoryTestType.Id to LaboratoryTestMeasureResult.TypeId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__UnitI__0539C240, Relationship 1 to Many LaboratoryTestUnit.Id to LaboratoryTestMeasureResult.UnitId] | Hidden [Relationship] | | | | | | | |
| | [FK__LaboratoryTe__Id__025D5595, Relationship 1 to 1 ParaclinicalTest.Id to LaboratoryTest.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

33. MEDICAL TESTS - Laboratory Tests – Auto-antibody Tests

33.1 Description

The Auto-antibody tests section, part of the broader Laboratory Tests, enables the user to enter data from exams and comment where the test value is abnormal.

33.2 Rules and Constraints

- Date of test field mandatory

33.3 Functions

- Add/Delete Lab test – You can add/delete Lab test details for a patient.
- Add/Delete Lab test Calendar Event – You can add/delete Calendar Event

| Myasthenia Antibodies | | Haematology | | Blood Chemistry | | Thyroid Tests | | Microbial Tests | | Auto-antibody Tests | |
|-------------------------------|------|-------------|-------------------|-----------------|--|--|----|-----------------|--|-------------------------------|-----|
| Date | | Unit | Negative/Positive | | | | | | | Comments | |
| 09/05/2008 | 101 | | | | | | | | | | |
| Anti MOG antibody | 12.4 | 1 | mmol/L | 2 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 3 | | | Anti MOG antibody | 4 |
| ANA Antibodies | 21.2 | 5 | umol/L | 6 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 7 | | | ANA Antibodies | 8 |
| Anti-Ro | 11.7 | 9 | U/L | 10 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 11 | | | Anti-Ro | 12 |
| Anti-La | 23.5 | 13 | U/L | 14 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 15 | | | Anti-La | 16 |
| Anti-Sm | 8.7 | 17 | mmol/L | 18 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 19 | | | Anti-Sm | 20 |
| Anti-RNP | 27.5 | 21 | 10e9/L | 22 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 21 | | | Anti-RNP | 24 |
| Anti-Sci-70 | 9.3 | 25 | g/dL | 26 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 25 | | | Anti-Sci-70 | 28 |
| Anti-Jo1 | 9.7 | 29 | g/dL | 30 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 29 | | | Anti-Jo1 | 32 |
| ANCA | 12.7 | 33 | g/L | 34 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 33 | | | ANCA | 36 |
| ANCA MPO | 24.5 | 37 | U/L | 38 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 37 | | | ANCA MPO | 40 |
| ANCA PR3 | 12.3 | 41 | g/L | 42 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 41 | | | ANCA PR3 | 44 |
| Anti-dsDNA | 16.7 | 45 | mmol/L | 46 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 45 | | | Anti-dsDNA | 48 |
| Anti-myositis | 8.9 | 53 | % | 50 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 49 | | | Anti-myositis | 52 |
| Anti-mitochondrial | 9.2 | 57 | g/L | 54 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 53 | | | Anti-mitochondrial | 56 |
| Anti-parietal cell | 12.9 | 61 | U/L | 62 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 63 | | | Anti-parietal cell | 64 |
| ASMA | 13.2 | 65 | mmol/L | 66 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 67 | | | ASMA | 68 |
| Anti-LKM | 18.7 | 69 | ? | 70 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 71 | | | Anti-LKM | 72 |
| Anti-cardiolipin | 21.6 | 73 | % | 74 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 75 | | | Anti-cardiolipin | 76 |
| Beta-2 micro-globulin | 27.8 | 77 | g/dL | 78 | <input checked="" type="checkbox"/> Positive | <input type="checkbox"/> Negative | 79 | | | Beta-2 micro-globulin | 80 |
| Lupus anticoagulant | 22.5 | 81 | U/L | 82 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 83 | | | Lupus anticoagulant | 84 |
| Serum protein electrophoresis | 27.8 | 85 | g/L | 86 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | 87 | | | Serum protein electrophoresis | 88 |
| Immunofixation | 25.3 | 89 | umol/L | 90 | <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | 91 | | | Immunofixation | 92 |
| Free light chains | 28.7 | 93 | mmol/L | 94 | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No | 95 | | | Free light chains | 96 |
| Anti-ganglioside antibody | 12.2 | 97 | 10e9/L | 98 | <input checked="" type="checkbox"/> Positive | <input checked="" type="checkbox"/> Negative | 99 | | | Anti-ganglioside antibody | 100 |

