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EudraCT

Supplementary Specification: Clinical Trial Results Validation Rules

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Document approval

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1. This document purpose

The purpose of this document is to identify and describe additional specifications to be followed for EudraCT version 9 results.

2. Actors

Roles involved with preparation of Clinical Trial Results. Namely,

- Primary Results User
- Back Results User
- Delegated Preparer/Poster
- Delegated Preparer
- EMA Super User

3. Context

The document is used to define the validation rules employed by EudraCT on the Results data entered by users with responsibility for preparation of results; e.g. those who work for Sponsors, CROs and MAHs.

These are rules applied by the system to the results data for a clinical trial when the user performs either the 'Validate' or 'Validate & Post' actions.

There are two kinds of rule in this supplementary specification, which are ERROR and WARNING. If the data contained within the results meets on or more error condition, the results would be considered invalid and could not be posted for publication. The warning conditions would not prevent the results from being posted for publication. However, the warnings will require the user to provide comments that justify the data contained in the results when posting.

4. List of main functional requirements

FEAT6.6 Clinical Trial results validation

> FEAT6.6.1 Clinical trial results validation business rules – The system shall provide a method of validating that the results data prepared by the user meets the defined business rules.
>
> FEAT6.6.2 User triggered validation of results – Users shall be able to request that system to validate the clinical trial results during preparation.
>
> FEAT6.6.3 Display results validation report – The system shall display the content of the clinical trial results validation report.
>
> FEAT6.6.4 Errors and warnings – The validation report will contain errors and warnings. Errors will prevent the results from being considered valid, however the results can be valid with warnings.

5. Business rules and information process

Rules defined below will use the title of the data items defined in the Simple Forms [See EMA/207459/2012 in References section] document that defines the Results Data Structure.

For ease of reading and to assist with the piecemeal approach to determining the validation rules, this document has been divided into sections corresponding with the sections of the Results data structure.

The rules are considered appropriate for validating results data whether they were prepared by using the EudraCT user interfaces or by using Sponsors' back-office systems capable of generating clinical trial results data in the required interchange format.

5.1. Data conformity

The assumption is that the data upon which the validation rules will be applied conforms to the following criteria:

- all data present is of the necessary data type (e.g. decimal number, integer number, character field, date field, email address, ISRCTN number, etc.);

- all character fields contain data within their minimum and maximum field lengths;

- all number fields contain data whose value is between the allowable minimum and maximum;

- fields designed as a picklist that are set with an initial value by the system are not empty;

- fields designed as a radio button control that are set with an initial value by the system are not empty;

- data contained in the uploaded results will not invalidate enhanced screen validation rules. That is:

    - for the 'other identifiers' present in the results both the 'identifier name' and the 'identifier code' are present;

    - if the blinding used is selected to be not applicable, the none of the clinical trial roles have been selected as roles blinded;

    - for all list that have 'other please specify' as an option, the field containing the other term is used only in conjunction with the selection of the term 'other' from the list;

    - reasons for subjects leaving or joining an arm also have a field to define, as a positive integer, the number of subjects applicable to that reason;

    - if the question 'Long term follow up planned?' is answered 'No' then the rationales, duration or value fields must be empty;

    - if the question 'Is trial part of an agreed Paediatric Investigation Plan (PIP)?' is answered 'No' the EMA Paediatric Investigation Plan(s) field must be empty;

    - if the question 'Is this the analysis of the primary completion data?' is answered 'No' then the Primary completion date must not contain a value;

    - if the question 'Global end of trial date reached?' is answered 'No' then the Global end of trial date must not contain a value;

    - the date of recruitment, the date of global end of trial and the date of primary completion are required to be in the past;

    - a maximum of one period will be considered the baseline period;- if the status of an end point is 'ready for collecting values' at least one of the reporting groups or subject analysis sets must have been selected;

- when the question ‘Do you want to use a different dictionary name and version or reporting this adverse event?’ is answered ‘No’, then the alternative dictionary name, alternative dictionary version and other dictionary name must be empty;

- for any interruption, the restart date must not be before the interruption date.

- if the question ‘Were there any global substantial amendments to the protocol?’ is answered with the response ‘No’, then there are no global amendments recorded.

- if the question ‘Were there any global interruptions to the trial?’ is answered with the response ‘No’, then there are no global interruptions recorded.

- terms referenced from an EUTCT list must be present with a status of CURRENT or NON-CURRENT.

5.2. Communication of errors and warnings

Errors and warnings will be communicated in a user interface within the system and will be available for download as an electronic document. The design of the electronic document can be found in Section 5.10. - Downloadable validation report.

Each error or warning will be output in the following way:

<Rule type> - <data item type: data item label> <Error/warning message>

The data item type: data item label will identify the object on which the error or warning has been found. The actual field containing the error or warning will not be contained here, because the message delivered by the system explains which field has the error.

For example:

Error – Sponsor: Pfizer Intl Sponsor street address incomplete. Provide the street address of the sponsor.

5.3. Trial information section

5.3.1. Trial Identification

5.3.1.1. Sponsor protocol code:

Rule type	Rule description	Message displayed
ERROR	Sponsor protocol code must contain a minimum of 1 alphanumeric character.	Error – The sponsor protocol code is incomplete. Complete the sponsor protocol code field.

5.3.1.2. Full title of trial:

Rule type	Rule description	Message displayed
ERROR	Full title of trial must contain a minimum of 1 alphanumeric character.	Error – The full title of the trial is incomplete. Complete the full title of trial field.

5.3.2. Sponsors

5.3.2.1. Sponsor details:

Rule type	Rule description	Message displayed
ERROR	There must be a minimum of one Sponsor present in the results.	Error – No sponsor information is provided. Enter the details of at least one for the trial.

Name of organisation:

Rule type	Rule description	Message displayed
ERROR	For each Sponsor, the Name of sponsor organisation must contain a minimum of 2 alphanumeric characters.	Error – The sponsor organisation name is incomplete. Provide the name of the sponsor organisation.

Street address:

Rule type	Rule description	Message displayed
ERROR	For each Sponsor, the sponsor street address must contain a minimum of 1 alphanumeric character.	Error – The street address for the sponsor is incomplete. Provide the street address for the sponsor.

Town/city:

Rule type	Rule description	Message displayed
ERROR	Sponsor town/city must contain a minimum of 1 alphanumeric character.	Error – The sponsor's town/city is incomplete. Provide the name of the sponsor's town/city.

Country:

Rule type	Rule description	Message displayed
ERROR	The country must have been selected for the Sponsor organisation address.	Error – The name of the sponsor's country is missing. Select the country of the sponsor..

5.3.2.2. Scientific contact point:

Name of organisation:

Rule type	Rule description	Message displayed
ERROR	Name of organisation for the scientific contact point must contain a minimum of 1 alphanumeric character.	Error – The organisation name is incomplete for the scientific contact point. Provide the name of the organisation for the scientific contact point.

Functional contact point name:

Rule type	Rule description	Message displayed
ERROR	Scientific contact point functional contact point name must contain a minimum of 1 alphanumeric character.	Error – The functional contact point name is incomplete for the scientific contact point. Provide the functional contact point name...

Telephone number:

Rule type	Rule description	Message displayed
ERROR	If country code field is contains a minimum of 1 numeric character then the telephone number field must contain a minimum of one numeric character.	Error – The telephone number is incomplete for the scientific contact point. Complete the country code and telephone number if entering the telephone number for the scientific contact point.
ERROR	If the telephone number field contains a minimum of one numeric character then the country code field must contain a minimum of one numeric character.	Error – The telephone number is incomplete for the scientific contact point. Complete the country code and telephone number if entering the telephone number for the scientific contact point.

Contact details:

Rule type	Rule description	Message displayed
ERROR	Both the telephone number and email address of the scientific contact point are empty or do are incomplete (see rule above)	Error –No email address or telephone number have been provided for the scientific contact point. The email address, telephone number, or both must be specified.

5.3.2.3. Public contact point:

Name of organisation:

Rule type	Rule description	Message displayed
ERROR	Name of organisation for the public contact point name of organisation must contain a minimum of 1 alphanumeric character.	Error – The organisation name is incomplete for the public contact point. Provide the organisation name.

Functional contact point name:

Rule type	Rule description	Message displayed
ERROR	Public contact point functional contact point name must contain a minimum of 1 alphanumeric character.	Error – The functional contact point name is incomplete for the public contact point. Provide the functional contact point name..

Telephone number:

Rule type	Rule description	Message displayed
ERROR	If country code field is contains a minimum of 1 numeric character then the telephone number field must contain a minimum of one numeric character.	Error –The telephone number is incomplete for the public contact point. Complete the country code and telephone number if entering the telephone number.
ERROR	If the telephone number field contains a minimum of one numeric character then the country code field must contain a minimum of one numeric character.	Error –The telephone number is incomplete for the public contact point. Complete the country code and telephone number.

Contact details:

Rule type	Rule description	Message displayed
ERROR	Both the telephone number and email address of the public contact point are empty or do are incomplete (see rule above).	Error – No email address or telephone number has been provided for the public contact point. Specify an email address, telephone number, or both.

5.3.3. Paediatric regulatory details

5.3.3.1. PIP Numbers

Rule type	Rule description	Message displayed
ERROR	If the question 'Is trial part of an agreed Paediatric Investigation Plan (PIP)?' is answered 'Yes' the EMA Paediatric Investigation Plan(s) field should contain a minimum of one PIP number.	Error – The PIP numbers are missing. Enter the PIP number(s) or indicate if the trial was not part of a paediatric investigation plan.

5.3.3.2. Article 45 and 46

Rule type	Rule description	Message displayed
ERROR	The questions: 'Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?', and 'Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?' must not both have the answer of 'Yes'.	Error – It has been identified that article 45 and article 46 of REGULATION (EC) No 1901/2006 apply to this trial. Only one of these articles may apply to a trial.
ERROR	If at least one of the questions 'Does Article 45 of Regulation (EC) No 1901/2006 apply to this trial?' or 'Does Article 46 of Regulation (EC) No 1901/2006 apply to this trial?' has received the response 'Yes', then there must be at least one subject recorded in at least one of the age groups, 'In utero', 'Preterm newborn infants', 'Newborns', 'Infants and toddlers', 'Children' or 'Adolescents' in the age group breakdown for trial in the trial information section.	Error - The numbers of subjects in the age group breakdown for trial are not consistent with this type of trial. The trial is indicated to be in scope of either Article 45 or Article 46 of Regulation (EC) No 1901/2006, therefore it must include subjects from the paediatric population. Amend the number of subjects in the age group breakdown for the trial or amend the responses to the questions about the trial being in scope of Article 45 or Article 46 of Regulation (EC) No 1901/2006.

