This version of Annexes 1-3 will come into use when Lot 2A of the EudraCT database goes live. Until then the version available from EudraCT should be used.

Annex 1: Application Form

REQUEST FOR AUTHORISATION OF A CLINICAL TRIAL ON A MEDICINAL PRODUCT FOR HUMAN USE TO THE COMPETENT AUTHORITIES AND FOR OPINION OF THE ETHICS COMMITTEES IN THE COMMUNITY

For official use:

Date of receiving the request : Date of request for information to make it valid :	Date of request for additional information :	Grounds for non acceptance/ negative opinion **:** ☐ Give date :
Date of valid application : Date of start of procedure:	Date of receipt of additional / amended information :	Authorisation/ positive opinion **:** ☐ Give date :
Competent authority registration number: Ethics Committee registration number :		Withdrawal of application ☐ Give date :

To be filled in by the applicant:

The questions in this form for the request for authorisation from the Competent Authority are also relevant for the opinion from an Ethics Committee (it represents module 1 of the form for applying to an ethics committee) and can be used as part of that application. Please indicate the relevant purpose in a box below.

REQUEST FOR AUTHORISATION TO THE COMPETENT AUTHORITY: ☐
REQUEST FOR OPINION OF THE ETHICS COMMITTEE: ☐

A TRIAL IDENTIFICATION

A.1	**Member State in which the submission is being made :**
A.2	**EudraCT number[1]**
A.3	**Full title of the trial :**
A.4	**Sponsor's protocol code number, version, and date[2]:**
A.5	**Name or abbreviated title of the trial where available:**
A.6	**ISRCTN number[3], if available**
A.7	**Is this a resubmission? yes ☐ no ☐ If yes, indicate the resubmission letter[4]**

B IDENTIFICATION OF THE SPONSOR RESPONSIBLE FOR THE REQUEST

B.1	**SPONSOR**
B.1.1	Name of organisation :
B.1.2	Name of the person to contact:
B.1.3	Address :
B.1.4	Telephone number :
B.1.5	Fax number :
B.1.6	e-mail:

[1] Append the EudraCT number confirmation receipt.
[2] Any translation of the protocol should be assigned the same date and version as those in the original document.
[3] International Standard Randomised Controlled Trial Number. Sponsors may wish to use an International Standardised Random Controlled Trial Number (ISRCTN) to identify their trial in addition to the EudraCT number; for instance if their trial is part of a multinational trial with sites outside the Community. They can obtain the number and guidance from the Current Controlled Trials website http://www.controlled-trials.com/isrctn to which there is a link from the EudraCT database website http://www.eudract.emea.eu.int. When available they should provide it in Section A.6 of the application form.
[4] For a resubmission following previous withdrawal of an application or unfavourable opinion of an ethics committee, or previous withdrawal of an application or refusal of a request by the competent authority, enter a letter in the sequence, A for first resubmission, B for second, C for third et seq.

B.2	**LEGAL REPRESENTATIVE[5] OF THE SPONSOR IN THE COMMUNITY FOR THE PURPOSE OF THIS TRIAL** (if different from the sponsor)
B.2.1	Name of organisation:
B.2.2	Name of the person to contact :
B.2.3	Address :
B.2.4	Telephone number :
B.2.5	Fax number :
B.2.6	e-mail:

B.3	**STATUS OF THE SPONSOR:**	
B.3.1	Commercial[6]	☐
B.3.2	Non commercial	☐

C APPLICANT IDENTIFICATION, (please tick the appropriate box)

C.1	**REQUEST FOR THE COMPETENT AUTHORITY**	☐
C.1.1	Sponsor	☐
C.1.2	Legal representative of the sponsor	☐
C.1.3	Person or organisation authorised by the sponsor to make the application	☐
C.1.4	Complete the details of the applicant below even if they are provided elsewhere on the form:	
C.1.4.1	Organisation :	
C.1.4.2	Name of contact person :	
C.1.4.3	Address :	
C.1.4.4	Telephone number :	
C.1.4.5	Fax number :	
C.1.4.6	E-mail	
C.1.5	Request to receive an .xml copy of CTA data:	
C.1.5.1	Do you want a .xml file copy of the CTA form data saved on EudraCT?	☐ yes ☐ no
C.1.5.1.1	If yes provide the e-mail address(es) to which it should be sent (up to 5 addresses):	
C.1.5.1.2	Do you want to receive this via password protected link(s)[7]?	☐ yes ☐ no
If you answer no to question C.1.5.1.2 the .xml file will be transmitted by less secure e-mail link(s)		

