**Mandatory Patient Tables – Demography, Visit and Dose**

**Demography information**

|  |  |  |  |
| --- | --- | --- | --- |
| **Data field** | **Description** | **Mandatory** | **Type** |
| Study identifier | The study identifier | Y | Text |
| Study part identifier | The study part identifier | Y | Text |
| Subject identifier | The subject identifier | Y | Text |
| Centre number | The identifier for the study centre | N | Number |
| Sex | The sex of the subject | N | Text |
| Race | The race of the subject | N | Text |
| Visit date | The date of the subject visit | N | Date |
| Date of birth | Birth date of subject | N | Date |

**Patient visit schedule information**

|  |  |  |  |
| --- | --- | --- | --- |
| **Data field** | **Description** | **Mandatory** | **Type** |
| Study identifier | The study identifier | Y | Text |
| Study part identifier | The study part identifier | Y | Text |
| Subject identifier | The subject identifier | Y | Text |
| Visit number | The number of the subject visit | Y | Number |
| Visit date | The date of the subject visit | Y | Date |

**Drug dose information**

|  |  |  |  |
| --- | --- | --- | --- |
| Data field | Description | Mandatory | Type |
| Study identifier | The study identifier | Y | Text |
| Study part identifier | The study part identifier | Y | Text |
| Subject identifier | The subject identifier | Y | Text |
| Study Drug Name | The name of study drug (investigational product) | Y | Text |
| Study Drug Total Daily Dose | The total daily dose of study drug | N | Number |
| Dose per Administration | The dose of medication given to subject per administration | Y | Number |
| Dose Unit | The unit in which the dose amount is measured | N | Text |
| Start date/time of the dose schedule | The date of first dose scheduled | Y | Date/Time |
| Medication Code | The Medication Code of study drug | N | Text |
| End date/time of the dose schedule | The date of last dose scheduled | N | Date/Time |
| Treatment Cycle Delayed (yes/no) | Whether treatment cycle was delayed or not (Y/N) | N | Text |
| Dosing Frequency | The dosing frequency, e.g. ‘BID’ for twice-daily. This field will be used in precedence over the dosing frequency per interval and interval unit fields | N | Text |
| Reason Treatment Cycle Delayed | The reason why treatment cycle was delayed | N | Text |
| Dosing Frequency (per Interval) | The dosing frequency per interval | N | Number |
| Medication Dictionary text | A value that provides the Medication Code of study drug | N | Text |
| Dosing Frequency Interval Unit | The unit of dosing frequency | N | Text |
| Reason Treatment Cycle Delayed, Other | The alternative reason why treatment cycle was delayed | N | Text |
| Study Drug ATC Code | The ATC code of study drug | N | Text |
| ATC Dictionary Text | The ATC dictionary text of study drug | N | Text |
| Action Taken, Study Drug | Type of change being made to the dosing schedule | N | Text |
| Study Drug Preferred Name | The preferred name of study drug | N | Text |
| Main Reason for Action Taken, Study Drug | The main reason for change being made to the dosing schedule | N | Text |
| Reason for Study Drug Dose Change Specification | The further reason for change being made to the dosing schedule | N | Text |
| Medication Grouping Name | Preferred grouping term of study drug | N | Text |
| Active Ingredient | The active ingredient of study drug (more than one can be provided, so aggregation function should be possible) | N | Text |
| Study Drug Category | The study drug category | N | Text |
| Planned Dose | The planned dose of study drug | N | Number |
| Planned Dose Units | The planned dose units of study drug | N | Text |
| Planned No. of Days Treatment | The planned number of treatment days | N | Number |
| AE number caused Action taken | The AE number caused action taken for study drug (aggregation should be possible) | N | Number |
| Formulation | The formulation of study drug | N | Text |
| Study Drug Route | The route of study drug | N | Text |
| Reason for Therapy | The reason for therapy | N | Text |
| AE number caused Treatment Cycle Delayed | The AE number caused treatment cycle delayed (aggregation should be possible) | N | Number |