EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information and Communications Technology

EudraCT v8 Tool Tips Information for Internet Explorer (IE) version 6 Users

This document is intended to replace field level tool tips for those users who access EudraCT v8 using Internet Explorer 6 (IE6).

- The tool tip implementation at field level does not function as designed when using IE6. Other browsers function as designed.
- Users are advised to use the Help system, available under the Help button at the top of every page in the EudraCT application, for context sensitive help.

CTA Form Field Number	Field Name	Tool Tip Description
A.1		Enter the name of the Member State (MS) concerned by the Application.
A.1	National Competent Authority	Select the concerned regulatory authority in the Member State.
A.2	EudraCT number	Obtained by the applicant through the EudraCT public web site, this number should be the same as the one mentioned on the receipt of confirmation of EudraCT number. See Create a EudraCT Number in the EudraCT Help.
A.3	Full title of the trial	Click in the free text field and enter the full title of the clinical trial (up to 2000 characters). The title should be identical to the one specified in the study protocol and other documents submitted as part of the Clinical Trial Application dossier. **Substantial Amendment Note:** If this is an electronic submission of a substantial amendment, 'A.3 Full title of the trial' (in the revised CTA form) and 'B.3 Full title of the trial' (in the Substantial Amendment Notification Form) should both include the proposed new 'Full title of the trial'.
A.3.1	Title of the trial for lay people, in easily understood, i.e. non-technical, language	Click in the free text field and enter the title of the clinical trial in non-technical terms, suitable for comprehension by individuals without medical/pharmaceutical training (up to 2000 characters). **Substantial Amendment Note:** If this is an electronic submission of a substantial amendment, 'A.3.1 Title of the trial for lay people, in easily understood, i.e. non-technical, language' (in the *revised* CTA form) should contain the updated title of the trial for lay people.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 +44 (0)20 7418 8669
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

CTA Form Field Number	Field Name	Tool Tip Description
A.3.2	Name or abbreviated title of the trial where available	Click in the free text field and enter a shortened title of the clinical trial, if one is available (up to 100 characters). This abbreviated title should be identical to the one mentioned in the protocol.
A.4.1	Sponsor's protocol code number	Click in the free text field and enter the sponsor protocol number, which is assigned by the sponsor (up to 35 characters). This should be identical to the protocol number provided when the EudraCT number was obtained and which appears on the receipt of confirmation of the EudraCT number and should remain unchanged throughout the study. The protocol number should not contain any date or blanks and should remain identical throughout the duration of the clinical trial. **Substantial Amendment Note:** If this is an electronic submission of a substantial amendment, 'A.4.1 Sponsor's protocol code number' (in the *revised* CTA form) should contain the updated Sponsor's protocol code number. This information should also be included in 'E.1 Sponsor's substantial amendment code number, version, date for the clinical trial concerned' (in the Substantial Amendment Notification Form).
A.4.2	Sponsor's protocol version	Click in the free text field and enter the sponsor protocol version is assigned by the sponsor (up to 10 characters). This should be identical to that appearing in the protocol, though may change according to any updates and amendments to the final protocol. If none is available, please leave blank. **Substantial Amendment Note:** If this is an electronic submission of a substantial amendment, 'A.4.2 Sponsor's protocol version' (in the *revised* CTA form) should contain the updated Sponsor's protocol version. This information should also be included in 'E.1 Sponsor's substantial amendment code number, version, date for the clinical trial concerned' (in the Substantial Amendment Notification Form).
A.4.3	Sponsor's protocol date	Click the calendar to select the date of the protocol in the following format: YYYY-MM-DD. The sponsor protocol date is assigned by the sponsor and should be identical to that appearing in the protocol. Any translation of the protocol should be assigned the same date as in the original document. This date may change according to any updates and amendments to the final protocol. However, the date included in this form should always be the date of the protocol which received the initial authorisation. (reference: footnote 3 on page 16 of the Commission Guidance on CT dossier for competent authorities published 30th March 2010). **Substantial Amendment Note:** If this is an electronic submission of a substantial amendment, 'A.4.3 Sponsor's protocol date' (in the *revised* CTA form) should contain the updated Sponsor's protocol date. This information should also be included in 'E.1 Sponsor's substantial amendment code number, version, date for the clinical trial concerned' (in the Substantial Amendment Notification Form).
A.5.1	ISRCTN number	If the trial is registered on the "Current Controlled Trials" web site (http://www.controlled-trials.com/isrctn/), please type the International Standard Randomised Controlled Trial Number here.
A.5.2	US NCT number	If the trial is registered on 'ClinicalTrials.gov', please type the ClinicalTrials.gov identifier (NCT number) here. http://www.clinicaltrials.gov
A.5.3	WHO Universal Trial Reference Number (UTRN)	If the trial is registered on the WHO Clinical Trials Portal, please type here the WHO International Clinical Trials Registry Platform's (ICTRP) registry number (http://www.who.int/ictrp/unambiguous_identification/utn/en/) where available.

CTA Form Field Number	Field Name	Tool Tip Description
A.5.4	Other Identifier - Name	If other identifiers are available click in the left hand field and enter the name of the identifier, then enter the identification number for this trial in the right hand field.
A.5.4	Other Identifier - Identifier	Click in the free text field and enter the additional identification number of this trial.
A.6	Is this a resubmission?	Select 'Yes' for any resubmission after the initial application has been withdrawn by the applicant or refused by the competent authority and 'No' for initial application. If this is simply an update of the CTA form prior to the final decision on the clinical trial by the competent authority or Ethics Committee the submission number should not be modified. If the application received a negative opinion from the Ethics Committee (or was withdrawn by the applicant from the Ethics Committee) and this is a resubmission to the Ethics Committee then select Yes when completing this form for the Ethics Committee.
A.6	Indicate the resubmission letter or else select 'First submission'	Click the drop-down list to select relevant option. For a first submission select 'First submission'. If the application is a resubmission, select 'A' for the first resubmission, 'B' for the second resubmission, etc. **Substantial Amendment Note:** If this is an electronic submission of a substantial amendment, 'A.6 Is this a resubmission?' should be set to 'NO'. Users are reminded to perform a check to ascertain which letter has previously been used for any previous resubmission to ensure that the incremental increase recorded in a subsequent resubmission is correct.
A.7	Is the trial part of a Paediatric Investigation Plan?	Select 'Yes' for a trial part of a paediatric investigation plan (PIP) or otherwise, should mark 'No'. A paediatric investigation plan is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of the medicine for children. For more information, refer to European Medicines Agency Paediatrics guidance pages (http://www.ema.europa.eu/htms/human/paediatrics/pips.htm).
A.8	EMEA Decision number of Paediatric Investigation Plan	Enter the European Medicines Agency's decision number for the Paediatric Investigation Plan (PIP) where available.
B.1 and B.3		These are the details for section B.1 and B.3 Sponsor Identification Details. Enter details, and click on other blue heading to open other uncompleted sections. Click 'Done' when the section is completed and you return to the section overview level, where additional sponsors may be added, or existing sponsor details edited or deleted.
B.1.1	Name of organisation	Click in the free text field and enter the name of the sponsor of the trial (see article 2 (e) of Directive 2001/20/EC) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0020:EN:PDF
B.1.2	Name of person to contact:	The sponsor contact should be a person who works within the company/organisation mentioned in section B.1.1. (it should not be a person working in an applicant company appointed by the sponsor (or by its legal representative) to submit the application to the National Competent Authority – applicant information is in section C).

CTA Form Field Number	Field Name	Tool Tip Description
B.1.2.1	Given name	Also known as first name or forename.
B.1.2.2	Middle name	The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter “Elizabeth” for “Ana Elizabeth”
B.1.2.3	Family name	Also known as Surname. Alternatively use this field to record a functional role (e.g. Head of regulatory affairs etc.).
B.1.3.1	Street Address	Please provide the full postal address to be used in case NCA/EC needs to contact sponsor by post.
B.1.3.2	Town/ city	Please provide the full postal address to be used in case NCA/EC needs to contact sponsor by post.
B.1.3.3	Post code	Please provide the full postal address to be used in case NCA/EC needs to contact sponsor by post.
B.1.3.4	Country	
B.1.4	Telephone number	The contact details (phone number, fax, e-mail) are those of the sponsor contact mentioned in section B.1.2. Please include the international or applicable area codes.
B.1.5	Fax number	The contact details (phone number, fax, e-mail) are those of the sponsor contact mentioned in section B.1.2. Please include the international or applicable area codes.
B.1.6	E-mail	The contact details (phone number, fax, e-mail) are those of the sponsor contact mentioned in section B.1.2. Please include the international or applicable area codes. Functional emails are preferred to personal ones(e.g. like regulatory@corporate.com or renalcancer.ct-unit@hospital.org).
B.3.1 and B.3.2	Status of the sponsor	Click the drop-down list to select relevant option. A commercial sponsor is a person or organisation that takes responsibility for a trial which is part of the development programme for a marketing authorisation of a medicinal product at the time of the application
B.2	For section B.2, first complete B.3 below then select 'Continue' and then add a legal representative if required by Article 19 of Directive 2001/20/EC.	Click another blue bar to contract the section. According to Article 19 of Directive 2001/20/EC, "the sponsor or a legal representative of the sponsor must be established in the Community". If the sponsor is not established in the EEA, they should appoint a legal representative established in the EEA. Like the sponsor, the legal representative can be an individual, company, institution or organisation. Enter details in this section if required to comply with Article 19 of Directive 2001/20/EC and complete any other fields. Click 'Done' when the section is completed and you return to the section overview level. Please note that only one legal representative in the EEA can act on behalf of one sponsor for the purpose of a given clinical trial.
B.2.1	Name of organisation	The legal representative may be a person or an organisation.
B.2.2	Name of person to contact:	
B.2.2.1	Given name	Also known as first name or forename.
B.2.2.2	Middle name	The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter “Elizabeth” for “Ana Elizabeth”

