***= mandatory field**

Green highlight = guidance for completion of mandatory fields

Yellow highlight = guidance for completion of optional fields

Blue highlight = subset of questions, visible dependent on prior question

SECTION 1 – TRIAL INFORMATION

TRIAL IDENTIFICATION AND ADDITIONAL STUDY IDENTIFIERS:

EudraCT Number*	Insert number
Sponsor Protocol Code *	Insert number
Full title of trial*	Insert title from approved protocol (max 2000 characters)
ISRCTN number	Insert number
Clinicaltrials.gov identifier (NCT number)	Insert number
WHO universal trial number	Insert number
Other trial identifier: *specify type*	Insert number
Other trial identifier: *specify type*	Insert number

SPONSOR DETAILS:

Organisation details*	Scientific contact point*	Public contact point*
Insert full address	Insert Chief Investigator details	Insert details of trial management team or Sponsor if no one allocated

PAEDIATRIC REGULATORY DETAILS:

Is trial part of an agreed paediatric investigation plan? *	Yes ☐ No ☐
If yes, *	*Insert all applicable PIP reference numbers (EMEA-xxxx-PIP-xxxx-xxxx)*
Does article 45 of Regulation (EC) No 1901/2006 apply to this trial? *	Yes ☐ No ☐
Does article 46 of Regulation (EC) No 1901/2006 apply to this trial? *	Yes ☐ No ☐

RESULTS ANALYSIS STAGE:

Analysis stage*	Interim ☐ Final ☐
Date of interim/final analysis *	*Insert date of cut-off data point for this analysis*
Is this the analysis of the primary completion data? *	Yes ☐ No ☐ NB: Primary completion date is LPLV for purposes of final collection of data for primary enpoint.
If yes, Primary completion date *	Insert date of which final data was collected
Global end of trial date reached? *	Yes ☐ No ☐
If yes, global end of trial date *	Insert date
Was the trial ended prematurely? *	Yes ☐ No ☐

GENERAL INFORMATION ABOUT THE TRIAL:

Main objective of the trial *	Insert a summary (only 1000 characters allowed)
Actual start date of recruitment *	Insert date
Long term follow-up planned? *	Yes ☐ No ☐
If, yes, long term follow-up rationale? *	*Select one or more from the following list:* *Safety* ☐ *Efficacy* ☐

	Ethical reason ☐ *Regulatory reason* ☐ *Scientific reason* ☐
If yes, long term follow-up duration? *	*Insert months, Insert years*
Independent data monitoring committee (IDMC) involvement? *	Yes ☐ No ☐
Protection of trial subjects *	Insert details of specific measures that were in place i.e measures to minimise pain and distress (max 2000 characters)
Background therapy	Insert details (max 2000 characters) – describe treatments that are not test or comparator products used across all arms/groups in the trial
Evidence for comparators	Insert details (max 2000 characters) – provide rationale for use of the comparators used. Provide evidence for use in context of trial design.

POPULATION OF TRIAL SUBJECTS:

For each country participating:

Country	Planned number of subjects	Actual number of subjects enrolled
Select from drop down list	Insert	Insert

Age range	Planned number of subjects	Actual number of subjects enrolled*
In utero	Insert	Insert
Preterm newborn infants (gestational age <37weeks)	Insert	Insert
Newborns (0-27 days)	Insert	Insert
Infants and toddlers (28 days – 23 months)	Insert	Insert
Children (2—11 years)	Insert	Insert
Adolescents (12-17 years)	Insert	Insert
Adults (18-64 years)	Insert	Insert
From 65 years	Insert	
From 65-84 years		Insert
84 years and above		Insert

SECTION 2 – SUBJECT DISPOSITION

RECRUITMENT:

Recruitment details:	Insert details of recruitment process i.e recruitment dates, periods and territories (max 350 characters)

PRE-ASSIGNMENT:

Screening details:	Insert details of screening criteria and process (max 350 characters) – provide number of patients screened and reasons for subsequent exclusion if applicable

If required, add another pre-assignment period, i.e. a pre-screening window for biomarker testing, washout period, etc

For each pre-assignment period added:

Date started *	Insert date	Number of subjects	Insert
Intermediate milestone date	Insert date	Number of subjects	Insert
Completed *	Insert date	Number of subjects	Insert
Subject non completion resaons	Select one or more from drop down: AE, non-fatal ☐ AE, serious fatal ☐ Consent withdrawn ☐ Physician decision ☐ Pregnancy ☐ Protocol deviation ☐ Other, specify ☐	Number of subjects	Provide number for each reason selected from drop down

PERIODS:

As a minimum, one period needs to be added in this section called 'Overall Trial'. Other periods can be added as required i.e. screening period, Dose escalation phase, dose expansion phase etc.

