Annex 1: Structure of data to be collected for inclusion of results in EudraCT and their making public in the EU Clinical Trials Register

Annex 1 Section A) Sets out fields that describe the study that are not currently in EudraCT but are part of the protocol related information in ClincalTrials.gov, only those fields considered necessary have been included. The rows are numbered P01, P02 etc.

The information and text relating to ClinicalTrials.gov is taken from the document: "Protocol Data Element Definitions (DRAFT)" March 2010 to be found at http://prsinfo.clinicaltrials.gov/definitions.html and displayed in the order used there.

Annex 1 Section B) Sets out the fields that capture the results of the trial. The rows are numbered R01, R02 etc.

The information and text relating to ClinicalTrials.gov is taken from the document: "Basic Results" Data Element Definitions (DRAFT)" February 2010 which can be found at http://prsinfo.clinicaltrials.gov/results_definitions.html and displayed in the order used there.

In this table the proposed content of EudraCT is provided on the left and the current content of ClinicalTrials.gov on the right. The following conventions have been used:

- Where a field or set of data is included in only one system, N/A is entered on the corresponding row for the other system.
- Where some additions are made to a field in EudraCT relative to the same field or set of information in ClinicalTrials.gov the text is underlined.
- Where some deletions are made to the text for a field in EudraCT relative to the same field or set of information in ClinicalTrials.gov the text is shown as "~~strikethrough~~".
- Comments are provided in the right hand column to rationalise certain differences.

Annex 1 Section A *EudraCT*			*ClinicalTrials.gov*		
	Field name	***Description***	***Field name***	***Description***	***Comments***
P1	**Scientific rationale**	Short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis. Example: The purpose of this study is to determine whether prednisone, methotrexate, and cyclophosphamide are effective in the treatment of rapidly progressive hearing loss in both ears due to autoimmune inner ear disease (AIED).	**Brief Summary**	Short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis. Example: The purpose of this study is to determine whether prednisone, methotrexate, and cyclophosphamide are effective in the treatment of rapidly progressive hearing loss in both ears due to autoimmune inner ear disease (AIED).	
P2	**Reasons for premature termination**	For temporarily halted or prematurely terminated ~~suspended, terminated or withdrawn~~ studies, provide a brief explanation of why the study has been halted or terminated. ~~If desired, use brief summary or detailed description to provide additional information.~~	**Why Study Stopped?**	For suspended, terminated or withdrawn studies, provide a brief explanation of why the study has been halted or terminated. If desired, use brief summary or detailed description to provide additional information.	For details on the status please see field "Recruitment/Termination status"
P3	**Date of the global end of the trial (completed or prematurely terminated)**	Final date on which data was ~~(or is expected to be)~~ collected. ~~Use the Type menu (Anticipated/Actual) as described above~~	**Study Completion Date**	Final date on which data was (or is expected to be) collected. Use the Type menu (Anticipated/Actual) as described above	
P4	**Blinding/masking <u>specific to period</u>**	At least one of the following required: ~~Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - knowledge of intervention assignments~~ Open: no masking is used. All involved know the identity of the intervention assignment. Single Blind: one party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study.	**Masking**	Open: no masking is used. All involved know the identity of the intervention assignment. Single Blind: one party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study. Double Blind: two or more parties are unaware of the intervention assignment If Single Blind or Double Blind is selected, check the role(s) that are to be masked: Subject, Caregiver, Investigator or	Blinding (Masking) is often different per period, so that it is important to specify the blinding per period for understanding the results. ClinicalTrials.gov does not currently provide for explicitly linking this information to specific periods or arms/groups.

Annex 1 Section A *EudraCT*			*ClinicalTrials.gov*		
	Field name	***Description***	***Field name***	***Description***	***Comments***
		Double Blind: two or more parties are unaware of the intervention assignment If Single Blind or Double Blind is selected, check the role(s) that are to be masked: Subject, Carer, Investigator or Outcomes Assessor.		Outcomes Assessor.	
P5	**Blinding implementation details**	How was blinding realized in practice?	N/A	N/A	It is necessary to specify how blinding was done. This is in line with e.g. CONSORT 2010 Statement.
P6	***Allocation* specific to arm within period**	At least one of the following required: ~~Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - participant assignment to intervention group~~ ~~N/A:~~ Single arm study Randomised Controlled Trial/period: participants are assigned to intervention groups by chance Nonrandomised Trial/period: participants are expressly assigned to intervention groups through a non-random method, such as physician choice EudraCT collects this information per arm/group per period whereas ClinicalTrials.gov collects it only per trial.	**Allocation**	N/A: single arm study Randomized Controlled Trial: participants are assigned to intervention groups by chance Nonrandomized Trial: participants are expressly assigned to intervention groups through a non-random method, such as physician choice	It is necessary to collect these data per arm/group per period as periods frequently differ in major design aspects.
P7	**Randomised allocation implementation details (in case of**	E.g., central, blocked, stratified, biased coin, block length, randomisation ratio(s)	N/A	N/A	The details on how randomisation was carried out are important in order to understand to which

Annex 1 Section A *EudraCT*			*ClinicalTrials.gov*		
	Field name	***Description***	***Field name***	***Description***	***Comments***
	randomisation)				extent the bias was actually controlled. This impacts on how the results can be interpreted and generalised, particularly in small trials.
P8	**Enrolment**	(~~Target or~~ Actual Number of Subjects) Number of subjects in the trial. ~~A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected enrollment, updating the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.~~	**Enrollment**	(Target or Actual Number of Subjects) Number of subjects in the trial. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected enrollment, updating the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.	
P9	**Arm/Group type**	Select one: Experimental, Active Comparator, Placebo Comparator,~~ Sham Comparator~~, No intervention, Other (specify)	**Arm Type**	Select one: Experimental, Active Comparator, Placebo Comparator, Sham Comparator, No intervention, Other	
P10	**Intervention type**	Select one per intervention: IMP (including Placebo), Device (including sham), ~~Biological/Vaccine~~, Procedure/Surgery, Radiation, Behavioral (e.g., Psychotherapy, Lifestyle Counseling), ~~Genetic (including gene transfer, stem cell and recombinant DNA~~), Dietary Supplement (e.g. vitamins, minerals), Other	**Intervention Type**	Select one per intervention: Drug (including placebo), Device (including sham), Biological/Vaccine, Procedure/Surgery, Radiation, Behavioral (e.g., Psychotherapy, Lifestyle Counseling), Genetic (including gene transfer, stem cell and recombinant DNA), Dietary Supplement (e.g., vitamins, minerals), Other	
P11	**Intervention title**	For drugs use generic name (INN); for other types of interventions provide a brief descriptive name. For IMPs that do not yet have a generic name, a chemical name or company code ~~or serial number~~ may be used on a	**Intervention Name**	For drugs use generic name; for other types of interventions provide a brief descriptive name. For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be	

Annex 1 Section A *EudraCT*			*ClinicalTrials.gov*		
	Field name	***Description***	***Field name***	***Description***	***Comments***
		temporary basis. ~~As soon as the generic name has been established, update the associated protocol records accordingly.~~ For non-IMP intervention types (as comparator) or background therapy, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.		used on a temporary basis. As soon as the generic name has been established, update the associated protocol records accordingly. For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.	
P12	**Intervention details**	Cover key details of the intervention. Must be sufficiently detailed to distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include ~~dosage~~ pharmaceutical form, dosage, frequency, ~~and~~ duration and route of administration. Example: 50 mg/m2, IV (in the vein) on day 5 of each 28 day cycle. Number of Cycles: until progression or unacceptable toxicity develops. EudraCT has some further fields which fall within scope of "Intervention Description": If intervention with medicinal product then state: "Dose" (number) "Dose unit" (e.g. mg) "Dose maximum" (number) "Frequency" (number) "Frequency unit" (e.g. daily, per week)	**Intervention Description**	Cover key details of the intervention. Must be sufficiently detailed to distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration. Example: 50 mg/m2, IV (in the vein) on day 5 of each 28 day cycle. Number of Cycles: until progression or unacceptable toxicity develops.	Version 2.2 of the BRIDG model (part of the CDISC/HL7 Joint Initiative Project) has comparable data structure, "Performed Substance Administration" with similar attributes.