CTA Form Field Number	Field Name	Tool Tip Description
B.2.2.3	Family name	Also known as Surname. Use this field to record a functional role (e.g. Head of regulatory affairs etc.).
B.2.3	Address:	
B.2.3.1	Street Address	Please provide the full postal address to be used in case NCA/EC needs to contact the legal representative by post.
B.2.3.2	Town/ city	Please provide the full postal address to be used in case NCA/EC needs to contact the legal representative by post.
B.2.3.3	Post code	Please provide the full postal address to be used in case NCA/EC needs to contact the legal representative by post.
B.2.3.4	Country	
B.2.4	Telephone number	The contact details (phone number, fax, e-mail) are those of the legal representative mentioned in section B.2.2. Please include the international or applicable area codes.
B.2.5	Fax number	The contact details (phone number, fax, e-mail) are those of the legal representative mentioned in section B.2.2. Please include the international or applicable area codes.
B.2.6	E-mail	The contact details (phone number, fax, e-mail) are those of the legal representative mentioned in section B.2.2. Please include the international or applicable area codes.
B.4	Source(s) of Monetary or Material Support for the clinical trial (repeat as necessary):	This section should identify the major organisations providing monetary or material support for the conduct of the trial. In many cases this will be the same as the sponsor. Where there are other organisations providing significant funding or material support these should be identified (e.g. where a funding organisation or pharmaceutical company provide support for a non-commercial trial (including (but not limited to) funding, design, implementation, data analysis and reporting)). Click another blue bar to contract the section.
B.4.1	Name of organisation	Include the name of the Organisation (or individual) who is providing the finance or resources for the clinical trial.
B.4.2	Country	Include the country name of the Organisation (or individual) who is providing the finance or resources for the clinical trial.
B.5	Contact point designated by the sponsor for further information on the trial	Click another blue bar to contract the section. Click 'Done' when the section is completed and you return to the section overview level.
B.5.1	Name of organisation	The contact point will be made publically available and is the place to which members of the public should address requests for additional information about the trial. The contact point may be at the sponsor, a trial site or another organisation, and there may be one per concerned Member State or one in the EEA.
B.5.2	Functional name of contact point	The contact point will be made publically available and is the place to which members of the public should address requests for additional information about the trial. Please provide a functional contact point rather than the name of a person (e.g. Clinical Trials Information).
B.5.3	Address:	

CTA Form Field Number	Field Name	Tool Tip Description
B.5.3.1	Street Address	Please provide a full postal address.
B.5.3.2	Town/ city	Please provide a full postal address.
B.5.3.3	Post code	Please provide a full postal address.
B.5.3.4	Country	Please provide a full postal address.
B.5.4	Telephone number	The contact details (phone number, fax, e-mail) are those of the further information contact in section B.5. Please include the international or applicable area codes.
B.5.5	Fax number	The contact details (phone number, fax, e-mail) are those of the further information contact in section B.5. Please include the international or applicable area codes.
B.5.6	E-mail	The contact details (phone number, fax, e-mail) are those of the further information contact in section B.5. Please include the international or applicable area codes.
B.5.7	SUSAR Reporting – indicate the process to be used for SUSAR reporting:	
B.5.7.1	To National Competent Authorities:	
B.5.7.2	To EudraVigilance Clinical Trial Module:	
B.5.8	EV Sender ID	
B.5.8.1	Organisation name	
B.5.8.2	Identifier	
C.1		Enter details for section C.1 Applicant Identification - Request for the National Competent Authority then click 'Done' button when the sub-section is complete.
C.1.1, C.1.2 and C.1.3	C.1.1 and C.1.2 and C.1.3	Click the drop-down list to select relevant option, dependant upon whether the applicant is the sponsor, the legal representative of the sponsor or the individual or organisation appointed by the sponsor to submit the application.
C.1.4	Complete the details of the applicant below even if they are provided elsewhere on the form:	This is the Applicant to the National Competent Authority (NCA) and is the party with whom the NCA will routinely correspond. Enter the details of the legal applicant (who will sign the form). The legal applicant may be the sponsor, the legal representative if the sponsor is established outside the EEA, or an individual or company appointed by the sponsor (or by its legal representative) to submit the application to the NCA. The applicant does not have to be based in the European Union. The NCA Applicant Contact may be a different individual at the same Location/Organisation, if necessary.
C.1.4.1	Name of Organisation	The full, official name of the Applicant Organisation.

CTA Form Field Number	Field Name	Tool Tip Description
C.1.4.2	Name of contact person	The NCA Applicant Contact (or contact person) should be a practical contact and might not be the signatory of the application, but may be the same person as the one mentioned in section B.1.2 if the sponsor is the applicant (or in section B.2.2 if the legal representative is the applicant). The family name, at least, should be provided in C.1.4.2, or be completed with a function (e.g. Head of regulatory affairs). All the fields should be completed even when this repeats the sponsor or legal representative information from B.1 and B.2.
C.1.4.2.1	Given name	Also known as first name or forename.
C.1.4.2.2	Middle name	The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter "Elizabeth" for "Ana Elizabeth"
C.1.4.2.3	Family name	Also known as Surname. Use this field to record a functional role (e.g. Head of regulatory affairs etc.).
C.1.4.3	Address:	
C.1.4.3.1	Street address	The building name and/or number and street name.
C.1.4.3.2	Town/ city	
C.1.4.3.3	Post code	The address' post code (where applicable).
C.1.4.3.4	Country	Click the drop-down list to select relevant option.
C.1.4.4	Telephone number	The contact details (phone number, fax, e-mail) are those of the National Competent Authority in section C.1.4.2. Please include the international or applicable area codes.
C.1.4.5	Fax number	The contact details (phone number, fax, e-mail) are those of the National Competent Authority in section C.1.4.2. Please include the international or applicable area codes.
C.1.4.6	E-mail	The contact details (phone number, fax, e-mail) are those of the National Competent Authority in section C.1.4.2. Please include the international or applicable area codes.
C.1.5	Request to receive a copy of this data as XML	
C.1.5.1	Do you want a copy of this data saved on EudraCT as an XML File	C.1.5.1 is a MANDATORY FIELD and if the answer is 'Yes' then C.1.5.1.1 should contain at least one email address.
C.1.5.1.1	E-mail	If you answered 'Yes' to C.1.5.1 then you may provide up to 5 email addresses below to which copies of the CT Application XML file will be sent via EudraLink. These email addresses must have Eudralink accounts for secure password protected delivery unless you answer 'No' to C.1.5.1.2 for delivery without password protection.
C.1.5.1.2	Secure E-mail (EudraLink account)?	Select 'Yes' if you require secure email delivery of the XML. For validation guidance, please note that C.1.5.1.2 is a MANDATORY FIELD: If C.1.5.1 is answered 'No' C.1.5.1.2 answer should also be 'No'. If C.1.5.1 is 'Yes', C.1.5.1.2 may be either 'Yes' or 'No'.C1.5.1.2. by default should be blank.
C.2		This section is not mandatory. It should be completed for applications to

CTA Form Field Number	Field Name	Tool Tip Description
		ethics committees in those Member States where the Ethics Committee requests this form as part of the application to them. Once complete, click 'Done' button when the sub-section is complete.
C.2.1, C.2.2, C.2.3 and C.2.4	C.2.1 and C.2.2 and C.2.3 and C.2.4	Click the drop-down list to select relevant option.
C.2.5	Complete the details of the applicant below even if they are provided elsewhere on the form:	This is the Applicant to the Ethics Committee. Enter the details of the legal Applicant (who will sign the form). The Contact Name may be a different individual at the same Location/ Organisation. The Phone, Fax and E-mail should be those of the Contact person.
C.2.5.1	Organisation	
C.2.5.2	Name of contact person	
C.2.5.2.1	Given name	Also known as first name or forename.
C.2.5.2.2	Middle name	The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter "Elizabeth" for "Ana Elizabeth"
C.2.5.2.3	Family name	Also known as Surname. Use this field to record a functional role.
C.2.5.3	Address:	
C.2.5.3.1	Street address	The building name and/or number and street name.
C.2.5.3.2	Town/city	
C.2.5.3.3	Post code	The address' post code (where applicable).
C.2.5.3.4	Country	Click the drop-down list to select relevant option.
C.2.5.4	Telephone number	The contact details (phone number, fax, e-mail) are those of the IEC in section C.2.5.2. Please include the international or applicable area codes.
C.2.5.5	Fax number	The contact details (phone number, fax, e-mail) are those of the IEC in section C.2.5.2. Please include the international or applicable area codes.
C.2.5.6	E-mail	The contact details (phone number, fax, e-mail) are those of the IEC in section C.2.5.2. Please include the international or applicable area codes.
D.1/D.2		Once the sub-section is complete click the 'Next' button at the bottom of the page to move to the next sub-section.. Use 'Next' at the foot of each screen to ensure completion of all questions in Section D. NOTE: If there is no clear 'Test IMP' or 'Comparator' in your study design, indicate all IMPs as 'Test IMP'. Each strength and pharmaceutical form should be recorded as a separate Investigational Medicinal Product (use 'copy IMP' and edit the strength of each active substance and/or pharmaceutical form of the IMP).
D.1.1		Unique sequence number for the repeating products. Format: PRnn.
D.1.2 and D.1.3	Category	Choose the IMP Category from the drop-down list.
D.2	Status of the IMP to be used in the clinical	If the IMP has a Marketing Authorisation in the Member State concerned by this application but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2.

CTA Form Field Number	Field Name	Tool Tip Description
	trial	
D.2.1	Has the IMP to be used in the trial a marketing authorisation?	If 'No' then go to D.2.3. If 'Yes' then complete section D.2.1.1.1 to D.2.1.1.4. UNLESS the IMP has a Marketing Authorisation in the Member State concerned by this application, but the trade name and marketing authorisation holder are not fixed in the protocol in which case complete D.2.1.2 with the name of the Member State to which the application is submitted, answer 'Yes' to D.2.1.2.1, and then go to section D.2.2.
D.2.1.1	If 'Yes', specify the product to be used in the trial	If the IMP has a Marketing Authorisation in the country from which it is sourced for use in this Clinical Trial, please complete this section with the information relevant to the country from which the product has been sourced.
D.2.1.1.1	Trade name	If the IMP has a Marketing Authorisation in the country from which it is sourced for use in this clinical trial, specify the Product Name as registered by the Marketing Authorisation Holder (MAH). It is available from the Summary of Product Characteristics (SmPC), or product labelling.
D.2.1.1.1.1	EV Product Code	Specify the EudraVigilance Product Code here when available (obtained from EudraVigilance Medicinal Product Dictionary EVMPD).
D.2.1.1.2	Name of the Marketing Authorisation holder	Available from the Summary of Product Characteristics (SmPC), or Product Labelling. For more information, see details in EudraPharm.
D.2.1.1.3	Marketing Authorisation number (if Marketing Authorisation granted by a Member State)	Available from the Summary of Product Characteristics (SmPC) or Product Labelling.
D.2.1.1.4	Is the IMP modified in relation to its Marketing Authorisation?	Answer 'Yes' if there are any trial-specific operations that could affect the product quality, such as modification of the pharmaceutical form (e.g. over-encapsulation, colour, dilution, re-tableting for blinding etc.) or removal from the primary packaging and repacking (e.g. removal from a blister and putting in a bottle). If the blinding consists in over encapsulating tablets, trial specific coating (modified colour, or debossing), this information should be reported here. Answer 'No' If the product has only been relabelled or repackaged.
D.2.1.1.4.1	If 'Yes', please specify	If question D.2.1.1.4 is answered 'Yes' then question D.2.1.1.4.1 should be answered, providing details of the modification.
D.2.1.2	The country which granted the Marketing Authorisation	Specify the name of the country where the holder was granted the Marketing Authorisation of the actual IMP to be used in the clinical trial in the Member State concerned by the application. If the IMP has a MA in several countries, enter the name of the country (or of one of the countries, if one of them is a Member State, choose this one) that granted the MA for the actual IMP to be used in the trial in accordance with section D.2.1.1.2. Where the product is a Centrally Authorised Product, give the Member State in which the product was intended to be marketed (i.e. the one for which it is labelled) or, if bulk product is used, choose one of the Member States.
D.2.1.2.1	Is this the Member State concerned with this application?	Answer 'Yes' if the Marketing Authorisation of the IMP to be used in the clinical trial in the Member State concerned by the application was granted by the same Member State. Answer 'No' if the Marketing Authorisation was granted by another country.
D.2.2	For situations	Complete this section when the IMP has a Marketing Authorisation in the