33.4 Laboratory Tests – Auto-antibody Test Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|-------------------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 33.01 | Anti-MOG antibody count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.02 | Anti-MOG antibody Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.03 | Anti-MOG antibody Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.04 | Anti-MOG antibody Comments | String | 100 | | Yes | | | N | |
| 33.05 | ANA Antibodies count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.06 | ANA Antibodies Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.07 | ANA Antibodies Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.08 | ANA Antibodies Comments | String | 100 | | Yes | | | N | |
| 33.09 | Anti-Ro count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.10 | Anti-Ro Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.11 | Anti-Ro Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.12 | Anti-Ro Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|----------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 33.13 | Anti-La count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.14 | Anti-La Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.15 | Anti-La Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.16 | Anti-La Comments | String | 100 | | Yes | | | N | |
| 33.17 | Anti-Sm count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.18 | Anti-Sm Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.19 | Anti-Sm Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.20 | Anti-Sm Comments | String | 100 | | Yes | | | N | |
| 33.21 | Anti-RNP count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.22 | Anti-RNP Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.23 | Anti-RNP Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.24 | Anti-RNP Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|-------------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 33.25 | Anti-Scl-70 count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.26 | Anti-Scl-70 Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.27 | Anti-Scl-70 Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.28 | Anti-Scl-70 Comments | String | 100 | | Yes | | | N | |
| 33.29 | Anti-Jo1 count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.30 | Anti-Jo1 Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.31 | Anti-Jo1 Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.32 | Anti-Jo1 Comments | String | 100 | | Yes | | | N | |
| 33.33 | ANCA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.34 | ANCA Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.35 | ANCA Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.36 | ANCA Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|------------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 33.37 | ANCA MPO count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.38 | ANCA MPO Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.39 | ANCA MPO Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.40 | ANCA MPO Comments | String | 100 | | Yes | | | N | |
| 33.41 | ANCA PR3 count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.42 | ANCA PR3 Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.43 | ANCA PR3 Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.44 | ANCA PR3 Comments | String | 100 | | Yes | | | N | |
| 33.45 | Anti-dsDNA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.46 | Anti-dsDNA Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.47 | Anti-dsDNA Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.48 | Anti-dsDNA Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--------------------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 33.49 | Anti-myositis count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.50 | Anti-myositis Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.51 | Anti-myositis Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.52 | Anti-myositis Comments | String | 100 | | Yes | | | N | |
| 33.53 | Anti-mitochondrial count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.54 | Anti-mitochondrial Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.55 | Anti-mitochondrial Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.56 | Anti-mitochondrial Comments | String | 100 | | Yes | | | N | |
| 33.57 | Anti parietal cell count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.58 | Anti parietal cell Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.59 | Anti parietal cell Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.60 | Anti parietal cell Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|------------------------------------|----------|-----|-------------|----------|------------------|---|------------------|--|
| 33.61 | ASMA count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.62 | ASMA Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.63 | ASMA Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.64 | ASMA Comments | String | 100 | | Yes | | | N | |
| 33.65 | Anti-LKM count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.66 | Anti-LKM Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.67 | Anti-LKM Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.68 | Anti-LKM Comments | String | 100 | | Yes | | | N | |
| 33.69 | Anti-cardiolipin count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.70 | Anti-cardiolipin Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.71 | Anti-cardiolipin Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.72 | Anti-cardiolipin Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|----------|-----|-------------|----------|------------------|---|------------------|--|
| 33.73 | Beta-2 micro-globulin count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.74 | Beta-2 micro-globulin Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.75 | Beta-2 micro-globulin Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.76 | Beta-2 micro-globulin Comments | String | 100 | | Yes | | | N | |
| 33.77 | Lupus anticoagulant count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.78 | Lupus anticoagulant Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.79 | Lupus anticoagulant Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.80 | Lupus anticoagulant Comments | String | 100 | | Yes | | | N | |
| 33.81 | Serum protein electrophoresis count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.82 | Serum protein electrophoresis Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.83 | Serum protein electrophoresis Negative/Positive | Checkbox | | | Yes | | Yes; No | Y | |
| 33.84 | Serum protein electrophoresis Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|----------|-----|-------------|----------|------------------|---|------------------|--|
| 33.85 | Immunofixation count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.86 | Immunofixation Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.87 | Immunofixation Negative/Positive | Checkbox | | | Yes | | Yes; No | Y | |
| 33.88 | Immunofixation Comments | String | 100 | | Yes | | | N | |
| 33.89 | Free light chains count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.90 | Free light chains Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.91 | Free light chains Negative/Positive | Checkbox | | | Yes | | Yes; No | Y | |
| 33.92 | Free light chains Comments | String | 100 | | Yes | | | N | |
| 33.93 | Anti-ganglioside antibody count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 4. See section below for database table information. |
| 33.94 | Anti-ganglioside antibody Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 33.95 | Anti-ganglioside antibody Negative/Positive | Checkbox | | | Yes | | Positive; Negative | Y | |
| 33.96 | Anti-ganglioside antibody Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----------------------------------|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|-------------------|
| 33.97 | Date [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today or Date of Death | Y | Defaults to Today |
| Database Table Information | | | | | | | | | |
| | Test Name [LaboratoryTestMeasureResult.TypeId] | Label [uniqueidentifier] | | | No | | Lookup Values from table LaboratoryTestType where Category = 4 | Y | |
| | Value [LaboratoryTestMeasureResult.Value] | Number [decimal] | | NNNNNN.NN | Yes | Format | | Y | |
| | Unit [LaboratoryTestMeasureResult.UnitId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| | Result [LaboratoryTestMeasureResult.Result] | Number [int] | | | Yes | | Normal: Negative[0]; Positive[1] Negative/Positive: Negative[0]; Positive[1]; Equivocal[2]; Not Tested/Unknown[3] or Not Detected[0]; Detected[1] or Non Reactive[0]; Reactive[1] or Negative[0]; Positive[1]; Indeterminate[2] or No[0]; Yes[1] | Y | |
| | Comments [LaboratoryTestMeasureResult.Comments] | String [nvarchar] | 100 | | Yes | Length | | N | |
| | [LaboratoryTestMeasureResult.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK_Laborator__Labor__035179CE, Relationship 1 to 1] | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|-----------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | LaboratoryTest.Id to LaboratoryTestMeasureResult.LaboratoryTestId] | | | | | | | | |
| | [FK__Laborator__TypeI__04459E07, Relationship 1 to Many LaboratoryTestType.Id to LaboratoryTestMeasureResult.TypeId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__UnitI__0539C240, Relationship 1 to Many LaboratoryTestUnit.Id to LaboratoryTestMeasureResult.UnitId] | Hidden [Relationship] | | | | | | | |
| | [FK__LaboratoryTe__Id__025D5595, Relationship 1 to 1 ParaclinicalTest.Id to LaboratoryTest.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