For each period added:

Period details:

Period title *	Insert
Is this the baseline period? *	Yes ☐ No ☐ NB: Enter No if this is not the period that will be covered by the baseline characteristics.
Allocation method *	Select from: *Randomised controlled* ☐ *Non randomised controlled* ☐ *Not applicable* ☐
Blinding used *	Select from: *Double blind* ☐ *Single blind* ☐ *Not blinded* ☐
Roles blinded *	Select one or more from: *Subject* ☐

	Investigator ☐ *Monitor* ☐ *Data analyst* ☐ *Carer* ☐ *Assessor* ☐
Blinding implementation details	Insert details of blinding processes here (max 500 characters) – i.e. double dummy techniques, measures to prevent unblinding by staff or lab measurements etc

Milestones:

Insert milestone title:	Insert details of any intermediate milestone in this period i.e. interim analysis, completion of Dose escalation cohort 1, completion of dose escalation cohort 2 etc where separate figures will be reported

Arms:

Are the arms mutually exclusive? *	Yes ☐ No ☐ NB: Only answer 'No' if subjects are present in more than one arm i.e. crossover study.

For each arm added:

Arm information:

Arm title *	Insert
Arm description	Insert brief description that will make it distinguishable from other arms
Arm type *	Select one from: Experimental ☐ Active comparator ☐ Placebo ☐ No intervention ☐ Other ☐ Specify:

Products:

For each product added:

IMP name *	Insert name of IMP
IMP code	Insert (if applicable)
Other names	Insert (if applicable)
Routes of administration *	Select from the drop down list provided
Pharmaceutical forms *	Select from the drop down list provided
Dosage and administration details *	Insert details (max 1000 characters)

Milestones:

Number of subjects at each milestone:	
Started *	Insert number of subjects
Completed *	Insert number of subjects
Subject non-completion reasons:	
Select one or more from drop down: AE, non-fatal ☐	Provide number of subjects for each reason selected from drop down

AE, serious fatal ☐ Consent withdrawn ☐ Physician decision ☐ Pregnancy ☐ Protocol deviation ☐ Other, specify ☐	
Subject joining reasons:	
If applicable, select one or more from drop down: Late recruitment ☐ Transferred from another group/arm ☐ Other ☐ specify:	Provide number of subjects for each reason selected from drop down

SECTION 3 – BASELINE CHARACTERISTICS

Select baseline period *	Select from drop down list (determined by periods entered Section 2)
How are baseline characteristics being reported? *	Per arm in the baseline period ☐ For the overall baseline period ☐

REPORTING GROUPS:

This is pre-populated depending on answer to question 2 above.

SUBJECT ANALYSIS SETS:

For each subject analysis set added:

Subject Analysis Title *	Insert
Subject Analysis Type*	Select from drop-down list: Full analysis ☐ Intention-to-Treat ☐ Modified Intention-to-Treat ☐ Per protocol ☐ Safety analysis ☐ Sub-group analysis ☐
Subject Analysis Description *	Insert (max 999 characters) – enter clear description which defines this set of subjects
Number of Subjects*	Insert number of subjects

AGE CHARACTERISTICS:

Age categorical characteristic:

Characteristic title *	Pre-populated 'Age categorical'
Units *	Pre-populated 'Subjects'
Description	Insert detail (max 600 characters)
Age category title *	Remove from the list all age categories that are not applicable to your study, ensuring that the list matches those entered in Section 1 'Trial Information' Remember to create a category (e.g. called Not recorded) for subjects who left the period before the characteristic.
Ready for collecting values? *	Only tick once all fields above are finalised as if this is subsequently unchecked and criteria for the characteristic definition are changed, all values already added in the next sub section are automatically deleted. Once completed, click 'Done- start collecting values'.