C.2	**REQUEST FOR THE ETHICS COMMITTEE**	☐
C.2.1	Sponsor	☐
C.2.2	Legal representative of the sponsor	☐
C.2.3	Person or organisation authorised by the sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[8]:	
	• Co-ordinating investigator (for multicentre trial)	☐
	• Principal investigator (for single centre trial).	☐
C.2.5	Complete the details of the applicant below even if they are provided elsewhere on the form:	
C.2.5.1	Organisation :	
C.2.5.2	Name :	
C.2.5.3	Address :	
C.2.5.4	Telephone number :	
C.2.5.5	Fax number :	
C.2.5.6	E-mail :	

[5] In accordance with Article 19 of Directive 2001/20/EC.
[6] 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.
[7] This requires a EudraLink account. (See www.eudract.emea.eu.int for details)
[8] According to national legislation.

D INFORMATION ON EACH IMP.

Information on each 'bulk product' before trial-specific operations (blinding, trial specific packaging and labelling) should be provided in this section for each investigational medicinal product (IMP) being tested including each comparator and each placebo, if applicable. If the trial is performed with several products use extra pages and give each product a sequential number in D1.1 If the product is a combination product information should be given for each active substance.

D.1 IMP IDENTIFICATION
Indicate which of the following is described below, then repeat as necessary for each of the numbered IMPs to be used in the trial(assign numbers from 1-n):
D.1.1 This refers to the IMP number: (..)
D.1.2 IMP being tested ☐
D.1.3 IMP used as a comparator ☐
For placebo go directly to D7

D.2 STATUS OF THE IMP.
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
D.2.1 Has the IMP to be used in the trial a marketing authorisation?: yes ☐ no ☐
D.2.1.1 If yes to D.2.1, specify for the product to be used in the trial:
D.2.1.1.1 Trade name[9]:
D.2.1.1.2 Name of the MA holder:[9]
D.2.1.1.3 MA number (if MA granted by a Member State):[9]
D.2.1.1.4 Is the IMP modified in relation to its MA? yes ☐ no ☐
D.2.1.1.4.1 If yes, please specify:
D.2.1.2 Which country granted the MA? (……)
D.2.1.2.1 Is this the Member State concerned with this application? yes ☐ no ☐
D.2.1.2.2 Is this another Member State? yes ☐ no ☐

D.2.2 Situations where an IMP to be used in the CT has a MA in the MS concerned, but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start
D.2.2.1 In the protocol, is treatment defined only by active substance? yes ☐ no ☐
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? yes ☐ no ☐
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 as IMPs are defined as belonging to an ATC group[6] yes ☐ no ☐
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
D.2.2.4 Other : yes ☐ no ☐
D.2.2.4.1 If yes, please specify :

D.2.3 IMPD submitted:
D.2.3.1 Full IMPD yes ☐ no ☐
D.2.3.2 Simplified IMPD[10] yes ☐ no ☐
D.2.3.3 Summary of product characteristics (SmPC) only yes ☐ no ☐

D.2.4 Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community? yes ☐ no ☐
D.2.4.1 If yes specify which Member States:

[9] Available from the Summary of Product Characteristics (SmPC).

[10] Provide justification for using simplified dossier in the covering letter (see Section 4.1.6.2.1 and table 1).