34. MEDICAL TESTS - Laboratory Tests – Other Tests

34.1 Description

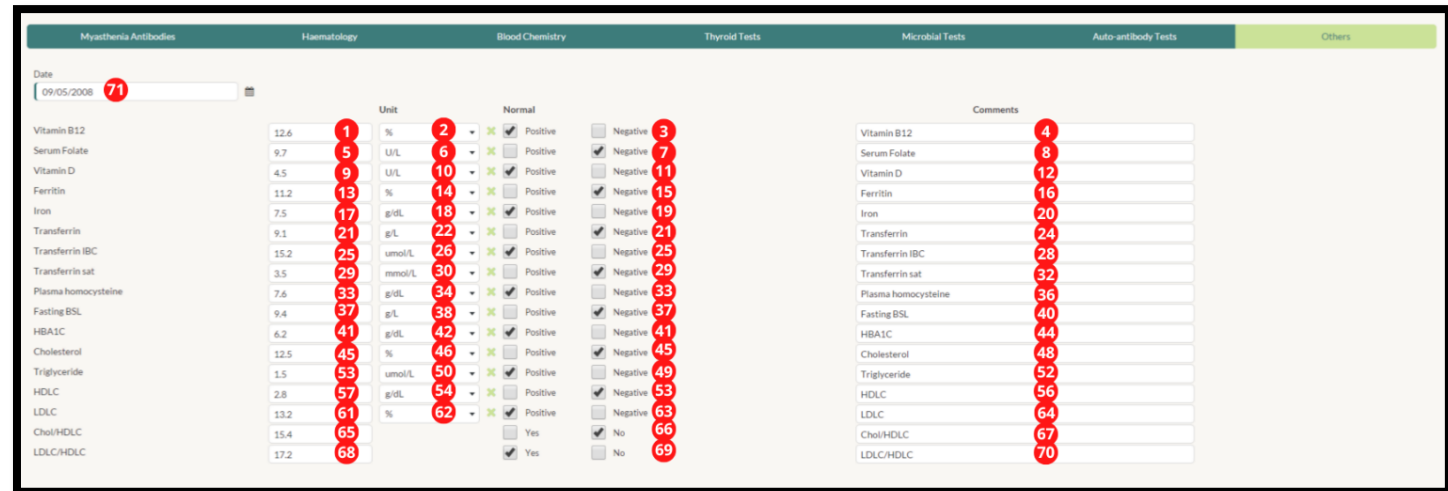
The Others section, part of the broader Laboratory Tests, enables the user to enter data from exams and comment where the test value is abnormal.

34.2 Rules and Constraints

- Date of test field mandatory

34.3 Functions

- Add/Delete Lab test – You can add/delete Lab test details for a patient.
- Add/Delete Lab test Calendar Event – You can add/delete Calendar Event



| Test Name | Value | Unit | Normal Range | Positive | Negative | Comments |
|---------------------|-------|--------|--------------|-------------------------------------|-------------------------------------|----------|
| Vitamin B12 | 12.6 | % | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Serum Folate | 9.7 | U/L | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Vitamin D | 4.5 | U/L | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Ferritin | 11.2 | % | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Iron | 7.5 | g/dL | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Transferrin | 9.1 | g/L | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Transferrin IBC | 15.2 | umol/L | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Transferrin sat | 3.5 | mmol/L | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Plasma homocysteine | 7.6 | g/dL | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Fasting BSL | 9.4 | g/L | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| HBA1C | 6.2 | g/dL | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Cholesterol | 12.5 | % | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Triglyceride | 1.5 | umol/L | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| HDLc | 2.8 | g/dL | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| LDLc | 13.2 | % | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Chol/HDLc | 15.4 | | | <input type="checkbox"/> | <input checked="" type="checkbox"/> | |
| LDLc/HDLc | 17.2 | | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

34.4 Laboratory Tests – Others Test Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|-----------------------|--------|-----|-------------|----------|------------------|---|------------------|--|
| 34.01 | Vitamin B12 count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.02 | Vitamin B12 Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.03 | Vitamin B12 Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.04 | Vitamin B12 Comments | String | 100 | | Yes | | | N | |
| 34.05 | Serum Folate count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.06 | Serum Folate Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.07 | Serum Folate Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.08 | Serum Folate Comments | String | 100 | | Yes | | | N | |
| 34.09 | Vitamin D count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.10 | Vitamin D Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.11 | Vitamin D Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.12 | Vitamin D Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|----------------------|--------|-----|-------------|----------|------------------|---|------------------|--|
| 34.13 | Ferritin count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.14 | Ferritin Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.15 | Ferritin Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.16 | Ferritin Comments | String | 100 | | Yes | | | N | |
| 34.17 | Iron count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.18 | Iron Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.19 | Iron Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.20 | Iron Comments | String | 100 | | Yes | | | N | |
| 34.21 | Transferrin count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.22 | Transferrin Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.23 | Transferrin Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.24 | Transferrin Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|------------------------------|--------|-----|-------------|----------|------------------|---|------------------|--|
| 34.25 | Transferrin IBC count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.26 | Transferrin IBC Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.27 | Transferrin IBC Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.28 | Transferrin IBC Comments | String | 100 | | Yes | | | N | |
| 34.29 | Transferrin sat count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.30 | Transferrin sat Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.31 | Transferrin sat Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.32 | Transferrin sat Comments | String | 100 | | Yes | | | N | |
| 34.33 | Plasma homocysteine count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.34 | Plasma homocysteine Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.35 | Plasma homocysteine Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.36 | Plasma homocysteine Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|----------------------|--------|-----|-------------|----------|------------------|---|------------------|--|
| 34.37 | Fasting BSL count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.38 | Fasting BSL Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.39 | Fasting BSL Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.40 | Fasting BSL Comments | String | 100 | | Yes | | | N | |
| 34.41 | HBA1C count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.42 | HBA1C Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.43 | HBA1C Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.44 | HBA1C Comments | String | 100 | | Yes | | | N | |
| 34.45 | Cholesterol count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.46 | Cholesterol Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.47 | Cholesterol Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.48 | Cholesterol Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|-----------------------|--------|-----|-------------|----------|------------------|---|------------------|--|
| 34.49 | Triglyceride count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.50 | Triglyceride Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.51 | Triglyceride Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.52 | Triglyceride Comments | String | 100 | | Yes | | | N | |
| 34.53 | HDLC count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.54 | HDLC Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.55 | HDLC Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.56 | HDLC Comments | String | 100 | | Yes | | | N | |
| 34.57 | LDLC count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.58 | LDLC Unit | Select | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| 34.59 | LDLC Normal | Select | | | Yes | | Negative; Positive | Y | |
| 34.60 | LDLC Comments | String | 100 | | Yes | | | N | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----------------------------------|---|--------------------------------|-----|-------------|----------|------------------|--|------------------|--|
| 34.61 | Chol/HDLC count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.62 | Chol/HDLC Normal | Select | | | Yes | | Yes; No | Y | |
| 34.63 | Chol/HDLC Comments | String | 100 | | Yes | | | N | |
| 34.64 | LDLC/HDLC count | Number | | NNNNNN.NN | Yes | | | Y | Presented on screen where table LaboratoryTestType Category = 5. See section below for database table information. |
| 34.65 | LDLC/HDLC Normal | Select | | | Yes | | Yes; No | Y | |
| 34.66 | LDLC/HDLC Comments | String | 100 | | Yes | | | N | |
| 34.67 | Date [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today or Date of Death | Y | Defaults to Today |
| Database Table Information | | | | | | | | | |
| | Test Name [LaboratoryTestMeasureResult.TypeId] | Label [uniqueidentifier] | | | No | | Lookup Values from table LaboratoryTestType where Category = 5 | Y | |
| | Value [LaboratoryTestMeasureResult.Value] | Number [decimal] | | NNNNNN.NN | Yes | Format | | Y | |
| | Unit [LaboratoryTestMeasureResult.UnitId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table LaboratoryTestUnit ?; %; g/dL; U/L; g/L; umol/L; mmol/L; 10e9/L; 10e12/L; nmol/L; pmol/L; L/L | Y | |
| | Result [LaboratoryTestMeasureResult.Result] | Number [int] | | | Yes | | Normal: Negative[0]; Positive[1] Negative/Positive: Negative[0]; Positive[1]; Equivocal[2]; Not Tested/Unknown[3] or Not Detected[0]; Detected[1] or Non Reactive[0]; Reactive[1] or | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|-----|-------------|----------|------------------|---|------------------|----------|
| | | | | | | | Negative[0]; Positive[1]; Indeterminate[2] or No[0]; Yes[1] | | |
| | Comments [LaboratoryTestMeasureResult.Comments] | String [nvarchar] | 100 | | Yes | Length | | N | |
| | [LaboratoryTestMeasureResult.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__Laborator__Labor__035179CE, Relationship 1 to 1 LaboratoryTest.Id to LaboratoryTestMeasureResult.LaboratoryTestId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__TypeI__04459E07, Relationship 1 to Many LaboratoryTestType.Id to LaboratoryTestMeasureResult.TypeId] | Hidden [Relationship] | | | | | | | |
| | [FK__Laborator__UnitI__0539C240, Relationship 1 to Many LaboratoryTestUnit.Id to LaboratoryTestMeasureResult.UnitId] | Hidden [Relationship] | | | | | | | |
| | [FK__LaboratoryTe__Id__025D5595, Relationship 1 to 1 ParaclinicalTest.Id to LaboratoryTest.Id] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title

