Experience from the CTR pilot and the VHP+ procedure: commercial sponsors' point of view

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pharma.be: who are we?

pharma.be, the General Association of the Medicines Industry, brings together nearly 125 innovative (bio)pharmaceutical companies active in Belgium.

The latter focus on the research and development of new drugs, both for human and veterinary use.

The presentation reflects the experience from the pharma.be members being part of its Task Force Clinical trials and conducting clinical trials in Belgium

More than 110 clinical trials have been submitted by these members via the Famhp CTR pilot project since its start in 2017

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Global experience about the Famhp CTR pilot project

- Regular information meetings about the CTR pilot and opportunities to raise questions

- Close and dynamic collaboration between the competent authorities and stakeholders, all showing willingness, understanding and flexibility

- Good and strong experience that has really allowed to get insight with the submission process according to the CTR and the new organisation of the work in Belgium between the Famhp, the CT-Collège and the ECs
  - Not only at the level of the Belgian affiliate but also at the level of the global headquarter
  - Learning and identification of attention points

- Increase of the CTR awareness in sponsor organisation, and global positive impact on its preparation

Key advantages of the CTR pilot to help Sponsors to prepare themselves in view of the CTR implementation

- Allow to **gain practical experience** with the new organisation **with regards to all aspects,** and to find solutions **to remove barriers identified during the pilot**
  - Timelines : stricter, shorter
  - Documents/templates to be used (e.g. written statement)
  - Submission structure (part I and II)
  - Already the possibility of *one single* package to be submitted *fully electronically*
- Clear **guidance**
- No fee
- No pre-scheduled date for package submission (until the set-up of timeslot in February 2021)

⇒ Positive impact on the time and work needed for preparation of a submission

⇒ Allow standardization / preparation of submission process by the sponsor (SOP)

- Still flexibility to have open discussion with Famhp, CT-Collège and good communication

General challenges that have been encountered by the sponsors during the course of the pilot

- Learning curve process: the first submissions could have been challenging
- Safety has been out of scope of the CTR pilot, and there are still a lot of remaining questions about how safety will be organized at the time of the CTR implementation
- Clinical trials with genetically modified organisms (GMOs) and with radiopharmaceuticals have been out of scope of the CTR pilot, and there is some uncertainty about how the submission of this type of trial will take place at the time of the CTR implementation
- The possibility to try the submission in CTIS would have been highly valuable
- Lack of environment for innovative trials such as adaptative trials
- The set-up of timeslots has created uncertainty about the submission possibility, and consequently the choice not to use the CTR pilot project anymore
- Delays in receiving To for the start of the procedure

Identified elements for which attention should be paid at the time of the implementation of the CTR

Received comments and questions about the submitted trial

- Level of received comments is different
  - High number of comments, for which the level of details can be highly variable from one dossier to another dossier for part II
- Communication flow for comments is different
  - No direct contact is allowed with EC, how to get assurance that responses from sponsor would meet expectation in case of doubt (!! One round of questions-responses)

⇒ **Specific attention from the sponsor side:**

- Comments from both the competent authorities and the EC are grouped in one letter, sponsor needs to adapt to dispatch questions internally
- The delay for the sponsor to respond to comments is shorter, i.e. 12 days, which could necessitate adaptation of internal sponsor process to ensure the timelines are respected

Identified elements for which attention should be paid at the time of the implementation of the CTR

Amendments

- Limitation in amendment submission for adaptive trials (wait for approval of running submission)

Approval with conditions

- No new final approval letter is issued when the conditions are met ⇒ if adapted documents have had to be generated, this creates confusion about the final approved version (date,…)
- More guidance would be welcome for further processing of the conditions (need to create a local amendment? Or not?)

⇒ **Specific attention from the sponsor side**

Patient documentation

- In case of VHP+, experience from sponsor is that some work is needed from its side to have patient related documents ready on time (e.g. translated PRO questionnaires)

Identified elements for which attention should be paid at the time of the implementation of the CTR

Name convention for submitted files

- Can be time consuming and a challenge because the amount of characters is limited

Additional local procedures

- In addition to the central process for approval of the clinical trial, new procedures are being set-up at local EC level with notification of many documents, which create additional timelines for start-up of the study
  - **Could have an impact at the time of the CTR implementation, with a simultaneous approval of the trial in all involved member states, by creating specific delay in Belgium**

Timelines & phase 1

- ! For phase 1 trials, the overall evaluation time comes to be longer in the CTR pilot than in the process under the European directive

Conclusion and take away messages

- Belgium is one of the pioneer countries to have set-up CTR pilot

⇒ **Positive experience**

  ⇒ that has given good advantages to all stakeholders in Belgium to prepare the CTR implementation and put Belgium in a good position

  ⇒ That has allowed a smooth change of mindset of all stakeholders

- Preparedness in partnership is crucial to be ready and competitive at the time of the CTR implementation
- The willingness and flexibility from the Competent Authorities and CT-college to adapt the CTR pilot during the pandemic with specific short timelines and prioritization for covid-19 trials has been appreciated

Any questions?

Acknowledgements

To all members of the Task Force Clinical Trials, pharma.be

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