5.3.4. Results analysis stage

5.3.4.1. Analysis stage:

Rule type	Rule description	Message displayed
ERROR	Analysis stage must be selected as either Interim or Final.	Error – The analysis stage is missing. Specify whether the analysis stage is interim, or final.

NOTE: Also see the Global end of trial date rules which depend on the value of the analysis stage.

5.3.4.2. Analysis stage date

Rule type	Rule description	Message displayed
ERROR	The field labelled 'Date of interim/final analysis' must not be empty.	Error – The analysis stage date has not been specified. Enter the date on which the analysis of the results data was performed.
ERROR	If the primary completion date is not empty and if the analysis stage date is not empty, then the analysis stage date must be greater than or equal to the primary completion date.	Error – The analysis stage date is on a date before the primary completion date. Amend the dates so the analysis stage date is on, or after the primary completion date.

5.3.4.3. Date of interim/final analysis:

Rule type	Rule description	Message displayed
ERROR	Date of interim/final analysis must not be on a date that is in the future.	Error – The interim/final analysis date is on a future date. When the results are posted this must not be a future date.

5.3.4.4. Primary completion date:

Rule type	Rule description	Message displayed
ERROR	The question, 'Is this the analysis of the primary completion data?' must be answered with either Yes or No.	Error - The question 'Is this the analysis of the primary completion data?' has not been answered. Answer yes or no.

Rule type	Rule description	Message displayed
ERROR	If the question 'Is this the analysis of the primary completion data?' is answered 'Yes' then the Primary completion date must contain a value and must not be a future date.	Error – The primary completion date is missing. If the question 'Is this the analysis of the primary completion data?' is answered yes, then provide the primary completion date.
ERROR	Primary completion date must not be on a date that is in the future.	Error – The primary completion date is on a future date. When the results are posted this must not be a future date.

5.3.4.5. Global end of trial date

Rule type	Rule description	Message displayed
ERROR	The question, 'Global end of trial date reached?' must be answered with either Yes or No.	Error – The question 'Global end of trial date reached?' has not been answered. Answer yes or no.
ERROR	The analysis stage cannot be Final if the answer to the question 'Global end of trial date reached?' is answered 'No'.	Error – The analysis stage of the results are considered final, but the global end of trial is not yet reached. Amend this data by changing the analysis stage to interim or provide the global end of trial date.
ERROR	Primary completion date must not be later than Global end of trial date.	Error – The primary completion date is later than the global completion date. Amend this date to ensure the primary completion date is not later than the global end of trial date.
ERROR	If the trial is in scope of article 46 of Regulation (EC) No 1901/2006 and if the global end of trial has been reached, then the global end of trial must be on or after 26 January 2007	Error – The global end of trial date entered is not permitted for a trial in scope of article 46 of Regulation (EC) No 1901/2006 because such a trial must be initiated on or after 26 January 2007. Correct the global end of trial date or amend the response to the question 'Does article 46 of Regulation (EC) No 1901/2006 apply to this trial?' in the trial information section.

5.3.5. General information about the trial

5.3.5.1.

Rule type	Rule description	Message displayed
ERROR	Main objective of trial must contain a minimum of 1 alphanumeric character.	Error – The main objective of the trial is incomplete. Complete the main objective of the trial field.

5.3.5.2. Actual start date of recruitment

Rule type	Rule description	Message displayed
ERROR	Actual start date of recruitment must contain a value.	Error – The actual start date of recruitment is missing. Provide the actual start date. .
ERROR	Actual start date of recruitment must not be after the global end of trial date.	Error – The actual start date of recruitment is later than the global end of trial date. Amend these dates so the actual start date of recruitment is not later than the global end of trial date.

Rule type	Rule description	Message displayed
ERROR	Actual start date of recruitment must not be after the primary completion date.	Error – The actual start date of recruitment is later than the primary completion date. Amend these dates so the actual start date of recruitment is not later than the primary completion date.
ERROR	Actual start date of recruitment must not be after the date of interim/final analysis.	Error – The actual start date of recruitment is later then the interim/final analysis date. Amend these dates so the actual start date of recruitment is not later than the interim/final analysis date.

5.3.5.3. Long term follow-up rationale

Rule type	Rule description	Message displayed
ERROR	If the question 'Long term follow up planned?' is answered 'Yes' then a minimum of one of the Long Term Follow-up rationales has to be selected.	Error – The long-term follow up rationale(s) are missing. If the question 'Long-term follow up planned?' is yes then select at least one long term follow up rationale.

5.3.5.4. Long term follow-up duration

Rule type	Rule description	Message displayed
ERROR	If the question 'Long term follow up planned?' is answered 'Yes' then 'Long term follow up units' must have been selected as either months or years.	Error – The units for the long-term follow up duration are missing. If the question 'Long- term follow up planned?' is yes then select the units for the long- term follow up duration.
ERROR	If the question 'Long term follow up planned?' is answered 'Yes' then Long term follow-up duration value must contain a value that is a positive integer (not including zero).	Error –The time value for the long-term follow up duration is missing. If the question 'Long-term follow up planned?' is yes then provide the time value.

5.3.5.5. Independent data monitoring committee involvement

Rule type	Rule description	Message displayed
ERROR	The question 'Independent data monitoring committee (IDMC) involvement?' must be answered with either Yes or No.	Error - The question 'Independent data monitoring committee (IDMC) involvement?' has not been answered. Answer yes or no.

5.3.5.6. Protection of trial subjects

Rule type	Rule description	Message displayed
ERROR	Protection of trial subjects must contain a minimum of 1 alphanumeric character.	Error –The protection of trial subjects is incomplete. Complete the protection of trial subject's field.

5.3.6. Population of trial subjects

5.3.6.1. Subject number per Country

Rule type	Rule description	Message displayed
ERROR	A minimum of one country must have been specified in the 'population of trial subjects' panel.	Error – The trial countries is missing. Specify at least one trial country.
ERROR	For a country, the number of subjects must be a positive integer.	Error – The number of subjects is missing Enter a positive integer for the number of trial subjects per country.

NOTE: Also see the Age breakdown for trial rules which depend on the number of subjects per trial country.

5.3.6.2. Age group breakdown for trial

Rule type	Rule description	Message displayed
ERROR	The number of subjects for all of the age categories must be a positive integer or zero. [There is only one rule that applies to all the categories]	Error – The number of subjects for the age breakdown is incomplete. The number of subjects for each age category must be a positive integer, or zero.
ERROR	The sum of the number of subjects for all age groups is equal to the worldwide number of subjects enrolled in the trial.	Error – The number of subjects per country are not the same as the worldwide number of subjects enrolled in the trial. Ensure the totals are the same.

5.4. Subject disposition section

5.4.1. Recruitment

5.4.1.1. Recruitment details

Rule type	Rule description	Message displayed
ERROR	The recruitment details field must be either blank or contain a minimum of 1 alphanumeric character.	Error – The recruitment details are incomplete. Complete this field if relevant to the trial.

5.4.2. Pre-assignment

5.4.2.1. Screening details

Rule type	Rule description	Message displayed
ERROR	The screening details field must be either blank or contain a minimum of 1 alphanumeric character.	Error – The screening details are incomplete. Complete this field if relevant to the trial.

5.4.2.2. Pre-assignment period: Number of subjects at started and completed milestone

Rule type	Rule description	Message displayed
ERROR	If the pre-assignment period exists for the results the number of subjects at the Started milestone for the Pre-assignment period must be a positive integer.	Error – The number of subjects that started the pre-assignment period is missing. Provide the number of subjects that started the pre-assignment period.

5.4.2.3. Pre-assignment period: Number of subjects in pre-assignment period

Rule type	Rule description	Message displayed
ERROR	The number of subjects at the Started milestone for the Pre-assignment period must be equal to the number of subjects at the Completed milestone plus the sum of the number of subjects that did not complete the Pre-assignment Period.	Error – The subject numbers in the pre-assignment period are incorrect. The difference between the number of subjects that started, and completed the pre-assignment period must be equal to the number of subjects that did not complete the pre-assignment period.

5.4.2.4. Pre-assignment period milestones

Rule type	Rule description	Message displayed
ERROR	The number of subjects at all the pre-assignment milestones is expected to be not greater than the number of subjects that started the pre-assignment period.	Error – The subject numbers at the milestones in the pre-assignment period are expected to be between the number that started, and the number that completed the pre-assignment period. Check the subject numbers specified in the pre-assignment period.
WARNING	For each milestone in the pre-assignment period, the number of subjects is expected to be greater than or equal to the number of subjects that completed the pre-assignment period.	Warning – The number of subjects at the milestone is less than the number that completed the pre-assignment period. It is expected the number of subjects at the milestones will be greater, than or equal to the number that completed the pre-assignment period.
WARNING	For each milestone in the pre-assignment period the number of subjects at the preceding milestone is expected to be greater than or equal to the number of subjects at the preceding milestone.	Warning – The number of subjects at the milestone exceeds the number at the preceding milestone. It is expected the number of subjects at each milestone will be less than, or equal to the number at the preceding milestone in the pre-assignment period.
ERROR	If there is a pre-assignment period and period 1 has mutually exclusive arms, then the number of subjects that completed the pre-assignment period must be equal to the sum of the number of subjects that started each of the arms in period 1.	Error – The number of subjects that completed the pre-assignment period is not equal to the number that started period 1. Amend the number of subjects in the pre-assignment period or change the number of subject starting period 1.
WARNING	If there is a pre-assignment period and period 1 has non-mutually exclusive arms, it is expected that the number of subjects that completed the pre-assignment period is equal to the arm with the largest number of subjects that started the arm.	Warning – The number of subjects reported to be in the pre-assignment period is not consistent with the number starting period 1. It is expected that the number completing the pre-assignment period are also present in the arms in period 1.
WARNING	If there is a pre-assignment period, the numbers of subjects at the started milestone is expected to be equal to the worldwide number of subjects enrolled in the trial.	Warning - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

5.4.2.5. Pre-assignment

Rule type	Rule description	Message displayed
ERROR	The results must contain one the other or both of the following: - a pre-assignment period, or; - the Screening details field must contain a minimum of 1 alphanumeric character.	Error – The pre-assignment details are incomplete. Provide screening details or enter valid details for the pre-assignment period.