35. MEDICAL TESTS - Flexifields

35.1 Description

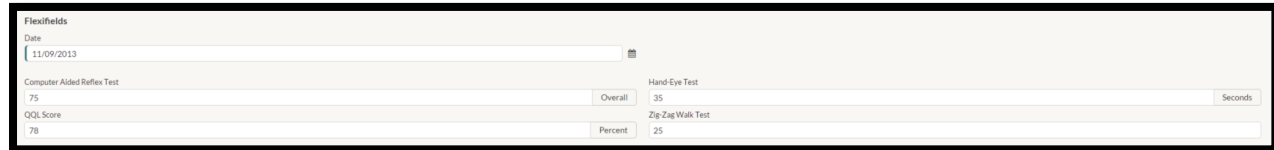
User specified Flexifields for Medical Tests are in this section.

35.2 Rules and Constraints

- Flexifields must be specified in the Preferences.

35.3 Functions

- Enter/Delete Data – You can enter/delete Flexifield data.



The screenshot shows a data entry form titled "Flexifields". It contains a date field set to "11/09/2013". Below this are two columns of data entry fields. The left column has "Computer Aided Reflex Test" with a value of "75" and "QOL Score" with a value of "78". The right column has "Hand-Eye Test" with a value of "35" and "Zig-Zag Walk Test" with a value of "25". There are also "Overall" and "Percent" labels between the columns. A "Seconds" label is visible at the end of the right column.

| Flexifields | |
|----------------------------|------------|
| Date | 11/09/2013 |
| Computer Aided Reflex Test | 75 |
| Overall | 35 |
| QOL Score | 78 |
| Percent | 25 |
| Hand-Eye Test | 35 |
| Zig-Zag Walk Test | 25 |
| | Seconds |

35.4 Medical Test Flexifield Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|------|-------------|----------|------------------|--|------------------|-------------------|
| | Date [ParaclinicalTest.DateOfTest] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered \geq Date of Birth and \leq Today or Date of Death | | Defaults to Today |
| | FlexiField Name [FlexiField.Name] | Field Label | | | | | | N | |
| | FlexiField Value [ParaclinicalTestFlexiField.Value] | String [nvarchar] | 1000 | | Yes | | Allowed values will depend on the type of flexifield. Dropdown lists comes from [FlexiFieldOption.Value] | N | |
| | [ParaclinicalTestFlexiField.FieldId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [ParaclinicalTestFlexiField.Id] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [ParaclinicalTestFlexiField.ParaclinicalTestId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [ParaclinicalTestFlexiField.CreatedByUserId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [ParaclinicalTestFlexiField.CreatedUtcDate] | Hidden [datetime] | | | No | | | N | |
| | [ParaclinicalTestFlexiField.ModifiedByUserId] | Hidden [uniqueidentifier] | | | No | | | N | |
| | [ParaclinicalTestFlexiField.ModifiedUtcDate] | Hidden [datetime] | | | No | | | N | |
| | [ParaclinicalTestFlexiField.RowVersion] | Hidden [bigint] | | | Yes | | | N | |
| | [FlexiFieldParaclinicalTest.Id] | Hidden [uniqueidentifier] | | | No | | | N | |

Notes:

- Type of Medical Test is stored in Table ParaclinicalTest, fields Type and Title
- Table ParaclinicalTestFlexiField contains the value that is entered for flexifields from the Medical Tests Flexifields screen in MDS
- Table FlexiField contains the definition of the flexifields, i.e. Name and Data Type
- Table FlexiFieldOptions contains the values defined for flexifields where type is a dropdown

36. TREATMENTS - Disease Modifying Treatments

36.1 Description

This section identifies Disease Specific treatments

36.3 Functions

- Add/Remove MG Specific Treatment – User can add treatment, modify data, and delete treatment.