Annex 1 Section A *EudraCT*			*ClinicalTrials.gov*		
	Field name	***Description***	***Field name***	***Description***	***Comments***
		"Route of administration" (value list, multiple select) "Type of dosing" (value list)			
P13	**Arms/Groups**	If arms or groups have been specified for the protocol, select the ones for which the intervention is to be administered. For interventional studies with arms specified, all arms must have at least one intervention (unless arm type is "No Intervention") and each intervention must be assigned to at least one arm. ~~For observational studies with groups specified, each intervention (if any) must be assigned to at least one group.~~	**Arms/Groups**	If arms or groups have been specified for the protocol, select the ones for which the intervention is to be administered. For interventional studies with arms specified, all arms must have at least one intervention (unless arm type is "No Intervention") and each intervention must be assigned to at least one arm. For observational studies with groups specified, each intervention (if any) must be assigned to at least one group.	
P14	**Recruitment/Termination status.** (To be updated by the sponsor during the active phase of the study)	Protocol accrual activity at a facility. Select one: Not yet recruiting: participants are not yet being recruited Recruiting: participants are currently being recruited Enrolling by invitation: participants are being (or will be) selected from a predetermined population Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) Temporarily halted: recruiting or enrolling participants has halted prematurely but potentially will resume Prematurely terminated: recruiting or enrolling participants has halted	**Recruitment Status**	Protocol accrual activity at a facility. Select one: Not yet recruiting: participants are not yet being recruited Recruiting: participants are currently being recruited Enrolling by invitation: participants are being (or will be) selected from a predetermined population Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume Terminated: recruiting or enrolling participants has halted prematurely and	

Annex 1 Section A *EudraCT*			*ClinicalTrials.gov*		
	Field name	***Description***	***Field name***	***Description***	***Comments***
		prematurely and will not resume; participants are no longer being examined or treated Withdrawn: study halted prematurely, prior to enrollment of first participant		will not resume; participants are no longer being examined or treated Withdrawn: study halted prematurely, prior to enrollment of first participant	
P15	**PubMed ID (PMID) or equivalent**	Citations to publications related to the protocol: background and/or results. Provide either the unique PubMed Identifier (PMID) of an article or enter the full bibliographic citation. MEDLINE Identifier Definition: unique PubMed Identifier (PMID) for the citation in MEDLINE Example: PMID: 10987815 Citation Definition: bibliographic reference in NLM's MEDLINE format Example: Barza M; Pavan PR; Doft BH; Wisniewski SR; Wilson LA; Han DP; Kelsey SF. Evaluation of microbiological diagnostic techniques in postoperative endophthalmitis in the Endophthalmitis Vitrectomy Study. Arch Ophthalmol 1997 Sep;115(9):1142-50 Results Reference? Indicate if the reference provided reports on results from this clinical research study.	**References**	Citations to publications related to the protocol: background and/or results. Provide either the unique PubMed Identifier (PMID) of an article or enter the full bibliographic citation. MEDLINE Identifier Definition: unique PubMed Identifier (PMID) for the citation in MEDLINE Example: PMID: 10987815 Citation Definition: bibliographic reference in NLM's MEDLINE format Example: Barza M; Pavan PR; Doft BH; Wisniewski SR; Wilson LA; Han DP; Kelsey SF. Evaluation of microbiological diagnostic techniques in postoperative endophthalmitis in the Endophthalmitis Vitrectomy Study. Arch Ophthalmol 1997 Sep;115(9):1142-50 Results Reference? Indicate if the reference provided reports on results from this clinical research study.	
P16	**Link(s) to public part of assessment report, if not existing: disclaimer; and other links**	~~A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links~~	**Links**	A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by	

Annex 1 Section A *EudraCT*			*ClinicalTrials.gov*		
	Field name	***Description***	***Field name***	***Description***	***Comments***
		~~are subject to review by ClinicalTrials.gov.~~ Link or reference to publication of the trial results in a scientific journal, or other relevant location. ~~URL: complete URL, including http://~~ ~~Example: http://www.alzheimers.org/~~ ~~Description: title or brief description of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol.~~ Links to the public assessment report (i.e. EPAR or PAR).		ClinicalTrials.gov. URL: complete URL, including http:// Example: http://www.alzheimers.org/ Description: title or brief description of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol.	

Annex 1: Structure of data to be collected for making public results (cont.)
Section B) Following the order of the ClinicalTrials.gov document "Basic Results" Data Element Definitions (DRAFT)