5.4.3. Periods

Rule type	Rule description	Message displayed
ERROR	There must be a minimum of one Period created for the results.	Error – The results for the clinical trial must contain at least one period. Create the period(s) for the results in the subject disposition section.

Rule type	Rule description	Message displayed
ERROR	There must be one and only one period designated as the Baseline period. [Recommend putting the highlighting on the Baseline characteristics setting page].	Error – None of the periods have been designated as the baseline period. Specify which of the periods is the baseline period.
WARNING	It is expected that period 1 is the baseline period.	Warning – Period 1 is not the baseline period. It is expected period 1 will be the baseline period.

5.4.3.1. Period title

Rule type	Rule description	Message displayed
ERROR	For each period, the title must contain a minimum of 2 alphanumeric characters.	Error – The period title is incomplete. Provide a meaningful title for the period.

5.4.3.2. Allocation method

Rule type	Rule description	Message displayed
ERROR	For each period the allocation method must have been selected.	Error – The allocation method is not specified. Select the allocation method used or indicate the allocation was not applicable to the period.

5.4.3.3. Blinding used

Rule type	Rule description	Message displayed
ERROR	For each period the blinding selection must have been made.	Error – The blinding used has not been specified. Select the blinding used or indicate the blinding was not applicable to the period.
ERROR	For each period, if the allocation method is 'Not applicable' then the blinding used must not be 'Single blinded' and must not be 'Double blinded'.	Error – The selected blinding is not allowed for a trial without an allocation method. Change the blinding used or show a different allocation method.

5.4.3.4. Roles blinded

Rule type	Rule description	Message displayed
ERROR	For each period, if the blinding used is 'Single blind' then the number of roles blinded must be at least one.	Error – The blinding used is a single blind but the roles blinded have not been specified. Specify the role(s).
WARNING	For each period, if the blinding used is 'Single blind' then it is not expected that more than one role blinded will be selected.	Warning – The number of roles blinded looks inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.
WARNING	For each period, if the blinding used is 'Single blind' then it is expected that 'Subject' will be selected in the roles blinded.	Warning – The roles blinded appear inconsistent with a single blinded trial.
ERROR	For each period, if the blinding used is 'Double blind' then the number of roles blinded must be greater than one.	Error – The number of roles blinded is not allowed with a double blinded trial. Amend the number of roles blinded to include more than one role, or amend the blinding used.
WARNING	For each period, if the blinding used is 'Double blind' then as a minimum both 'Subject' and 'Investigator' must have been selected as the roles blinded.	Warning – The roles blinded appear to be inconsistent with a double blind trial.

5.4.3.5. Blinding implementation details

Rule type	Rule description	Message displayed
ERROR	For each period, the 'blinding implementation details' field is either blank or contains more than 1 alphanumeric character.	Error – The blinding implementation field is incomplete. Leave this field blank or enter at least one alphanumeric character.

5.4.4. Arms

Rule type	Rule description	Message displayed
ERROR	Each period must have a minimum of one Arm.	Error – The period has no arms. Each period in the results must have at least one arm.

5.4.4.1. Arm title

Rule type	Rule description	Message displayed
ERROR	Arm title must contain a minimum of 4 characters. **[Note this is not limited to alphanumeric characters only. Symbols are allowed]**	Error – The arm title is not complete. The arm title must contain more than 4 characters.

5.4.4.2. Arm description

Rule type	Rule description	Message displayed
ERROR	For each arm, if the arm description field is not blank then it must contain one or more alphanumeric character.	Error – The arm description is incomplete. Complete this field if relevant to the trial.

5.4.4.3. Arm Type

Rule type	Rule description	Message displayed
ERROR	For each arm, the arm type must not be empty and must have been selected from one of the terms in the list.	Error – The arm type has not been specified. Specify the arm.
ERROR	For each arm, if the arm type is selected as 'Other', then 'Other arm type' must contain a minimum of 1 alphanumeric character.	Error – The arm type is incomplete. Provide a meaningful other arm type when selecting Other from the list.
ERROR	For each arm, if the Arm type is 'No IMP' then the arm must not contain products.	Error – The selected arm type is not allowed if the arm has products. Change the arm type, or remove the products.
ERROR	If the arm type is 'Experimental', 'Active comparator' or 'Placebo comparator' then the arm must contain a minimum of one Product.	Error – The selected arm type is not consistent with the number of products. Change the arm type, or enter at least one product for the arm.

5.4.4.4. Number of subjects that started an arm

Rule type	Rule description	Message displayed
ERROR	For each arm, the number of subjects at the started milestone must not be empty and must be an integer greater than zero.	Error – The number of subjects that started this arm is empty. Specify the number of subjects that started this arm.

Rule type	Rule description	Message displayed
ERROR	For each arm, the number of subjects at the started milestone plus the number that joined must not be greater than the worldwide number of subjects enrolled in the trial.	Error – The number of subjects in this arm exceeds the worldwide number of subjects enrolled in the trial. Amend the number of subjects who started, or who joined this arm, or amend the subject numbers per country in the trial information.
ERROR	For each arm, the number of subjects at the started milestone for an arm should be equal to the number of subjects at the completed the milestone for the arm plus the sum of the number of subjects that did not complete the arm minus the sum of subjects that joined the arm.	Error – The number of subjects in the arm are incorrect. The difference between the number of subjects who started and completed the arm must be equal to the number of subjects who did not complete, minus those that joined the arm.

5.4.4.5. Number of subjects that completed an arm

Rule type	Rule description	Message displayed
ERROR	For each arm, the number of subject at the completed milestone must not be empty and must be an integer or equal to zero.	Error – the number of subjects that completed this arm is empty. Specify the number of subjects that completed this arm.
WARNING	For each arm, the number of subject at the completed milestone must not be empty and must be an integer.	Warning – the number of subjects that completed this arm is equal to zero. It is expected the number of subjects completed this arm is be greater than zero.

5.4.4.6. Number of subjects at intermediate milestones

Rule type	Rule description	Message displayed
ERROR	For each intermediate milestone of each arm, the number of subjects must not be empty and must be an integer greater than or equal zero.	Error – The number of subjects for this intermediate milestone is empty. Specify the number of subjects that reached this intermediate milestone in this arm.
ERROR	For each arm, the number of subjects at each milestone must not greater than the number of subjects that started the arm plus the number that joined.	Error – The number of subjects at this intermediate milestone exceeds the number of subjects in the arm. Amend the number of subjects at this intermediate milestone so it does not exceed the number that started, plus the number that joined.
WARNING	For each intermediate milestone for each arm, the number of subjects is expected to be greater than or equal to the number that started minus the number that did not complete. Note: considered a warning because those subjects that did not receive the event that occurred at the milestone (e.g. washout) may not be included.	Warning – The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected the number of subjects will be greater than, or equal to the number that completed minus those that left.

5.4.4.7. Number of subjects transferring in/out of the arms

Rule type	Rule description	Message displayed
WARNING	For each period, the difference between the number of subjects that joined the arms with the reason 'Transferred in from other arm/group' and the number of subjects that did not complete the arms with the reason 'Transferred to other arm/group' must be equal to zero.	Warning – The number of subjects transferring in and out of the arms in the period are not the same. It is expected the net number of transfers in and out of the arms in a period, will be zero.

5.4.4.8. Number of subjects in a period

Rule type	Rule description	Message displayed
ERROR	For the baseline period, if the arms are mutually exclusive then the sum of the numbers of subjects that started plus those that joined all the arms must not exceed the worldwide number of subjects enrolled in the trial.	Error – The number of subjects reported to be in the baseline period exceeds the worldwide number enrolled in the trial. Amend the number of subjects in the arms of the baseline period, or change the number of subjects per country in the trial information.
WARNING	For the baseline period, if arms are mutually exclusive the sum of the numbers of subjects at the started milestone plus those that joined for all arms in the period is expected to be equal to the worldwide number of subjects enrolled in the trial.	Warning – The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
ERROR	For each period, if the arms are mutually exclusive in the current and previous period the number of subjects that started must not exceed the number of subjects that completed the previous period.	Error – The number of subjects starting the period exceeds the number that completed the preceding period. Amend the subject numbers to ensure the number in a subsequent period does not exceed a previous period.
WARNING	For each period, if arms are mutually exclusive in the current and previous period the number of subjects starting the period is expected to be equal to the number of subjects that completed previous period. Note: considered a warning because it is not possible to determine whether some protocols are invalid if this condition is met.	Warning – The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

5.4.5. Products

Rules for the number of products allowed in an arm based on the arm type are contained in section 5.4.4.3.

5.4.5.1. Products

Rule type	Rule description	Message displayed
ERROR	For the baseline period, there must be at least one product belonging to any of the arms.	Error – The baseline period has no products. Enter at least one product in any of the arms in the baseline period.

5.4.5.2. IMP Name

Rule type	Rule description	Message displayed
ERROR	For each product in each arm, the IMP name must contain a minimum of 2 alphanumeric characters.	Error – The product details are incomplete. Provide the name of the product.

5.4.5.3. Routes of administration

Rule type	Rule description	Message displayed
ERROR	For each arm, all the products must have a minimum of one route of administration.	Error - The product details are incomplete. Select at least one route of administration for each product.

5.4.5.4. Pharmaceutical form

Rule type	Rule description	Message displayed
ERROR	For each arm, all products must have a minimum of one pharmaceutical form.	Error – The product details are incomplete. Select at least one pharmaceutical form for each product.

5.4.5.5. Dosage and administration details

Rule type	Rule description	Message displayed
ERROR	For each arm, all the products must have a minimum of 1 alphanumeric character in the dosage and administration details field.	Error – The product details are incomplete. Specify the dosage and administration details for each product.

5.5. Baseline characteristics section

5.5.1. Total number of subjects in the baseline period

Rule type	Rule description	Message displayed
ERROR	If arms in the baseline period are not mutually exclusive, then the value entered in the 'total number of subjects in the baseline period' field must not exceed the worldwide number of subjects enrolled in the trial.	Error – The total number of subjects in the baseline period exceeds the worldwide number enrolled in the trial. As the arms are not mutually exclusive, update the total number of subjects in the baseline period, or amend the number of subjects per country in the trial information.
WARNING	If arms in the baseline are not mutually exclusive, then the value entered in the 'total number of subjects in the baseline period' field plus those that joined for all arms in the baseline period is expected to be equal to the worldwide number of subjects enrolled in the trial.	Warning – The number of subjects reported to be in the baseline period are not the same as the worldwide number of enrolled in the trial. It is expected that these numbers will be the same.
ERROR	If arms in the baseline period are not mutually exclusive, then the value entered in the 'total number of subjects in the baseline period' field must be less than the sum of the subjects that started plus joined all of the arms in the baseline period.	Error – The total number of subjects in the baseline period is not less than the sum of the subjects in the arms of that period. As the arms are not mutually exclusive, update the total number of subjects in the baseline period, or amend the number in the arms defined in subject disposition.