36.2 Rules and Constraints

- MG Treatment must be present in the list of MG Specific Treatments. Dose, unit, period may be populated with default values and may be modified.
- Concurrent MG Specific Treatments are possible, but where concurrent treatments are initiated MDS will attempt to close the existing treatment at the start date of the new treatment. MDS will prompt and ask whether you wish to continue the ongoing DMT
- Changing the dosage of an ongoing MG Specific Treatment will be met with a confirmation prompt from MDS. In the instance where it is a valid change (for example an error) then you can ignore the prompt. Where it is a change to dosage, MDS will automatically end the existing treatment and start a new treatment with the new dosage.
- If a Corticosteroid Treatment is selected, there is now an option to create a variable dosing schedule. When Yes is selected, the Add Dose Line button will become visible when the first treatment has an end date and there must be more than 1 dose line entered.
- The start date of the next treatment is always prepopulated with the previous treatment end date + 1 day.
- A zero-dose line is permissible to indicate that the patient is not receiving treatment during the selected period.
- An alert will be displayed if there is a gap in the dosing schedule and will result in a zero-dose line being added after saving.

36.4 Disease Specific Treatment Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|--------------------------------|-----|-------------|----------|------------------|--|------------------|--|
| 36.01 | Disease modifying treatment [DMTreatment.TreatmentTypeid] | Dropdown [uniqueidentifier] | | | No | Mandatory | Lookup values from table TreatmentType Please refer to the tab for the Table in the Db Schema file to see the selection options (and associated ids) available for this field. List is filtered based on field IsDmt = 1 | Y | |
| 36.02 | Is this treatment a variable dosing corticosteroid schedule | Radio | | | | | Yes; No Defaults to No | Y | Becomes visible when TreatmentType.IsCorticoSteroidScheduledSupported = 1: True where Treatment has child treatments |
| 36.03 | Starting on [Treatment.StartDate] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered \geq Date of Birth and \leq Today or Date of Death | Y | Defaults to Today When dosing schedule, next dose line starting on date defaults to previous dose line ending on date plus 1 day. |
| 36.04 | Ending on [Treatment.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered \geq Starting on date | Y | |
| 36.05 | Dose [PosologyTreatment.Dose] | Number [decimal] | | | Yes | Mandatory | | Y | |
| 36.06 | Unit [PosologyTreatment.UnitId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table UnitType Other; mcg; mg; MIU; ml; g; MU; mg/kg; mg/m2; Episodes | Y | |
| 36.07 | Period [PosologyTreatment.PeriodId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table PeriodType Other; 2 / Week; / Week; 2 / Day; 3 / Week; / 3 Hour; / 2 Hour; 3 / Day; / 3 Days; / 2 Days; / Hour; / | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|--------------------------------|---------------|-------------|----------|-------------------------------|--|------------------|--|
| | | | | | | | Day; / 4 Hour; 4 / Day; / Month; / 3 Month; / 4 Week; / 5 Weeks; / 6 Weeks; / 7 Weeks; / 8 Weeks; Single Dose; Daily for 5 days; Daily for 3 days; / 2 Weeks; / 6 Month; / 3 Weeks; 5 Day Course; 5 Day Course (Week 1 and Week 5); Variable, up to 8x/d; Daily or bd; Up to qid; Up to tds; Daily through to every 8 weeks; Weekly - every 4 weeks; Daily - bd; Bd; Monthly; Daily; Single episodes; over 1 day; over 2 days; over 3 days; over 4 days; over 5 days | | |
| 36.08 | Route [PosologyTreatment.RouteId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table RouteType SC; OTHER; IV; ORAL; IM; ORAL LIQUID; PO | Y | |
| 36.09 | Reason for discontinuation [PosologyTreatment.ReasonForDiscontinuation] | Dropdown [nvarchar] | 100 | | Yes | | Scheduled Stop; Lack of tolerance; Treatment-related adverse event; Lack of efficacy; Patient Choice/Convenience; Progression of disease; Pregnancy planning; Pregnancy confirmed; Allergic reaction; Persisting MRI activity; Progression of EDSS; Persistence of relapses; Non adherence; Anti-JCV Ab positive / PML risk; Other; Dose Change | Y | Note: Dose change used when additional dose lines are added. |
| 36.10 | Remarks [Treatment.Remarks] | Memo [text] | 2,147,483,647 | | Yes | Maximum length 500 characters | | N | |
| | [DMTreatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|--|------------------------------|-----|-------------|----------|------------------|----------------|------------------|---|
| | [DMTreatment.ExacerbationId] | Hidden [uniqueidentifier] | | | Yes | | | Y | |
| | [Treatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PosologyTreatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | Set where this treatment has a parent treatment in a schedule |
| | [FK__Treatment__Patie__4242D080, Relationship 1 to many Patient.Id to Treatment.PatientId] | Hidden [Relationship] | | | | | | | |
| | [FK__MSSpecificTr__Id__1387E197, Relationship 1 to 1 Treatment.Id to DMTreatment.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__PosologyTrea__Id__3118447E, Relationship 1 to many Treatment.Id to PosologyTreatment.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__mg.Treatment__mg.Treatment_Id, Relationship 1 to many Treatment.Id to Treatment.TreatmentId] | Hidden [Relationship] | | | | | | | |
| | [FK__MSSpecifi__Treat__1293BD5E, Relationship 1 to many TreatmentType.Id to MSSpecificTreatment.TreatmentTypeId] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Treatment is stored in Table Treatment, fields Type and Title