D.2.5 Has the IMP been designated in this indication as an orphan drug in the Community?	**y**es ☐ no ☐
D.2.5.1 If yes, give the orphan drug designation number[11] **: ( )**	

D.2.6 Has the IMP been the subject of scientific advice related to this clinical trial?	yes ☐ no ☐
D.2.6.1 If yes to D.2.6 please indicate source of advice and provide a copy in the CTA request:	
D.2.6.1.1 From the CHMP[12]?	yes ☐ no ☐
D.2.6.1.2 From a MS competent authority?	yes ☐ no ☐

D.3 DESCRIPTION OF THE IMP	
D.3.1 Product name where applicable[13] :	
D.3.2 Product code where applicable[14] :	
D.3.3 ATC code, if officially registered[15]:	
D.3.4 Pharmaceutical form (use standard terms) :	
D.3.5 Maximum duration of treatment of a subject according to the protocol :	
D.3.6 Maximum dose allowed (specify : per day or total dose; units and route of administration,):	
D.3.7 Route of administration (use standard terms):	
D.3.8 Name of each active substance (INN or proposed INN if available):	
D.3.9 Other available name for each active substance (CAS[16], current sponsor code(s), other descriptive name, etc ; provide all available) :	
D.3.10 Strength (specify all strengths to be used) :	
D.3.10.1 Concentration unit:	
D.3.10.2 Concentration type (“exact number”, “range", "more than” or “up to”) :	
D.3.10.3 Concentration (number).	

D.3.11 Type of IMP			
Does the IMP contain an active substance :			
D.3.11.1	Of chemical origin?	yes ☐	no ☐
D.3.11.2	Of biological / biotechnological origin?[17]	yes ☐	no ☐
Is this a :			
D.3.11.3	Cell therapy medicinal product[17] ?	yes ☐	no ☐
D.3.11.4	Gene therapy medicinal product[17]?	yes ☐	no ☐
D.3.11.5	Radiopharmaceutical medicinal product?	yes ☐	no ☐
D.3.11.6	Immunological medicinal product (such as vaccine, allergen, immune serum)?	yes ☐	no ☐
D.3.11.7	Plasma derived medicinal product?	yes ☐	no ☐
D.3.11.8	Other extractive medicinal product?	yes ☐	no ☐
D.3.11.9	Herbal medicinal product?	yes ☐	no ☐
D.3.11.10	Homeopathic medicinal product?	yes ☐	no ☐
D.3.11.11	Medicinal product containing genetically modified organisms?	yes ☐	no ☐
If yes to D.3.11.11:			
D.3.11.11.1	Has the authorisation for contained use or release been granted?	yes ☐	no ☐
D.3.11.11.2	Is it pending?	yes ☐	no ☐
D.3.11.12	Another type of medicinal product?	yes ☐	no ☐
D.3.11.12.1	If yes, specify :		

[11] According to the Community register on orphan medicinal products (Regulation (EC) n° 141/2000) : http://pharmacos.eudra.org/F2/register/orphreg.htm

[12] Committee for Medicinal Products for Human Use of the European Medicines Agency

[13] To be provided only when there is no trade name. This is the name routinely used by a sponsor to identify the IMP in the CT documentation (protocol, IB…).

[14] To be provided only when there is no trade name. 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.

[15] Available from the Summary of Product Characteristics (SmPC).

[16] Chemical Abstracts Service.

[17] Complete also sections D.4,and where applicable sections D.5,and D.6.

D.4 BIOLOGICAL / BIOTECHNOLOGICAL INVESTIGATIONAL MEDICINAL PRODUCTS INCLUDING VACCINES	
D.4.1 Type of product	
D.4.1.1 Extractive	yes ☐ no ☐
D.4.1.2 Recombinant	yes ☐ no ☐
D.4.1.3 Vaccine	yes ☐ no ☐
D.4.1.4 GMO	yes ☐ no ☐
D.4.1.5 Plasma derived products	yes ☐ no ☐
D.4.1.6 Others	yes ☐ no ☐
D.4.1.6.1 If others, specify :	