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
Title	***B.5 Further information contact*** *(default values from protocol data)*	*Point of contact for scientific information about the posted clinical trial results.*	***Results Point of Contact***	*Point of contact for scientific information about the posted clinical trial results.*	
R1	**B. 5.2 Functional Name** *(default values from protocol data)*	The name of the individual and/or the individual role for the point of contact for further information on the trial (e.g. "Trial Information Desk").	**Name or Official Title**	For the designated individual. Note that this may be a specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials).	
R2	**B.5.1 Name of organisation** *(default values from protocol data)*	The contact point may be at the sponsor, a trial site or another organization. Full name of the designated individual's organisational affiliation.	**Organization Name**	Full name of the designated individual's organizational affiliation.	
R3	**B.5.4 Telephone number** *(default values from protocol data)*	~~(or "E-mail" required)~~ Office phone of the designated individual. ~~Use the format 123-456-7890 within the United States and Canada. Otherwise,~~ Provide the country code and phone number. EudraCT requests the country code also for contacts in the United States and Canada.	**Phone**	(or "E-mail" required) Office phone of the designated individual. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code and phone number.	
R4	**B.5.4 Telephone number** *(default values from protocol data)*	Phone extension, if needed	**Ext.**	Phone extension, if needed	
R5	**B.5.6 E-mail:** *(default values from protocol data)*	~~(or "Phone" required)~~ Electronic mail address of the designated individual.	**Email**	(or "Phone" required) Electronic mail address of the designated individual.	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
Title	*N/A*	*N/A*	***Certain Agreements***	*Information certifying whether there exists an agreement between the sponsor or its agent and the principal investigators (unless the sponsor is an employer of the principal investigators) that restricts in any manner the ability of the principal investigators (PIs), after the completion of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial. This does not include an agreement solely to comply with applicable provisions of law protecting the privacy of participants.*	
R6	N/A	N/A	**Are all PIs Employees of Sponsor? (Y/N)**	If all principal investigators are employees of the sponsor, select "Yes" and skip the remaining questions. If any principal investigator (PI) is not an employee of the sponsor, select "No" and answer the remaining questions.	
R7	N/A	N/A	**Results Disclosure Restriction on PI(s)? (Y/N)**	If there is an agreement between the sponsor (or its agent) and any non-employee PI(s) that restricts the PI's rights to discuss or publish trial results after the trial is completed, select "Yes" and select a "Restriction Type." Trial completion is defined as the final date on which data were collected. (ie, the Study Completion Date from the Protocol Data Elements).If there are agreements with multiple non-employee PIs and there is a disclosure restriction on at least one PI, select "Yes" and answer the remaining question. If there are varying	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
				agreements with PIs, choose the type below that represents the most restrictive of the agreements (e.g., the agreement with the greatest embargo time period).	
R8	N/A	N/A	**PI Disclosure Restriction Type** :	The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo. The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
R9	N/A	N/A	**Other Disclosure Restriction Type**	If "Other disclosure agreement..." is selected, please describe the type of agreement including any provisions allowing the sponsor to require changes, ban the communication, or extend an embargo. (Limit: 500 characters)	
R10	**Protection of participants**	Actual Measure(s) to … • minimise distress • minimise pain • minimise risk • minimise sampling blood (incl. maximum volume drawn) • withdraw and initiate rescue treatment • implement continuous consent and assent	N/A	N/A	Paediatric trials and trials in other vulnerable populations should report on how they ensured that the vulnerable participants were protected against various sources of harm.
Title	***Participant Flow***	*Progress of research participants through each stage of a trial in a tabular format, including the number of participants who dropped out of the clinical trial. (Identical in purpose to a CONSORT flow diagram, but represented as tables.) The tabular presentation may be separated into "periods," each of which comprises an interval of trial activity. Each period consists of "milestones" for reporting numbers of participants at particular points in time within that period.*	***Participant Flow***	*Progress of research participants through each stage of a trial in a tabular format, including the number of participants who dropped out of the clinical trial. (Identical in purpose to a CONSORT flow diagram, but represented as tables.) The tabular presentation may be separated into "periods," each of which comprises an interval of trial activity. Each period consists of "milestones" for reporting numbers of participants at particular points in time within that period.*	
R11	**Recruitment Details**	Key information relevant to the recruitment	**Recruitment Details**	Key information relevant to the recruitment	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		process for the overall study, such as dates of the recruitment period and types of location (e.g., medical clinic), to provide context. (Limit: 350 characters)		process for the overall study, such as dates of the recruitment period and types of location (e.g., medical clinic), to provide context. (Limit: 350 characters)	
R12	**Information on the screening prior to assignment to group if not specified as a special period, as relevant**	Description of any significant events and approaches for the overall study (e.g., wash out, run-in, transition) following participant enrollment, but prior to group assignment. For example, an explanation of why enrolled participants were excluded from the trial before assignment to groups. (Limit: 350 characters)	**Pre-assignment Details**	Description of any significant events and approaches for the overall study (e.g., wash out, run-in, transition) following participant enrollment, but prior to group assignment. For example, an explanation of why enrolled participants were excluded from the trial before assignment to groups. (Limit: 350 characters)	
Title	***Arm/Group***	*Arms or comparison groups in a trial (Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)* Given per period. "Arm/Group" refers to simultaneously proceeding, alternative groups.	***Arm/Group***	*Arms or comparison groups in a trial (Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)*	
R13	**Title**	Label used to identify the arm or comparison group. Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Examples: fluoxetine; sertraline; drug-eluting stent; placebo (Limit: >=4 and <=62 characters)	**Arm/Group Title**	Label used to identify the arm or comparison group. Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Examples: fluoxetine; sertraline; drug-eluting stent; placebo (Limit: >=4 and <=62 characters)	
R14	**Description**	Brief description of the arm or comparison	**Arm/Group Description**	Brief description of the arm or comparison	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		group to distinguish it from other arms/groups in the trial. (Limit: 999 characters)		group to distinguish it from other arms/groups in the trial. Examples: fluoxetine, 20mg qhs; Sirolimus-eluting stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach. (Limit: 999 characters)	
R15	**Background therapy details [pharmaceutical form, dosage, frequency, duration, route of administration]**	Background therapy: This is an option to detail the therapy used across arms/groups, on top of which an IMP is used in a trial, for example.	N/A	N/A	The background therapy can vary by period, can be complex, and is important for understanding how the results can be related to a standard of care.
R16	**Is the background therapy identical across all periods?**	**(Y/N)**	N/A	N/A	
Title	***Period(s)***	*Discrete stages of a clinical trial during which numbers of participants at specific significant events or points of time are reported. If only one period, use Overall Study for "Period Title."* *There is no limit to the number of periods that may be used to describe a single trial. Each subsequent period represents a trial stage following the previous period. That is, participants "flow" from earlier to later periods. All results sections must cover participant flow from initial assignment to arms/groups to completion of the trial.* Given per arm/group.	***Period(s)***	*Discrete stages of a clinical trial during which numbers of participants at specific significant events or points of time are reported. If only one period, use Overall Study for "Period Title."* *There is no limit to the number of periods that may be used to describe a single trial. Each subsequent period represents a trial stage following the previous period. That is, participants "flow" from earlier to later periods. All results sections must cover participant flow from initial assignment to arms/groups to completion of the trial.*	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
R17	**Title**	Title describing a stage of the trial. If only one period is defined, the default title is "Overall Study." When a trial has more than one period, none of the period titles should be "Overall Study." (Limit: 40 characters)	**Period Title**	Title describing a stage of the trial. If only one period is defined, the default title is "Overall Study." When a trial has more than one period, none of the period titles should be "Overall Study." (Limit: 40 characters)	
Title	***Milestone(s)***	*Specific events or time points in the trial when the numbers of participants are reported. While there is no limit to the number of milestones that may be used in a single period, data are required for two milestones, STARTED and COMPLETED, within each period.*	***Milestone(s)***	*Specific events or time points in the trial when the numbers of participants are reported. While there is no limit to the number of milestones that may be used in a single period, data are required for two milestones, STARTED and COMPLETED, within each period.*	
R18	**STARTED this period and arm**	Number of participants at the beginning of the period	**STARTED:**	Number of participants at the beginning of the period	
R19	**Comments**	Additional information about the STARTED milestone. (Limit: 100 characters)	**Comments**	Additional information about the STARTED milestone. (Limit: 100 characters)	
R20	**COMPLETED this period and arm**	Number of participants at the end of the period.	**COMPLETED**	Number of participants at the end of the period.	
R21	**Comments**	Additional information about the COMPLETED milestone. (Limit: 100 characters)	**Comments**	Additional information about the COMPLETED milestone. (Limit: 100 characters)	
R22	**Not completed**	Number of participants that did not complete the period. *Calculated automatically* by subtracting COMPLETED from STARTED	[**Not Completed**]	Number of participants that did not complete the period. *Calculated automatically* by subtracting COMPLETED from STARTED	
R23	**Is this the baseline period?**	**(Y/N)** One period should be identified as baseline period.	N/A	N/A	
Title	***Additional Milestone(s)***	*Any number of milestones may be added between the two required milestones, STARTED and COMPLETED*	***Additional Milestone(s)***	*Any number of milestones may be added between the two required milestones, STARTED and COMPLETED*	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
R24	**Milestone Title**	Label describing milestone (Limit: 40 characters)	**Milestone Title**	Label describing milestone (Limit: 40 characters)	
R25	**Reached this milestone for this period and arm/group**	(Per milestone, per arm/group): Number of participants to reach the milestone.	**Milestone Data**	(Per milestone, per arm/group): Number of participants to reach the milestone.	
R26	**Comments**	Additional information about the milestone. (Limit: 100 characters)	**Comments**	Additional information about the milestone. (Limit: 100 characters)	
Title	***Reason not completed***	*Additional information about participants who did not complete the period. If any are provided, the total number of participants accounted for by all reasons must equal the number of participants listed under "Not Completed."*	***Reason Not Completed***	*Additional information about participants who did not complete the period. If any are provided, the total number of participants accounted for by all reasons must equal the number of participants listed under "Not Completed."*	
R27	**Reason not completed type** Only conditionally required	Select one for each reason not completed Serious adverse event(s), non-fatal; Adverse Event(s), not serious; Serious Adverse Event, Fatal (mandatory reporting); Physician Decision, Pregnancy, Withdrawal by Subject, not due to adverse event; Lack of Efficacy, Protocol Violation, specify; Lost to Follow-up ,Other(s), specify (repeat).	**Reason Not Completed Type** Only conditionally required	Select one for each reason not completed: Adverse Event, Death, Physician Decision, Pregnancy Withdrawal by Subject, Lack of Efficacy, Protocol Violation, Lost to Follow-up ,Other .	
R28	**Other reason** Only conditionally required	If "Other" is selected, provide label (Limit: 40 characters)	**Other Reason** Only conditionally required	If "Other" is selected, provide label (Limit: 40 characters)	
R29	**Reason not completed data**	(Per reason, per arm/group): Number of participants for each arm or comparison group.	**Reason Not Completed Data**	(Per reason, per arm/group): Number of participants for each arm or comparison group.	
Title	***Population***	*The section "Population" is optional and can be repeated.* *This data structure is necessary to create*	*N/A*	*N/A*	*This is a feature which is required by several*