CTA Form Field Number	Field Name	Tool Tip Description
	where the IMP to be used in the CT has a Marketing Authorisation in the Member State concerned but the protocol allows that any brand of the IMP with a Marketing Authorisation in that Member State be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start	Member State concerned by this application, but the trade name and marketing authorisation holder are not fixed in the protocol. You should also have answered Yes to D.2.1 and have completed D.2.1.2 with the name of the Member State to which the application is submitted, and 'Yes' to D.2.1.2.1.
D.2.2.1	In the protocol, is treatment defined only by active substance?	This should be answered 'Yes' when the protocol only identifies the INN and the investigator can use whichever brand is locally available. The protocol of the clinical trial may specify only the INN of the product used in the trial (for example paracetamol) when, for the same active substance there are several different trade names available in the Member state concerned and no one of them is specified by the protocol.
D.2.2.1.1	If 'Yes', give active substance in D.3.8 or D.3.9	
D.2.2.2	In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS?	If D.2.2.1 (above) is answered 'Yes' then D.2.2.2 may be 'Yes' or 'No'. The applicant should tick the 'Yes' box if, in the protocol, treatment regimens for the Investigational Medicinal Product allow different combinations of marketed products (only defined by their INN) used according to local practice at some or all investigator site in the concerned Member State (this case is frequently observed in oncology or HIV clinical trials). In this case each site might have a different combination compared to other sites.
D.2.2.2.1	If 'Yes', give active substance in D.3.8 or D.3.9	
D.2.2.3	The products to be administered	If D.2.2.1 (above) is answered 'Yes' then D.2.2.3 must be 'No'. However, if the answer to this field is 'Yes' then D.2.2.1, D.2.2.2 and D.2.2.4 should be 'No'.

CTA Form Field Number	Field Name	Tool Tip Description
	as IMPs are defined as belonging to an ATC group	
D.2.2.3.1	If 'Yes', give the ATC group of the applicable authorised codes in the ATC code field (level 3 or the level that can be defined) in D.3.3	This should only be answered when the parent question (D.2.2.3) is answered 'Yes'.
D.2.2.4	Other:	If D.2.2.1 (above) is answered 'Yes' then D.2.2.4 must be 'No'.
D.2.2.4.1	If 'Yes', then please specify	Click in the free text field and enter the specification of the IMP identification (up to 500 characters). This should only be answered when the parent question (D.2.2.4) is answered 'Yes'.
D.2.3	IMPD Submitted:	
D.2.3.1	Full IMPD:	
D.2.3.2	Simplified IMPD:	If 'Yes' please provide justification for using simplified dossier in the covering letter. Refer to the detail guideline CT1 Section 2.7.3 and Table 1 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:082:0001:0019:EN:PDF
D.2.3.3	Summary of product characteristics (SmPC) only:	When the IMP has a marketing authorisation in the EEA or in an ICH country and it is used within the conditions of the SmPC, the applicant may submit the current version of the SmPC (or, as regards ICH countries, the documentation equivalent to the SmPC) as the IMPD.
D.2.4	Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?	In this section, the term "authorised" should be understood in the context of Directive 2001/20/EC (that is to say an authorisation, according to Directive 2001/20/EC, has been given for a trial using this IMP).
D.2.4.1	If 'Yes', specify which Member States:	To select one country, click the country and then click 'Copy'. To select more than one country, hold CTRL then click the countries and then click 'Copy'. To select all countries, click 'Copy All' button.
D.2.5	Has the IMP been designated in this indication as an orphan drug in the Community?	According to the Community register on orphan medicinal products (Regulation (EC) n° 141/2000): http://ec.europa.eu/health/documents/community-register/html/alforphreg.htm
D.2.5.1	If 'Yes', give the orphan drug designation number	The orphan drug designation number is available on the following web site: http://ec.europa.eu/health/documents/community-register/html/alforphreg.htm
D.2.6	Has the IMP	D.2.6.1 should be answered 'Yes' if scientific advice in relation to the

CTA Form Field Number	Field Name	Tool Tip Description
	been the subject of scientific advice related to this clinical trial?	clinical trial concerned by this application has been given by a European regulator. This scientific advice may be given by a National Competent Authority or by the CHMP (European Medicines Agency) or both.
D.2.6.1	If 'Yes' to D.2.6., Please indicate the source of advice and provide a copy in the CTA request:	
D.2.6.1.1	From the CHMP?	Was Scientific Advice (SA) from Committee for Medicinal Products for Human Use (CHMP) received?
D.2.6.1.2	From a National Competent Authority?	Was Scientific Advice (SA) from a National Competent Authority received?
D.3	Description of the IMP	
D.3.1	Product name where applicable	To be provided only when there is no tradename. This is the name routinely used by a sponsor to identify the IMP in the CT documentation (protocol, IB...) Note: It is Mandatory to complete D.3.1.and/or D.3.2 if question D.2.1 was answered 'No' if question D.2.1 was answered 'No'.
D.3.2	Product code where applicable	To be provided only when there is no tradename. This is a code designated by the sponsor which represents the name routinely used by the sponsor to identify the product in the CT documentation. For example, a code may be used for combinations of drugs or drugs and devices. Note: It is Mandatory to complete D.3.1.and/or D.3.2 if question D.2.1 was answered 'No' if question D.2.1 was answered 'No'.
D.3.3	ATC codes if officially registered (enter up to 5):	If the product has a Marketing Authorisation in the concerned Member State, the applicant should include the Anatomical, Therapeutic, Chemical (ATC) code for this product. This is available from the Summary of Product Characteristics (SmPC). Click 'Add ATC code' button if you wish to include an additional ATC code. Note: It is mandatory to include at least one ATC code in this field if question D.2.2.3 is answered 'Yes'.
D.3.4	Pharmaceutical form	Select the pharmaceutical form of the actual IMP to be used in the clinical trial from the drop down menu. Note: Mandatory field unless D.2.2 is 'Yes'.
D.3.4.1	Is this a specific paediatric formulation?	Answer 'Yes' if the formulation is specifically for paediatric usage.
D.3.5	Maximum duration of treatment of a subject according to the protocol	This field should NOT be completed by simply indicating 'See protocol'. Include the duration of administration of the IMP to a subject. (e.g. If it is intended, in accordance with the protocol, to treat a subject during 3 weeks, specify 'three weeks'. If the IMP is not administered on a continued basis, specify the rhythm of the product administration. For example, regarding a clinical trial in oncology, if the treatment is administered at day 1 and day 2 every four weeks, specify 'D1 and D2 every four weeks', mentioning the maximum number of cycles foreseen. Warning: The treatment duration (period of time during which the patient is administered with the IMP) is not the same as the period of participation of a patient (period of time during

CTA Form Field Number	Field Name	Tool Tip Description
		which the subject is followed up within the context of the clinical trial). Note: Mandatory field unless D.2.2 is 'Yes'.
D.3.6	Dose allowed	D.3.6 are MANDATORY FIELDS. Choose the most appropriate answers in each sub-section by checking the appropriate box (dose per day or total dose), and by specifying the maximum dose administered (concentration and concentration unit, and the route of administration related to the maximum dose). It is evident that the maximum dose may relate to one of the other strengths or routes of administration for this IMP so the same answer may apply to several of the related copies of this IMP data in this CTA.. The route of administration should be one of those checked at D.3.7.
D.3.6.1	First dose for first-in-human clinical trial	If the IMP is administered in this trial for the first time in humans (FIH), click in the free text field and enter the details of the first dose (up to 250 characters).
D.3.6.1	Specify per day or total	Select relevant option. Choose the most appropriate answer from 'Dose per day' or 'Total dose'.
D.3.6.1	Specify total dose (number):	Click in the free text field and specify the amount of IMP (numeric quantity) administered per dose. Use drop-down list at the next field to specify units.
D.3.6.1	Specify total dose (unit):	Specify the units of the dose being described.
D.3.6.1	Route of administration (relevant to the first dose):	Click the drop-down list to select relevant option - specify the route of administration related to the first dose.
D.3.6.2	Maximum dose allowed	Click in the free text field and specify the maximum single dose allowed in numbers and units.
D.3.6.2	Specify per day or total	Choose the most appropriate answer from 'Dose per day' or 'Total dose'.
D.3.6.2	Specify total dose (number and unit):	Click in the free text field and specify the amount of IMP (numeric quantity) administered per dose. Use drop-down list at the next field to specify units.
D.3.6.2	Specify total dose (number and unit):	Specify the units of the dose being described.
D.3.6.2	Route of administration (relevant to the maximum dose):	Click the drop-down list to select the Route of Administration which the maximum dose refers to.
D.3.7	Routes of administration for this IMP	To select one Route of Administration, click the appropriate option and then click 'Copy'. To select more than one Route of Administration hold CTRL then click the Routes of Administration and then click 'Copy'. To select all Routes of Administration click ‘Copy All’ button. Click the 'Continue' button at the bottom of the page to move to the next sub-section. Note that selecting 'Continue' will take you to section D.3.11 Type of IMP and from there, if applicable, to sections D.4, D.5 and D.6. Only then can sections D.3.8 to D.3.10 for active substances be accessed by selecting 'add active substance' for this IMP at the IMP Identification Index screen. You are encouraged to use terms that are not 'non-current'. Note: This is a Mandatory field if your precise term is not available use the free text field and include it in your cover letter.
D.3.8 to D.3.10	IMP Identification Details (Active	Complete all fields that currently apply to this Active Substance in this IMP. If you have IMPs with different concentrations of the Active Substance please complete a new IMP entry for each concentration of the