D.5 SOMATIC CELL THERAPY INVESTIGATIONAL MEDICINAL PRODUCT (NO GENETIC MODIFICATION)	
D.5.1 Origin of cells	
D.5.1.1 Autologous	yes ☐ no ☐
D.5.1.2 Allogeneic	yes ☐ no ☐
D.5.1.3 Xenogeneic	yes ☐ no ☐
D.5.1.3.1 If yes, specify species of origin :	
D.5.2 Type of cells	
D.5.2.1 Stem cells	yes ☐ no ☐
D.5.2.2 Differentiated cells	yes ☐ no ☐
D.5.2.2.1 If yes, specify the type (e.g. keratinocytes, fibroblasts, chondrocytes,…) :	
D.5.2.3 Others :	yes ☐ no ☐
D.5.2.3.1 If others, specify :	

D.6 GENE THERAPY INVESTIGATIONAL MEDICINAL PRODUCTS	
D.6.1 Gene(s) of interest :	
D.6.2 In vivo gene therapy:	**yes ☐ no ☐**
D.6.3 Ex vivo gene therapy:	**yes ☐ no ☐**
D.6.4 Type of gene transfer product	
D.6.4.1 Nucleic acid (e.g. plasmid) :	yes ☐ no ☐
If yes, specify if:	
D.6.4.1.1 Naked:	yes ☐ no ☐
D.6.4.1.2 Complexed	yes ☐ no ☐
D.6.4.2 Viral vector:	yes ☐ no ☐
D.6.4.2.1 If yes, specify the type: adenovirus, retrovirus, AAV, …:	
D.6.4.3 Others :	yes ☐ no ☐
D.6.4.3.1 If others, specify :	

D.6.5 Genetically modified cells :	yes ☐ no ☐
If yes, specify - origin of the cells :	
D.6.5.1 Autologous :	yes ☐ no ☐
D.6.5.2 Allogeneic :	yes ☐ no ☐
D.6.5.3 Xenogeneic :	yes ☐ no ☐
D.6.5.3.1 If yes, specify species of origin :	
D.6.5.4 Other type of cells (hematopoietic stem cells, …) : If yes specify:	yes ☐ no ☐

D.6.6 Comments on novel aspects of gene therapy investigational product if any *(free text)***:**

D.7	**INFORMATION ON PLACEBO (if relevant; repeat as necessary)**	
D.7.1	Is a there a placebo:	yes ☐ no ☐
D.7.2	This refers to placebo number:	(..)
D.7.3	Pharmaceutical form :	
D.7.4	Route of administration :	
D.7.5	Which IMP is it a placebo for? Specify IMP Number(s) from D1.1:	(..)
D.7.5.1	Composition, apart from the active substance(s):	
D.7.5.2	Is it otherwise identical to the IMP?	yes ☐ no ☐
D.7.5.2.1	If not, specify major ingredients :	

D.8 SITE WHERE THE QUALIFIED PERSON CERTIFIES BATCH RELEASE[18]

*This section is dedicated to **finished** IMPs, i.e. medicinal products randomised, packaged, labelled and certified for use in the clinical trial. If there is more than one site or more than one IMP is certified, use extra pages and give each IMP its number from section D.1.1 or D.7.2 In the case of multiple sites indicate the product certified by each site.*

D.8.1 Do not fill in section D.8.2 for an IMP that:

*Has a MA in the EU **and***

*Is sourced from the EU market **and***

*Is used in the trial without modification(e.g. not overencapsulated) **and***

The packaging and labelling is carried out for local use only as per Article 9.2. of the Directive 2005/28/EC (GCP Directive)

If all these conditions are met tick ☐ and list the number(s) of each IMP including placebo from sections D.1.1 and D.7.2 to which this applies: (..);

D.8.2 Who is responsible in the Community for the certification of the finished IMP?