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		transparency and a link between any combination of periods with any specific analysis of that population. Also, the type of population (e.g., ITT, PP) should be clearly identified to understand the analysis.			*guidelines, in particular ICH E 9, and also the EC guidance and the CONSORT statement.* *Analyses usually cover more than one period, which can be logically summarised with this data structure.* *A defined combination of periods (that is, a population) can be efficiently re-used for several analyses (e.g., sensitivity / robustness of results). This is necessary for statistical validity of results.*
R30	**Population Type (value list)**	Value list including: • Intention to treat • Per protocol • Full analysis set • Safety population • Other (Description)	N/A	N/A	
R31	**Population description**	Include definition of population type chosen	N/A	N/A	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		above			
R32	**Period(s)**	This is a continuous sequence of pre-defined periods (selected from the section "Period(s)")	N/A	N/A	
R33	**Number of participants in this population**	Integers	N/A	N/A	
R34	**Number of participants completed last selected period**	Data from R20 redisplayed	N/A	N/A	
R35	**Not completed reasons (value list, integers)**	Data from R27 redisplayed	N/A	N/A	
R36	**Number of participants not included in this population**	Integers	N/A	N/A	
R37	**Not included in this population reasons (value list, integers)**	Number by specific reason: Serious adverse event(s), not death; Adverse Event(s), not serious; Death (mandatory to report); Physician Decision, Pregnancy, Withdrawal ~~by Subject~~, not due to adverse event; Protocol Violation, specify; Lost to Follow-up ,Other(s), specify (repeat).	N/A	N/A	
Title	***Baseline Characteristics***	*A table of demographic and baseline data for the entire trial population and for each arm or comparison group. Note that only baseline measures for Age and Gender are*	***Baseline Characteristics***	*A table of demographic and baseline data for the entire trial population and for each arm or comparison group. Note that only baseline measures for Age and Gender are*	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		required; all other baseline measures are optional. The table cells accommodate different types of data: *Categorical - create customised categories and then report a count or a measure of central tendency and a measure of dispersion for each category by arm or comparison group* *Continuous - report a measure of central tendency and a measure of dispersion for each arm or comparison group* *Time-to-Event Data - report as either (1) continuous data (e.g., mean time to event with measure of dispersion) or (2) categorical data at different time points by arm or comparison group* *In addition to presenting baseline characteristics per arm/group, data can optionally be pooled for all groups ("overall") or per "population" defined.*		*required; all other baseline measures are optional. The table cells accommodate different types of data:* *Categorical - create customized categories and then report a count or a measure of central tendency and a measure of dispersion for each category by arm or comparison group* *Continuous - report a measure of central tendency and a measure of dispersion for each arm or comparison group* *Time-to-Event Data - report as either (1) continuous data (e.g., mean time to event with measure of dispersion) or (2) categorical data at different time points by arm or comparison group*	
Title	***Arm/Group***	*Arms or comparison groups in a trial* *(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section ~~– you will also need to update the protocol section, as appropriate.~~)*	***Arm/Group***	*Arms or comparison groups in a trial* *(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)*	
R38	**Arm/Group title**	Label used to identify the arm or comparison group. Minimum length is 4 characters.	**Arm/Group Title**	Label used to identify the arm or comparison group. Minimum length is 4 characters.	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Examples: fluoxetine; sertraline; drug-eluting stent; placebo (Limit: >=4 and <=62 characters)		Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Examples: fluoxetine; sertraline; drug-eluting stent; placebo (Limit: >=4 and <=62 characters)	
R39	**Arm/Group description**	Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial. Examples: fluoxetine, 20mg qhs; Sirolimus-eluting stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach. (Limit: 999 characters)	**Arm/Group Description**	Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial. Examples: fluoxetine, 20mg qhs; Sirolimus-eluting stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach. (Limit: 999 characters)	
R40	**Overall Number of Baseline Participants**	(Per arm/group): Overall number of participants for which baseline characteristics were measured for all baseline measures reported. Note that if the participant population differs for a particular baseline measure, the number of participants should be included in the Baseline Measure Description.	**Overall Number of Baseline Participants**	(Per arm/group): Overall number of participants for which baseline characteristics were measured for all baseline measures reported. Note that if the participant population differs for a particular baseline measure, the number of participants should be included in the Baseline Measure Description.	
Title	***Baseline Variable***	*Name and description of a characteristic measured at the beginning of the trial. Note that baseline measure data for "Age" (at least one of the three types) and "Gender" are required. There is no limit to the number of additional "Study-Specific Measures" that may be provided.* *All variables measured at baseline used for endpoint should be included.*	***Baseline Measure(s)***	*Name and description of a characteristic measured at the beginning of the trial. Note that baseline measure data for "Age" (at least one of the three types) and "Gender" are required. There is no limit to the number of additional "Study-Specific Measures" that may be provided.*	
R41	***Baseline* Variable title**	~~Select one.~~ Note that baseline measures for at least one "Age" and "Gender" title are required.	***Baseline Measure Title***	Select one. Note that baseline measures for at least one "Age" and "Gender" title are required.	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		• Study-Specific Measure (as many as needed) • Age (at least one of the following): Age, Continuous: example - mean age in years Age, Categorical: In Utero Preterm Newborn Infants (up to gestational age < 37 weeks) Newborns (0-27 days) Infants and toddlers (28 days - 23 months) Children (2-11 years) Adolescents (12-17 years) Less than 18 years Adults (18-64 years) Elderly (>= 65 years) Age, Customized: example - number in each category (birth-10 years, 11-20 years, 21-30 years, etc.) Gender (one of the following): Gender, female, male Gender, Customized Race ~~(NIH/OMB): U.S. National Institutes of Health and U.S. Office of Management~~		• Study-Specific Measure (as many as needed) • Age (at least one of the following): Age, Continuous: example - mean age in years Age, Categorical: <=18 years >18 and <65 years >=65 years Age, Customized: example - number in each category (birth-10 years, 11-20 years, 21-30 years, etc.) Gender (one of the following): Gender, female, male Gender, Customized Race (NIH/OMB): U.S. National Institutes of Health and U.S. Office of Management and Budget Classification Categories Race, Customized Ethnicity (NIH/OMB): U.S. National	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		~~and Budget Classification Categories~~ Race, Customized Ethnicity ~~(NIH/OMB): U.S. National Institutes of Health and U.S. Office of Management and Budget Classification Categories~~ Ethnicity, Customized Region of Enrollment		Institutes of Health and U.S. Office of Management and Budget Classification Categories Ethnicity, Customized Region of Enrollment	
R42	**Baseline variable title** Only conditionally required	~~If "Study-Specific Measure" is chosen,~~ Provide the name of the measure. Examples: Systolic blood pressure; Prior anti-depressant treatment. (Limit: 100 characters)	**Study-Specific Baseline Measure Title(s)** Only conditionally required	If "Study-Specific Measure" is chosen, provide the name of the measure. Examples: Systolic blood pressure; Prior anti-depressant treatment. (Limit: 100 characters)	
R43	**Baseline variable description**	Additional information about the measure, such as details about the collection method or participant population, if different from Overall Number of Baseline Participants. (Limit: 600 characters)	**Baseline Measure Description**	Additional information about the measure, such as details about the collection method or participant population, if different from Overall Number of Baseline Participants. (Limit: 600 characters)	
R44	**Baseline variable type**	Select one : Number (e.g., number of participants) Measure of Central Tendency, if a continuous measure is reported :Mean ,Median, Least Squares Mean, Geometric Mean , Log Mean	**Measure Type**	Select one : Number (e.g., number of participants) Measure of Central Tendency, if a continuous measure is reported :Mean ,Median, Least Squares Mean, Geometric Mean , Log Mean	
R45	**Measure of dispersion**	Select one. Please select "Not Applicable" if the Measure Type is "Number". Please do	**Measure of Dispersion**	Select one. Please select "Not Applicable" if the Measure Type is "Number". Please do	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		NOT select "Not Applicable" for other measure types. Not Applicable ,Standard Deviation ,Inter-Quartile Range ,Full Range		NOT select "Not Applicable" for other measure types. Not Applicable ,Standard Deviation ,Inter-Quartile Range ,Full Range	