CTA Form Field Number	Field Name	Tool Tip Description
	Substances)	active substance. To do this you can complete one full section D IMP and Active Substance then copy the IMP and edit the concentration in the copy(ies). CAS=Chemical Abstract Services Number. Other Descriptive Name may be used for biological/ biotechnological Products that do not have an INN or Proposed INN.
D.3.8	INN - Proposed INN	Specify the International Nonproprietary Name (proposed or final) (up to 150 characters). If the product is a combination product, specify the name of all active substances, by adding each active substance separately to the IMP. For marketed products, the INN is available in the SmPC. For EU marketed products, the INN is available in section 2 of the EU SmPC entitled "Qualitative and quantitative composition". Another descriptive name may be used in specific situations, for example for products of biological or biotechnological origin that have no INN or proposed INN, or where it is an alternative name which is not registered as INN or proposed INN. Note: It is not necessary to answer D.3.8 if D.2.2.3, D.2.2.4 are answered 'Yes'.
D.3.9.1	CAS number	If available, specify this active substance's CAS number (a unique numeric identifier for chemical entities). CAS' format is nnnnnn-nnn-c where c is a check digit and leading zeros may be suppressed (up to 12 characters). For more information, please check http://www.cas.org
D.3.9.2	Current sponsor code	Click in the free text field and specify the active substance's (AS) current sponsor code (up to 100 characters).
D.3.9.3	Other descriptive name	Click in the free text field and specify another descriptive name for biological/ biotechnological Products that do not have an INN or Proposed INN (up to 500 characters).
D3.9.4	EV Substance Code	Click in the free text field and specify the active substance's EudraVigilance Substance Code (up to 15 characters).
D.3.9.5	Full Molecular formula	Include the full molecular formula for the active substance.
D.3.9.6	Chemical/biological description of the Active Substance	
D.3.10	Strength	Please note that in this section the strength / concentration should be given for each different pharmaceutical form and/or strength of the Investigational Medicinal Product being used in the trial (for example amount of active substance per tablet) and not the dose administered to the subject. D.3.10, D.3.10.1, D.3.10.2, D.3.10.3 are Mandatory fields except where D.2.2 is 'Yes'. D.3.10.3 should be a single numeric value in the first field (can be a decimal) or in both fields only where D.3.10.2 is set to 'Range'.
D.3.10.1	Concentration unit	The unit of measurement used for the concentration of the active substance from the drop-down list.
D.3.10.2	Concentration type	Select the active substance's concentration type from the drop-down list.
D.3.10.3	Concentration number (only use both fields for range)	Use this field only if D.3.10.2 is NOT set to 'Range'.
D.3.10.3	Concentration number (only use both fields for range)	Use this field only if D.3.10.2 is set to 'Range'.
D.3.11	Type of IMP	
D.3.11	Does the IMP	D.3.11.1 and D.3.11.2 are MANDATORY fields - at least one should be

CTA Form Field Number	Field Name	Tool Tip Description
	contain an active substance of:	marked 'Yes'.
D.3.11.1	Of chemical origin?	Select 'Yes' if the IMP is obtained by chemical synthesis. Note: In some cases, where there are two or more active substances in one IMP, it is possible that both D.3.11.1 and D.3.11.2 would be marked 'Yes'.
D.3.11.2	Of biological/ biotechnological origin (other than Advanced Therapy IMP (ATIMP)?	Select 'Yes' for IMPs where the active ingredient(s) are biological product(s) of human or animal origin, or contain biological components of human or animal origin, or the manufacturing of which requires such components. If the IMP is an advanced therapy medicinal product select 'No' and instead select 'Yes' to D.3.11.3.
	Is this IMP a:	
D.3.11.3	Advanced Therapy IMP (ATIMP)	Select 'Yes' if the IMP is considered an Advanced Therapy IMP. Note: If this field is marked 'Yes', ensure that the following subquestions below, as well as section D.5 are completed.
D.3.11.3 .1	Somatic cell therapy medicinal product?	Select 'Yes' if this Advanced Therapy IMP is a somatic cell therapy medicinal product?
D.3.11.3 .2	gene therapy medical product?	Select 'Yes' if this Advanced Therapy IMP is a gene therapy medicinal product?
D.3.11.3 .3	Tissue Engineered Product?	Select 'Yes' if this Advanced Therapy IMP is a tissue engineered medicinal product?
D.3.11.3 .4	Combination ATIMP (i.e. one involving a medical device)?	Select 'Yes' if the Advanced Therapy IMP is a combined product involving a medical device?
D.3.11.3 .5	Has the Committee on Advanced therapies issued a classification for this product?	If the Committee on Advanced Therapies (CAT) has issued a recommendation for classification for this IMP, select 'Yes'. For more information on the Committee on Advanced Therapies, see CAT Overview: http://www.ema.europa.eu/htms/general/contacts/CAT/CAT.html
D.3.11.3 .5.1	If yes, please provide that classification and its reference number	Click in the free text field and specify the CAT classification and reference number. See <insert CAT site hyperlink> for more details.
D.3.11.4	Combination product that includes a device, but does not involve an Advanced Therapy	Select 'Yes' if this IMP includes a medical device but does not involve an advance therapy medicinal product.
D.3.11.5	radiopharmaceutical medicinal product?	Select 'Yes' if this IMP is a radiopharmaceutical medicinal product.
D.3.11.6	immunological	Select 'Yes' if this IMP is an immunological medicinal product (such as a

CTA Form Field Number	Field Name	Tool Tip Description
	medicinal product (such as vaccine, allergen, immune serum)?	vaccine, allergen, immune serum, etc.), whether it is for prophylactic or therapeutic use.
D.3.11.7	plasma derived medicinal product?	Select 'Yes' if the IMP is a medicinal product derived from human blood or plasma. Note: if you answered yes here, D.3.11.2 should also have been answered Yes.
D.3.11.8	Extractive medicinal product?	Select 'Yes' if the IMP is of biological or biotechnological origin but does not fit any of the categories listed above and is obtained by extraction from biological material. Note: If this question is answered 'Yes', D.3.11.2 should also have been answered 'Yes'.
D.3.11.9	Recombinant medicinal product?	Select 'Yes' if the IMP was produced using recombinant technology. Note: If this question is answered 'Yes', D.3.11.2, should also have been answered 'Yes'.
D.3.11.10	medicinal product containing genetically modified organisms?	Select 'Yes' if this IMP contains Genetically Modified Organisms. Note: If 'this question is answered 'Yes', D.3.11.2, should also have been answered 'Yes'.
	If 'Yes', has the authorisation for contained use or release been granted?	This section should be completed only if the IMP is a medicinal product containing genetically modified organisms.
D.3.11.10.1	granted?	This question should be answered only if the IMP is a medicinal product containing genetically modified organisms.
D.3.11.10.2	or is it pending?	This question should be answered only if the IMP is a medicinal product containing genetically modified organisms.
D.3.11.11	Herbal medicinal product?	Select 'Yes' if this IMP contains an active substance of herbal origin.
D.3.11.12	Homeopathic medicinal product?	Select 'Yes' if this IMP is a homeopathic medicinal product.
D.3.11.13	Another type of medicinal product?	Select 'Yes' if the IMP is a medicinal product of a type not detailed above. E.g medicinal gas.
D.3.11.13.1	If 'another type of medicinal product' specify the type of medicinal product	If this is 'Other' type of IMP, specify the type of IMP (up to 200 characters).
D.3.12	Specify the mode of action for the active substance in this medicinal product	Enter the mode of action of the active substance of this medicinal product (up to 500 characters). Abbreviation should be avoided if possible.
D.3.13	Is it an IMP to	Select 'Yes' if the active substance contained in this IMP is to be

CTA Form Field Number	Field Name	Tool Tip Description
	be used in a first-in-human clinical trial?	administered for the first time in a clinical trial (first-in-human (FIH) clinical trial). Note: If you answer 'Yes' here, you should also answer 'Yes' in E.7.1.1. and also complete question D.3.6.1.
D.3.13.1	If yes, are there risk factors identified, according to the guidance FIH	Click in the free text field and enter any risk factors identified in accordance with first-in-human guidance (up to 500 characters).
D.4.1	Type of product	
Replaced by D.3.11.8	Extractive	N/A
Replaced by D.3.11.9	Recombinant	N/A
Replaced by D.3.11.6	Vaccine	N/A
Replaced by D.3.11.12	GMO	N/A
Replaced by D.3.11.7	Plasma derived products	N/A
Replaced by D.3.11.13	Others	N/A
Removed	If others, specify:	N/A
D.4	Somatic Cell Therapy Investigational Medicinal Product (No Genetic Modification)	The questions on this part of the form relate to IMPs containing cell therapy medicinal products. These questions are MANDATORY if you have answered 'Yes' at D.3.11.3.1 and should be completed only if the IMP is a cell therapy medicinal product. All of D.4.1 and D.4.2 should be answered. Click the 'Continue' button at the bottom of the page to move to the next sub-section.
D.4.1	Origin of cells	
D.4.1.1	Autologous	Select 'Yes' if cells to be used in the therapy derive from the trial subject himself.
D.4.1.2	Allogeneic	Select 'Yes' if cells to be used in the therapy derive from a human donor other than the trial subject.
D.4.1.3	Xenogeneic	Select 'Yes' if cells to be used in the therapy derive from a species other than human.
D.4.1.3.1	If 'xenogeneic', specify the species of origin	Click in the free text field and enter the species origin (up to 200 characters).
D.4.2	Type of cells	
D.4.2.1	Stem cells	Select 'Yes' if the cells come from an undifferentiated (stem) line.
D.4.2.2	Differentiated	Select 'Yes' if the cells come from an differentiated cell line (non-stem).

CTA Form Field Number	Field Name	Tool Tip Description
	cells	Also you should specify the type of cells in D.4.2.2.1.
D.4.2.2.1	If 'differentiated', specify the type of cells (e.g. keratinocytes, fibroblasts, chondrocytes...)	Click in the free text field and enter the differentiated type of cells (up to 200 characters).
D.4.2.3	Others	Select 'Yes' if cells to be used in the therapy derive from a type other than the options available above.
D.4.2.3.1	If 'others', specify the type of cells	Click in the free text field and enter the type of cells, if not available in the above options (up to 200 characters).
D.5	Gene Therapy Investigational Medicinal Product	The questions on this part of the form relate to IMPs containing gene therapy medicinal products. These questions are asked if you have answered 'Yes' at D.3.11.3.2.Note: If D.3.11.4 is 'Yes' then section D.5 is MANDATORY. All questions D.5.1 to D.5.5 should be answered. The free text boxes should only be completed when the related parent question is ticked 'Yes'. Click the 'Continue' button at the bottom of the page to move to the next sub-section.
D.5.1	Gene(s) of interest	Click in the free text field and enter the genes of interest (up to 500 characters).
D.5.2	Is this 'in vivo' gene therapy?	Select 'Yes' if the gene therapy medicinal product is administered to the trial subject.
D.5.3	Is this 'ex vivo' gene therapy?	Select 'Yes' if the gene therapy medicinal product is used in order to modify cells outside the trial subject's body and that these modified cells are administered to the trial subject.
D.5.4	Type of gene transfer product	The sub-questions D.5.4.1., D.5.4.2. and D.5.4.3 should be completed.
D.5.4.1	Nucleic acid (e.g. plasmid)	Select 'Yes' if the gene transfer product is a nuclelic acid. Note: If section D.5.4.1. is answered 'Yes', sub-sections D.5.4.1.1. and D.5.4.1.2 should be completed.
D.5.4.1.1	naked	Select 'Yes' if the gene therapy entails operations with naked nuclelic acid.
D.5.4.1.2	complexed	Select 'Yes' if the gene therapy entails operations with nuclelic acid, other than naked.
D.5.4.2	Viral vector	Select 'Yes' if the gene therapy entails the use of a viral particle as a vehicle for the nuclelic acid.
D.5.4.2.1	If yes, specify the type (adenovirus, retrovirus, AAV...)	Enter the type of virus used as vector, for instance, adenovirus, retrovirus, AAV, etc (up to 100 characters).
D.5.4.3	Others	
D.5.4.3.1	If 'others', specify the type of gene transfer product	Enter the gene transfer product type (up to 100 characters).
D.5.5	Does the IMP contain genetically modified cells?	Select 'Yes' if the IMP contain genetically modified cells.
	If yes, specify the origin of	

