SPF SANTÉ PUBLIQUE, SÉCURITÉ DE LA CHAÎNE ALIMENTAIRE ET ENVIRONNEMENT
DG Soins de Santé

DGGS

CTR - Information Session for Sponsors

College

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College

College ?

Independent federal body created within the FPS of Health, Food Chain Safety and Environment

Administrative Staff + BOARD of experts (physicians, lawyers, experts in quality)

Role of the College :

- single point of contact FAMHP and Ethics Committees (ECs);
- coordination of ECs activities;
- selection of Ethics Committees in charge of evaluation
  - *objective criteria defined by Royal Decree*
  - *cannot be the EC of the study site(s)*
- harmonization of EC procedures, Quality Assurance by the EC;
- advises for the Minister.

College does not take part in the evaluation of dossiers

Ethics Committees

Ethics committees with 2017 recognition

11 ECs recognized under the law of 7 May 2017 (currently 15 ECs in CTR pilot project)

list available at website of the CT-College: www.ct-college.be > sheet Legislation

Communication with the Ethics Committees

In order to guarantee an independent evaluation of the CTAs, the Sponsors are not allowed to communicate with the evaluating Ethics Committees or the College.

FAMHP (NCP) is the only contact point for the Sponsors !

Working groups

WG CTR-MDR

Collaboration CT-College – FAMHP – Representatives of the Ethics Committees - BAREC

Focus on practical implementation of the evaluation process under CTR (and MDR) (templates, procedures, …)

≈ 10 meetings a year

WG ICF template

Task: prepare ICF templates for patients, healthy volunteer trials, vaccine trials,…

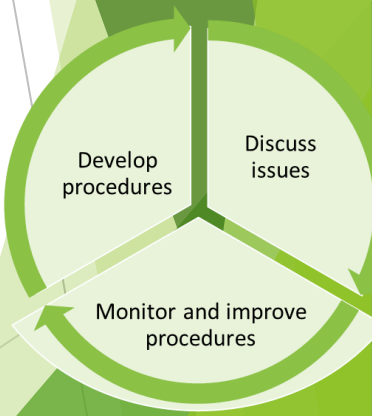
Composition representatives of:

Ecs / BAREC

BeCROs

pharma.be

VPP/LUSS



Templates / information documents

In order to implement the CTR in Belgium, different information documents are available for the Ethics Committees and Sponsors:

- Documents developed by the Working Group ICF
- Documents developed by the CTEG (European Commission), and if needed adapted for Belgium by the Working Group CTR-MDR
- Documents available on www.ct-college.be and/or on the website of the FAMHP (in the Dossier structure zip-folder)

Templates / information documents

National Guidance/information documents

Documents	Author	Date (version)
Implementation of CTR in Belgium and the impact on the ethical review process	Admin staff of College	2018, to be updated
Information for ECs and sponsors on informed consent procedure after implementation of GDPR (25/05/2018)	WG ICF	5/12/2018
Information Brochure for interventional trials with IMP on adult patients	WG ICF	19/03/2020
Guidance for sponsors on use of e-ICF in Belgium	WG ICF	30/09/2020

Templates / information documents

Part II templates : highly recommended to avoid questions from EC !

Documents	Author	Date (version)
CV Investigator (entry into force from 01/10/2021 – date of signature)	CTEG (EU) + WG CTR-MDR	26/05/2021
Declaration of Interest Investigator	CTEG (EU)	June 2019
Sites and facilities suitability (BE template mandatory !!) (entry into force from 01/10/2021 – date of signature)	Academic CTCs & WG CTR-MDR	02/06/2021
Recruitment and informed consent procedure	CTEG (EU)	November 2020
Compensation for trial participants	CTEG (EU)	November 2020
Model ICF for interventional trials with IMP on adult patients	WG ICF	28/06/2019, revision ongoing
Model ICF for Vaccine trials in adult Healthy volunteers	WG ICF	12/10/2020

Tips & tricks for a good quality CTR dossier

CTA dossier

- **List of documents provided by the sponsor in WORD**: really useful for the Ethics Committees and a real gain of time !
  - Please adapt this list of documents in case of response to RFI questions;
  - Adapted documents have to be submitted in track change and as clean versions;
  - Please leave the last columns “assessed/approved” as is, these last columns will be completed by the evaluating Ethics Committee;
  - List of documents template available on the website of the FAMHP (in the Dossier structure zip-folder).
- **Only the participants’ documents evaluated in the language of the Ethics Committee are approved**. The translation to other languages is the responsibility of the sponsor.

Tips & tricks for a good quality CTR dossier

CTA dossier (List of documents provided by the sponsor used for the approval letter)

Documents	*Version and/or date*	*Assessed (completed by Ethics Committees)*	*Approved (completed by Ethics Committees)*
PART I			
A. INTRODUCTION			
…			
B. COVER LETTER			
Ex:Pilot222_2019-111111-22_Cover-Letter_20190910.pdf	10/09/2019		
…			
C. EU APPLICATION FORM			
Ex:Pilot222_2019-111111-22_Application-Form_20190910.pdf	10/09/2019		
…			
D. PROTOCOL			
Ex:Pilot222_2019-111111-22_Protocol_v1.1.pdf	*V1.1*		
Ex:Pilot222_2019-111111-22_Protocol_v1.2.pdf	*V1.2*		
…			
E. INVESTIGATOR'S BROCHURE			
Ex:Pilot222_2019-111111-22_IB_v1.2_20190901.pdf	V1.2 / 01/09/2019		
Ex:Pilot222_2019-111111-22_IB_v1.3_20190930.pdf	V1.3. /30/09/2019		
…			
F. DOCUMENTATION RELATING TO COMPLIANCE WITH GOOD MANUFACTURING PRACTICE (GMP) FOR THE INVESTIGATIONAL MEDICINAL PRODUCT			
…		*NA*	*NA*
G. INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER (IMPD)			
…		*NA*	*NA*
H. AUXILIARY MEDICINAL PRODUCT DOSSIER			
…		*NA*	*NA*
I. SCIENTIFIC ADVICE AND PIP			
…			