Rule type	Rule description	Message displayed
ERROR	If arms in the baseline period are not mutually exclusive, then the value entered in the 'total number of subjects in the baseline period' field must not be less than the greatest sum of subjects that started plus joined any of the arms in the baseline period.	Error – The total number of subjects in the baseline period is less than the greatest number of subjects in any of the arms for that period. As the arms are not mutually exclusive, update the total number of subjects in the baseline period number or amend the number for the arms defined in the subject disposition.

5.5.2. Age characteristics

5.5.2.1. Age categorical characteristic

Age categorical characteristic description:

Rule type	Rule description	Message displayed
ERROR	The age categorical characteristic description field must be empty or must contain a minimum of 1 alphanumeric character.	Error – The description of the age categorical characteristic description is incomplete. Complete this field if relevant to the trial.

Age categorical characteristic status:

Rule type	Rule description	Message displayed
ERROR	If the age categorical characteristic has a status of 'ready for collecting values', all categories must have a value for all the reporting groups, including the total reporting group. **[Note: Values for the subject analysis sets are optional and are therefore not included in this rule]**	Error – The age categorical characteristic is incomplete. Provide the number of subjects in all categories, for each of the reporting groups.
ERROR	If the age categorical characteristic has the status not 'ready for collecting values' then values must not have been entered for any of the reporting groups or subject analysis sets for any of its categories.	Error – The age categorical characteristic does not have the required status. If this characteristic will not be used the data value fields must remain empty.

Age categorical characteristic values:

Rule type	Rule description	Message displayed
ERROR	If the age categorical characteristic has a status of 'ready for collecting values' then for each of the reporting groups in the age categorical characteristic (not including the total reporting group) the sum of the number of subjects for all the age categories must equal the number of subjects at the started milestone plus the number of subjects that joined the corresponding arm for the reporting group.	Error – The number of subjects for the reporting group in the age categorical characteristic is not the same as the number of subjects in the baseline period. Ensure that the number of subjects recorded in the subject disposition, and in the baseline characteristics are the same.

Rule type	Rule description	Message displayed
ERROR	For the total reporting group, the sum of the number of subjects per age category must equal the total number of subjects for the total group.	Error – The total number of subjects for all age categories in the age categorical characteristic are not the same as the total number of subjects in the baseline period. Ensure the number recorded for the age categories account for all subjects in the baseline period.
ERROR	For the total reporting group of the age categorical characteristic, if the arms in the baseline period are not mutually exclusive, the number of subjects per category must not be less that the greatest number of subjects in any reporting group AND it must not exceed the sum of the numbers of subjects for the category.	Error – The total number of subjects entered for the category is invalid. As the arms are not mutually exclusive, update the total number of subjects for the category. Ensure this number is not less than the greatest number of subjects in any reporting group, and does not exceed the sum of the numbers of subjects for the category.

5.5.2.2. Age continuous characteristic

Age continuous characteristic description:

Rule type	Rule description	Message displayed
ERROR	The age continuous characteristic description field must be empty or must contain a minimum of 1 alphanumeric character.	Error – The age continuous characteristic description is incomplete. Complete this field if relevant to the trial.

Age continuous characteristic status:

Rule type	Rule description	Message displayed
ERROR	If the age continuous characteristic has a status of 'ready for collecting values', both the measure type and dispersion type must have valid values for all of the reporting groups.	Error – The age continuous characteristic is incomplete. Values must be specified for the measure dispersion type for each of the reporting groups.
ERROR	If the age continuous characteristic has the status not 'ready for collecting values' then values must not have been entered for any of the reporting groups or subject analysis sets.	Error – The age continuous characteristic does not have the required status. If this characteristic will not be used the data value fields must remain empty.

Age continuous characteristic values:

Rule type	Rule description	Message displayed
ERROR	For each reporting group or subject analysis set, the value entered for the measure type of the age continuous characteristic must be less than or equal to: - 120 years; - 1,440 months; - 6,240 weeks; - 43,800 days; - 1,051,200 hours; - 63,072,000 minutes.	Error – The value of the age continuous characteristic exceeds the maximum allowable of 120 years (or equivalent). Amend the measured age statistic so it does not exceed this limit.
ERROR	For each reporting group or subject analysis set, the value entered for the measure type of the age continuous characteristic must be greater than or equal to zero.	Error – The value of the age continuous characteristic is less than zero. Amend the measured age statistic so it is greater than, or equal to zero.

Rule type	Rule description	Message displayed
ERROR	If the dispersion type of 'full range' is used is for the age continuous characteristic, then for each reporting group and subject analysis set the value entered for the minimum of the full range must be greater than or equal to zero.	Error – The minimum value for the full range of the age continuous characteristic is less than zero. Amend the full range so the minimum value is greater than, or equal to zero.
ERROR	If the dispersion type of 'full range' is used is for the age continuous characteristic, then for each reporting group and subject analysis set the value entered for the maximum of the full range must be less than or equal to: - 120 years; - 1,440 months; - 6,240 weeks; - 43,800 days; - 1,051,200 hours; - 63,072,000 minutes.	Error – The maximum value for the full range of the age continuous characteristic exceeds the maximum allowable of 120 years (or equivalent). Amend the measured age statistic so it does not exceed this limit.
ERROR	If the dispersion type of 'interquartile range' is used is for the age continuous characteristic, then for each reporting group and subject analysis set the value entered for the minimum of the full range must be greater than or equal to zero.	Error – The minimum value of the interquartile range for the age continuous characteristic is less than zero. Amend the full range so the minimum value is greater than, or equal to zero.
ERROR	If the dispersion type of 'interquartile range' is used is for the age continuous characteristic, then for each reporting group and subject analysis set the value entered for the maximum of the full range must be less than or equal to: - 120 years; - 1,440 months; - 6,240 weeks; - 43,800 days; - 1,051,200 hours; - 63,072,000 minutes.	Error – The maximum value of the interquartile range for the age continuous characteristic exceeds the maximum allowable of 120 years (or equivalent). Amend the measured age statistic so it does not exceed this limit.

5.5.2.3. Age characteristics completeness

Rule type	Rule description	Message displayed
ERROR	A minimum of one of the age continuous or age categorical characteristics must meet the following conditions: - the status is 'ready for collecting values', and; - all value fields for the reporting groups are complete with numbers in the required range.	Error – The age characteristics for the subjects in the trial have not been specified. Complete at least one of the age characteristics for the reporting groups in the trial.

5.5.2.4. Gender categorical characteristic

Gender categorical characteristic description:

Rule type	Rule description	Message displayed
ERROR	The Gender categorical characteristic description field must be empty or must contain a minimum of 1 alphanumeric character.	Error – The gender categorical characteristic description is incomplete. Complete this field if relevant to the trial.

Gender categorical characteristic status:

Rule type	Rule description	Message displayed
ERROR	For the gender categorical characteristic the status must be 'ready for collecting values'.	Error – The gender characteristic is incomplete. Provide values for the subjects for this characteristic.
ERROR	If the gender categorical characteristic has a status of 'ready for collecting values', all categories must have a value for all the reporting groups.	Error – The gender categorical characteristic is incomplete. Provide the number of subjects for all categories for each of the reporting groups.

Gender categorical characteristic values:

Rule type	Rule description	Message displayed
ERROR	If the gender categorical characteristic has a status of 'ready for collecting values' then for each of the reporting groups in the gender categorical characteristic (not including the total reporting group) the sum of the number of subjects for all the gender categories must equal the number of subjects at the started milestone plus the number of subjects that joined the corresponding arm for the reporting group.	Error – The number of subjects for the gender categorical characteristic are not the same as the number in the baseline period. The number of subjects recorded in the subject disposition, and in the baseline characteristics must be the same.
ERROR	For the total reporting group, the sum of the number of subjects per gender category must equal the total number of subjects for the total group.	Error – The total number of subjects for all the gender categories in the gender categorical characteristic are not the same as the total number in the baseline period. Ensure that the number of subjects recorded for the gender categories account for all the subjects in the baseline period.
ERROR	For the total reporting group of the gender categorical characteristic, if the arms in the baseline period are not mutually exclusive, the number of subjects per category must not be less that the greatest number of subjects in any reporting group AND it must not exceed the sum of the numbers of subjects for the category.	Error – The total number of subjects entered for the category is invalid. As the arms are not mutually exclusive, update the total number for the category. Ensure this number is not less than the greatest number of subjects in any reporting group, and does not exceed the total number of subjects for the category.

5.5.2.5. Study specific characteristics

Study specific characteristic title:

Rule type	Rule description	Message displayed
ERROR	For each study specific characteristic, the title must contain a minimum of 2 alphanumeric characters. **[This rule applies to both the categorical and continuous characteristics]**	Error – The title of the study specific characteristic is incomplete. Provide a meaningful title for this characteristic.

Study specific characteristic description:

Rule type	Rule description	Message displayed
ERROR	For each study specific characteristic, the description must be empty or must contain a minimum of 1 alphanumeric character. **[This rule applies to both the categorical and continuous characteristics]**	Error – The description for the study specific characteristic is incomplete. Complete this field if relevant to the trial.

Study specific characteristic status:

Rule type	Rule description	Message displayed
ERROR	For each study specific characteristic the status must be 'ready for collecting values'. **[This rule applies to both the categorical and continuous characteristics]**	Error – The study specific characteristic is incomplete. Provide values for the subjects in the trial for this characteristic.