CTA Form Field Number	Field Name	Tool Tip Description
	the cells:	
D.5.5.1	Autologous	Select 'Yes' if cells derive from the trial subject himself.
D.5.5.2	Allogeneic	Select 'Yes' if cells derive from a donor other than the trial subject.
D.5.5.3	Xenogeneic	Select 'Yes' if cells derive from a species other than human.
D.5.5.3.1	If yes, specify the species of origin	Click in the free text field and enter the species origin (up to 200 characters).
D.5.5.4	Specify type of cells (hematopoietic stem cells...)	Click in the free text field and specify the type of cells involved in the IMP (up to 200 characters). If D.6.5 is 'Yes', this field must be completed.
D.6	Tissue Engineered Product	The questions on this part of the form relate to IMPs containing Tissue Engineered medicinal products. Note: If you have answered 'Yes' at D.3.11.3.3, section D.6. should be completed. If D.3.11.3.3, is answered No, section D.6.should be left blank.
D.6.1	Origin of cells	Indicate the origin of cells in the tissue engineered product.
D.6.1.1	Autologous	Select 'Yes' if cells derive from the trial subject himself.
D.6.1.2	Allogeneic	Select 'Yes' if cells derive from a donor other than the trial subject.
D.6.1.3	Xenogeneic	Select 'Yes' if cells derive from a species other than human.
D.6.1.3.1	If yes, specify the species of origin	Click in the free text field and enter the species origin (up to 200 characters).
D.6.2	Type of cells	
D.6.2.1	Stem cells	Select 'Yes' if the tissue has been grown or is made of non-differentiated cells.
D.6.2.2	Differentiated cells	Select 'Yes' if the tissue has been grown or is made of differentiated cells.
D.6.2.2.1	If 'differentiated', specify the type of cells (e.g. keratinocytes, fibroblasts, chondrocytes...)	Enter the differentiated type of cells (up to 200 characters).
D.6.2.3	Others	Select 'Yes' if the tissue is of other type than those mentioned in previous items. Please specify the type in D.6.2.3.1.
D.6.2.3.1	If 'others', specify the type of cells	
D.7	Products containing devices (i.e. Medical Devices, scaffolds, etc.)	The questions on this part of the form relate to IMPs containing devices. Note: If you have answered 'Yes' at D.3.11.3.4 or D.3.11.4 section D.7 should be completed.
D.7.1	Give a brief description of the device	Click in the free text field and enter a short description of the device (up to 200 characters).
D.7.2	What is the name of the device?	Click in the free text field and enter the tradename of the device (up to 200 characters).
D.7.3	Is the device implantable?	Select 'Yes' if the device is to be located within the subject's body.
D.7.4	Does this product	

CTA Form Field Number	Field Name	Tool Tip Description
	contain:	
D.7.4.1	A medical device?	Select 'Yes' if the IMP contains a medical device, otherwise select 'No'.
D.7.4.1.1	Does this medical device have a CE mark?	For more information on the CE Mark: http://en.wikipedia.org/wiki/CE_marking
D.7.4.1.1.1	The notified body is:	Click in the free text field and enter the name and address of the notified body (up to 200 characters).
D.7.4.2	Bio-materials?	Select 'Yes' if the device contains material of Biological Origin.
D.7.4.3	Scaffolds?	Select 'Yes' if the device contains a Scaffold.
D.7.4.4	Matrices?	Does the device contain extracellular matrices (ECM)?
D.7.4.5	Other?	Is it another type of Device?
D.7.4.5.1	If 'other', specify:	Click in the free text field and enter the type of device, if it does not fall under D.7.4.2-D.7.4.4 (up to 200 characters).
D.8	Information on Placebo	If you are using one or more Placebo IMPs use 'add placebo'. Complete for each different Placebo used.
D.8.1	Is there a placebo?	
D.8	Information on Placebo	The following applies for one Placebo. Click 'Done' button then click 'add placebo' for each different Placebo.
D.8.2		
D.8.3	Pharmaceutical form	Click the drop-down list, then select the pharmaceutical form of the placebo to be used in the Clinical Trial.
D.8.4	Route of administration	Click the drop-down list, then select the Route of Administration of the placebo to be used in the Clinical Trial.
D.8.5	Which IMP(s) is it a placebo for? Specify IMP number(s) from D.1.1	Tick box by each listed product to select those for which this placebo is a replacement. Note: This is a MANDATORY FIELD if D.8.1 is answered 'Yes'.
D.8.5.1	Composition, apart from the active substance(s):	
D.8.5.2	Is it otherwise identical to the IMP?	Note: This is a MANDATORY FIELD and if it is 'Yes', D.8.5.2.1 should be completed.
D.8.5.2.1	If composition is not otherwise identical, specify the major ingredients	Click in the free text field and enter the composition of the placebo, including all major ingredients (up to 200 characters).
D.9	Site(s) where the qualified person certifies batch release	This section records the Sites responsible for final Qualified Person (QP) Release of the IMPs prior to distribution to Investigators. Click 'add responsible site'. Or answer D.9.1 in cases where the IMP has a marketing authorisation in EU and is sourced from the EU market and is used in the trial without modification (e.g. not over-encapsulated) and the packaging and labelling are carried out for local use only as per article 9.2 of Directive 2005/28/EC.
D.9.1	If all the conditions above are met, then tick	Click the tick box if ALL the conditions above are met.

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	this box and select below the IMPs and placebos to which this applies.	
D.9.3	Finished IMP {Product seq no.}	Click the associated tick box if ALL the conditions for not requiring a responsible site in the Community for the certification of the finished IMP (qualified person) are met.
D.9.4	Finished IMP {Product seq no.}	Click the associated tick box if ALL the conditions for not requiring a responsible site in the Community for the certification of the finished IMP (qualified person) are met.
D.9.2	Who is responsible in the Community for the certification of the finished IMPs?	Where products are to be identified under D.9.2, all sub-questions (D.9.2.1 to D.9.2.4) are MANDATORY, except post code when none exists for that address.
D.9.2.1 and D.9.2.2	As a manufacturer, importer or both?	Click the drop-down list, then select the Responsible Site Role from the list of options.
D.9.2.3	Site organisation name	Click in the free text field and enter the name of the organisation responsible of the product release for its use in the concerned clinical trial (up to 120 characters).
D.9.2.4	Address	
D.9.2.4.1	Street address	Enter the street name and building name and/or number, of the site responsible for product release. (up to 120 characters).
D.9.2.4.2	Town/ city	Click in the free text field and enter the name of the town or city where the responsible site is located (up to 50 characters).
D.9.2.4.3	Post code	Click in the free text field and enter the post code of the responsible site location (up to 15 characters).
D.9.2.4.4	Country	Click the drop-down list to select the country in which the responsible site is located.
D.9.2.5	Manufacturer authorisation number	Click in the free text field and enter the manufacturer's authorisation number (up to 100 characters). If there is no manufacturing authorisation number but the site is authorised – enter 'Site authorised' – this is applicable in some Member States (e.g. Germany) where no manufacturing authorisation number is issued.
D.9.2.5.1	If no authorisation, give the reasons	Click in the free text field and enter the reasons why an authorisation was not given (up to 500 characters).
E.1	Medical condition or disease under investigation.	
E.1.1	Specify the medical condition(s) to be investigated (free text)	Click in the free text field and enter: 1) In the case of healthy volunteer trials, state 'healthy volunteers' as well as the intended indication for the product under development, which should be provided in parentheses. 2) If the trial is to be conducted on patients, only the name of the disease, which is the indication for which the IMP is administered, is required (up to 500 characters). Click the <Add Other Languages icon/eudract-web/img/add.png> to add text in another language than English.
E.1.1.1	Medical condition in	Click in the free text field and include a description of the medical condition in non-medical language - e.g. Avian Influenza Virus A (H5N1)

CTA Form Field Number	Field Name	Tool Tip Description
	easily understood language	might be described as Bird Flu (up to 500 characters). Click the <Add Other Languages icon/eudract-web/img/add.png> to add text in another language than English.
E.1.1.2	Identify the therapeutic area	Click the drop-down list, then select the Therapeutic Area from the list of options. Note: This list is based upon on one taken from the Medical Subject Headings list (MeSH®). MeSH® is the National Library of Medicine's controlled vocabulary thesaurus. It consists of sets of terms naming descriptors in a hierarchical structure that permits searching at various levels of specificity.
E.1.2	MedDRA information	To add new MedDRA data, enter search details for the MedDRA term and/or level. Alternatively enter the classification code you wish to add. Then click 'Search' button. You should routinely use the level "LLT" (Lower Level Term). Click the adjacent check box to select found terms from the Results list, then click 'Add Selected' button to add them to the CTA. Note: MedDRA® is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
E.1.2	Version	The version of MedDRA the term is from. It is recommended, of course, that applicants use terms from the latest version of MedDRA wherever possible. For more information on MedDRA see: http://www.meddramsso.com/
E.1.2	Level	Key to MedDRA hierarchical levels (highest to lowest): SOC (System Organ Class); HLGT (High Level Group Term); HLT (High Level Term); PT (Preferred Term); LLT (Lowest Level Term). For more information on MedDRA see: http://www.meddramsso.com/
E.1.2	Classification code	Specify here the 8-digit numeric code of the MedDRA term. For more information on MedDRA see: http://www.meddramsso.com/
E.1.2	Term	Click in the free text field (on the right) and enter the MedDRA term (or part of a term). You may use the filter drop-down options to narrow or widen your search look-up. (up to 120 characters). For more information on MedDRA see: http://www.meddramsso.com/
E.1.2	SOC	
E.1.3	Is any of the conditions being studied a rare disease?	A rare disease concerns a restricted number of patients in the general population and shows evidence of gravity (because it is life-threatening, invalidating or serious and chronic). The limit accepted in Europe is 1 / 2000 person affected by the disease. If, in the view of the sponsor, the indication investigated in the trial answers this definition, select 'Yes'. If not, the applicant should select 'No'. Note: Points to consider on the calculation and reporting of the prevalence of a condition for Orphan drug designation: COM/436/01.
E.2	Objective of the trial	
E.2.1	Main objective of the trial	Click in the free text field and include a description of the main objectives of the trial, if applicable (up to 1000 characters). The main (primary) objectives of the trial should be described in this section. The wording used here should be consistent with the wording in the protocol. Click the <add button icon> to add text in another language than English. Note: This is a MANDATORY FIELD.
E.2.2	Secondary objectives of the trial	Click in the free text field and include a description of the secondary objectives of the trial, if applicable (up to 1000 characters). The wording of the objective(s) mentioned here should be consistent with the wording in the protocol. Click the <add button icon> to add text in another language than English. Note: This is a MANDATORY FIELD.
E.2.3	Is there a sub-study?:	If a sub-study is planned and if this sub-study is taking place in the Member State concerned by the application, select 'Yes'. If not, select