This site is responsible for certification of (list the number(s) of each IMP including placebo from sections D.1.1 and D.7.2): (..);

please tick the appropriate box :

D.8.2.1 Manufacturer ☐

D.8.2.2 Importer ☐

D.8.2.3 Name of the organisation:

D.8.2.3.1 Address :

D.8.2.4 Give the manufacturing authorisation number :

D.8.2.4.1 If no authorisation, give the reasons :

*Where the product does not have a MA in the EU, but is supplied in bulk **and** final packaging and labelling for local use is carried out in accordance with Article 9.2. of Directive 2005/28/EC (GCP Directive) then enter the site where the product was finally certified for release by the Qualified Person for use in the clinical trial at D.8.2 above.*

E GENERAL INFORMATION ON THE TRIAL

This section should be used to provide information about the aims, scope and design of the trial. When the protocol includes a sub-study in the MS concerned section E.2.3 should be completed providing information about the sub-study. To identify it check the sub-study box in the 'Objective of the trial' question below

E.1	**MEDICAL CONDITION OR DISEASE UNDER INVESTIGATION**	
E.1.1	**Specify the medical condition(s) to be investigated[19] (free text) :**	
E.1.2	**MedDRA version, level, term and classification code[20](repeat as necessary) :**	
E.1.3	**Is any of the conditions being studied a rare disease[21]?**	**yes ☐ no ☐**

[18] In accordance with paragraph 38 of Annex 13 of Volume 4 of the Rules Governing Medicinal Products in the European Union

[19] In the case of healthy volunteer trials, the intended indication for the product under development should be provided.

E.2	OBJECTIVE OF THE TRIAL
E.2.1	**Main objective:**
E.2.2	**Secondary objectives:**
E.2.3	**Is there a sub-study?** **yes ☐ no ☐**
E.2.3.1	**If yes give the full title, date and version of each sub-study and their related objectives:**

E.3	PRINCIPAL INCLUSION CRITERIA *(list the most important)*

E.4	PRINCIPAL EXCLUSION CRITERIA *(list the most important)*

E.5	PRIMARY END POINT(S) :

E.6	SCOPE OF THE TRIAL – Tick all boxes where applicable	
E.6.1	**Diagnosis**	☐
E.6.2	**Prophylaxis**	☐
E.6.3	**Therapy**	☐
E.6.4	**Safety**	☐
E.6.5	**Efficacy**	☐
E.6.6	**Pharmacokinetic**	☐
E.6.7	**Pharmacodynamic**	☐
E.6.8	**Bioequivalence**	☐
E.6.9	**Dose Response**	☐
E.6.10	**Pharmacogenetic**	☐
E.6.11	**Pharmacogenomic**	☐
E.6.12	**Pharmacoeconomic**	☐
E.6.13	**Others**	☐
E.6.13.1	**If others, specify:**	

E.7	TRIAL TYPE[22] AND PHASE	
E.7.1	**Human pharmacology (Phase I)**	☐
Is it:		
E.7.1.1	First administration to humans	☐
E.7.1.2	Bioequivalence study	☐
E.7.1.3	Other :	☐
E.7.1.3.1	If other, please specify	
E.7.2	**Therapeutic exploratory (Phase II)**	☐
E.7.3	**Therapeutic confirmatory (Phase III)**	☐
E.7.4	**Therapeutic use (Phase IV)**	☐

[20] Applicants are encouraged to provide the MedDRA lower level term if applicable and classification code. These can be accessed from the EMEA EudraCT website (http:\\www.eudract.emea.eu.int).

[21] Points to consider on the calculation and reporting of the prevalence of a condition for Orphan drug designation : COM/436/01 (www.emea.eu.int/htms/human/comp/orphaapp.htm).

[22] The descriptions of the trial types provided are those recommended in preference to Phases. See page 5 of Community guideline CPMP/ICH/291/95. The development of a new indication after initial approval of a medicine should be considered as a new development plan.