5.5.2.6. Study specific categorical characteristic values

Rule type	Rule description	Message displayed
ERROR	For each study specific categorical characteristic with a status of 'ready for collecting values' then for each of the reporting groups in the study specific categorical characteristic (not including the total reporting group) the sum of the number of subjects for all the categories must equal the number of subjects at the started milestone plus the number of subjects that joined the corresponding arm for the reporting group.	Error – The number of subjects for the reporting group in this categorical characteristic are not the same as the number of subjects in the baseline period. Ensure that the number of subjects recorded in the subject disposition and in the baseline characteristics are the same.
ERROR	For each study specific categorical characteristic, if the status is 'ready for collecting values' then: - all of the categories for all of the reporting groups must have a value OR - all the categories for at least one subject analysis set must have a value.	Error – The study specific characteristic is incomplete. Provide the number of subjects for all categories for each of the reporting groups.
ERROR	For the total reporting group, the sum of the number of subjects per category must equal the total number of subjects for the total group.	Error – The total number of subjects for all categories in the study specific categorical characteristic are not the same as the total number of subjects in the baseline period. Ensure the number of subjects recorded for the categories account for all subjects in the baseline period.
ERROR	For the total reporting group of a study specific categorical characteristic, if the arms in the baseline period are not mutually exclusive, the number of subjects per category must not be less that the greatest number of subjects in any reporting group AND it must not exceed the sum of the numbers of subjects for the category.	Error – The total number of subjects entered for the category is invalid. As the arms are not mutually exclusive, update the total number of subjects for that category. Ensure this number is not less than the greatest number of subjects in any reporting group, and does not exceed the total number of subjects for the category.

5.5.2.7. Study specific continuous characteristic values

Rule type	Rule description	Message displayed
ERROR	For each study specific continuous characteristic, if the status is 'ready for collecting values' then: - all of the reporting groups must have a central tendency value and a dispersion value OR - at least one subject analysis set and any number of reporting groups must have a central tendency value and a dispersion value.	Error – The study specific characteristic is incomplete. Provide values for the central tendency type and dispersion type for the reporting groups or subject analysis sets.

5.5.2.8. Continuous characteristic values for full range and interquartile range dispersion types

Age continuous characteristics values:

Rule type	Rule description	Message displayed
ERROR	For the age continuous characteristic using a dispersion type of full range (min-max) or interquartile range (min-max), the values present for the reporting groups and subject analysis sets must meet the following requirement: The value in the 'max' field must not be less than the value present in the 'min' field.	Error – The age continuous characteristic values for the dispersion type is not allowed. When using either of the full range or interquartile range dispersion types, ensure the maximum value is not less than the minimum value entered.

Study specific continuous characteristic values:

Rule type	Rule description	Message displayed
ERROR	For each study specific continuous characteristic using a dispersion type of full range (min-max) or interquartile range (min-max), the values present for the reporting groups and subject analysis sets must meet the following requirement: The value in the 'max' field must not be less than the value present in the 'min' field.	Error – The study specific continuous characteristic values for dispersion type are not allowed. When using either of the full range or interquartile range dispersion types, ensure the maximum value is not less than the minimum value entered.

Continuous characteristic values for full range and interquartile range values:

Rule type	Rule description	Message displayed
ERROR	For each continuous characteristic using a dispersion type of full range, the value in the 'min' field must not exceed the value in the measure type field.	Error – The measure type value is not between the low and high values reported by the full range. Amend this data accordingly.
ERROR	For each continuous characteristic using a dispersion type of full range, the value in the 'max' field must not be less than the value in the measure type field.	Error – The measure type value is not between the low and high values reported by the full range. Amend this data accordingly.
ERROR	For each continuous characteristic using a dispersion type of interquartile range, the value in the 'min' field must not exceed the value in the measure type field.	Error – The measure type value is not between the low and high values reported by the interquartile range. Amend this data accordingly.

Rule type	Rule description	Message displayed
ERROR	For each continuous characteristic using a dispersion type of interquartile range, the value in the 'max' field must not be less than the value in the measure type field.	Error – The measure type value is not between the low and high values reported by the interquartile range. Amend this data accordingly.

5.5.3. Subject analysis sets

5.5.3.1. Subject analysis set title

Rule type	Rule description	Message displayed
ERROR	For each subject analysis set, the title must contain a minimum of 2 alphanumeric characters.	Error – The subject analysis set title is incomplete. Provide a meaningful title for the subject analysis set.

5.5.3.2. Subjects analysis set type

Rule type	Rule description	Message displayed
ERROR	For each subject analysis set, the subject analysis set type must have been selected.	Error – The subject analysis set type has not been selected. Select a type from the drop-down list.

5.5.3.3. Subjects analysis set description

Rule type	Rule description	Message displayed
ERROR	For each subject analysis set, the subject analysis set description must contain a minimum of 1 alphanumeric character.	Error - The description of the subject analysis set is incomplete. Complete this field if relevant to the trial.

5.5.3.4. Number of subjects in subject analysis set

Rule type	Rule description	Message displayed
ERROR	For each subject analysis set, the number of subjects must not be empty and must be an integer greater than zero.	Error – The number of subjects in the subject analysis set is incomplete. Provide the number of subjects as an integer greater than zero.
ERROR	For each subject analysis set, the number of subjects must not be greater than the worldwide number of subjects enrolled in the trial.	Error – The number of subjects in the subject analysis set is too big. The number of subjects in the subject analysis sets must not exceed the worldwide number enrolled in the trial.

5.6. End points section

5.6.1. End points

Rule type	Rule description	Message displayed
ERROR	There must be a minimum of one end point with type = 'Primary'.	Error – The primary end points are missing. There must be at least one primary end point in the trial.
ERROR	For each end point, the description field must be blank or contain a minimum of 1 alphanumeric character.	Error – The description field for the end point is incomplete. Complete this field if these relevant to the trial.

Rule type	Rule description	Message displayed
WARNING	For each end point, if at least one arm is selected then all of the arms in the baseline period should have also been selected.	Warning – The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
ERROR	For each end point, the status must be 'ready for collecting values'.	Error – The end point is incomplete. The end point must be in a state to indicate it is complete.
WARNING	For each end point of type "Primary", it is expected that there will be at least one statistical analysis.	Warning – No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

5.6.2. End point – Reporting group number of subjects analysed

Rule type	Rule description	Message displayed
ERROR	For each end point, the number of subjects analysed for each of the selected reporting group must have been entered.	Error – The number of subjects analysed for the reporting group is incomplete. Enter the number of subjects analysed for the reporting group.
ERROR	The number of subjects analysed for the reporting group is not expected to exceed the number of subjects that started plus the number that joined the corresponding arm in the subject disposition.	Error – The reported number of subjects analysed is not allowed. The number of subjects analysed must not exceed the number of subjects who started, plus the ones that joined.

5.6.3. End point values

End point values (countable or measurable):

Rule type	Rule description	Message displayed
ERROR	For each end point, if the number of subjects analysed for a reporting group is zero, then the value fields for the reporting group must be empty (i.e. not containing a value).	Error – The end point values are reported incorrectly. No subjects were analysed for this reporting group, therefore the value fields for this reporting group must remain empty.
ERROR	For each end point, if the number of subjects analysed for a subject analysis set is zero, then the value fields for the subject analysis set must be empty (i.e. not containing a value).	Error – The end point values are reported incorrectly. No subjects were analysed for this subject analysis set, therefore the value fields for this subject analysis set must remain empty.

Countable end point values:

Rule type	Rule description	Message displayed
ERROR	For each countable end point the values, as integers, must be present for all combinations of categories (if used) and the selected reporting groups and subject analysis sets for the end point.	Error – The end point values are incomplete. Integer values must be provided for each category, for all selected reporting groups, and subject analysis sets.

Measurable end point - measure type values:

Rule type	Rule description	Message displayed
ERROR	For each measurable end point the values as any number (positive or negative) for the measure type must be present for all combinations of the categories (if used) and the selected reporting groups and subject analysis sets for the end point.	Error – The end point values are incomplete. Values for the selected measure type must be provided for each category, for all selected reporting groups, and subject analysis sets.

Measurable end point – single-value dispersion type values:

Rule type	Rule description	Message displayed
ERROR	For each measurable end point the values, as any positive number, for the dispersion type (i.e. standard deviation or standard error) must be present for all combinations of the categories (if used) and the selected reporting groups and subject analysis sets for the end point.	Error – The end point values are incomplete. Values for the selected dispersion type must be provided for each category, for all selected reporting groups, and subject analysis sets.

Measurable end point – two-value dispersion type values:

Rule type	Rule description	Message displayed
ERROR	For each measurable end point both values, as any positive or negative number, for the dispersion type (i.e. full range (min-max) or interquartile range (min-max)) must be present for all combinations of the categories (if used) and the selected reporting groups and subject analysis sets for the end point.	Error – The end point values are incomplete. Values for the selected dispersion type must be provided for each category, for all selected reporting groups, and subject analysis sets.
ERROR	For each measurable end point using a dispersion type of full range (min-max) or interquartile range (min-max), the values present for the combination of the categories (if used) and the reporting groups and subject analysis sets must meet the following requirement: The value in the 'max' field must not be less than the value present in the 'min' field.	Error – The end point values are not allowed. When using either the full range, or interquartile range dispersion types, ensure the maximum value is not less than the minimum value entered.
ERROR	For measureable end point using a dispersion type of full range, the value in the 'min' field must not exceed the value in the measure type field.	Error – The measure type value is not between the low and high values reported by the full range. Amend this data accordingly.
ERROR	For measureable end point using a dispersion type of full range, the value in the 'max' field must not be less than the value in the measure type field.	Error – The measure type value is not between the low and high values reported by the full range. Amend this data accordingly.
ERROR	For measureable end point using a dispersion type of interquartile range, the value in the 'min' field must not exceed the value in the measure type field.	Error – The measure type value is not between the low and high values reported by the interquartile range. Amend this data accordingly.
ERROR	For measureable end point using a dispersion type of interquartile range, the value in the 'max' field must not be less than the value in the measure type field.	Error – The measure type value is not between the low and high values reported by the interquartile range. Amend this data accordingly.

Measurable end point - precision type values:

Rule type	Rule description	Message displayed
ERROR	For each measurable end point the values as any number (positive or negative) for all the attribute(s) of the precision type (i.e. confidence interval) must be present for all combinations of categories (if used) and the selected reporting groups and subject analysis sets for the end point.	Error – The end point values are incomplete and must be provided for each category, for all selected reporting groups, and subject analysis sets.
ERROR	For each measurable end point using the precision type of confidence interval, the low value must not be greater than the high value for each reporting group or statistical analysis set.	Error – The low and high values for the confidence interval for this reporting group are incorrect. The low value must not be greater than the high value.
ERROR	For each measurable end point using the precision type of confidence interval, the low value must not exceed the measure type value.	Error – The measure type value is not between the low and high values reported by the confidence interval. Amend this data accordingly.
ERROR	For each measurable end point using the precision type of confidence interval, the high value must not be less than the measure type value.	Error – The measure type value is not between the low and high values reported by the confidence interval. Amend this data accordingly.

5.7. Statistical Analyses

5.7.1. Statistical analysis details

5.7.1.1. Statistical analysis title

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, the statistical analysis title must contain a minimum of 2 alphanumeric characters.	Error – The title is incomplete. Provide a meaningful title for the statistical analysis.