CTA Form Field Number	Field Name	Tool Tip Description
		'No'. Note: A sub-study, or ancillary study, is a study performed on a sub-group of the subjects included in the clinical trial. For example, a pharmacokinetics or pharmacogenetic sub-study may include a sample of the patients participating in the clinical trial.
E.2.3.1	If Yes give the full title, date and version of each sub-study and their related objectives	Click in the free text field and include the details of each sub-study (up to 4000 characters). If a sub-study does not have a title, the nature of the sub-study should be entered here instead of a title (for example: pharmacogenomic study). Note: This is a mandatory field if there is a sub-study planned.
	E.3 Principal Inclusion Criteria, E.4 Principal Exclusion Criteria and E.5 End point(s)	
E.3	Principal inclusion criteria (list the most important, max 5000 characters)	Click in the free text field and list the details of the most important reasons for the inclusion of subjects in the clinical trial (up to 5000 characters). Click the <add button icon> to add text in another language than English. Note: This is a mandatory field.
E.4	Principal exclusion criteria (list the most important, max 5000 characters)	Click in the free text field and list the details of the most important reasons for exclusion of subjects from the clinical trial from among the exclusion criteria described in the protocol (up to 5000 characters). Click the <add button icon> to add text in another language than English. Warning: Exclusion criteria should not be described as the contrary of the inclusion criteria listed in the free text field E.3. Warning: The principal exclusion criteria should not be mistaken for the criteria of study termination or treatment halt. Note: This is a mandatory field.
E.5	End points	
E.5.1	Primary end point(s) (max 5000 characters)	Click in the free text field and list the primary end points of the clinical trial (up to 5000 characters). Warning: The primary end point(s) should not be mixed with the objectives described in the section E.2.1. For example, for a trial which objective is to evaluate the efficacy of a treatment for hypercholesterolemia, the primary end point could be a 20% decrease of the cholesterol level. Click the <add button icon> to add text in another language than English.
E.5.1.1	Timepoint(s) of evaluation of this end point	Click in the free text field and include a time point for each of the primary end points detailed in the section above (up to 800 characters). Click the <add button icon> to add text in another language than English.
E.5.2	Secondary end point(s) (max 5000 characters)	Click in the free text field and list the secondary end points of the clinical trial (up to 5000 characters). Click the <add button icon> to add text in another language than English. Warning: The secondary end point(s) should not be mixed with the objectives described in the section E.2.1.
E.5.2.1	Timepoint(s) of evaluation of this end point	Click in the free text field and include a timepoint for each of the secondary end points detailed in the section above (up to 800 characters).

CTA Form Field Number	Field Name	Tool Tip Description
E.6 and E.7	Scope of the Trial, Trial Type and Phase	
E.6	Scope of the trial	This is a MANDATORY section and each sub question should be answered. Take into account all the objectives of the clinical trial (not only the primary objectives) and all the assessments conducted during the clinical trial. Tick more than one answer where applicable.
E.6.1	Diagnosis	Select 'Yes' if the assessment of the IMP efficacy as a diagnostic tool is within the clinical trial objectives.
E.6.2	Prophylaxis	Select 'Yes' if the assessment of the IMP efficacy as a prophylactic pr preventive intervention is within the clinical trial objectives.
E.6.3	Therapy	Select 'Yes' if the assessment of the IMP efficacy as a therapeutic intervention is within the clinical trial objectives.
E.6.4	Safety	Select 'Yes' if the study includes the assessment of the safety of use of the IMP(s).
E.6.5	Efficacy	Select 'Yes' if the study assesses efficacy of the IMP(s).
E.6.6	Pharmacokinetic	Select 'Yes' if the study will determine pharmacokinetic parameter of the IMP(s).
E.6.7	Pharmacodynamic	Select 'Yes' if the study will determine pharmacodynamics of the IMP(s).
E.6.8	Bioequivalence	Select 'Yes' if the study will determine bioequivalence of two or more IMP(s). Note: You should also mark 'Yes' in E.7.1.2.
E.6.9	Dose response	Select 'Yes' if the study will determine dose-response patterns of the IMP(s).
E.6.10	Pharmacogenetic	Select 'Yes' if the study will involve pharmacogenetic research of the IMP(s).
E.6.11	Pharmacogenomic	Select 'Yes' if the study will involve pharmacogenomic research of the IMP(s).
E.6.12	Pharmacoeconomic	Select 'Yes' if the study will involve pharmacoeconomic research of the IMP(s).
E.6.13	Others	A trial scope other than those options available above. If applicable then complete the free text field E.6.13.1, below.
E.6.13.1	If 'others', specify scope of the trial	Click in the free text field and include details of the trial scope, if E.6.13 is 'Yes' (up to 500 characters). Click the <add button icon> to add text in another language than English.
E.7	Trial type and phase	This is a MANDATORY section and each sub question should be answered. Identify the trial type and phase (Phase I, II, III or IV). Emphasis is placed on the ICH terms, human pharmacology, and therapeutic exploratory, therapeutic confirmatory and therapeutic use. Please refer to the ICH E8 Note for Guidance on general Considerations for Clinical Trials (CHMP/ICH/291/95) http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002877.pdf in particular Table 1 and section 3.1.3 of that guidance. Note: If the trial is a combination of more than one phase, select the item most applicable to this trial. Explanation of more than one phase trials should be given in the covering letter.
E.7.1	Human pharmacology (Phase I)	Human pharmacology (Phase I) trials are the first stage of testing in human subjects, generally comprising a small group of healthy volunteers. This phase includes trials designed to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of a drug. Note: If 'Yes' is selected, one item from E.7.1.1. to E.7.1.3. should be marked 'Yes' too.
E.7.1.1	First	Select 'Yes if this trial is the first time the IMP will be administered to

CTA Form Field Number	Field Name	Tool Tip Description
	administration to humans	humans. All the following trials will not be considered as a first administration to humans, in any country. Select 'No' in the case of new generics or new formulations of a medicinal product. Warning: If the medicinal product has been administered to humans in a previous trial, the trial in the present application cannot be considered a first administration to humans, even if this trial is the first administration to a new population or in a new indication. For example, if previous trials have been conducted on adults, and if the new trial is conducted on children, this new trial (concerned by the present application) cannot be considered the first administration to humans.
E.7.1.2	Bioequivalence study	Select 'Yes' for bioequivalence studies. Note: You should also mark 'Yes' in E.6.8
E.7.1.3	Other	Select 'Yes' if the phase 1 trial is neither a first administration to humans nor a bioequivalence study. Then complete the free text field 'Trial type Other specification' below.
E.7.1.3.1	If 'other', specify trial type	Click in the free text field and include details of the trial type (up to 100 characters). Click the <add button icon> to add text in another language than English.
E.7.2	Therapeutic exploratory (Phase II)	Therapeutic exploratory (Phase II) trials are performed on larger groups and are designed to assess how well an IMP works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients.
E.7.3	Therapeutic confirmatory (Phase III)	Therapeutic confirmatory (Phase III) trials are randomized clinical trials on large groups, designed to be a definitive assessment of how effective the drug is, in comparison with current best alternative treatment.
E.7.4	Therapeutic use (Phase IV)	Therapeutic use (Phase IV trials) involves products with a marketing authorisation.
E.8	Design of the trial	This is a MANDATORY section and each sub question should be answered.
E.8.1	Controlled	If 'Yes' selected, E.8.1.1-E.8.1.7.1 applying to the design of the trial should be completed. In a controlled trial, the tested product is compared to a reference treatment. The reference treatment can be, for example, a placebo, a product known to be effective, a surgical procedure, or a different dose of the same product.
E.8.1.1	Randomised	If each subject in the trial is randomly assigned to receive either the study treatment or a placebo, select 'Yes'.
E.8.1.2	Open	If the investigators and the subjects know which treatment is actually given, select 'Yes'.
E.8.1.3	Single blind	If the subjects (healthy volunteers or patients) included in the trial don't know which treatment they are given, select 'Yes'.
E.8.1.4	Double blind	If the investigators and the subjects included in the trial (healthy volunteers or patients) don't know which treatment is given, select 'Yes'.
E.8.1.5	Parallel group	Select 'Yes', if the trial compares groups of subjects concurrently, each group receiving different dose or treatment.
E.8.1.6	Cross over	Select 'Yes', if comparing two (or more) treatments in which patients are switched to the alternative treatment after a specified period of time.
E.8.1.7	Other	If there is another methodological characteristic to the trial design, select 'Yes' and complete free text field E.8.1.7.1 with a description.
E.8.1.7.1	If 'other', specify the design of the trial	Click in the free text field and include details of the trial design (up to 100 characters). Click the <add button icon> to add text in another language than English.
E.8.2	If controlled, specify the comparator:	Note: In a comparative trial, the investigational product or marketed product is compared against a standard drug (or placebo). The standard (or reference) or placebo medication is called the comparator drug. Ref: ("comparator drug." Pharmaceutical Medicine Dictionary. Philadelphia: Elsevier Health Sciences, 2001. Credo Reference. Web. 26 January 2010.). Warning: If the placebo is not used as a comparator but is only used in the trial in order to maintain the blind, the placebo should not be

CTA Form Field Number	Field Name	Tool Tip Description
		considered as a comparator and “No” should be ticked for the item E.8.2.2.
E.8.2.1	Other medicinal product(s)	Select 'Yes' if the comparator drug is another medicinal product.
E.8.2.2	Placebo	Select 'Yes' if the comparator drug is a placebo. Warning: If the placebo is only used in the trial in order to maintain the blind, the placebo should not be considered as a comparator and 'No' should be selected.
E.8.2.3	Other	If the comparator is neither another medicinal product nor a placebo, select 'Yes' here and provide details in the free text field below.
E.8.2.3.1	If 'other', specify the comparator	Click in the free text field and include details of comparators which are neither other medicinal products nor placebos - e.g. A medical device, a surgical procedure, the lack of treatment, a different treatment schedule, different dosage of the same product (up to 100 characters).
E.8.2.4	Number of treatment arms in the trial	Click in the free text field and include the number of treatment arms (groups) in the trial (up to 10 characters).
E.8.3	Single site in the Member State concerned (see also Section G)	Select 'Yes' if the trial is conducted in a single centre (clinical trial site) in the Member State concerned by the application.
E.8.4	Multiple sites in the Member State concerned (see also Section G)	Select 'Yes' if the trial is conducted in multiple sites in the concerned Member State. In this case, the number of sites in the Member State concerned should be entered in section E.8.4.1, below.
E.8.4.1	Number of sites anticipated in Member State concerned	Click in the free text field and include the number of sites in the Member State concerned where the trial will take place (up to 2 numbers).
E.8.5	Multiple Member States	Select 'Yes' if the trial will be conducted in more than one Member State of the EEA.
E.8.5.1	Number of sites anticipated in the EEA	Click in the free text field and include the number of sites in the European Economic Area where the trial is planned to take place (up to 2 numbers). Note: Please include the sites in the Member State concerned in your total.
E.8.6	Trial involving sites outside the EEA	
E.8.6.1	Trial being conducted both within and outside the EEA	Trial involves Investigator Sites in at least one Member State and at least one third country. A third country means a country which is not a Member State of the EU/EEA.
E.8.6.2	Trial being conducted completely outside of the EEA	Applicant must select "Yes" or "No". Trial only involves Investigator sites in third country. A third country means a country which is not a Member State of the EU/EEA.
E.8.6.3	If E.8.6.1 or E.8.6.2 are yes, specify	To select one country, click the country and then click 'Copy'. To select more than one country, hold CTRL then click the countries and then click 'Copy'.