E.8	DESIGN OF THE TRIAL	
E.8.1	**Controlled**	yes ☐ no ☐
If yes, specify:		
E.8.1.1	Randomised	yes ☐ no ☐
E.8.1.2	Open :	yes ☐ no ☐
E.8.1.3	Single blind :	yes ☐ no ☐
E.8.1.4	Double blind:	yes ☐ no ☐
E.8.1.5	Parallel group:	yes ☐ no ☐
E.8.1.6	Cross over :	yes ☐ no ☐
E.8.1.7	Other :	yes ☐ no ☐
E.8.1.7.1	If yes to other specify:	
E.8.2	**If controlled, specify the comparator**:	
E.8.2.1	Other medicinal product(s)	yes ☐ no ☐
E.8.2.2	Placebo	yes ☐ no ☐
E.8.2.3	Other	yes ☐ no ☐
E.8.2.3.1	If yes to other, specify :	
E.8.3	**Single site in the Member State concerned (see also section G) :**	yes ☐ no ☐
E.8.4	**Multiple sites in the Member State concerned(see also section G) :**	yes ☐ no ☐
E.8.4.1	Number of sites anticipated in Member State concerned ( )	
E.8.5	**Multiple Member States:**	yes ☐ no ☐
E.8.5.1	Number of sites anticipated in the Community ( )	
E.8.6	**Does this trial involve countries outside the EU?**	yes ☐ no ☐
E.8.7	**Does this trial have a data monitoring committee?**	yes ☐ no ☐
E.8.8	**Definition of the end of trial, and justification in the case where it is not the last visit of the last subject undergoing the trial :**[23]	
E.8.9	**Initial estimate of the duration of the trial**[24]**(years ,months and days):**	
E.8.9.1	In the MS concerned years months days	
E.8.9.2	In all countries concerned by the trial years months days	

F POPULATION OF TRIAL SUBJECTS

F.1	AGE SPAN	
F.1.1	**Less than 18 years**	yes ☐ no ☐
If yes specify:		
F.1.1.1	In Utero	yes ☐ no ☐
F.1.1.2	Preterm Newborn Infants (up to gestational age ≤ 37 weeks)	yes ☐ no ☐
F.1.1.3	Newborn (0-27 days)	yes ☐ no ☐
F.1.1.4	Infant and toddler (28 days - 23 months)	yes ☐ no ☐
F.1.1.5	Children (2-11 years)	yes ☐ no ☐
F.1.1.6	Adolescent (12-17 years)	yes ☐ no ☐
F.1.2	**Adult (18-65 years)**	yes ☐ no ☐
F.1.3	**Elderly (> 65 years)**	yes ☐ no ☐

F.2	GENDER	
F.2.1	**Female**	☐
F.2.2	**Male**	☐

[23] If not provided in the protocol.
[24] From the first inclusion until the last visit of the last subject.

F.3	GROUP OF TRIAL SUBJECTS	
F.3.1	**Healthy volunteers**	yes ☐ no ☐
F.3.2	**Patients**	yes ☐ no ☐
F.3.3	**Specific vulnerable populations**	yes ☐ no ☐
F.3.3.1	Women of child bearing potential	yes ☐ no ☐
F.3.3.2	Women of child bearing potential using contraception	yes ☐ no ☐
F.3.3.3	Pregnant women	yes ☐ no ☐
F.3.3.4	Nursing women	yes ☐ no ☐
F.3.3.5	Emergency situation	yes ☐ no ☐
F.3.3.6	Subjects incapable of giving consent personally	yes ☐ no ☐
F.3.3.6.1	If yes, specify :	
F.3.3.7	Others : ☐	yes ☐ no
F.3.3.7.1	If yes, specify	

F.4	PLANNED NUMBER OF SUBJECTS TO BE INCLUDED :	
F.4.1	**In the Member State**	( )
F.4.2	**For a multinational trial:**	
F.4.2.1	In the Community	( )
F.4.2.2	In the whole clinical trial	( )

F.5 PLANS FOR TREATMENT OR CARE AFTER A SUBJECT HAS ENDED HIS/HER PARTICIPATION IN THE TRIAL[25]. If it is different from the expected normal treatment of that condition, please specify (free text):

G CLINICAL TRIAL SITES/INVESTIGATORS IN THE MEMBER STATE CONCERNED BY THIS REQUEST

G.1	CO-ORDINATING INVESTIGATOR (*for multicentre trial*) and principal investigator (*for single centre trial*)
G.1.1	**Given name**
G.1.2	**Middle name, if applicable**
G.1.3	**Family name**
G.1.4	**Qualification (MD…….)**
G.1.5	**Professional address**:

G.2	PRINCIPAL INVESTIGATORS *(for multicentre trial ; where necessary, use additional forms)*
G.2.1	**Given name**
G.2.2	**Middle name, if applicable**
G.2.3	**Family name**
G.2.4	**Qualification (MD…….)**
G.2.5	**Professional address**

G.3	CENTRAL TECHNICAL FACILITIES TO BE USED IN THE CONDUCT OF THE TRIAL **Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralised** (repeat as needed for multiple organisations).
G.3.1	**Organisation**:
G.3.2	**Name of contact person** :
G.3.3	**Address** :
G.3.4	**Telephone number** :
G.3.5	**Duties subcontracted** :

[25] If not already provided in the protocol.

G.4	ORGANISATIONS TO WHOM THE SPONSOR HAS TRANSFERRED TRIAL RELATED DUTIES AND FUNCTIONS (repeat as needed for multiple organisations)	
G.4.1	**Has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party?**	yes ☐ no ☐
Repeat as necessary for multiple organisations:		
G.4.1.1	Organisation :	
G.4.1.2	Name of contact person :	
G.4.1.3	Address :	
G.4.1.4	Telephone number :	
G.4.1.5	All tasks of the sponsor	yes ☐ no ☐
G.4.1.6	Monitoring	yes ☐ no ☐
G.4.1.7	Regulatory (e.g. preparation of applications to CA and ethics committee)	yes ☐ no ☐
G.4.1.8	Investigator recruitment	yes ☐ no ☐
G.4.1.9	IVRS[26] – treatment randomisation	yes ☐ no ☐
G.4.1.10	Data management	yes ☐ no ☐
G.4.1.11	E-data capture	yes ☐ no ☐
G.4.1.12	SUSAR reporting	yes ☐ no ☐
G.4.1.13	Quality assurance auditing	yes ☐ no ☐
G.4.1.14	Statistical analysis	yes ☐ no ☐
G.4.1.15	Medical writing	yes ☐ no ☐
G.4.1.16	Other duties subcontracted	yes ☐ no ☐
G.4.1.16.1	If yes to other please specify:	

H COMPETENT AUTHORITY / ETHICS COMMITTEE IN THE MEMBER STATE CONCERNED BY THIS REQUEST

H.1	TYPE OF APPLICATION	
If this application is addressed to the Competent Authority, please tick the Ethics Committee box and give information on the Ethics committee concerned. If this application is addressed to the Ethics Committee, please tick the Competent Authority box and give the information on the Competent Authority concerned.		
H.1.1	**Competent authority**	☐
H.1.2	**Ethics Committee**	☐

H.2	INFORMATION ON COMPETENT AUTHORITY/ETHICS COMMITTEE
H.2.1	**Name and address :**
H.2.2	**Date of submission :**

H.3	AUTHORISATION/ OPINION :	
H.3.1	**To be requested**	☐
H.3.2	**Pending**	☐
H.3.3	**Given**	☐
If 'Given', specify:		
H.3.3.1	Date of authorisation / opinion:	
H.3.3.2	Authorisation accepted / opinion favourable	☐
H.3.3.3	Not accepted / not favourable	☐
If not accepted / not favourable, give :		
H.3.3.3.1	The reasons	
H.3.3.3.2	The eventual anticipated date of resubmission :	

[26] Interactive Voice Response System: commonly used for randomisation of treatment and controlling the shipment of stock of product.

I SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

I.1	I hereby confirm that /confirm on behalf of the sponsor (delete which is not applicable) that: • The above information given on this request is correct; • The trial will be conducted according to the protocol, national regulation and the principles of good clinical practice; • It is reasonable for the proposed clinical trial to be undertaken; • I will submit reports of suspected unexpected serious adverse reactions and safety reports according to applicable guidance; • I will submit a summary of the final study report to the competent authority and the ethics committee concerned within a maximum 1 year deadline after the end of the study in all countries.