5.7.1.2. Analysis description

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, the analysis description field must be either blank or contain a minimum of 1 alphanumeric character.	Error – The analysis description is incomplete. Complete this field if relevant to the trial.

5.7.1.3. Comparison groups

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, a minimum of two comparison groups must have been selected.	Error – The comparison groups are incomplete. There must be at least two comparison groups selected for the statistical analysis.
ERROR	For each statistical analysis, each of the selected comparison groups must have a number of subjects analysed that is greater than zero.	Error – The comparison group is invalid. Select a comparison group that has a number of subjects analysed and is greater than zero.

5.7.1.4. Analysis specification

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, the analysis specification must be either pre-specified or post-hoc.	Error – The analysis specification is incomplete. Select an analysis specification.

5.7.1.5. Analysis type comment

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, the 'Analysis type comment' field must be either blank or contain a minimum of 1 alphanumeric character.	Error – The analysis type comment is incomplete. Complete this field if relevant to the trial.

5.7.2. Statistical hypothesis test

5.7.2.1. P-Value comparator

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, if the P-value field contains a valid value, then a mathematical comparator (either <, >, =, ⩽ or⩾) must have been selected from the P-value comparator list.	Error – The statistical hypothesis test is incomplete. When providing a P-value, select one of the mathematical comparison symbols to indicate less than, greater than, equal to, less than, or equal to, or greater than, or equal to.

5.7.2.2. Method

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, if the P-value field contains a valid value, then the 'Method' must be selected.	Error – The statistical hypothesis test is incomplete. When providing a P-value, select a method type from the list.
ERROR	For each statistical analysis, if the 'Method' is selected to be 'Other' then the 'Other method' field must contain a minimum of 1 alphanumeric character.	Error – The method type is incomplete. Provide a meaningful other method if selecting other from the list of methods.

5.7.2.3. P-value comment

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, the P-value comment field must be blank or contain a minimum of 1 alphanumeric character.	Error – The P-value comment is incomplete. Complete this field if relevant to the trial.

5.7.3. Parameter estimate

5.7.3.1. Parameter type

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, if the Point estimate contains a valid value, then the Parameter type must be selected.	Error – The parameter type is incomplete. When providing a point estimate, select a parameter estimate type from the list.
ERROR	For each statistical analysis, if the Parameter type is 'Other' then the 'Other parameter type' must contain a minimum of 1 alphanumeric character.	Error – The parameter type is incomplete. Provide a meaningful other parameter type if selecting other from the list of methods.

5.7.3.2. Confidence interval: sides

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, if the Point estimate contains a valid value, then confidence interval sides must have been selected.	Error – The confidence interval for the parameter estimate is incomplete. Select if the confidence interval is either 1-sided or 2-sided.

5.7.3.3. Confidence interval: level

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, if the Point estimate contains a valid value, then confidence interval level must have been selected (i.e. one of the radio button selected).	Error – The confidence interval for the parameter estimate is incomplete. Specify the level of confidence.
ERROR	For each statistical analysis, if the radio button labelled other for the confidence interval level is selected, then a valid value must be specified.	Error – The confidence interval for the parameter estimate is incomplete. Enter the percentage to state the level of confidence when selecting other from the user interface.

5.7.3.4. Confidence interval: lower/upper limit

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, if the number of sides is one, then one and only one of the lower limit or upper limit fields may contain a value.	Error – The values provided for the lower and upper limits of the confidence interval are invalid. For a 1-sided confidence interval, only one of the lower or upper limits must be provided.
ERROR	For each statistical analysis, if the number of sides is two, then at least one of the 'lower limit' or 'upper limit' fields must contain a value.	Error – The values provided for the lower and upper limits of the confidence interval are invalid. For a 2-sided confidence interval, at least one of the lower or upper limits must be provided.
WARNING	For each statistical analysis, if the number of sides is two, then it is expected that both the lower limit and upper limit fields should contain a value.	Warning – A low or upper value for the confidence interval may be missing. Values for both the lower and upper limit are expected with a 2-sided confidence interval.
ERROR	For each statistical analysis, if the lower limit field is not empty then the value in the lower limit field must not be greater than the value in the point estimate field.	Error – The point estimate value is not between the low and high values reported by the confidence interval. Amend this data accordingly.
ERROR	For each statistical analysis, if the upper limit field is not empty then the value in the upper limit field must not less than the value in the point estimate field.	Error – The point estimate value is not between the low and high values reported by the confidence interval. Amend this data accordingly.

5.7.3.5. Variability estimate

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, if the dispersion value contains a valid value then the variability estimate must be one of the allowable terms.	Error – The variability estimate is incomplete. If a dispersion type is provided, a dispersion type must be selected.

5.7.4. Statistical analysis completeness

Rule type	Rule description	Message displayed
ERROR	For each statistical analysis, the 'P-value' field or 'Point estimate' field or both fields must contain a valid value.	Error – The statistical analysis is incomplete. A value is required in at least one of the P-value, or parameter estimate fields.

5.8. Adverse events section

5.8.1. Adverse events information

5.8.1.1. Timeframe for adverse event reporting

Rule type	Rule description	Message displayed
ERROR	The field for timeframe adverse event reporting must contain a minimum of 1 alphanumeric character.	Error – The timeframe for adverse event reporting is incomplete. Provide a meaningful timeframe.

5.8.1.2. Adverse event reporting additional description

Rule type	Rule description	Message displayed
ERROR	The field for the adverse event reporting additional description must be blank or must contain a minimum of 1 alphanumeric character.	Error – An additional description for adverse event reporting is incomplete. Complete this field if relevant to the trial.

5.8.1.3. Assessment type

Rule type	Rule description	Message displayed
ERROR	The assessment type must have selected one of possible terms in the list.	Error – The assessment type for adverse event reporting is incomplete. Select an assessment type from the list.

5.8.1.4. Frequency threshold for reporting non-serious adverse events

Rule type	Rule description	Message displayed
ERROR	The frequency threshold must not be empty and must contain a number from 0 to 5. [Note: this field is a decimal field so can accept any decimal value bounded by this rule].	Error – The threshold for non-serious adverse event reporting is incomplete. Specify the threshold up to a maximum of 5%.

5.8.1.5. Dictionary name

Rule type	Rule description	Message displayed
ERROR	The dictionary name must be one of the terms in the list, including the selection of 'Other'.	Error – The dictionary used for reporting adverse events is incomplete. Specify the default dictionary name.

5.8.1.6. Other Dictionary name

Rule type	Rule description	Message displayed
ERROR	If the dictionary name is 'Other' then the Other dictionary name field must contain a minimum of 1 alphanumeric character.	Error – The other dictionary name used for adverse event reporting is incomplete. Enter the name of the other dictionary.

5.8.1.7. Dictionary version

Rule type	Rule description	Message displayed
ERROR	The dictionary version must contain a minimum of 1 alphanumeric character	Error – The dictionary version used for adverse event reporting is incomplete. Enter the dictionary version.

5.8.2. Adverse events reporting groups

5.8.2.1. Adverse event reporting groups title

Rule type	Rule description	Message displayed
ERROR	For each reporting group, the adverse event reporting group title must contain a minimum of 4 characters. **[Note this is not limited to alphanumeric characters only. Symbols are allowed]**	Error – The adverse event reporting group title is incomplete. The title must contain at least 4 characters.

5.8.2.2. Adverse events reporting groups description

Rule type	Rule description	Message displayed
ERROR	For each reporting group, the adverse event reporting group description must be blank or contain a minimum of 1 alphanumeric character.	Error –The adverse event reporting group description is incomplete. Complete this field if relevant to the trial.

5.8.2.3. Total number of subjects affected by serious adverse events

Rule type	Rule description	Message displayed
ERROR	For each reporting group, the subjects affected by serious adverse events must contain a value.	Error – The total number of subjects affected by serious adverse events for the reporting group is incomplete. Complete the field subjects affected by serious adverse events for the reporting group.
ERROR	For each reporting group, the total number of subjects affected by serious adverse events must not exceed the total number of subjects exposed.	Error – The number of subjects affected by serious adverse events exceeds the number of subjects exposed. The number of subjects in a reporting group affected must not exceed the total number exposed to adverse events.

5.8.2.4. Total number of subjects affected by non-serious adverse events

Rule type	Rule description	Message displayed
ERROR	For each reporting group, the subjects affected by non-serious adverse events must contain a value.	Error –The total number of subjects affected by non-serious adverse events for the reporting group is incomplete. Complete the field 'Subjects affected by non-serious adverse events'.
ERROR	For each reporting group, the total number of subjects affected by non-serious adverse events must not exceed the number of subjects exposed.	Error – The number of subjects affected by non-serious adverse events exceeds the number of subjects exposed. The number of subjects in a reporting group affected must not exceed the number exposed to adverse events.

5.8.2.5. Total number of subjects exposed

Rule type	Rule description	Message displayed
ERROR	For each reporting group, the subjects exposed must contain a value.	Error – The total number of subjects exposed is incomplete. Complete the field Subjects exposed for the reporting group.
ERROR	For each reporting group, the total number of subjects exposed should not exceed the worldwide number of subjects enrolled in the trial.	Error – The recorded number of subjects exposed to adverse events is not allowed. The total number of subjects exposed to adverse events must not exceed the worldwide number enrolled in the trial.

5.8.2.6. Total number of deaths all causes

Rule type	Rule description	Message displayed
ERROR	For each reporting group, the total number of deaths (all causes) must contain a value.	Error – The total number of deaths all causes is incomplete. Complete the field Total number of deaths (all causes) for the reporting group.
ERROR	For each reporting group, the total number of deaths all causes must not exceed the number of subjects exposed.	Error – The recorded number of deaths from all causes is not allowed. The total number of deaths all causes must not exceed the total number of subjects exposed for this reporting group.

5.8.2.7. Total number of deaths resulting from adverse events

Rule type	Rule description	Message displayed
ERROR	For each reporting group, if entered the total number of death resulting from adverse events must not exceed the value of the total number of deaths (all causes).	Error –The recorded number of deaths resulting from adverse events is not allowed. The total number of deaths resulting from adverse events must not exceed the total number of deaths all causes for the reporting group.
ERROR	For each reporting group, if entered then the total number of deaths resulting from adverse events must not exceed the total number of subjects affected by serious adverse events.	Error – The recorded number of deaths resulting from adverse events is not allowed. Ensure that the recorded number of deaths does not exceed the total number of subjects affected by serious adverse events for the reporting group.
ERROR	For each reporting group, the total of values for fatalities reported for all serious adverse events must be equal or greater than the total number of deaths resulting from adverse events.	Error – The total of values for fatalities reported for all serious adverse events is less than the total number of deaths resulting from adverse events. Account for all the reported deaths when reporting the serious adverse events.