R46	**Variable unit**	e.g., participants, mm Hg (Limit: 40 characters)	**Unit of Measure**	e.g., participants, mm Hg (Limit: 40 characters)	
R47	**Category title**	(required for categorical data) Name of distinct category for a baseline measure, if reporting categorical data. (Limit: 50 characters)	**Category Title**	(required for categorical data) Name of distinct category for a baseline measure, if reporting categorical data. (Limit: 50 characters)	
R48	**Other variable result data**	(per baseline measure and per arm/group) Baseline measure data (either "Number" or "Descriptive Statistics"). Either Number or Descriptive Statistics	**Baseline Measure Data**	(per baseline measure and per arm/group) Baseline measure data (either "Number" or "Descriptive Statistics"). Either Number or Descriptive Statistics	
Title	***Results***	*A table of values for each of the outcome measures by arm (i.e., initial assignment of groups to interventions) or comparison group (i.e., groups receiving interventions regardless of initial assignment).* *Arms/groups can be different from arms/groups defined in participant flow.* *Additional columns (arms/groups) e.g. to present data of pooled treatment groups are possible.* *The table cells accommodate different types of data:* *Categorical - create customised categories and then report a count or a measure of central tendency and a measure of dispersion for each category by arm or comparison group* *Continuous - report a measure of central tendency and a measure of dispersion for*	***Outcome Measures***	*A table of values for each of the outcome measures by arm (i.e., initial assignment of groups to interventions) or comparison group (i.e., groups receiving interventions regardless of initial assignment).* *The table cells accommodate different types of data:* *Categorical - create customized categories and then report a count or a measure of central tendency and a measure of dispersion for each category by arm or comparison group* *Continuous - report a measure of central tendency and a measure of dispersion for*	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		each arm or comparison group *Time-to-Event Data - report as either (1) continuous data (e.g., mean time to event with measure of dispersion) or (2) categorical data at different time points by arm or comparison group* *Note that data reported for each outcome measure will be displayed as a separate table. All statistical analyses on those data will be associated with that table.*		*each arm or comparison group* *Time-to-Event Data - report as either (1) continuous data (e.g., mean time to event with measure of dispersion) or (2) categorical data at different time points by arm or comparison group* *Note that data reported for each outcome measure will be displayed as a separate table. All statistical analyses on those data will be associated with that table.*	
Title	***Arm/Group***	*Arms or comparison groups in a trial* *(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)*	***Arm/Group***	*Arms or comparison groups in a trial* *(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)*	
R49	**Arm/Group title**	Label used to identify the arm or comparison group. Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Examples: fluoxetine; sertraline; drug-eluting stent; placebo (Limit: >=4 and <=62 characters)	**Arm/Group Title**	Label used to identify the arm or comparison group. Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Examples: fluoxetine; sertraline; drug-eluting stent; placebo (Limit: >=4 and <=62 characters)	
R50	**Arm/Group description**	Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial. Examples: fluoxetine, 20mg qhs; Sirolimus-eluting	**Arm/Group Description**	Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial. Examples: fluoxetine, 20mg qhs; Sirolimus-eluting	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach. (Limit: 999 characters)		stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach. (Limit: 999 characters)	
R51	**Number of participants analysed**	(per outcome measure, per arm/group) For the outcome reported Can be associated with the participant flow table of selected arm(s)/group(s) and period(s) or with "population"	**Number of Participants Analyzed**	(per outcome measure, per arm/group) For the outcome reported	
R52	**Population type (value list)?**	In addition to "Population description" EudraCT provides a value list for "population type" (e.g. intention to treat, per protocol, full analysis set, safety population) One of the populations defined in "Populations" can be selected (optional). Otherwise it can be specified with "Population definition", "Population description".	N/A	N/A	
R53	**Population description**	Explanation of how the number of participants for analysis was determined. Indicate whether the analysis was "per protocol", "intention to treat (ITT)", or another method. Also provide relevant details such as imputation technique (e.g., Last Observational Carried Forward [LOCF]), as appropriate. (Limit: 350 characters)	**Analysis Population Description**	Explanation of how the number of participants for analysis was determined. Indicate whether the analysis was "per protocol", "intention to treat (ITT)", or another method. Also provide relevant details such as imputation technique (e.g., Last Observational Carried Forward [LOCF]), as appropriate. (Limit: 350 characters)	
Title	***Variable***	*Name and description of the measure used to assess the effect of experimental variables in the trial. (Note that primary and secondary endpoint information from the protocol section of the record will be copied into the results section the first time results are created. After that, "Variable type,"*	***Outcome Measure***	*Name and description of the measure used to assess the effect of experimental variables in the trial. (Note that primary and secondary outcome measure information from the protocol section of the record will be copied into the results section the first time results are created. After that, "Outcome Measure*	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		"Variable title," "Variable time frame" and "Variable safety issue? (Y/N)" for primary or secondary endpoints may only be changed in the results section.)		*Type," "Outcome Measure Title," "Outcome Measure Time Frame" and "Outcome Measure Safety Issue? (Y/N)" for primary or secondary outcome measures may only be changed in the results section.)*	
R54	**Variable type**	Select one : Primary endpoint (from Protocol section) ,Secondary endpoint (from Protocol section) ,Other Pre-specified endpoint, Post-Hoc endpoint	**Outcome Measure Type**	Select one : Primary Outcome Measure (from Protocol section) ,Secondary Outcome Measure (from Protocol section) ,Other Pre-specified Outcome Measure, Post-Hoc Outcome Measure	
R55	N/A	N/A	**Outcome Measure Reporting Status**	Indicate whether posting results data for this outcome measure. Note that each record is required to have "Posted" data for at least one outcome measure. Posted: Results data included ; Not Posted: Results data not included	
R56	N/A	N/A	**Anticipated Posting Date**	If "Outcome Measure Reporting Status" is "Not Posted", then indicate the expected month and year it will be "Posted."	
R57	**Variable title**	Name of variable	**Outcome Measure Title**	Name of outcome measure	
R58	**Time frame**	Time point(s) at which variable was assessed. (Limit: 255 characters)	**Outcome Measure Time Frame**	Time point(s) at which outcome measure was assessed. (Limit: 255 characters)	
R59	**Measurement description**	Additional information about variable. (Limit: 600 characters)	**Outcome Measure Description**	Additional information about outcome measure. (Limit: 600 characters)	
R60	**Safety variable? (Y/N)**	Is this variable assessing a safety issue? (e.g. evaluation of laboratory parameters, vital signs) Select: Yes/No	**Outcome Measure Safety Issue? (Y/N)**	Is this outcome measure assessing a safety issue? Select: Yes/No	
R61	**Efficacy variable? (Y/N)**	Is this variable assessing efficacy? Select: Yes/No	N/A	N/A	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
R62	**If safety variable and clinical laboratory evaluation: Criterion**	If you are entering clinical laboratory evaluation provide criterion (e.g. threshold value). Otherwise leave blank.	N/A	N/A	This is required in EudraCT in line with ICH E3.
R63	**If safety variable and vital sign: Baseline value and value type**	If you are entering vital sign assessments provide baseline value and select value type from list. Otherwise leave blank.	N/A	N/A	This is required in EudraCT in line with ICH E3.
R64	**Result type**	Select one: Number (e.g., number of participants), Measure of Central Tendency, if a continuous measure is reported, Mean, Median, Least Squares Mean, Geometric Mean, Log Mean Measure of Dispersion: Select one. Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other Measure Types : Not Applicable; Standard Deviation; Inter-Quartile Range; Full Range; Standard Error; 95% Confidence Interval; 90% Confidence Interval	**Measure Type**	Select one: Number (e.g., number of participants), Measure of Central Tendency, if a continuous measure is reported, Mean, Median, Least Squares Mean, Geometric Mean, Log Mean Measure of Dispersion: Select one. Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other Measure Types : Not Applicable; Standard Deviation; Inter-Quartile Range; Full Range; Standard Error; 95% Confidence Interval; 90% Confidence Interval	
R65	**Result unit**	e.g., participants, mm Hg (Limit: 40 characters)	**Unit of Measure**	e.g., participants, mm Hg (Limit: 40 characters)	
R66	**Category Title**	(required for categorical data, as many as needed) Name of distinct category used to measure outcome, if reporting categorical data. (Limit: 50 characters)	**Category Title**	(required for categorical data, as many as needed) Name of distinct category used to measure outcome, if reporting categorical data. (Limit: 50 characters)	