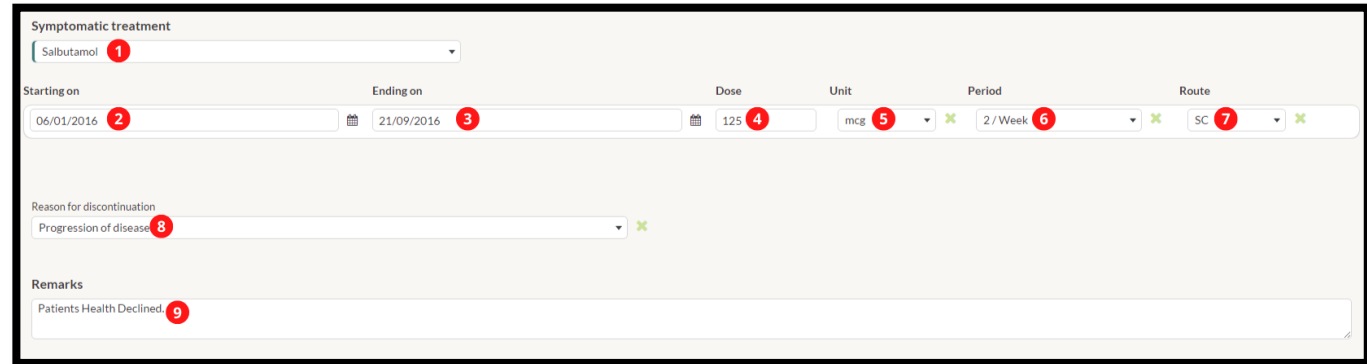
37. TREATMENTS - Symptomatic

37.1 Description

This section identifies Symptomatic treatments.

37.3 Functions

- Add/Remove Symptomatic Treatment – User can add treatment, modify data and delete treatment.



The screenshot shows the 'Symptomatic treatment' form in MGBase. It includes a dropdown for the treatment name (Salbutamol), fields for starting and ending dates, dose, unit, period, and route. There is also a dropdown for the reason for discontinuation and a remarks field.

37.2 Rules and Constraints

- Treatment must be present in the list of *Symptomatic Treatments*. Dose, unit, period may be populated with default values and may be modified.
- If a Corticosteroid Treatment is selected, there is now an option to create a variable dosing schedule. When Yes is selected, the Add Dose Line button will become visible when the first treatment has an end date and there must be more than 1 dose line entered.
- The start date of the next treatment is always prepopulated with the previous treatment end date + 1 day.
- A zero-dose line is permissible to indicate that the patient is not receiving treatment during the selected period.
- An alert will be displayed if there is a gap in the dosing schedule and will result in a zero-dose line being added after saving.

37.4 Symptomatic Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|--------------------------------|-----|-------------|----------|------------------|--|------------------|--|
| 37.01 | Symptomatic Treatment [SymptomaticTreatment.TreatmentTypeId] | Dropdown [uniqueidentifier] | | | Yes | Mandatory | Lookup values from table TreatmentType Please refer to the tab for the Table in the Db Schema file to see the selection options (and associated ids) available for this field. List is filtered based on field IsDmt = 0 | Y | |
| 37.02 | Is this treatment a variable dosing corticosteroid schedule | Radio | | | | | Yes; No Defaults to No | Y | Becomes visible when TreatmentType.IsCorticoSteroidScheduledSupported = 1: True where Treatment has child treatments |
| 37.03 | Starting on [Treatment.StartDate] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered \geq Date of Birth and \leq Today or Date of Death | Y | Defaults to Today When dosing schedule, next dose line starting on date defaults to previous dose line ending on date plus 1 day. |
| 37.04 | Ending on [Treatment.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered \geq Starting on date | Y | |
| 37.05 | Dose [PosologyTreatment.Dose] | Number [decimal] | | | Yes | Mandatory | | Y | |
| 37.06 | Unit [PosologyTreatment.UnitId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table UnitType Other; mcg; mg; MIU; ml; g; MU; mg/kg; mg/m ² ; Episodes | Y | |
| 37.07 | Period [PosologyTreatment.PeriodId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table PeriodType Other; 2 / Week; / Week; 2 / Day; 3 / Week; / 3 Hour; / 2 Hour; 3 / Day; / 3 Days; / 2 Days; / Hour; / Day; / 4 Hour; 4 / Day; / Month; / 3 Month; / 4 Week; / 5 Weeks; / 6 Weeks; / 7 | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|--------------------------------|---------------|-------------|----------|-------------------------------|--|------------------|--|
| | | | | | | | Weeks; / 8 Weeks; Single Dose; Daily for 5 days; Daily for 3 days; / 2 Weeks; / 6 Month; / 3 Weeks; 5 Day Course; 5 Day Course (Week 1 and Week 5); Variable, up to 8x/d; Daily or bd; Up to qid; Up to tds; Daily through to every 8 weeks; Weekly - every 4 weeks; Daily - bd; Bd; Monthly; Daily; Single episodes; over 1 day; over 2 days; over 3 days; over 4 days; over 5 days | | |
| 37.08 | Route [PosologyTreatment.RouteId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table RouteType SC; OTHER; IV; ORAL; IM; ORAL LIQUID; PO | Y | |
| 37.09 | Reason for discontinuation [PosologyTreatment.ReasonForDiscontinuation] | Dropdown [nvarchar] | 100 | | Yes | | Scheduled Stop; Lack of tolerance; Treatment-related adverse event; Lack of efficacy; Patient Choice/Convenience; Progression of disease; Pregnancy planning; Pregnancy confirmed; Allergic reaction; Persisting MRI activity; Progression of EDSS; Persistence of relapses; Non adherence; Anti-JCV Ab positive / PML risk; Other; Dose Change | Y | Note: Dose change used when additional dose lines are added. |
| 37.10 | Remarks [Treatment.Remarks] | Memo [text] | 2,147,483,647 | | Yes | Maximum length 500 characters | | N | |
| | [SymptomaticTreatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [SymptomaticTreatment.CorticosteroidScheduleId] | Hidden [uniqueidentifier] | | | Yes | | | Y | |
| | [SymptomaticTreatment.ExacerbationId] | Hidden [uniqueidentifier] | | | Yes | | | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|------------------------------|-----|-------------|----------|------------------|----------------|------------------|---|
| | [Treatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [PosologyTreatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | Set where this treatment has a parent treatment in a schedule |
| | [FK__Treatment__Patie__4242D080, Relationship 1 to many Patient.Id to Treatment.PatientId] | Hidden [Relationship] | | | | | | | |
| | [FK__SymptomaticT__Id__414EAC47, Relationship 1 to 1 Treatment.Id to SymptomaticTreatment.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__PosologyTrea__Id__3118447E, Relationship 1 to many Treatment.Id to PosologyTreatment.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__mg.Treatment__mg.Treatment_Id, Relationship 1 to many Treatment.Id to Treatment.TreatmentId] | Hidden [Relationship] | | | | | | | |
| | [FK__Symptomat__Treat__405A880E, Relationship 1 to many TreatmentType.Id to SymptomaticTreatment.TreatmentTypeId] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Treatment is stored in Table Treatment, fields Type and Title