Documents	*Version and/or date*	*Assessed (completed by Ethics Committees)*	*Approved (completed by Ethics Committees)*
PART II			
K. RECRUITMENT ARRANGEMENTS			
…			
L. SUBJECT INFO, ICF AND ICF PROCEDURE			
Ex:Pilot222_2019-111111-22_Patient Card-NL.pdf	V1.0		
…			
M. SUITABILITY OF THE INVESTIGATOR			
Ex:Pilot222_2019-111111-22_Application-Form_20190910.pdf	10/09/2019		
…			
N. SUITABILITY OF THE FACILITIES			
Ex: Pilot222_2019-111111-22_CV-Janssens_20160223.pdf	23/02/2016		
…			
O. PROOF OF INSURANCE			
Ex:Pilot222_2019-111111-22_IB_v1.2_20190901.pdf	V1.2 / 01/09/2019		
Ex:Pilot222_2019-111111-22_IB_v1.3_20190930.pdf	V1.3 /30/09/2019		
…			
P. FINANCIAL AND OTHER ARRANGEMENTS			
…			
R. STATEMENT DATA PROTECTION			
…			

Tips & tricks for a good quality CTR dossier

CTA dossier

- Ensure that the list of sites in the EU application form is in line with the documents in Part II (Written statements, CVs investigators).
- Written statements: mention the name of the institution and not of the campus (NEW template).
- the ICF should not contain a sentence that refers to the EU-US privacy shield since the EU-US “privacy shield” is not longer valid anymore (EU-Court of Justice’s Judgment 16/07/2020).
- Protocol synopsis: to be provided in English and at least in the official national language(s) of the region(s) where the trial is conducted.

Tips & tricks for a good quality CTR dossier

CTA dossier

- for each PI a CV has to be submitted using the EU CV template or another CV template containing the same information as those required in the EU template + relevant technique/experience required in the performance of the applied CT (NEW template).
- Not allowed to submit new documents during the second round. New documents have to be submitted at the submission or with a SM dossier.
- All documents for the recruitment (letters, flyers, press statement, posters,…) have to be approved by the evaluating Ethics Committee.
- For the sites CTU or Private Practice that have not their own ombudsman service, please do not refer to the federal ombudsman.
- If the sponsor wants to use satellites sites, it has to be clearly mentioned in the dossier ! Satellite sites with another CEO than the CEO of the main site have to submit their own written statement !

Tips & tricks for a good quality CTR dossier

CTA dossier (Validity data protection statement)

R. Statement that data will be collected and processed in accordance with the GDPR	Data-Protection-Statement.pdf	R	A stand-alone document (statement) has to be provided **This document should at least contain**: "[name of sponsor] confirms that collection and processing during clinical trials is done in full compliance with the European Regulation 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR)"

When no trial specific information is included in the data protection statement, it is deemed acceptable that one data protection statement is signed for different trials at the beginning of the year and used for the whole year for all pilot submissions during that time period.

It is foreseen to prepare a template regarding the data protection statement.

Other tips & tricks

Notifications of DSUR/ASR & SUSAR for CTR pilot dossiers

->distinction has to be made between **CTR pilot dossiers** and **CTR dossiers (CTIS)**

- USM and annual progress reports are part of the CTR pilot project.

- DSUR/ASR and SUSAR are not part of the CTR pilot project. Sponsors have to follow the procedure as described in CT-3 detailed guidance and circular letters 586 and 593 (see FAMHP website). Notifications have to be addressed **directly** to the evaluating Ethics Committee (acting as central EC) and to FAMHP.

- When the CTR will be applicable (01/2022), all safety aspects will be communicated through CTIS by the sponsor and the Annual Safety Report will be assessed by the SaMs (Safety assessment Member State).

- The continuous evaluation of the benefit/risk balance remains the legal responsibility of the sponsor.

- The evaluating Ethics Committee may send any concern to the FAMHP by sending an email to CTRPilot@fagg-afmps.be

Other tips & tricks

Information of the sites

- Sponsors have to contact the sites as soon as possible to obtain the written statement on time.
- Local ECs do not play a role anymore in the assessment of the CTA. Nevertheless, the local ECs can always request the CTA dossier.
- During the pilot period, the College informs the sites at 3 different steps:
  - when the dossier is validated;
  - at the decision step;
  - when conditions are met (if applicable)
- When the CTR will enter into force (31/01/2022):
  - the sites will not be informed anymore by the College of the CT decision.
  - It is up to the Sponsor to provide the sites with the decision and the final approved documents.

Other tips & tricks

Local recruitment material

If the studies were evaluated within the CTR Pilot project, on the local recruitment material (poster, flyer, website):

- put a general sentence such as ‘the study received a positive opinion of the evaluating Ethics Committee’ instead of the local EC ;
- Mention the EUDRACT number instead of the local study number.

Other tips & tricks

Certificate of vaccination (COVID-19)

Observation of GCP inspector regarding Vaccine trials:

In a Vx trial: some participants received placebo, others received the IMP-Vx.

Participants that first received a placebo, can receive (after unblinding) their Vx via the Vaccination centre

Participants that received the IMP-Vx cannot receive a vaccin at the Vaccination centre

Message to Sponsors: please foresee the certificate for the IMP-Vx group!

Thanks for your attention !