R67	**Result data**	(per category, per arm/group) Outcome measure summary data (either "Number" or "Descriptive Statistics"). "Result type/unit/data" can be repeated within "variable". Figures for the same	**Outcome Data**	(per category, per arm/group) Outcome measure summary data (either "Number" or "Descriptive Statistics").	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		variable should be presentable in different ways of summaries, such as by means with standard deviation and by number of responding patients.			
R68	**Graph/Chart**	Supplementary data (figures) can be submitted in order for the system to generate graphic result representation (e.g diagrams, charts).	N/A	N/A	This graphic representation will be linked to relevant tables. Concise graphical representations of results can convey additional outcome information. For example, plots of continuous time-related events add to analyses for specific time points.
Title	***Statistical analyses*** *Only conditionally required*	*One or more statistical analyses conducted on the outcome data.* *If a statistical analysis is reported, the following data elements are required: "Comparison Group Selection," "Non-inferiority or Equivalence Analysis," and at least "P-Value" or "Confidence Interval" with the associated information.*	***Statistical Analyses*** *Only conditionally required*	*One or more statistical analyses conducted on the outcome data.* *If a statistical analysis is reported, the following data elements are required: "Comparison Group Selection," "Non-inferiority or Equivalence Analysis," and at least "P-Value" or "Confidence Interval" with the associated information.*	
R69	**Statistical analysis title**	Summary description of the analysis performed	**Statistical Analysis Overview**	Summary description of the analysis performed	
R70	**Comparison group selection** Only conditionally required	Identifies the arms or comparison groups involved in the statistical analysis (check all to indicate an "omnibus" analysis) Can be associated with arms/groups as in ClinicalTrials.gov but additionally also with periods or with “populations” that were	**Comparison Group Selection** Only conditionally required	Identifies the arms or comparison groups involved in the statistical analysis (check all to indicate an "omnibus" analysis)	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		defined.			
R71	**Number of participants in comparison group**	Can be calculated automatically by the system.	N/A	N/A	
R72	**Comments**	Additional details about the statistical analysis, such as null hypothesis and description of power calculation (Limit: 500 characters)	**Comments**	Additional details about the statistical analysis, such as null hypothesis and description of power calculation (Limit: 500 characters)	
R73	**Analysis type: Non-inferiority or Equivalence Analysis? (Y/N)** Only conditionally required	Identifies whether the analysis is a test of non-inferiority or equivalence (Choose "Yes") or superiority (Choose "No").	**Non-inferiority or Equivalence Analysis? (Y/N)** Only conditionally required	Identifies whether the analysis is a test of non-inferiority or equivalence (Choose "Yes") or superiority (Choose "No").	
R74	**Comments**	If, "Yes", provide additional details, including details of the power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters (Limit: 500 characters)	**Comments**	If, "Yes", provide additional details, including details of the power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters (Limit: 500 characters)	
R75	**Analysis scope**	EudraCT provides a value list including pre-specified in protocol, sensitivity analysis, post hoc, explanatory.	N/A	N/A	
Title	***Analysis method***	*Procedure used for statistical analysis of outcome data and calculated p-value.*	***Statistical Test of Hypothesis***	*Procedure used for statistical analysis of outcome data and calculated p-value.*	
R76	**P-value** Only conditionally required	(if applicable): Calculated p-value given the null-hypothesis	**P-Value** Only conditionally required	(if applicable): Calculated p-value given the null-hypothesis	
R77	**Comments**	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance (Limit: 250 characters)	**Comments**	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance (Limit: 250 characters)	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
R78	**Analysis method** Only conditionally required	(required if "P-Value" is reported): Select a statistical test: ANCOVA, ANOVA, Chi-squared, Chi-squared, Corrected, Cochran-Mantel-Haenszel, Fisher Exact, Kruskal-Wallis, Log Rank, Mantel Haenszel, McNemar, Mixed Models Analysis, Regression, Cox, Regression, Linear, Regression, Logistic, Sign Test, t-Test, 1-sided , t-Test, 2-sided, Wilcoxon (Mann-Whitney) , Other	**Method** Only conditionally required	(required if "P-Value" is reported): Select a statistical test: ANCOVA, ANOVA, Chi-squared, Chi-squared, Corrected, Cochran-Mantel-Haenszel, Fisher Exact, Kruskal-Wallis, Log Rank, Mantel Haenszel, McNemar, Mixed Models Analysis, Regression, Cox, Regression, Linear, Regression, Logistic, Sign Test, t-Test, 1-sided , t-Test, 2-sided, Wilcoxon (Mann-Whitney) , Other	
R79	**Other method name** Only conditionally required	If "Other" is selected, provide name of statistical test. (Limit: 40 characters)	**Other Method Name** Only conditionally required	If "Other" is selected, provide name of statistical test. (Limit: 40 characters)	
R80	**Comments**	Any other relevant information, such as adjustments or degrees of freedom (Limit: 150 characters)	**Comments**	Any other relevant information, such as adjustments or degrees of freedom (Limit: 150 characters)	
Title	***Method of estimation***	*Procedure used to estimate effect of intervention.*	***Method of Estimation***	*Procedure used to estimate effect of intervention.*	
R81	**Confidence interval** Only conditionally required	(if applicable, provide the following sub-elements):	**Confidence Interval** Only conditionally required	(if applicable, provide the following sub-elements):	
R82	**Level** Only conditionally required	Expressed as a percentage. (Default "95").	**Level** Only conditionally required	Expressed as a percentage. (Default "95").	
R83	**Number of sides**	Select 1-sided or 2-sided (default).	**Number of Sides**	Select 1-sided or 2-sided (default).	
R84	**Lower limit** Only conditionally required	(required if confidence interval is 2-sided or if confidence interval is 1-sided and no Upper Limit is entered.)	**Lower Limit** Only conditionally required	(required if confidence interval is 2-sided or if confidence interval is 1-sided and no Upper Limit is entered.)	
R85	**Upper limit** Only conditionally required	(required if confidence interval is 2-sided or if confidence interval is 1-sided and no Lower Limit is entered.)	**Upper Limit** Only conditionally required	(required if confidence interval is 2-sided or if confidence interval is 1-sided and no Lower Limit is entered.)	
R86	**Estimated value** Only conditionally required	(if provided, Estimation Parameter required)	**Estimated Value** Only conditionally required	(if provided, Estimation Parameter required)	
R87	**Effect estimate**	Select one:	**Estimation Parameter**	Select one:	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
	Only conditionally required	Cox Proportional Hazard, Hazard Ratio (HR) ,Hazard Ratio, log, Mean Difference (Final Values), Mean Difference (Net), Median Difference (Final Values) Median Difference (Net), Odds Ratio (OR), Odds Ratio, log, Risk Difference (RD) Risk Ratio (RR) ,Risk Ratio, log, Slope, Other	Only conditionally required	Cox Proportional Hazard, Hazard Ratio (HR) ,Hazard Ratio, log, Mean Difference (Final Values), Mean Difference (Net), Median Difference (Final Values) Median Difference (Net), Odds Ratio (OR), Odds Ratio, log, Risk Difference (RD) Risk Ratio (RR) ,Risk Ratio, log, Slope, Other	
R88	**Other parameter name** Only conditionally required	If "Other" is selected, provide name (Limit: 40 characters)	**Other Parameter Name** Only conditionally required	If "Other" is selected, provide name (Limit: 40 characters)	
R89	**Estimate variability**	Parameter Dispersion Type : Select one: Standard Deviation, Standard Error of the Mean Dispersion Value	**Dispersion of Confidence Interval**	Parameter Dispersion Type : Select one: Standard Deviation, Standard Error of the Mean Dispersion Value	
R90	**Estimate comments**	Any other relevant estimation information, including the direction of the comparison (e.g., describe which arm or comparison group represents the numerator and denominator for relative risk) (Limit 250 characters)	**Estimation Comments**	Any other relevant estimation information, including the direction of the comparison (e.g., describe which arm or comparison group represents the numerator and denominator for relative risk) (Limit 250 characters)	
R91	**Overall Limitations and Caveats**	If appropriate, describe significant limitations of the trial. Examples: Early termination leading to small number of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data. (Limit 250 characters)	**Overall Limitations and Caveats**	If appropriate, describe significant limitations of the trial. Examples: Early termination leading to small number of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data. (Limit 250 characters)	
Title	***Events table***	*Two* types *of adverse event data are to be reported* *1) Serious Adverse Events: A table of all anticipated and unanticipated serious adverse events, grouped by organ system, with number and frequency of such events in each arm of the clinical trial. (See Adverse*	***Adverse Events***	*Two types of adverse event data are to be reported* *1) Serious Adverse Events: A table of all anticipated and unanticipated serious adverse events, grouped by organ system, with number and frequency of such events in each arm of the clinical trial. (See Adverse*	*The opportunity to add further adverse events tables is necessary to provide options as mentioned in ICH E3, Chapter 12.*