5.8.3. Serious adverse events

5.8.3.1. Serious adverse events

Rule type	Rule description	Message displayed
ERROR	If the total number of subjects affected by serious adverse events (for all of the reporting groups collectively) is equal to zero, then there must not be any serious adverse events.	Error – Serious adverse events have been created although none of the reporting groups recorded subjects were affected by serious adverse events. Correct the number of subjects affected for each reporting group or remove all serious adverse events.

Rule type	Rule description	Message displayed
ERROR	For each reporting group, the total number of subjects affected by all serious adverse events, collectively, must not be less than the value in the field labelled 'total number of subjects affected by serious adverse events' for the reporting group.	Error – The total number of subjects affected by the serious adverse events is less than the total number of subjects affected by serious adverse events for the reporting group. Account for all subjects affected or correct the total number of subjects affected by serious adverse events for the reporting group.

5.8.3.2. Event term

Rule type	Rule description	Message displayed
ERROR	For each serious adverse event, the event term field must contain a minimum of 2 alphanumeric characters.	Error – The event term is incomplete. Provide a meaningful event term.
ERROR	For each serious adverse event, the event term must not have been used for any other serious adverse event in these results, unless it belongs to a different system organ class.	Error – Duplicate serious adverse event term for the same system organ class. Use an event term for a maximum of one non-serious adverse event per system organ class, unless terms belong to different system organ class.

5.8.3.3. System organ class

Rule type	Rule description	Message displayed
ERROR	For each serious adverse event, the system organ class must have been selected.	Error – The system organ class is incomplete and must be selected for the adverse event.

5.8.3.4. Additional description

Rule type	Rule description	Message displayed
ERROR	For each serious adverse event, the additional description must be either blank or contain a minimum of 1 alphanumeric character.	Error –The additional description for this adverse event is incomplete. Complete this field if relevant to the trial.

5.8.3.5. Alternative dictionary

Rule type	Rule description	Message displayed
ERROR	For each serious adverse event, if the question 'Do you want to use a different dictionary name and version for reporting this adverse event?' is answered with the response 'Yes', then a value for the Dictionary name must have been selected AND the Dictionary version must contain a minimum of 1 alphanumeric character.	Error – The alternative dictionary used for reporting this adverse event is incomplete. Enter the name and version of the alternative dictionary.

5.8.3.6. Other dictionary name

Rule type	Rule description	Message displayed
ERROR	For each serious adverse event, if the Dictionary name is selected as 'Other', then the 'Other dictionary name' field must contain a minimum of 1 alphanumeric character.	Error – The alternative dictionary used for this adverse event is incomplete. Enter the dictionary name when selecting 'other' from the list.

5.8.3.7. Serious adverse event values

Serious Adverse event reporting groups values

Rule type	Rule description	Message displayed
ERROR	For each reporting group, all of the following fields on the serious adverse event user interface: - subjects affected; - subjects exposed; - occurrences all; - occurrences causally related to treatment; - fatalities; - fatalities causally related to treatment; must contain a numerical value in its required range.	Error – The adverse event values are incomplete. Provide values for all fields belonging to the specified reporting groups.
ERROR	For each serious adverse event, the number of subjects affected must be greater than zero for at least one of the reporting groups.	Error –An invalid number of subjects have been affected by this reported adverse event. To be recorded in the results, an adverse event must have affected one or more subjects.
ERROR	For each reporting group, the number of subjects exposed for each serious adverse event must not exceed the total number of subjects exposed per reporting group.	Error – The reported number of subjects exposed to this adverse event is not allowed for the reporting group. The number of subjects exposed to the adverse event must not exceed the total number exposed for the reporting group.
ERROR	For each reporting group, the number of subjects affected for each serious adverse event must not exceed the total number of subjects affected per reporting group.	Error – The reported number of subjects affected for each adverse event is not allowed. The number of subjects affected must not exceed the total number affected for the reporting group.
WARNING	For each serious adverse event, the value entered in the field labelled 'subjects exposed #' is expected to be equal to the value of the total number of subjects exposed for the reporting group (entered in the field labelled Subjects exposed on the reporting groups details user interface). If this condition is not met then this warning is displayed.	Warning – The number of subjects exposed to this adverse event differs from the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
ERROR	For each serious adverse event, the value entered in the field labelled 'subjects affected #' must not exceed the value entered for the field labelled 'subjects exposed #' for a reporting group.	Error – The reported number of subjects affected by this adverse event is not allowed. The number of subjects affected must not exceed the number exposed.
ERROR	For each serious adverse event, the value entered in the field labelled 'occurrences causally related to the treatment #' must not exceed the value entered for the field labelled 'occurrences - all #' for a reporting group.	Error –The reported number of occurrences causally related to the treatment is not allowed. The number of occurrences must not exceed the total number for the reporting group.
ERROR	For each serious adverse event, the value entered in the field labelled 'fatalities causally related to the treatment #' must not exceed the value entered for the field labelled 'fatalities #' for a reporting group.	Error – The reported number of fatalities causally related to the treatment is not allowed. The number of fatalities causally must not exceed the number of fatalities for the reporting group.

Rule type	Rule description	Message displayed
ERROR	For each serious adverse event, the value entered in the field labelled 'fatalities #' must not exceed the value entered for the field labelled 'subjects exposed #' for a reporting group.	Error – The reported number of fatalities is not allowed. The number of fatalities must not exceed the number of subjects exposed for a reporting group.

5.8.4. Non-serious adverse events

Rule type	Rule description	Message displayed
WARNING	It is expected that there will be a minimum of one non-serious adverse event.	Warning – There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
ERROR	If the total number of subjects affected by non-serious adverse events (for all of the reporting groups collectively) is equal to zero, then there must not be any non-serious adverse events.	Error – Non-serious adverse events have been created although none of the reporting groups have recorded subjects were affected by non-serious adverse events. Correct the number of subjects affected for each reporting group or remove all non-serious adverse events.
ERROR	For each reporting group, the total number of subjects affected by all non-serious adverse event, collectively, must not be less than the value in the field labelled 'total number of subjects affected by non-serious adverse events' for the reporting group.	Error – The total number of subjects affected by the non-serious adverse events is less than the total number of subjects affected by non-serious adverse events for the reporting group. Account for all subjects affected or correct the total number of subjects affected by non-serious adverse events for the reporting group.

5.8.4.1. Event term

Rule type	Rule description	Message displayed
ERROR	For each non-serious adverse event, the event term field must contain a minimum of 2 alphanumeric characters.	Error – The event term is incomplete. Provide a meaningful event term.
ERROR	For each non-serious adverse event, the event term must not have been used for any other non-serious adverse event in these results, unless it belongs to a different system organ class.	Error – Duplicate non-serious adverse event term for the same system organ class. Use an event term for a maximum of one non-serious adverse event per system organ class, unless terms belong to different system organ class

5.8.4.2. System organ class

Rule type	Rule description	Message displayed
ERROR	For each non-serious adverse event, the system organ class must have been selected.	Error – The system organ class is incomplete. The system organ class must have been selected for the adverse event.

5.8.4.3. Additional description

Rule type	Rule description	Message displayed
ERROR	For each non-serious adverse event, the additional description must be either blank or contain a minimum of 1 alphanumeric character.	Error – An additional description for this adverse event is incomplete. Complete this field relevant to the trial.

5.8.4.4. Alternative dictionary

Rule type	Rule description	Message displayed
ERROR	For each non-serious adverse event, if the question 'Do you want to use a different dictionary name and version for reporting this adverse event?' is answered with the response 'Yes', then a value for the Dictionary name must have been selected AND the Dictionary version must contain a minimum of 1 alphanumeric character.	Error – The alternative dictionary used for reporting this adverse event is incomplete. Enter the name and version of the alternative dictionary.

5.8.4.5. Other dictionary name

Rule type	Rule description	Message displayed
ERROR	For each non-serious adverse event, if the Dictionary name is selected as 'Other', then the 'Other dictionary name' field must contain a minimum of 1 alphanumeric character.	Error – The alternative dictionary used for this adverse event is incomplete. Enter the dictionary name when selecting other from the dictionary list.

5.8.4.6. Non-serious adverse event values

Non-serious Adverse event reporting groups values

Rule type	Rule description	Message displayed
ERROR	For each reporting group, all of the following fields on the non-serious adverse event user interface: - subjects affected; - subjects exposed; - occurrences all; must contain a numerical value in its required range.	Error – The adverse event values are incomplete. Provide values for all fields belonging to the specified reporting groups.
ERROR	For each non-serious adverse event, the number of subjects affected must be greater than zero for at least one of the reporting groups.	Error – An invalid number of subjects affected by this adverse event was recorded. To be recorded in the results, an adverse event must have affected one or more subjects.
ERROR	For each reporting group, the number of subjects exposed for each adverse event must not exceed the total number of subjects exposed per reporting group.	Error – The reported number of subjects exposed to this adverse event is not allowed for the reporting group. The number of subjects exposed to the adverse event must not exceed the total number exposed to for the reporting group.
ERROR	For each reporting group, the number of subjects affected for each non-serious adverse event must not exceed the total number of subjects affected per reporting group.	Error – The reported number of subjects affected for each adverse event is not allowed. The number of subjects affected by the adverse event must not exceed the total number affected for the reporting group.

Rule type	Rule description	Message displayed
WARNING	For each adverse event, the value entered in the field labelled 'subjects exposed #' is expected to be equal to the value of the total number of subjects exposed for the reporting group (entered in the field labelled Subjects exposed on the reporting groups details user interface). If this condition is not met then this warning is displayed.	Warning – The number of subjects exposed to this adverse event differs from the total number exposed for the reporting group. These numbers are expected to be equal.
ERROR	For each non-serious adverse event, the value entered for the field labelled 'subjects affected #' must not exceed the value entered for the field labelled 'subjects exposed #' for a reporting group.	Error – The reported number of subjects affected by this adverse event is not allowed. The number of subjects affected by the adverse event must not exceed the number exposed.