38. TREATMENTS - Non-pharmacological

38.1 Description

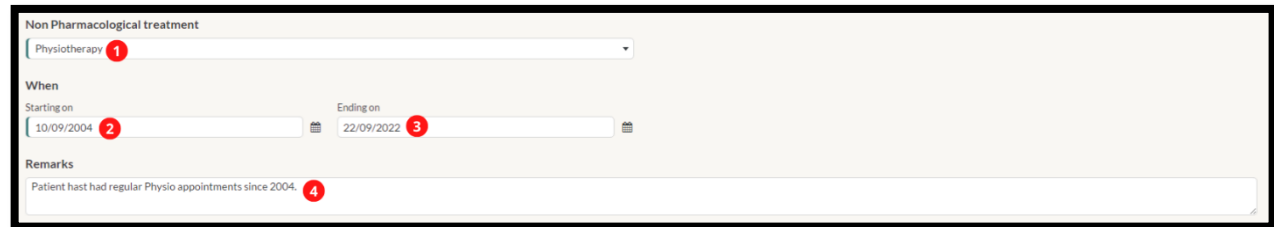
This section identifies non-pharmacological treatments.

38.2 Rules and Constraints

- Treatment must be present in the list of non-pharmacological treatments.

38.3 Functions

- Add/Remove non-pharmacological Treatment – User can add treatment, modify data, and delete treatment.



The screenshot shows a form titled "Non Pharmacological treatment". It contains a dropdown menu for "Physiotherapy" (marked with a red 1), a "When" section with "Starting on" (10/09/2004, marked with a red 2) and "Ending on" (22/09/2022, marked with a red 3) date pickers, and a "Remarks" text area containing "Patient has had regular Physio appointments since 2004" (marked with a red 4).

38.4 Non-pharmacological Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|--------------------------------|---------------|-------------|----------|-------------------------------|---|------------------|---|
| 38.01 | Non-pharmacological treatment [NonPharmacologicalTreatment.TreatmentTypeId] | Dropdown [uniqueidentifier] | | | No | Mandatory | Lookup Values from table NonPharmaTreatment | Y | Note: there is no seed data for the Non-pharmacological treatment list. Each centre will need to add treatments under Preferences > Non-pharmacological treatments. |
| 38.02 | Starting on [Treatment.StartDate] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | Filtered ≥ Date of Birth and ≤ Today or Date of Death | Y | |
| 38.03 | Ending on [Treatment.EndDate] | Date [datetime] | | dd/mm/yyyy | Yes | | Filtered ≥ Starting on date | Y | |
| 38.04 | Remarks [Treatment.Remarks] | Memo [text] | 2,147,483,647 | | Yes | Maximum length 500 characters | | N | |
| | [NonPharmacologicalTreatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [Treatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__Treatment__Patie__4242D080, Relationship 1 to many Patient.Id to Treatment.PatientId] | Hidden [Relationship] | | | | | | | |
| | [FK__NonPharmacol__Id__1758727B, Relationship 1 to 1 Treatment.Id to NonPharmacologicalTreatment.Id] | Hidden [Relationship] | | | | | | | |
| | [FK__NonPharma__Treat__16644E42, Relationship 1 to many NonPharmaTreatment.Id to NonPharmacologicalTreatment.TreatmentTypeId] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Treatment is stored in Table Treatment, fields Type and Title

38. TREATMENTS - Thymectomy

38.1 Description

This section identifies thymectomy treatments.

38.2 Rules and Constraints

- Surgery date field is mandatory.

38.3 Functions

- Add/Remove thymectomy Treatment – User can add treatment, modify data, and delete treatment.

Surgery date
 1

Thymectomy procedure
 2

Preoperative treatment
 Yes No Unknown 3

Select treatment(s)
 Intravenous immunoglobulin 4
 Plasma exchange

Thymectomy hospital length of stay
 5 Days

Postoperative complications
 Yes No Unknown 6

Select complication(s)
 Wound infection (superficial)
 Wound infection (deep)
 Nerve injury 7
 Thrombosis
 Respiratory complications
 Bleeding
 Cardiac complications
 Myasthenic crisis
 Death
 Others