NB: Titles of reporting groups and subject analysis sets will be pre-populated. Also, each of the category titles provided in the table above will be pre-populated in the tables below. Number of tables that appear depends on the number of reporting groups and subject analysis sets entered.

Rep. group 1	
No of subjects	Insert
Category title	Insert
Category title	Insert

Rep. group 1	
No of subjects	Insert
Category title	Insert
Category title	Insert

Total	
No of subjects	*pre-populated*
Category title	*pre-populated*
Category title	*pre-populated*

Subject analysis set 1	
No of subjects	Insert

Category title	Insert
Category title	Insert

Age continuous characteristic:

Characteristic title *	Pre-populated 'Age continuous'
Units *	Pre-populated 'Years'
Description	Insert details (max 600 characters)
Central tendency type *	Select from drop-down list below: Arithmetic mean ☐ Median ☐ Least squares mean ☐ Geometric mean ☐ Log mean ☐
Dispersion type *	Select from drop-down list below: Standard deviation ☐ Inter-quartile range ☐ Full range (min-max) ☐
Ready for collecting values? *	Only tick once all fields above are finalised as if this is subsequently unchecked and criteria for the characteristic definition are changed, all values already added in the next sub section are automatically deleted. Once completed, click 'Done- start collecting values'.

NB: Titles of reporting groups and subject analysis sets will be pre-populated. Also, each of the category titles provided in the table above will be pre-populated in the tables below. Number of tables that appear depends on the number of reporting groups and subject analysis sets entered.

Rep. group 1	
No of subjects	Insert
Central tend.	Insert
Disp type.	Insert

Rep. group 1	
No of subjects	Insert
Central tend.	Insert
Disp type.	Insert

Total	
No of subjects	*pre-populated*
Central tend.	*pre-populated*
Disp type.	*pre-populated*

Subject analysis set 1	
No of subjects	Insert
Central tend.	Insert
Disp type.	Insert

GENDER CHARACTERISTIC:

Gender categorical characteristic:

Characteristic title *	Pre-populated 'Gender categorical
Units *	Pre-populated 'Subjects'
Description	Insert details (max 600 characters)
Category title *	Pre-populated 'Male', 'Female' Remember to create a category (e.g. called Not record) for subjects who left the period before the characteristic.
Ready for collecting values? *	Only tick once all fields above are finalised as if this is subsequently unchecked and criteria for the characteristic definition are changed, all values already added in the next sub section are automatically deleted. Once completed, click 'Done- start collecting values'.

NB: Titles of reporting groups and subject analysis sets will be pre-populated. Also, each of the category titles provided in the table above will be pre-populated in the tables below. Number of tables that appear depends on the number of reporting groups and subject analysis sets entered.

Rep. group 1	
No of subjects	Insert
Male	Insert
Female	Insert

Rep. group 1	
No of subjects	Insert
Male	Insert
Female	Insert

Total	
No of subjects	*pre-populated*
Male	*pre-populated*
Female	*pre-populated*

Subject analysis set 1	
No of subjects	Insert
Male	Insert
Female	Insert

STUDY-SPECIFIC CHARACTERISTIC:

For each study-specific categorical characteristic added:

Study-specific categorical characteristic:

Characteristic title *	Insert
Units *	Insert
Description	Insert details (max 600 characters)
Category title *	Add each category required for this study-specific characteristic Remember to create a category (e.g. called Not record) for subjects who left the period before the characteristic.
Ready for collecting values? *	Only tick once all fields above are finalised as if this is subsequently unchecked and criteria for the characteristic definition are changed, all values already added in the next sub section are automatically deleted. Once completed, click 'Done- start collecting values'.

NB: Titles of reporting groups and subject analysis sets will be pre-populated. Also, each of the category titles provided in the table above will be pre-populated in the tables below. Number of tables that appear depends on the number of reporting groups and subject analysis sets entered.

