Info Session on the Clinical Trials Regulation (CTR) – 15 december 2021

Come back to some crucial information for preparation of implementation of CTR

Anne Lenaers

famhp
federal agency for medicines and health products

.be

Introduction

First Info Session organized on 23 September 2021

- Around 100 questions received in the Teams event Q&A space during previous session
- A part of them directly answered during session
- All questions gathered in a Q&A document now available on FAMHP website

Introduction

Today

- Come back on crucial information for preparation of CTR implementation
- New panel discussion on your questions in the Q&A today

CTR pilot project

CTR pilot initial dossiers

- Last accepted CTR pilot initial dossiers submitted mid-October

- All started and ongoing

Consequence :

Before CTR coming into force on 31 January 2022, new initial dossiers have to be submitted according to the Directive process, Covid-19 trials included

CTR pilot project

CTR pilot substantial modifications (SMs)

- CTR pilot process continues with submission of SMs for approved pilot initial trials

- Can still be submitted via CESP until the end of the trial or transition of the trial to CTR

Consequence:

If a trial still ongoing at the end of the transition period, the application to transition the trial to the CTR needs to be submitted in CTIS at least 60 days before 31 January 2025

Directive process

- Only available process for submission of initial dossiers until CTR go life
- Including Covid-19 initial dossiers
- Accelerated timelines still apply for Directive Covid-19 initial dossiers and amendments and for CTR pilot SMs
- However timelines have been adapted : see News published on 19 November 2021 and related to Circular letter 653

Directive process

- During first year after go life, sponsors can still submit Clinical Trials dossiers according to the Directive process
- For these dossiers, current submission procedure will still apply
- All information related to content and submission of Directive dossiers via CESP still available on the FAMHP website

CTR process

Communication

- A new page will be soon created (**around mid- January 2022**) on the FAMHP website, dedicated to communication on CTR and on the Clinical Trials Information System (CTIS)

- All questions related to CTR and/or CTIS can be provided to this new generic e-mail address : CTR@fagg-afmps.be

- The CTR pilot generic e-mail address (CTRpilot@fagg-afmps.be) remains for any question on the CTR pilot in general or on a specific CTR pilot dossier

CTR evaluation process

Validation phase

- Please provide a complete dossier from the beginning
- Opportunity to gain time on the entire process length
- Validation phase length : 10 days*
- But can be prolonged with up to 15 days in case of validation Request For Information (RFI)

* In this presentation all timelines are maximum timelines and are expressed in calendar days

CTR evaluation process

Assessment phase in case of Request For Information (RFI)

- Total timeline : 45 days + 31 days = 76 days
- Timeline for the sponsor to provide answers : 12 days

CTR evaluation process

Assessment phase in case of Request For Information (RFI)

What if question received in the RFI unclear ?

- Questions provided to the sponsor should be as clear and as complete as possible
- The same applies to the answers to the RFI provided by the sponsor within CTIS
- However, if clarification is needed, CTIS does not foresee any space for this

Consequence:

This will have to be done outside CTIS.

If Belgium is the RMS, an e-mail should be sent to the National Contact Point's (NCP) e-mail address: CTR@fagg-afmps.be

Local EC procedures and documents

A lot of questions received on the local EC procedures after approval of the CTR pilot dossiers by FAMHP and by independent evaluating EC

From sponsor's side this is a concern as it could delay the start of the trial

⇒ We are aware of this and understand this can be a problem

⇒ Discussions have started at Belgian level (FAMHP, BAREC and College)

⇒ BAREC will investigate the question and work on harmonisation of the way of working in each local EC

⇒ We will follow up on this

What are the different types of modifications in CTR ?

When CTR will come into force, there will be 3 types of modifications:

- substantial modification (CTR article 2.2.13)

- change that is relevant to the supervision of the trial (CTR article 81.9)

- change outside the scope of substantial modifications and irrelevant to the supervision of the trial

What are the different types of modifications in CTR ?

Only substantial modifications (article 2.2.13) will be assessed

But changes relevant for the supervision of the trials have also to be submitted within CTIS (81.9NSM)

Changes outside the scope of substantial modifications and irrelevant to the supervision of the trial should not be submitted stand-alone within CTIS and should be kept by the sponsor to be submitted together with the next substantial modification

Classification of modifications in CTIS

What if the sponsor is submitting a notification as non-substantial but the authority classifies it as SM, will it be rejected?

This could be processed as a corrective measure: a member state could request for the submission of a substantial modification instead of the submission of the non-substantial modification (more precisely, a change relevant to the supervision of the trial following article 81.9)

However ,this remains the responsibility of the sponsor to determine how the modification should be submitted within CTIS. We refer you to the CTR questions and answers document in EudraLex volume 10 for examples of modifications and how to submit them

End of trial and Clinical Study report

Trials under CTD that have submitted an end of trial notification before 31 January 2025, but have not yet submitted the CSR, should they be transitioned to CTR or not?

No, the trial should not be transitioned to CTR

To our understanding, the end of the transition period refers to the end of the trial which should be defined in the protocol (most of the time Last Subject Last Visit/LSLV)

Eudra-CT will still be available several years after CTR will enter into force, to allow submission of CSR for directive dossiers still ongoing during the transition period

Fee for Belgium and short timelines for Phases I trials

Submission will remain free of charge for :

- CTR pilot SMs dossiers
- CTR initial and SM dossiers

As stated in Law of 7 May 2017, short timelines will remain :

- For phase I mono-national trials submitted in Belgium
- Timeline : 20 days (validation included)

Conclusion and questions

Thanks a lot for your interest and participation

- Do you have questions ?

- Don’t hesitate to send us your questions to CTR@fagg-afmps.be

Contact

Federal Agency for Medicines and Health Products – FAMHP

Victor Hortaplein - Place Victor Horta 40/40
1060 BRUSSELS

tel. + 32 2 528 40 00
fax + 32 2 528 40 01
e-mail welcome@fagg-afmps.be

www.famhp.be

Follow the FAMHP on Facebook, Twitter and LinkedIn

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.be