Other
 8

Pathology
 9

Other
 10

Thymus weight 11 g Thymus volume 12 ml

Thymus size
 Thymus height 13 cm Thymus width 14 cm Thymus depth 15 cm

Thymoma Masaoka classification
 16

Thymoma WHO histological classification
 17

Thymoma treatment
 18

38.4 Thymectomy Data Fields

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|--|--------------------------------|-----|-------------|----------|--|---|------------------|--|
| 38.01 | Surgery Date [Treatment.StartDate] | Date [datetime] | | dd/mm/yyyy | No | Mandatory | | Y | Defaults to Today |
| 38.02 | Thymectomy procedure [ThymectomyTreatment.ThymectomyProcedureId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table ThymectomyProcedure Open sternotomy; Transcervical approach; Video assisted thoracoscopic surgery (VATS); Robotic-assisted approach | Y | |
| 38.03 | Preoperative treatment [ThymectomyTreatment.HasPreOpTreatments] | Radio [bit] | | | Yes | | Yes[1]; No[0]; Unknown[NULL] | Y | |
| 38.04 | Select treatment(s) [ThymectomyTreatmentPreOpTreatment.ThymectomyPreOpTreatmentId] | Checkbox [uniqueidentifier] | | | No | At least one must be selected when Preoperative treatment = Yes | Lookup Values from table ThymectomyPreOpTreatment Intravenous immunoglobulin; Plasma exchange | Y | Visible when Preoperative treatment = Yes |
| 38.05 | Thymectomy hospital length of stay (Days) [ThymectomyTreatment.HospitalStayDays] | Number [int] | | NNN | Yes | Format | | Y | |
| 38.06 | Postoperative complications [ThymectomyTreatment.HasPostOpComplications] | Radio [bit] | | | Yes | | Yes[1]; No[0]; Unknown[NULL] | Y | |
| 38.07 | Select complication(s) [ThymectomyTreatmentPostOpComplication.ThymectomyPostOpComplicationId] | Checkbox [uniqueidentifier] | | | No | At least one must be selected when Postoperative complications = Yes | Lookup Values from table ThymectomyPostOpComplication Wound infection (superficial); Wound infection (deep); Nerve injury; Thrombosis; Respiratory complications; Bleeding; Cardiac complications; Myasthenic crisis; Death; Others | Y | Visible when Postoperative complications = Yes |
| 38.08 | Other (complication) [ThymectomyTreatment.ComplicationsOther] | String [nvarchar] | 500 | | Yes | Length Mandatory when Select complication(s) = Others | | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|--------------------------------|-----|-------------|----------|--|---|------------------|----------|
| 38.09 | Pathology [ThymectomyTreatment.PathologyId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table Pathology Normal; Hyperplasia; Thymoma; Other | Y | |
| 38.10 | Other (pathology) [ThymectomyTreatment.PathologyOther] | String [nvarchar] | 500 | | Yes | Length Mandatory when Pathology = Other | | Y | |
| 38.11 | Thymus weight (g) [ThymectomyTreatment.ThymusWeight] | Number [decimal] | | NNNNNN.NNN | Yes | Format | | Y | |
| 38.12 | Thymus volume (ml) [ThymectomyTreatment.ThymusVolume] | Number [decimal] | | NNNNNN.NNN | Yes | Format | | Y | |
| | Thymus size | Section Header | | | | | | Y | |
| 38.13 | Thymus height (cm) [ThymectomyTreatment.ThymusHeight] | Number [decimal] | | NNNNNN.NNN | Yes | Format | | Y | |
| 38.14 | Thymus width (cm) [ThymectomyTreatment.ThymusWidth] | Number [decimal] | | NNNNNN.NNN | Yes | Format | | Y | |
| 38.15 | Thymus depth (cm) [ThymectomyTreatment.ThymusDepth] | Number [decimal] | | NNNNNN.NNN | Yes | Format | | Y | |
| 38.16 | Thymoma Masaoka classification [ThymectomyTreatment.ThymomaMasaokaClassificationId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table ThymomaMasaokaClassification Stage 1: noninvasive thymoma; Stage II: invasion beyond the capsule; Stage II1: Microscopic transcapsular invasion; Stage IIb: Macroscopic capsular invasion; Stage III: Macroscopic invasion of neighbouring organs; Stage IVA: Pleural or pericardial dissemination; Stage IVB: Haematogenous or lymphatic dissemination | Y | |
| 38.17 | Thymoma WHO histological classification [ThymectomyTreatment.ThymomaWHOHistologicalClassificationId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table ThymomaWHOHistologicalClassification | Y | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-------|---|--------------------------------|-----|-------------|----------|------------------|---|------------------|----------|
| | | | | | | | Type A; Type AB; Type B1; Type B2; Type B3; Thymic Carcinoma | | |
| 38.18 | Thymoma treatment [ThymectomyTreatment.ThymomaTreatmentId] | Dropdown [uniqueidentifier] | | | Yes | | Lookup Values from table ThymomaTreatment Complete surgical excision; Complete surgical excision and postoperative radiotherapy; Surgical debulking, radiotherapy, and chemotherapy | Y | |
| | [ThymectomyTreatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [ThymectomyTreatmentPostOpComplication.ThymectomyTreatmentId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [ThymectomyTreatmentPreOpTreatment.ThymectomyTreatmentId] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [Treatment.Id] | Hidden [uniqueidentifier] | | | No | | | Y | |
| | [FK__Treatment__Patie__4242D080, Relationship 1 to many Patient.Id to Treatment.PatientId] | Hidden [Relationship] | | | | | | | |
| | [FK__ThymectomyTr__Id__1352D76D, Relationship 1 to 1 Treatment.Id to ThymectomyTreatment.Id] | Hidden [Relationship] | | | | | | | |
| | [FK_ThymectomyTreatment_PathologyId, Relationship 1 to many Pathology.Id to ThymectomyTreatment.PathologyId] | Hidden [Relationship] | | | | | | | |
| | [FK_ThymectomyTreatment_ThymectomyProcedureId, Relationship 1 to many | Hidden [Relationship] | | | | | | | |

| Ref | Field | Type | Len | Data Format | Nullable | Validation/check | Allowed Values | Sent to Registry | Comments |
|-----|---|-----------------------|-----|-------------|----------|------------------|----------------|------------------|----------|
| | ThymectomyProcedure.Id to ThymectomyTreatment.ThymectomyProcedureId] | | | | | | | | |
| | [FK_ThymectomyTreatment_ThymomaMasaokaClassificationId, Relationship 1 to many ThymomaMasaokaClassification.Id to ThymectomyTreatment.ThymomaMasaokaClassificationId] | Hidden [Relationship] | | | | | | | |
| | [FK_ThymectomyTreatment_ThymomaTreatmentId, Relationship 1 to many ThymomaTreatment.Id to ThymectomyTreatment.ThymomaTreatmentId] | Hidden [Relationship] | | | | | | | |
| | [FK_ThymectomyTreatment_ThymomaWHOHistologicalClassificationId, Relationship 1 to many ThymomaWHOHistologicalClassification.Id to ThymectomyTreatment.ThymomaWHOHistologicalClassificationId] | Hidden [Relationship] | | | | | | | |

Notes:

- Type of Treatment is stored in Table Treatment, fields Type and Title