CTA Form Field Number	Field Name	Tool Tip Description
	the countries in which trial sites are planned	To select all countries, click ‘Copy All’ button.
E.8.6.4	If E.8.6.1 or E.8.6.2 are yes, specify the number of sites anticipated outside of the EEA	Click in the free text field and include the number of sites outside the European Economic Area where the trial is planned to take place (up to 2 numbers).
E.8.7	Trial having a data monitoring committee?	Select 'Yes' if a data monitoring committee will be used for this trial.
E.8.8	Definition of the end of the trial and justification in the case where it is not the last visit of the last subject undergoing the trial	Click in the free text field and, if it is the last visit of the last subject, enter 'LVLS'. If it is not 'LVLS', provide the definition and justification (up to 500 characters). Click the <add button icon> to add text in another language than English.
E.8.9	Initial estimate of the duration of the trial (years, months and days)	The duration should be measured from the 1st inclusion until the last visit of the last subject (LVLS).
E.8.9.1	In the Member State concerned years	Click in each field and enter relevant numbers for years, months and days (up to 2 numbers per field).
E.8.9.1	In the Member State concerned months	
E.8.9.1	In the Member State concerned days	
E.8.9.2	In all countries concerned by the trial years	Click in each field and enter relevant numbers for years, months and days (up to 2 numbers per field).
E.8.9.2	In all countries concerned by the trial months	
E.8.9.2	In all countries concerned by the trial days	

CTA Form Field Number	Field Name	Tool Tip Description
E.8.10	Proposed date of start of recruitment	
E.8.10.1	In the Member State concerned	Enter the date on which recruitment of subjects for the trial is planned to commence in the MS concerned in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
E.8.10.2	In any country	Enter the date on which recruitment of subjects for the trial is planned to commence in all countries in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
F.1	Age Range	If there are no subjects under 18 it is sufficient to answer 'No' and then answer questions relevant to adults and elderly.
F.1.1	Are the trial subjects under 18?	If 'Yes' all fields from F.1.1.1. to F.1.1.6.should be completed (e.g. If subjects aged 2 to 11 are enrolled in the trial, select 'Yes' for F.1.1.5. and 'No' for F.1.1.1, F.1.1.2, F.1.1.3, F.1.1.4 and F.1.1.6.). .
F.1.1	Number of subjects for this age range:	Click in the field and enter relevant number of subjects (up to 10 numerals).
F.1.1.1	In Utero	Select 'Yes' if the subjects are unborn infants, still in the womb.
F.1.1.1.1	Number of subjects for this age range:	Click in the field and enter relevant number of subjects (up to 10 numerals).
F.1.1.2	Preterm newborn infants (up to gestational age < 37 weeks)	Select 'Yes' if the subjects are not more than 37 weeks from their conception.
F.1.1.2.1	Number of subjects for this age range:	Click in the field and enter relevant number of subjects (up to 10 numerals).
F.1.1.3	Newborns (0-27 days)	Select 'Yes' if the subjects are newborn babies aged 0-27 days.
F.1.1.3.1	Number of subjects for this age range:	Click in the field and enter relevant number of subjects (up to 10 numerals).
F.1.1.4	Infants and toddlers (28 days-23 months)	Select 'Yes' if the subjects are aged 28 days to 23 months.
F.1.1.4.1	Number of subjects for this age range:	Click in the field and enter relevant number of subjects (up to 10 numerals).
F.1.1.5	Children (2-11years)	Select 'Yes' if the subjects are aged 2 to 11 years.
F.1.1.5.1	Number of subjects for this age range:	Click in the field and enter relevant number of subjects (up to 10 numerals).
F.1.1.6	Adolescents (12-17 years)	Select 'Yes' if the subjects are aged 12 to 17 years.
F.1.1.6.1	Number of subjects for	Click in the field and enter relevant number of subjects (up to 10 numerals).

CTA Form Field Number	Field Name	Tool Tip Description
	this age range:	
F.1.2	Adults (18-64 years)	Select 'Yes' if the subjects are aged 18 to 64 years.
F.1.2.1	Number of subjects for this age range:	Click in the field and enter relevant number of subjects (up to 10 numerals).
F.1.3	Elderly (>=65 years)	Select 'Yes' if the subjects are aged 65 years or more.
F.1.3.1	Number of subjects for this age range:	Click in the field and enter relevant number of subjects (up to 10 numerals).
F.2	Gender	
F.2.1	Female	Select 'Yes' if the trial includes female subjects. This is mandatory.
F.2.2	Male	Select 'Yes' if the trial includes male subjects. This is mandatory.
F.3	Group of trial subjects	
F.3.1	Healthy volunteers	Select 'Yes' if the trial includes subjects in good health. This is mandatory
F.3.2	Patients	Select 'Yes' if the trial includes subjects, who are currently patients. This is mandatory.
F.3.3	Specific vulnerable populations	Select 'Yes' if the trial includes subjects (healthy volunteers or patients), who are considered to be part of a vulnerable population (see ICH GCP definition of 'Vulnerable Subjects' here). If 'Yes', please complete sections F.3.3.1-F.3.3.7.1. This is mandatory.
F.3.3.1	women of childbearing potential not using contraception	Select 'Yes' if the trial includes women subjects who have the potential to give birth and are not using contraception.
F.3.3.2	women of child-bearing potential using contraception	Select 'Yes' if the trial includes women subjects who have the potential to give birth and are using contraception.
F.3.3.3	pregnant women	
F.3.3.4	nursing women	Select 'Yes' if the trial includes women subjects who are breastfeeding.
F.3.3.5	emergency situation	Select 'Yes' if an emergency situation, where urgent care is needed for the patient and this involves enrolment in the trial (for example: myocardial infarction, or head injury).
F.3.3.6	subjects incapable of giving consent personally?	Select 'Yes' if subjects who are incapable of giving consent personally are to be enrolled in the trial. For example: -Subjects incapable of giving consent for physical or physiological reasons, or reasons linked to their medical condition (e.g. coma, mental disability and in accordance with national requirements). -Subjects under age incapable of giving consent personally. -Subjects with a condition which makes them incapable of giving consent personally and who need urgent care. In this last case, select 'Yes' for F.3.3.5, above. Note: This section is for subjects who are vulnerable for reasons other than their age alone. Children are already identified under F.1.1, but institutionalised, or mentally handicapped children should be mentioned here.
F.3.3.6.	If 'Yes',	Click in the free text field and include details of the groups of population

CTA Form Field Number	Field Name	Tool Tip Description
1	specify	subjects incapable of giving consent. Click the <add button icon> to add text in another language than English. Note: This section is for subjects who are vulnerable for reasons other than their age alone. Children are already identified under F.1.1, but institutionalised, or mentally handicapped children should be mentioned here (up to 250 characters).
F.3.3.7	others	Select 'Yes' if other categories of vulnerable subjects will be enrolled in the trial. For example : -Subjects who are in prison -Subjects hospitalised without their consent. If 'Yes', complete section F.3.3.7.1 by adding details.
F.3.3.7.1	If 'others', specify the specific vulnerable populations	Click in the free text field and include details of the other category of vulnerable populations (up to 100 characters). Click the <add button icon> to add text in another language than English.
F.4	Planned number of subjects to be included	The information entered in this section should match the information presented in sections E.8.3., E.8.4., E.8.5. and E.8.6.
F.4.1	In the member state	Click in the free text field and include details of the planned number of subjects to be enrolled in the Member State to which the application is submitted (up to six numerals). **Substantial Amendment Note:** For clarification purposes, ICH E6, section 6.9.2 states: "The number of subjects planned to be enrolled. In multicentre trials, the numbers of enrolled subjects projected for each trial site should be specified".
F.4.2	For a multinational trial	
F.4.2.1	In the EEA	Click in the free text field and include details of the planned number of subjects to be enrolled in the EEA (including the concerned Member State) in total (up to six numerals).
F.4.2.2	In the whole clinical trial	Click in the free text field and include details of the planned number of subjects to be included in the entire world (up to six numerals).
F.5	Plans for treatment or care after the subject has ended the participation in the trial (if it is different from the expected normal treatment of that condition)	Click in the free text field and include details of post-trial treatment or care, if not already provided in the protocol (up to 500 characters).
G.1 / G.2	G.1 and G.2 Investigator Details	Complete the Investigator Sites in this Member State only. At least one (the principal of a single centre or coordinator of a multicentre trial should be added.
G.1 / G.2	What is the role of this investigator?	Click the drop-down list, then select the investigator's role from the available options.
G.1.1 / G.2.1	Given name	Also known as first name or forename.
G.1.2 / G.2.2	Middle name	Click in the free text field and include the investigator's middle name. The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example,