5.9. More information section

5.9.1. Global Amendments

Rule type	Rule description	Message displayed
ERROR	The question 'Were there any global substantial amendments to the protocol?' must be answered with the response 'Yes' or 'No'.	Error –The question 'Were there any global substantial amendments to the protocol?' has not been answered. Provide an answer to this question.
ERROR	If the question 'Were there any global substantial amendments to the protocol?' is answered with the response yes, then a minimum of one amendment for the trial must be recorded.	Error – No global substantial amendments to the protocol have been recorded. Enter details of the global substantial protocol amendments, or indicate no global substantial amendments occurred during the trial.
ERROR	For any amendment, the amendment date must not be after the global end of trial date.	Error – The amendment date is not allowed. Amendment dates must not be later than the global end of trial date.
ERROR	For any amendment, the amendment description must contain a minimum of 1 alphanumeric character.	Error – The amendment description is incomplete. This field must contain at least one alphanumeric character.

5.9.2. Global Interruptions

Rule type	Rule description	Message displayed
ERROR	The question 'Were there any global interruptions to the trial?' must be answered with the response 'Yes' or 'No'.	Error – The question 'Were there any global interruptions to the trial?' has not been answered. Provide an answer to this question.
ERROR	If the question 'Were there any global interruptions to the trial?' is answered with the response yes, then a minimum of one interruption for the trial must be recorded.	Error - No global interruptions have been recorded. Enter details of global interruptions, or indicate that no global interruptions occurred during the trial.
ERROR	For any interruption, the interruption description must contain a minimum of 1 alphanumeric character.	Error – The interruption description is incomplete. Complete this field if relevant to the trial.
ERROR	For each interruption, it must have a restart date unless it is the chronologically last global interruption.	Error – The interruption details are incomplete. A maximum of one interruption is allowed to not have a restart date.

Rule type	Rule description	Message displayed
ERROR	If the global end of trial date has been provided then for each interruption, the interruption date must not be later than the global end of trial date.	Error – The interruption date is not allowed. Interruption dates must not be later than the global end of trial date.
ERROR	If the global end of trial date has been provided then for each interruption, the restart date must not be later than the global end of trial date.	Error – The restart date is not allowed. The restart date must not be later than the global end of trial date.

5.9.3. Limitations and caveats

5.9.3.1. Limitations and caveats applicable to this summary of the results

Rule type	Rule description	Message displayed
ERROR	This field must be blank or contain a minimum of 1 alphanumeric character.	Error – The details of the limitations and caveats are incomplete. Complete this field if relevant to the trial.

5.10. Downloadable validation report

This section contains the design of the validation report that can be downloaded from the system as a document file.

Page 1	EudraCT - results validation report EudraCT Number: <yyyy>-<nnnnnn>-<nn> Date and time: <hh:mm:ss dd-mmm-yyyy>
Page 2	Trial information Field: <fully qualified field name> <error/warning message> etc
Page 3	Subject disposition Field: <fully qualified field name> <error/warning message> etc.
Page 4	Baseline characteristics Field: <fully qualified field name> <error/warning message> Etc

Page 5	End points Field: <fully qualified field name> <error/warning message> etc
Page 6	Adverse events Field: <fully qualified field name> <error/warning message> etc
Page 7	More information Field: <fully qualified field name> <error/warning message> etc

6. Integration with other systems or other modules

This supplementary specification is used by the following system use cases:

- UC27 Prepare Results

- UC35 Post Results

7. Related Non-functional requirements

Please refer to the common set of non–functional requirements for EudraCT V9. See referenced documents Non-Functional Requirements.

In addition, the following non-functional requirements are relevant to this use case.

Maintenance:

The design qualities of the system shall support the following non-functional requirements for maintaining the system:

- Validation rules into the system with an effective from a future date.

- Existing validation rules can be removed from the system effective from a future date.

- Maintenance of the validation rules and the subsequent system testing activity can be performed in isolation from the remainder of the system's code base.

8. Related documents

None

9. Implementation Notes

9.1. Exposing rules to third party systems

Consideration should be given to a solution that will also enable Sponsors to use the rules documented in this supplementary specification to perform validation of results data in their back-office systems.

10. About this document

10.1. Document location

The document is located in the following folder on EDMS: _____Cabinets/13. Projects/00464 EudraCT Clinical Trials System Implementation/Requirements/Requirements Specification/Supplementary Specifications

10.2. Definitions, acronyms, and abbreviations

Additional definitions, acronyms and abbreviations are described in the Glossary.

10.3. Open issues

None

10.4. Referenced documents

Doc ID	Title	Locator
EMA/207459/2012	EMA Clinical Trials Results Simple forms	https://docs.eudra.org/webtop/drl/objectId/090142b281e20e32
EMA/534108/2010	EU CTR Glossary	https://docs.eudra.org/webtop/drl/objectId/090142b281a890f6
EMA/216131/2012	EudraCT V9 Results Non-Functional Requirements	https://docs.eudra.org/webtop/drl/objectId/090142b281c01fa3

10.5. Document history

Version	Who	Date	What
0.1	SFL	24/08/2012	Initial draft. Issued to dev team for estimating.

Version	Who	Date	What
0.2	SFL	20/11/2012	Updates made: - Added a new rule to ensure that the age continuous values do not exceed a logical maximum. - Removed field name references from the error and warning messages to make the messages un-parameterised in order to allow them to be maintained without the need to a change to code.
0.3	SFL	26/11/2012	- Addressed review comments from Noémi and Gunter. New rules added and some rules removed. - Added an open issue about the rules related to AEs reported by subject analysis set. - Included requirements for the content of the downloadable validation report file. - Updated the error and warning messages.
0.4	SFL	14/01/2013	Second round of review comment from business stakeholders. - Rules and error/warning messages updated. - Open issues amended.
0.5	SFL	23/01/2013	Added rules related to model update. - A P-value must have be prefixed mathematical comparator symbol; either <, >, =, ≤ or ≥. - When using the dispersion type of full range or interquartile range for either baseline characteristics or end points, the value provided for the maximum attribute must not be less than the value provided for the minimum value.
1.0	SFL	26/02/2013	Signed off

Version	Who	Date	What

1.1	SFL	26/02/2013	Changes post system test:
			- Remove redundant validation rules for test of non-future dates for recruitment, global end date and primary completion date [ECTRES-980].
			- Cleared up typographical error in the Article 45 and Article 46 rule check. There was a missing word (the word 'of') and the number 46 was mentioned twice. It now reads:
			`Error – It has been identified that article 45 and article 46 of REGULATION (EC) No 1901/2006 apply to this trial. A maximum of one of these articles may apply to a trial.`[ECTRES-941]
			- Relaxed the rule for checking that the screening section is complete. The rule does not check for a valid pre-assignment period to be present. Other rules exist to ensure the pre-assignment period is valid if it present. This now reads:
			`The results must contain one the other or both of the following:`
			`- a pre-assignment period, or;`
			`- the Screening details field must contain a minimum of 1 alphanumeric character.`
			- Typographical error in the blinding used rule. [ECTRES-981]
			- Typographical error in the message displayed for the number of subjects in an arm rule. The word plus was used instead of minus. This now reads:
			`"The subject numbers in the arm are incorrect. The difference between the number of subjects that started and completed the arm must be equal to the number of subjects that did not complete the arm minus those that joined the arm."` [ECTRES-973]
			- Missing rule to check that the Gender characteristic is present. [ECTRES-984]
			- Updated the data conformity rules to describe all of the user interface rules that apply to the conformity of the data.

1.2	SFL	26/04/2013	New validation rules for total number of subjects for non-mutually exclusive arms. For consistency reasons, added rules to ensure that the number of subjects in the baseline period with mutually exclusive arms is not able to exceed the worldwide total. As a result there is a need for a rule to check that the net number of subjects transferring between arms in a period is zero. Also added rules to ensure that subject numbers in subsequent periods are sensible. Removal of obsolete rules caused by the previous changes.[ECTRES-1227]
1.3	SFL	04/06/2013	Update to non-serious adverse events rules owing to the removal of the causality reporting requirement in the Adverse event section. [ECTRES-1412].
1.4	SFL	19/06/2013	Included rules to check the min and max values entered for the dispersion values of the age continuous characteristic. [ECTRES-1374]

Version	Who	Date	What
1.5	SFL	21/06/2013	Correction to the validation rules entered for ECTRES-1374 mentioned above. The rules for min and max values of the dispersion types should also apply to the subject analysis sets.
1.6	SFL	27/06/2013	New rule for the analysis stage date. [ECTRES-1447]
1.7	SFL	05/07/2013	Missing rules from the More information section. The questions about global interruptions and Global amendments must be answered with either Yes or No and cannot be left empty.
1.8	SFL	09/07/2013	- Additional validation rules to check that the sum of the category values for the categorical characteristics is the same as the number of subjects in the reporting groups. [ECTRES-1446] - Permit zero subjects analysed for Primary end point. Have additional messaging for zero subjects analysed. Also, add a rule to check the statistical analysis is used to compare subject groups that contain a number of subjects that is greater than zero. [ECTRES-1428]
1.9	SFL	11/07/2013	- New rule: Participant under 18 years of age included in the trial when the trail is in scope of Art. 45 or Art. 46. [ECTRES-1315] - New rule: Trial information> new art-46 validation rule to check that the global end of trial date is in range. [ECTRES-1448] - Missing validation rule to check that the mandatory field labelled Date of interim/final analysis is not empty. [ECTRES-1576] - Missing validation rule to check that the number of subjects that complete an arm cannot be left empty. [ECTRES-1588]
1.10	SFL	16/07/2013	- New rule: ensure that one and only one of the periods is designated as the baseline period. [ECTRES-1589]
2.0	SFL	19/08/2013	Sign off version for first release
2.1	SFL	17/10/2013	New rules identified in UAT-6. - Pre-assignment subject numbers have to be accurate. - The full range and interquartile range values should correspond with the measured values they describe. - The confidence interval in the statistical analysis must correspond with the point estimate value.

Version	Who	Date	What
3.0	RAC	15/09/2017	New rules and corrections - allow duplication of Adverse Event terms if they belong to different system organ class. This applies both to SAE and NSAE events [JIRA SD-42976] - In the adverse event section related to the number of deaths when they are not causally related to treatment. [JIRA SD-90802] - Fix for the EudraCT Result users being locked out when there are more than 1000 trials [JIRA SD-90924] - Change the name of Parameter Type in the Parameter Estimates (Hazard ratio, log...) [JIRA SD-84414] - allow sponsors to manage users when the results are in finalised status [JIRA SD-57605] - allow system to retain numbers with trailing zero after a decimal [JIRA SD-17401] - Email sent by Result should contain the helpdesk website URL [JIRA SD-82986]