Rep. group 1	
No of subjects	Insert
Male	Insert
Female	Insert

Rep. group 1	
No of subjects	Insert
Male	Insert
Female	Insert

Total	
No of subjects	*pre-populated*
Male	*pre-populated*
Female	*pre-populated*

Subject analysis set 1	
No of subjects	Insert
Male	Insert
Female	Insert

For each study-specific continuous characteristic added:

Study-specific continuous characteristic:

Characteristic title *	Insert
Units *	Insert

Description	Insert details (max 600 characters)
Central tendency type *	Select from drop-down list below: Arithmetic mean ☐ Median ☐ Least squares mean ☐ Geometric mean ☐ Log mean ☐
Dispersion type *	Select from drop-down list below: Standard deviation ☐ Inter-quartile range ☐ Full range (min-max) ☐
Ready for collecting values? *	Only tick once all fields above are finalised as if this is subsequently unchecked and criteria for the characteristic definition are changed, all values already added in the next sub section are automatically deleted. Once completed, click 'Done- start collecting values'.

NB: Titles of reporting groups and subject analysis sets will be pre-populated. Also, each of the category titles provided in the table above will be pre-populated in the tables below. Number of tables that appear depends on the number of reporting groups and subject analysis sets entered.

Rep. group 1	
No of subjects	Insert
Central tend.	Insert
Disp type.	Insert

Rep. group 1	
No of subjects	Insert
Central tend.	Insert
Disp type.	Insert

Total	
No of subjects	*pre-populated*
Central tend.	*pre-populated*
Disp type.	*pre-populated*

Subject analysis set 1	
No of subjects	Insert
Central tend.	Insert
Disp type.	Insert

SECTION 4 – END POINTS

REPORTING GROUPS:

This is pre-populated depending on information entered in Section 2.

END-POINT DEFINITIONS:

For each end-point added:

End point definition:

End point title *	Insert
Countable or measurable? *	Countable ☐ Measurable ☐
If countable, what units? *	
If measurable, what units? *	
If measurable, what type? *	Select from drop-down list below: Number ☐ Arithmetic mean ☐ Median ☐ Least squares mean ☐ Geometric mean ☐ Log mean ☐
If measurable, what precision/dispersion type? *	Select from drop-down list below: Standard deviation ☐ Inter-quartile range ☐ Full range (min-max) ☐ Standard error ☐ Confidence Interval ☐
End point type *	Select from drop-down list below: Primary ☐ Secondary ☐ Other pre-specified ☐ Post-hoc ☐
Timeframe *	Insert details (max 255 characters)
Description	Insert details (max 255 characters)
Specify the groups of subjects applicable to this end point *	All reporting groups and subject analysis sets previously added to the system in section 2 will appear here. Select which ones (no limit to how many, but minimum one) are applicable to the endpoint. Values will then have to be added for each of the groups selected at the next stage. Make sure all applicable are selected as once you start collecting values, and changes to this list of groups etc will lead to deletion of all data values already entered.
Ready for collecting values? *	Only tick once all fields above are finalised as if this is subsequently unchecked and criteria for the characteristic definition are changed, all values already added in the next sub section are automatically deleted. Once completed, click 'Done- start collecting values'.

End point values:

Reporting groups / Subject analysis sets:

NB: Titles of reporting groups and subject analysis sets will be pre-populated. Also, the format for which data is to be entered depends on whether countable or measurable units have been selected when defining the endpoint. Number of tables that appear depends on the number of reporting groups and subject analysis sets entered.

Rep. group 1	
No of subjects	Insert
Value (C or M)	Insert
Dispersion	Insert

Rep. group 1	
No of subjects	Insert
Value (C or M)	Insert
Dispersion	Insert

Total	
No of subjects	*pre-populated*
Value (C or M)	*pre-populated*
Dispersion	*pre-populated*

Subject analysis set 1	
No of subjects	Insert
Value (C or M)	Insert
Dispersion	Insert

Statistical Analysis:

For each statistical analysis entered within the endpoint:

Statistical Analysis details:

Statistical analysis title *	Insert
Analysis description	Insert
Comparison groups *	Prepopulated (as per selections made in the end point definition)
Subjects in this analysis *	Prepopulated (as per selections made in the end point definition)
Analysis specification *	Prespecified ☐ Post-hoc ☐
Analysis type *	Select from the following list: Non-inferiority ☐ Equivalence ☐ Superiority ☐ Other ☐
Analysis type comment	Insert

Statistical hypothesis test:

P-value	Insert –value for primary comparison. If want to enter other p-values i.e. for multiple comparisons, then enter these in the 'p-value comments' field
P-value comment	Insert
If p-value entered, method?	Select from the drop-down list

Parameter estimate:

Parameter type	Select from drop down list. If other selected, specify
Point estimate	Insert
Confidence interval	1-sided ☐ 2-sided ☐
	Level: 90% ☐ 95% ☐ Other ☐
	Lower limit: Insert
	Upper limit: Insert
Variability estimate	Standard deviation ☐ Standard error of the mean ☐
Dispersion value	Insert

Charts:

Upload copies of relevant graphs, charts and diagrams for the end point analysis in question.

