Federal agency for medicines and health products

Feedback on the CTR pilot project
FAMHP point of view

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Agenda

- Introduction
- Realised so far in the pilot
- Challenges for FAMHP
- Results of the survey to sponsor
- The future

Introduction (1)

What is the CTR pilot project in Belgium ?

- Since the publication of the new CTR law 7/5/2017, at national level, we work in collaboration with the College and ECs for the processing of a limited set of CTA national dossiers following rules of the CTR

- Voluntary basis for sponsors and ECs

- A CTR pilot project guideline for sponsors has been published on our website and is updated on regular basis (currently V3.0)

Introduction (2)

- The pilot follows the spirit of the regulation :
  - CTR dossier with Part I and Part II
  - FAMHP is NCP for sponsors
  - Exchanges with College which selects the independent EC (law of 7 May 2017)
  - CTR assessment report templates
  - One single decision and approval E-mail at the end of the process (with the 2 approval letters following 7/5/2004 appended)
  - Modifications of approved pilot initial dossiers submitted as SM within the CTR pilot project

… but with timelines of the law of 7 May 2004

Introduction (3)

- This is a learning by doing process
- A survey is sent to each stakeholder at the end of the process
- Target 2017 : 10 trials => goal achieved December 2017
- The purpose is to go as quick as possible to the pilot for a higher number of trials in 2018
- The CTR pilot project will continue until the CTR is implemented

Realised so far in the pilot (1)

Closed dossiers

Initials

– 5 trials completed :

- 3 phase III trials, 1 phase II and 1 phase I
- 4 conditional approvals (conditions met in the meantime) and 1 full approval

Substantial modification

– 1 completed : conditional approval

Realised so far in the pilot (2)

Ongoing dossiers

Initials

- 1 phase II trial : finalization step
- 1 phase III trial : consolidation of the draft AR step
- 1 phase III trial : Beginning of the assessment step
- 1 phase I trial : validation step

Substantial modifications

- 1 in assessment step

Realised so far in the pilot (3)

Foreseen submissions

- 1 phase II trial to be submitted mid-December 2017
- 2 Substantial modifications in preparation
- 5 initial dossiers submissions foreseen in January 2018 (2 phase IV, 1 phase III, 1 phase II and 1 phase I trials)

=> This is a call for more trials with foreseen submission from February 2018 ☺

Challenges for FAMHP (1)

- FAMHP is the National Contact Point (NCP)

  => validation of the entire dossier (part I and part II) is performed by the FAMHP file managers

  => full correspondence with sponsors and College is resource intensive as the portal is not yet available

- Each initial dossier has also to be assessed for clinical and statistics => the processing of CTR pilot dossiers requests more efforts in the assessor's team

- Assessment process is more complex with a clinical part completed by the EC and by the FAMHP assessors => consolidation needed for assessment report part I section 5

Challenges for FAMHP (2)

- ECs are not familiar with the EU assessment report and the principle of a **single** round of questions
- Management of the planning of the pilot based on the proposals for submissions from the sponsors not always easy as submissions are sometimes re-scheduled
- Pilot is resource intensive and staffing is not obvious

... But very useful to gain experience in the CTR process !!

Result of the survey to sponsor

- Globally positive on communication and timelines
- Sponsors willing to participate again in the pilot
- Difficulties:
  - Procedure to be followed with local sites not always clear
  - Sometimes difficult to obtain the written statement of the sites
  - Difficult to answer the RFI within 12 days and particularly on part II (ICF)

The future

- Continuous process of learning by doing
- Will to increase the number of CTAs in the pilot to gain more and more experience
- Meetings with College and ECs on regular bases

⇒ Monitoring and Quality management of the pilot

⇒ Updates of the pilot guidance for sponsors for new information and or fine tuning of the process

- Follow up of the results of the surveys

Do you have questions ?

Thank you for your attention

Your medicines and health products, our concern

10 Year

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