I.2	**APPLICANT OF THE REQUEST FOR THE COMPETENT AUTHORITY**(as stated in section C.1) :
I.2.1	Date :
I.2.2	Signature[27] :
I.2.3	Print name:

I.3	**APPLICANT OF THE REQUEST FOR THE ETHICS COMMITTEE** (as stated in section C.2) :
I.3.1	Date :
I.3.2	Signature [28]:
I.3.3	Print name:

[27] On an application to the Competent Authority only, the applicant to the Competent Authority needs to sign.
[28] On an application to the Ethics Committee only, the applicant to the Ethics Committee needs to sign.

J. CHECK LIST OF INFORMATION

(Information that the concerned Member State's Competent Authority and Ethics Committees (CA & EC[1]) require according to the table in Attachment 1)

CA	EC		INFORMATION PROVIDED
		1	**General**
o	o	**1.1**	Receipt of confirmation of EudraCT number
o	o	**1.2**	Covering letter
o	o	**1.3**	Application form
o	o	**1.4**	List of Competent Authorities within the Community to which the application has been submitted and details of decisions
o	o	**1.5**	Copy of ethics committee opinion in the MS concerned when available
o	o	**1.6**	Copy/summary of any scientific advice
o	o	**1.7**	If the applicant is not the sponsor, a letter of authorisation enabling the applicant to act on behalf of the sponsor
		2	**Subject related**
o	o	**2.1**	Informed consent form
o	o	**2.2**	Subject information leaflet
o	o	**2.3**	Arrangements for recruitment of subjects
		3	**Protocol related**
o	o	**3.1**	Clinical trial protocol with all current amendments
o	o	**3.2**	Summary of the protocol in the national language
o	o	**3.3**	Peer review of trial when available
o	o	**3.4**	Ethical assessment made by the principal/coordinating investigator, if not given in the application form or protocol
		4	**IMP related**
o	o	**4.1**	Investigator's brochure
o	o	**4.2**	Investigational Medicinal Product Dossier (IMPD)
o	o	**4.3**	Simplified IMPD for known products (see table 1)
o	o	**4.4**	Summary of Product Characteristics (SmPC) (for products with marketing authorisation in the Community)
o	o	**4.5**	Outline of all active trials with the same IMP
		4.6	If IMP manufactured in E.U. and if no marketing authorisation in EU:
o	o	**4.6.1**	Copy of the manufacturing authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization
		4.7	If IMP not manufactured in E.U. and if no marketing authorisation in EU:
o	o	**4.7.1**	Certification of the QP that the manufacturing site works in compliance with GMP at least equivalent to EU GMP, or that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality
o	o	**4.7.2**	Certification of GMP status of active biological substance
o	o	**4.7.3**	Copy of the importers manufacturing authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization
		4.8	Certificate of analysis for test product in exceptional cases :
o	o	**4.8.1**	Where impurities are not justified by the specification or when unexpected impurities (not covered by specification) are detected
o	o	**4.9**	Viral safety studies when applicable.

[1] Tick all boxes to show information provided to the ethics committee concerned (EC) and the competent authority (CA).

CA	EC		INFORMATION PROVIDED
o	o	**4.10**	Applicable authorisations to cover trials or products with special characteristics (if available) e.g. GMOs, radiopharmaceuticals
o	o	**4.11**	TSE Certificate when applicable
o	o	**4.12**	Examples of the label in the national language
		5	**Facilities & staff related**
o	o	**5.1**	Facilities for the trial
o	o	**5.2**	CV of the coordinating investigator in the MS concerned (for multicentre trials)
o	o	**5.3**	CV of each investigator responsible for the conduct of a trial in a site in the MS concerned (principal investigator)
o	o	**5.4**	Information about supporting staff
		6	**Finance related**
o	o	**6.1**	Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial
o	o	**6.2**	Any insurance or indemnity to cover the liability of the sponsor or investigator
o	o	**6.3**	Compensation to investigators
o	o	**6.4**	Compensation to subjects
o	o	**6.5**	Agreement between the sponsor and the trial site
o	o	**6.6**	Agreement between the investigators and the trial sites
o	o	**6.7**	Certificate of agreement between sponsor and investigator when not in the protocol