CTA Form Field Number	Field Name	Tool Tip Description
		enter “Elizabeth” for “Ana Elizabeth” (up to 100 characters).
G.1.3 / G.2.3	Family name	Click in the free text field and include the investigator's family name, which is also known as the surname.
G.1.4 / G.2.4	Qualification (MD...)	Click in the free text field and include the investigator's qualifications (up to 50 characters).
G.1.5 / G.2.5	Professional address	
G.1.5 / G.2.5	Institution name	
G.1.5 / G.2.5	Institution department name	
G.1.5.1 / G.2.5.1	Street address	The building name and/or number and street name.
G.1.5.2 / G.2.5.2	Town/city	
G.1.5.3 / G.2.5.3	Post code	The address' post code (where applicable).
G.1.5.4 / G.2.5.4	Country	
G.1.6 / G.2.6	Telephone number	The contact details (phone number, fax, e-mail) are those of the Network contact mentioned in section G.4.2.
G.1.7 / G.2.7	Fax number	The contact details (phone number, fax, e-mail) are those of the Network contact mentioned in section G.4.2.
G.1.8 / G.2.8	E-mail	The contact details (phone number, fax, e-mail) are those of the Network contact mentioned in section G.4.2.
G.3	G.3 Central Technical Facility Details	Only central facilities should be completed who supply services for at least this Member State. The facility may be in this Member State, another Member State or a 3rd Country. Central Technical Facilities includes central laboratories and central ECG or image processing facilities.
G.3.1	Name of Organisation	
G.3.2	Central technical facility organisation department	
G.3.3	Name of contact person	
G.3.3.1	Given name	Also known as first name or forename.
G.3.3.2	Middle name	The middle name is mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter “Elizabeth” for “Ana Elizabeth”
G.3.3.3	Family name	Also known as Surname. Use this field to record a functional role.
G.3.4	Address	
G.3.4.1	Street address	The building name and/or number and street name.
G.3.4.2	Town/ city	
G.3.4.3	Post code	The address' post code (where applicable).
G.3.4.4	Country	
G.3.5	Telephone number	The contact details (phone number, fax, e-mail) are those of the central technical facility contact mentioned in section G.3.1. Please include the

CTA Form Field Number	Field Name	Tool Tip Description
		international or applicable area codes.
G.3.6	Fax number	The contact details (phone number, fax, e-mail) are those of the central technical facility contact mentioned in section G.3.1. Please include the international or applicable area codes.
G.3.7	E-mail	The contact details (phone number, fax, e-mail) are those of the central technical facility contact mentioned in section G.3.1. Please include the international or applicable area codes.
G.3.8	Enter the details of any duties subcontracted to this central technical facility in this trial	Central technical facilities or Sponsor's subcontractor facilities should be detailed where used, below.
G.3.8.1	Routine clinical pathology testing	Select 'Yes' if the CTF will provide routine clinical pathology testing.
G.3.8.2	Clinical chemistry	Select 'Yes' if the CTF will provide clinical chemistry analysis or testing.
G.3.8.3	Clinical haematology	Select 'Yes' if the CTF will provide Clinical haematology analysis or testing.
G.3.8.4	Clinical microbiology	Select 'Yes' if the CTF will provide Clinical microbiology analysis or testing.
G.3.8.5	Histopathology	Select 'Yes' if the CTF will provide Histopathology analysis or testing.
G.3.8.6	Serology/ endocrinology	Select 'Yes' if the CTF will provideSerology/ endocrinology analysis or testing.
G.3.8.7	Analytical chemistry	Select 'Yes' if the CTF will provide Analytical chemistry.
G.3.8.8	ECG analysis/ review	Select 'Yes' if the CTF will provide ECG analysis/ review.
G.3.8.9	Medical image analysis/ review - X-ray, MRI, ultrasound, etc.	Select 'Yes' if the CTF will provide medical image analysis/ review - X-ray, MRI, ultrasound, etc.
G.3.8.10	Primary/ surrogate endpoint test	Select 'Yes' if the CTF will provide Primary/ surrogate endpoint test.
G.3.8.11	Other Duties subcontracted?	Select 'Yes' if the services provided by a central technical facility are not covered in the above options. Then complete the free text field below.
G.3.8.11.1	If 'Yes', specify the other duties	Click in the free text field and include the services provided by a central technical facility (up to 100 characters).
G.4	Networks to be involved in the Trial	Include details of any Clinical Investigator Network involved in the Clinical Trial.
G.4.1	Name of Organisation	
G.4.2	Name of contact person	
G.4.2.1	Given name	Also known as first name or forename.
G.4.2.2	Middle name	The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For

CTA Form Field Number	Field Name	Tool Tip Description
		example, enter “Elizabeth” for “Ana Elizabeth”
G.4.2.3	Family name	Also known as Surname. Use this field to record a functional role.
G.4.3	Address	
G.4.3.1	Street address	The building name and/or number and street name.
G.4.3.2	Town/ city	
G.4.3.3	Post code	The address' post code (where applicable).
G.4.3.4	Country	
G.4.4	Telephone number	The contact details (phone number, fax, e-mail) are those of the network contact mentioned in section G.4.2. Please include the international or applicable area codes.
G.4.5	Fax number	The contact details (phone number, fax, e-mail) are those of the network contact mentioned in section G.4.2. Please include the international or applicable area codes.
G.4.6	E-mail	The contact details (phone number, fax, e-mail) are those of the network contact mentioned in section G.4.2. Please include the international or applicable area codes.
G.4.7	Activities carried out by the network	Click in the free text field and include the activities performed by the trial network (up to 2000 characters).
G.5	Organisations to whom the sponsor has transferred trial related duties and functions	Only central CRO facilities supplying services for at least this Member State should be entered (not e.g. individual field-based CRAs). The facility may be in this Member State, another Member State or a 3rd Country Note that the answer to question 'G.5.1 Has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party'? will be filled in automatically by the system once the details of the first subcontractor have been entered.
G.5.1	Enter the details if the sponsor has transferred any major or all the sponsor’s trial related duties and functions to another organisation or third party.	
G.5.1.1	Organisation name	
G.5.1.2	Organisation department	
G.5.1.3	Name of contact person	
G.5.1.3.1	Given name	Also known as first name or forename.
G.5.1.3.2	Middle name	The middle name is not mandatory. Middle name refers to the second given name and does not refer to any part of the family name. For example, enter “Elizabeth” for “Ana Elizabeth”
G.5.1.3.3	Family name	Also known as Surname. Use this field to record a functional role.
G.5.1.4	Address	
G.5.1.4.1	Street address	The building name and/or number and street name.
G.5.1.4.	Town/ city	

CTA Form Field Number	Field Name	Tool Tip Description
2		
G.5.1.4.3	Post code	The address' post code (where applicable).
G.5.1.4.4	Country	
G.5.1.5	Telephone number	The contact details (phone number, fax, e-mail) are those of the subcontractor contact mentioned in section G.5.1.2. Please include the international or applicable area codes.
G.5.1.6	Fax number	The contact details (phone number, fax, e-mail) are those of the subcontractor contact mentioned in section G.5.1.2. Please include the international or applicable area codes.
G.5.1.7	E-mail	The contact details (phone number, fax, e-mail) are those of the subcontractor contact mentioned in section G.5.1.2. Please include the international or applicable area codes.
G.5.1.8	All tasks of the sponsor	Select 'Yes' if the sponsor will delegate all tasks of sponsor.
G.5.1.9	Monitoring	Select 'Yes' if the vendor will undertake monitoring duties.
G.5.1.10	Regulatory (e.g. preparation of applications to CA and Ethics Committee)	Select 'Yes' if the vendor will undertake regulatory duties (e.g. preparation of applications to CA and Ethics Committee).
G.5.1.11	Investigator recruitment	Select 'Yes' if the vendor will undertake investigator recruitment/selection duties.
G.5.1.12	IVRS - treatment randomisation	Select 'Yes' if the vendor will undertake treatment randomisation duties or duties include the setup, maintenaince and operation of automated Interactive Response systems, like IVRS (voice), IWRS (internet/world wide web based) or hybrid ones.
G.5.1.13	Data Management	Select 'Yes' if the vendor will undertake Data Management duties.
G.5.1.14	E-data capture	Select 'Yes' if the vendor will undertake electronic data capture (EDC) duties.
G.5.1.15	SUSAR reporting	Select 'Yes' if the vendor will undertake drug safety duties that involve SUSAR reporting.
G.5.1.16	Quality assurance auditing	Select 'Yes' if the vendor will perform Quality Assurance auditing.
G.5.1.17	Statistical analysis	Select 'Yes' if the vendor will undertake statistical analysis.
G.5.1.18	Medical writing	Select 'Yes' if the vendor will undertake Medical writing duties.
G.5.1.19	Other Duties subcontracted ?	Select 'Yes' if the vendor will undertake other duties subcontracted not mentioned above.
G.5.1.19.1	If 'Yes', specify the other duties	Click in the free text field and include other duties performed by the subcontractor on behalf of the sponsor, if not detailed in the above options (up to 100 characters).
H.2.1	National Competent authority name	
H.2.2	Address	
H.2.2.1	Street address	The building name and/or number and street name.
H.2.2.2	Town/ city	
H.2.2.3	Post code	The address' post code (where applicable).
H.2.2.4	Country	

CTA Form Field Number	Field Name	Tool Tip Description
H.2.3	Date of submission	Enter the date on which the application was submitted to the NCA concerned in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
H.3	Authorisation/ Opinion	
H.3.1 / H.3.2 / H.3.3	What is the status of the National Competent Authority's authorisation?	Select relevant option from drop-down list.
	If 'Given' specify:	
H.3.3.1	Date of authorisation	Enter the date on which the application was authorised by the NCA concerned in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
H.3.3.2 / H.3.3.3	Indicate whether accepted or not	
H.3.3.3.1	If 'not accepted', give the reasons	Click in the free text field and include reasons for non-acceptance of NCA Authorisation (up to 1000 characters).
H.3.3.3.2	If 'not accepted', give the eventual anticipated date of resubmission	Enter the date on which the application is expected to be resubmitted to NCA in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
H.2.1	Ethics committee name	
H.2.2	Address	
H.2.2.1	Street address	The building name and/or number and street name.
H.2.2.2	Town/ city	
H.2.2.3	Post code	The address' post code (where applicable).
H.2.2.4	Country	
H.2.3	Date of submission	Enter the date on which the application was submitted to the Independent Ethics Committee concerned in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
H.3	Authorisation/ Opinion	
H.3.1 / H.3.2 / H.3.3	What is the status of the Ethics Committee's opinion?	Select relevant option from drop-down list.
	If 'Given' specify:	
H.3.3.1	Specify the date of opinion	Enter the date on which the Independent Ethics Committee provided their opinion in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
H.3.3.2 / H.3.3.3	Indicate whether favourable or not	Select relevant option from drop-down list.
H.3.3.3.	If 'not	Click in the free text field and include reasons for non-favourable opinion

CTA Form Field Number	Field Name	Tool Tip Description
1	favourable', give the reasons	from the Independent Ethics Committee (up to 1000 characters).
H.3.3.3.2	If 'not favourable', give the eventual anticipated date of resubmission	Enter the date on which the application is expected to be resubmitted to Independent Ethics Committee in the following format: YYYY-MM-DD. Alternatively, click the calendar and select the start date.
H.4	Third Country in which the trial was first authorised:	
H.4.1	Clinical trial has been reviewed and given the necessary approval(s) by the Regulatory Authority (where required) and by the Ethics Committee(s).	Select relevant third country from drop-down list.