Supported formats: PDF, DOC, DOCX, RTF, TXT, PPT, PPTX, XLS, XLSX, TIFF, TIF, PNG, GIF, JPEG, JPG, BMP
Maximum file size: 50MB per file

SECTION 5 – ADVERSE EVENTS

ADVERSE EVENTS INFORMATION:

Timeframe for adverse event reporting *	Insert details (max 255 characters)
Adverse event reporting additional description	Insert details (max 350 characters)
Assessment type *	Systematic ☐ Non-systematic ☐
Frequency threshold for reporting non-serious adverse events *	Insert number (maximum value is 5%)
Dictionary name *	Select from drop-down list: MedDRA ☐ SNOMED CT ☐ Other ☐ specify: Insert

ADVERSE EVENTS REPORTING GROUPS

Add the reporting groups required for your adverse event reporting breakdown i.e. overall trial, Phase I, Phase II, Dose escalation phase, Arm 1, Arm 2 etc. These are independent from Reporting groups/Subject analysis sets previously entered for the statistical analysis sections.

Reporting group title *	Insert
Reporting group description	Insert (max 999 characters)
Subjects exposed *	Insert number of subjects – it is assumed that all subjects who have received at least one dose of treatment should be included in this total
Subjects affected by serious adverse events *	Insert number of subjects for whom at least one SAE was reported
Subjects affected by non-serious adverse events *	Insert number of subjects for whom at least one non-serious AE was reported
Total number of deaths (all causes) *	Insert number of deaths (including all non-treatment-related)
Total number of deaths resulting from adverse events *	Insert number of deaths causally related to treatment

SERIOUS ADVERSE EVENTS

For each Serious Adverse Event added:

Serious adverse event details:

System Organ Class *	Select from drop down list provided
Event term *	This field is predictively populated as typing progresses. Select the option from the drop-down where possible.
Additional description	Insert if required (max 250 characters)
Assessment type	Systematic ☐ Non-systematic ☐
Do you want to use a different dictionary to the one specified?	Yes ☐ No ☐

Values for serious adverse event per reporting group:

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number	Occurrences causally related to treatment number	Fatalities number	Fatalities causally related to treatment number
Prepopulated with reporting group title as per entries in prior section	Insert	Insert	Insert	Insert	Insert	Insert
Prepopulated with reporting group title as per entries in prior section	Insert	Insert	Insert	Insert	Insert	Insert

NON-SERIOUS ADVERSE EVENTS

For each Non-Serious Adverse Event added:

Non-serious adverse event details

System Organ Class *	Select from drop down list provided
Event term *	This field is predictively populated as typing progresses. Select the option from the drop-down where possible.
Additional description	Insert if required (max 250 characters)
Assessment type	Systematic ☐ Non-systematic ☐
Do you want to use a different dictionary to the one specified?	Yes ☐ No ☐

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number
Prepopulated with reporting group title as per entries in prior section	Insert	Insert	Insert
Prepopulated with reporting group title as per entries in prior section	Insert	Insert	Insert

SECTION 6 – MORE INFORMATION

SUBSTANTIAL PROTOCOL AMENDMENTS (GLOBALLY)

Were there any global substantial amendments to the protocol? *	Yes ☐ No ☐

For each substantial amendment added:

Date of amendment *	Insert date
Description of amendment *	Insert description (max 2000 characters)

INTERRUPTIONS (GLOBALLY)

For each interruption added:

Date of interruption *	Insert date
Description of interruption *	Insert description (max 2000 characters)
Date of restart, if applicable	Insert date

LIMITATIONS AND CAVEATS

Limitations and caveats applicable to this summary of the results?	Insert details of any significant limitations to the data i.e. early termination and small numbers of subjects, technical problems that led uninterpretable data etc (max 250 characters)

ONLINE REFERENCES

Enter PubMed identifier (PMID)	Insert the PubMed ID and then click 'Add this link'. Unlimited number of links can be added.