SPF SANTÉ PUBLIQUE, SÉCURITÉ DE LA CHAÎNE ALIMENTAIRE ET ENVIRONNEMENT
DG Soins de Santé – CT-College

DGGS

Second CTR Information Session

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College Board

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Templates / information documents

In order to implement the CTR in Belgium, different information documents are available for the Ethics Committees, CTCs 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 are available on www.ct-college.be and/or on the website of the FAMHP (in the Dossier structure zip-folder)

All the documents still need to be endorsed by the College Board

- Adaptations are possible
- Please check regularly these websites

Templates / information documents

National Guidances/information documents

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

available on www.ct-college.be/**publications**

Templates / information documents

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

Documents	Date (version)
CV Investigator (EU, BE addendum: specific (technical) expertise) NEW version published in 7/2021	26/05/2021
Declaration of Interest Investigator (EU)	June 2019
Sites and facilities suitability (BE only, mandatory !) NEW version published in 7/2021	02/06/2021
Recruitment and informed consent procedure (EU)	November 2020
Compensation for trial participants (EU)	November 2020
Model ICF for interventional trials with IMP on adult patients (BE only)	28/06/2019, revision ongoing
Model ICF for Vaccine trials in adult Healthy volunteers (BE only)	12/10/2020

available on EudraLex Volume 10 and the website **of the FAMHP** (in the Dossier structure zip-folder)

Q&A

- ICF template is too long?
  - BAREC will try to tackle this with a BAREC WG.
- Language of ICF?
  - Submit ICF at least in the official national language(s) of the region where the trial will be running.
  - The sponsor should have a procedure to ensure the quality of the translations.
- ICF for private site without Ombudsman service, to whom should we refer the participant for questions about its rights?
  - Discussions are still ongoing with our Federal Ombudsman service for patients' rights.
  - For the moment no reference can be given.
  - If the evaluating EC proposes its own Ombudsman service or its own name, this can be a temporary solution. However, when language region of the EC is different from language region of the participant, this approach cannot be used.

Q&A

- ICF Template used, and still receiving questions from the EC?
  - If questions are about mandatory parts of the template: inform College, not yet a consensus among ECs? -> harmonisation is still needed
- CV template, specific for each trial?
  - It should be clear what is the specific (technical) expertise of the PI for the submitted trial;
  - if not mentioned, the EC cannot assess the suitability of the PI;
  - could be an option to provide the full “standard” CV and add an addendum with trial specific information

Q&A

- The site does not agree with some GDPR aspects in a CTA?
  - A GDPR statement template is being prepared to support sponsors & evaluating ECs
  - The evaluation of GDPR aspects is the responsibility of the jurist in the EC.

- What is the role of ECs in ASR(DSUR) and SUSAR assessments?
  - Per CTR: ECs will only be involved when this is defined in national legislation.
  - In Belgium, this is not described in the legislation.
  - The ASR & SUSARS will be evaluated by the SaMS.
  - If BE is SaMS, the FAMHP will evaluate these documents.

Q&A

- Will a local EC still receive a compensation for a CT running at its site?
  - Not for CTAs that are submitted via the admin pathway involving the College
  - Local ECs should not assess the CTAs when submitted via the CTR Pilot or in CTR.

- Can a local EC request the documents of the CTA to give a “green light” ?
  - Yes, but they cannot ask (for a fee) to assess the dossier.
  - They should at least receive the protocol
    The law on hospitals mentions:
    Wet op de ziekenhuizen”, Art. 70:

“Het comité oefent volgende opdrachten uit telkens het een verzoek in die zin ontvangt : 2°) een adviserende opdracht met betrekking tot alle protocollen inzake experimenten op mensen en op reproductief menselijk materiaal.”

It is highly recommended to give this “green light” before the written statement is signed or during the assessment procedure by the evaluating EC & FAMHP. This to avoid any delays in the start-up of the CT after approval.

Questions?