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		Events definition below). *2) Other (Not Including Serious) Adverse Events: A table of anticipated and unanticipated events (not included in the serious adverse event table) that exceed a frequency threshold within any arm of the clinical trial, grouped by organ system, with number and frequency of such events in each arm of the clinical trial. EudraCT allows for additional, separate adverse events tables which can be defined by the data provider (e.g. AEs without frequency threshold, TEAE (treatment emergent adverse events), other significant adverse events. The events tables can be presented by arm AND period.*		*Events definition below).* *2) Other (Not Including Serious) Adverse Events: A table of anticipated and unanticipated events (not included in the serious adverse event table) that exceed a frequency threshold within any arm of the clinical trial, grouped by organ system, with number and frequency of such events in each arm of the clinical trial.*	
Title	***Arm/Group***	*Arms or comparison groups in a trial* *(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)*	***Arm/Group***	*Arms or comparison groups in a trial* *(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)*	
R92	**Arm/Group title**	Label used to identify the arm or comparison group. Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Examples: fluoxetine; sertraline; drug-eluting stent; placebo (Limit: >=4 and <=62 characters)	**Arm/Group Title**	Label used to identify the arm or comparison group. Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Examples: fluoxetine; sertraline; drug-eluting stent; placebo (Limit: >=4 and <=62 characters)	
R93	**Arm/Group**	Brief description of the arm or comparison	**Arm/Group Description**	Brief description of the arm or comparison	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
	description	group to distinguish it from other arms/groups in the trial. Examples: fluoxetine, 20mg qhs; Sirolimus-eluting stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach. (Limit: 999 characters)		group to distinguish it from other arms/groups in the trial. Examples: fluoxetine, 20mg qhs; Sirolimus-eluting stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach. (Limit: 999 characters)	
R94	**Time frame for adverse event reporting**	Period in which the reported adverse event data were collected (e.g., 1 year, 6 months) (Limit: 255 characters)	**Time Frame for Adverse Event Reporting**	Period in which the reported adverse event data were collected (e.g., 1 year, 6 months) (Limit: 255 characters)	
R95	**Adverse event reporting additional description**	Additional relevant information about adverse event collection, including details about the method of systematic assessment (e.g., daily questionnaire) (Limit: 350 characters)	**Adverse Event Reporting Additional Description**	Additional relevant information about adverse event collection, including details about the method of systematic assessment (e.g., daily questionnaire) (Limit: 350 characters)	
R96	**Dictionary used**	Default value for Source Vocabulary Name to be applied to all adverse event terms ~~entered in the "Serious" and "Other" adverse event tables~~, unless otherwise specified (e.g., SNOMED CT, MedDRA 10.0). (Limit: 20 characters)	**Source Vocabulary Name for Table Default**	Default value for Source Vocabulary Name to be applied to all adverse event terms entered in the "Serious" and "Other" adverse event tables, unless otherwise specified (e.g., SNOMED CT, MedDRA 10.0). (Limit: 20 characters)	
R97	**Method**	Default value for Adverse Event Assessment Type (Systematic or Non-Systematic Assessment Type) to be applied to all adverse event terms entered in the "Serious" or "Other" adverse event tables, ~~unless otherwise specified~~.	**Assessment Type for Table Default**	Default value for Adverse Event Assessment Type (Systematic or Non-Systematic Assessment Type) to be applied to all adverse event terms entered in the "Serious" or "Other" adverse event tables, unless otherwise specified.	
R98	**Definition of this table**	Value list including e.g. SAE, AE, TEAE (treatment emergent adverse event), TESS (treatment emergent signs and symptoms), other	N/A	N/A	
Title	***Events***	*Unfavorable changes in health, including abnormal laboratory findings, that occur in*	***Adverse Events***	*Unfavorable changes in health, including abnormal laboratory findings, that occur in*	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		trial participants during the clinical trial or within a specified period following the trial. Two types of adverse event data are to be reported: "Serious" and "Other (Not Including Serious)" adverse events.		*trial participants during the clinical trial or within a specified period following the trial. Two types of adverse event data are to be reported: "Serious" and "Other (Not Including Serious)" adverse events.*	
R99	**Event term**	Word or phrase describing an adverse event. (Limit: 100 characters) Is to be chosen from dictionary.	**Adverse Event Term**	Word or phrase describing an adverse event. (Limit: 100 characters)	
R100	**Term level**	Is to be chosen from dictionary.	N/A	N/A	
R101	N/A	N/A EudraCT does not ask for the Source Vocabulary Name again for each event term but only once per event table.	**Source Vocabulary Name**	Standard terminology, controlled vocabulary, or classification and version from which adverse event terms are drawn, if any (e.g., SNOMED CT, MedDRA 10.0). Leave blank to indicate that the value specified as the Source Vocabulary for Table Default should be used. (Limit: 20 characters)	
R102	**Organ system**	High-level categories used to group adverse event terms by body or organ system. Select one. Adverse events that affect multiple systems should be classified as "General disorders.": • Blood and lymphatic system disorders • Cardiac disorders • Congenital, familial and genetic disorders • Ear and labyrinth disorders • Endocrine disorders • Eye disorders • Gastrointestinal disorders • General disorders	**Organ System**	High-level categories used to group adverse event terms by body or organ system. Select one. Adverse events that affect multiple systems should be classified as "General disorders.": • Blood and lymphatic system disorders • Cardiac disorders • Congenital, familial and genetic disorders • Ear and labyrinth disorders • Endocrine disorders • Eye disorders • Gastrointestinal disorders • General disorders	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
		• Hepatobiliary disorders • Immune system disorders • Infections and infestations • Injury, poisoning and procedural complications • Investigations • Metabolism and nutrition disorders • Musculoskeletal and connective tissue disorders • Neoplasms benign, malignant and unspecified (including cysts and polyps) • Nervous system disorders • Pregnancy, puerperium and perinatal conditions • Psychiatric disorders • Renal and urinary disorders • Reproductive system and breast disorders • Respiratory, thoracic and mediastinal disorders • Skin and subcutaneous tissue disorders • Social circumstances • Surgical and medical procedures • Vascular disorders		• Hepatobiliary disorders • Immune system disorders • Infections and infestations • Injury, poisoning and procedural complications • Investigations • Metabolism and nutrition disorders • Musculoskeletal and connective tissue disorders • Neoplasms benign, malignant and unspecified (including cysts and polyps) • Nervous system disorders • Pregnancy, puerperium and perinatal conditions • Psychiatric disorders • Renal and urinary disorders • Reproductive system and breast disorders • Respiratory, thoracic and mediastinal disorders • Skin and subcutaneous tissue disorders • Social circumstances • Surgical and medical procedures • Vascular disorders	
R103	N/A	N/A EudraCT does not ask for the Assessment Type again for each event term but only once per event table.	**Assessment Type**	Method used to assess the adverse event. Select one or leave blank to indicate that the value specified as the Assessment Type for Table Default should be used. - Systematic Assessment	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
				- Non-systematic Assessment	
R104	**Event term additional description**	Additional relevant information about the adverse event, including any deviation from the Time Frame for Adverse Event Reporting. (Limit: 250 characters)	**Adverse Event Term Additional Description**	Additional relevant information about the adverse event, including any deviation from the Time Frame for Adverse Event Reporting. (Limit: 250 characters)	
R105	**Total number affected by any serious adverse event**	(Per arm/group): Overall number of participants affected by one or more Serious Adverse Events.	**Total Number Affected by Any Serious Adverse Event**	(Per arm/group): Overall number of participants affected by one or more Serious Adverse Events.	
