



CTIS and CTCG/CTAG guidance CRO perspective

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(Vaccine trials, AxMPs)

General considerations

Multiple information sources

Eudralex Volume 10, MedEthics EU, EMA,
CTCG, ACT EU, CTIS landing page
Sponsor handbook, multiple Q&As
Walk-in clinics, bitesize talks, CTIS info day
EMA Newsletters and newsflash articles

Information consistency ?

National guidance on MS agency websites
(sometimes divergent with EU level info)
Timeline for implementation sometimes very
short (RFI received for new templates even
for submissions completed prior update)

The extensive range of guidance and their regular update / upgrade is very welcome

BUT

- A lot of time and resource needs to be dedicated to monitor new and updated information
- The change management related to those constant updates also needs to be factored in
(process changes, internal template updates, new training roll out)

This requires dedicated effort and resources that may not be equally available to all applicants

Note: published guidance document to systematically include version / date / summary of change

Cover letter templates

- CTCG templates:
 - [Initial application cover letter](#) (Version 3, March 2025)
 - Substantial Modification (SM) [Cover letter](#) (Version 2, Jul2024) and [Modification description](#) (Version 2 - Jul 2024)
 - [RFI Response List of Changes to the Application](#) (Version 1 - July 2024)
- Late addition to the template library that required significant changes to established processes upon release
- Some of the requested information is not part of CTR Annex I – B (Cover Letter). We still welcome this template if the result leads to greater harmonization of requests (upfront instead of via RFI) and swifter validation as a result. MS acceptance of this template is critical though (less country-specific requests)
- CTCG published cover letters and other templates (RFI list of changes, Modification descriptions) benefits
 - One location and not multiplicity of locations/websites
 - Reliable they will be accepted by all MSCs (also Ethics Committees), something that is not always the case for other published guidance, e.g. EudraLex 10 templates
 - Updated easily to address further aspects for which harmonisation or common approach has been agreed by MS
 - Permitted to use company specific templates as long as they contain the same level of information
- Note: Cover letter template for Add-MSA welcome...

IMPD Q only applications & cross-reference

- IMPD-Q Only: [IMPDEudralex Volume 10 Q&A](#) (version 7.1, March 2025) – Question 2.15 (Sponsor / Product Owner)
- **Cross-reference** is not widespread because of the operational complexities to maintain a “source trial” when considering trial lifecycle, country overlap and trial-specific nuances. Very rare for two multinational trials share the same MSCs or duration... Also affected by the currently limited functionalities for multi-trial SMS
- IMPD-Q Only applications are not too frequent but are critical for collaborations:
 - Distinct Sponsor / Product Owner organizations
 - Industry-Academia
- The IMPD-Q only application remains a work-around that helps to overcome certain limitations of the current CTIS system in this context, but remains extremely burdensome. A longer term (operationally viable) solution is still needed.
- Stepping away from the current CTIS structure and CTR requirements, the set up of a **dedicated product module** in CTIS where non study specific product documents may be approved, maintained and cross referenced for all trials sharing that product would be a huge improvement in the right direction (“IND-like approach”)

Change of Main Sponsor

- CTEG Guidance: [Guide for Change of Trial Sponsor](#) (Version 1 – February 2025)
- Changes to a sponsor details or changes of the sponsor were a real problem through 2023 and most of 2024 in absence of CTIS functionality.
- Supportive guidance and EMA events around this new CTIS functionality was very welcome
- Limited concerns on the procedure, mainly around
 - Its potential length (first an administrative transfer of the trial from one organisation to another, then SM related to the documentation)
 - Uncertainty on the timing of those SM activities in relation to the actual asset / company transfer and the users transfer in CTIS
- Any best practices aiming to shorten the assessment period for a change that is mostly administrative in terms of clinical trial application documents is appreciated (OMS details of the new Sponsor organization for first step, reference of the new Sponsor into trial documents for second step).
- Consistency and predictability in this process is critical for planning reasons

Other topics

Seasonal Vaccine Trials

- [CTCG Best practice Seasonal Vaccines for Sponsor](#) (8 January 2025)
- Limited experience yet on this procedure
- The main challenge for this type of trial remains the assessment timelines and Part I / Part II misalignment requiring further SMs after initial submission, both leading to a risk of missing the recruitment season
- We therefore welcome any opportunity for the timely decision of such trials and will test the proposed submission approach

Auxiliary Medicinal Products

- CTCG templates: [Initial application cover letter](#) (Version 3, March 2025)
- We welcome the relaxation around AxMP entry in CTIS to those that are not authorised in the EU, or are modified outside the scope of the marketing authorization. Entering the others in the cover letter works well for us.
- The challenge remains when an AxMP without an EEA central/local marketing authorization has to be registered in XEVMPD as a DMP, as this sponsor activity may have a significant impact on the timelines to prepare and submit the clinical trial application

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Thank You

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