R106	**Number at risk for serious adverse events**	(or Number of Participants at Risk for each Serious Adverse Event Term required) (per arm/group) : Overall number of participants included in the assessment of serious adverse events during the trial (i.e., the denominator for calculating frequency of serious adverse events)	**Total Number of Participants at Risk for Serious Adverse Event**	(or Number of Participants at Risk for each Serious Adverse Event Term required) (per arm/group) : Overall number of participants included in the assessment of serious adverse events during the trial (i.e., the denominator for calculating frequency of serious adverse events)	
R107	**Frequency threshold for reporting other (not including serious) adverse event**	The frequency of Other (Not Including Serious) Adverse Events that, when exceeded within any arm or comparison group, are reported in the results database for all arms or comparison groups. The number must be less than or equal to the allowed maximum (5%), and must not include any symbols (e.g., >= , %). Expressed as a percentage. For example, a threshold of 5 percent indicates that all Other (Not Including Serious) Adverse Events with a frequency greater than 5 percent within at least one arm or comparison group are reported.	**Frequency Threshold for Reporting Other (Not Including Serious) Adverse Event**	The frequency of Other (Not Including Serious) Adverse Events that, when exceeded within any arm or comparison group, are reported in the results database for all arms or comparison groups. The number must be less than or equal to the allowed maximum (5%), and must not include any symbols (e.g., >= , %). Expressed as a percentage. For example, a threshold of 5 percent indicates that all Other (Not Including Serious) Adverse Events with a frequency greater than 5 percent within at least one arm or comparison group are reported.	
R108	**Total Number Affected by any Other (Not**	(per arm/group): Overall number of participants affected by one or more Other (Not Including Serious) Adverse Events	**Total Number Affected by any Other (Not**	(per arm/group): Overall number of participants affected by one or more Other (Not Including Serious) Adverse Events	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
	Including Serious) Adverse Event above the Frequency Threshold	above the specified Frequency Threshold (e.g., 5%) reported in the table.	**Including Serious) Adverse Event above the Frequency Threshold**	above the specified Frequency Threshold (e.g., 5%) reported in the table.	
R109	**Total Number of Participants at Risk for Other (Not Including Serious) Adverse Event**	(or Number of Participants at Risk for each Other, *Not Including Serious*, Adverse Event Term required) (per arm/group) : Overall number of participants included in the assessment of other, *not including serious*, adverse events during the trial (i.e., the denominator for calculating frequency of other, *not including serious*, adverse events).	**Total Number of Participants at Risk for Other (Not Including Serious) Adverse Event**	(or Number of Participants at Risk for each Other, *Not Including Serious*, Adverse Event Term required) (per arm/group) : Overall number of participants included in the assessment of other, *not including serious*, adverse events during the trial (i.e., the denominator for calculating frequency of other, *not including serious*, adverse events).	
Title	***Event data***	*(per adverse event, per arm/group)*	***Adverse Event Data***	*(per adverse event, per arm/group)*	
R110	**Number of Affected Participants**	Number of participants experiencing at least one event being reported	**Number of Affected Participants**	Number of participants experiencing at least one event being reported	
R111	**Number**	Number of occurrences of the adverse event being reported	**Number of Events**	Number of occurrences of the adverse event being reported	
R112	**Event severity**	Value list including mild, moderate, severe, other classification (specify)	N/A	N/A	
R113	**Number of participants at risk**	Number of participants assessed for adverse events during the trial (i.e., the denominator for calculating frequency of adverse events). Leave blank to indicate that the value specified as the total at risk in the arm/group for the table should be used. Note, when the number at risk in the arm/group is blank, the total at risk in the arm/group for the table must be entered.	**Number of Participants at Risk**	Number of participants assessed for adverse events during the trial (i.e., the denominator for calculating frequency of adverse events). Leave blank to indicate that the value specified as the total at risk in the arm/group for the table should be used. Note, when the number at risk in the arm/group is blank, the total at risk in the arm/group for the table must be entered.	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
R114	**Number of deaths (all causes)**	Per arm/group	N/A	N/A	This is a separate table.
R115	**Competent authority: discussion and interpretation if a link to a public part of the assessment report is not available**	**To allow for comment to be included if considered necessary.**	N/A	N/A	
R116	**Date of this results submission (date)**	The date should be automatically displayed	**Last Updated**	Assigned by the Protocol Registration System (PRS) when the record is "released" by the data provider)	
R117	**Date of first results submission (date)**	The date should be automatically displayed	**Results First Received**	Assigned by the Protocol Registration System (PRS) when the results are first "released" by the data provider)	
R118	N/A	N/A	**Delayed Results Posting** OPTIONAL: If delayed results posting information is provided, then all marked data elements are required, except as noted below.	Information to be provided when (1) delaying submission of results with certification or (2) requesting an extension of the deadline for submitting results in accordance with U.S. Public Law 110-85, Title VIII, Section 801. *The information provided may be displayed publicly as part of the protocol record.*	
R119	N/A	N/A	**Delay Results Type**	Select one : 1) Results Not Required - not subject to US Public Law 110-85, Title VIII, Section 801 (FDAAA), 2) Certify Initial Approval - seeking initial FDA approval of a drug, biological product, or device, 3) Certify New Use - seeking FDA approval of a new use for the drug or device, 4)	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
				Extension - requesting an extension of the deadline for the submission of results	
R120	N/A	N/A	**Intervention Name(s)**	Required when Delay Results Type is "Certify Initial Approval" or "Certify New Use." Provide the name of one or more drugs, biological products, or devices for which approval ("initial" or "new use") is being sought. For drugs use generic name; for other types of interventions provide a brief descriptive name. The name(s) entered should match Intervention Name(s) provided in the protocol record.	
R121	N/A	N/A	**FDA Application Number(s)**:	Provide at least one FDA application number (e.g., NDA, BLA, or PMA number), if available, when Delay Results Type is "Certify Initial Approval" or "Certify New Use."	
R122	N/A	N/A	**Requested Submission Date**	Required when Delay Results Type is "Extension." Provide the month and year when results are to be submitted.	
R123	N/A	N/A	**Explanation**	Required when Delay Results Type is "Extension." Provide a detailed justification for the extension. The justification must contain sufficient information to allow for evaluation of the request. Note that "pending publication" is not considered "good cause" for an extension. Reminder: The explanation may be made public on ClinicalTrials.gov as part of the	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
				protocol record. (Limit: 600 characters)	
Title	***Trial interruption***		N/A	N/A	Information on trial interruption may be represented as successive historical version of (protocol) data sets in ClinicalTrials.gov (suspended or terminated recruiting status and Why Study Stopped?). However, this represents important information, e.g., safety or accrual issues so that the results data can be put in perspective.
R124	**Was the trial ever interrupted, in any country?**	(Y/N)	N/A	N/A	
R125	**Interruption start (date)**	Can be repeated	N/A	N/A	
R126	**Restart of trial (date)**	Can be repeated	N/A	N/A	
R127	**Details and reasons for interruption and**	Can be repeated	N/A	N/A	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
	restart				
Title	***Amendments***		*N/A*	*N/A*	Information on amendments may be represented as successive historical versions of (protocol) data sets in ClinicalTrials.gov. However, there is no specific provision for explaining the relevant protocol changes, which should therefore be added so that the result data can be put in perspective, particularly when changes concerned the design and analysis plan.
R128	**Was there any protocol amendment after recruitment started with any relevance to the results, e.g., change of inclusion criteria, dose, size, analysis plan?**	(Y/N)	N/A	N/A	

Annex 1 Section B **EudraCT**			**ClinicalTrials.gov**		
	Field name	*Description*	*Field name*	*Description*	*Comments*
R129	**Date (date)**	Can be repeated	N/A	N/A	
R130	**Details**	Can be repeated	N/A	N/A	