European Federation of Pharmaceutical Industries and Associations

How Sponsors are Preparing for CTIS: Large Sponsor Perspective

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Presentation

Introductions

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- Member of EFPIA CREG (Clinical Research Expert Group) and
  - **Pillar 1 member (CTR implementation)**

- Representing EFPIA (European Federation of Pharmaceutical Industries and Associations)
  - **Perspective of a Large Sponsor**

Preparing for CTIS – Large Sponsor Perspective

Change management:

- **Adapting internal processes and systems at scale**
  - With an R&D organisation with 10,000s of personnel working globally
  - With a system, CTIS, which continues to evolve and change

- **External challenge of managing the complexity that harmonisation/CTIS brings:**
  - Phase III multi-national clinical trials with many Member States involved
  - Complex trial designs
  - Transitioning long term trials from the Directive to the Regulation

Adapting internal processes and systems at scale

So how are we preparing?

Currently CTA/IRB submissions are initiated globally and prepared/ submitted/ updated locally by in country personnel

- **Document flow will change to permit central compilation/submission**
  - From country to central functions for submission via CTIS
- **All submissions will have to be coordinated:**
  - End to staggered submissions when country specific documentation is ready
- **Need alignment on:**
  - New process (reflected in updated SOPs)
  - Internal systems to support this new flow (QMS)
  - Function to coordinate submission (who, when and how)

Managing the complexity of harmonisation/CTIS

Some new challenges….

- **User permissions:**
  - Sponsor Administrator? 100s of staff currently work in EudraCT
  - Access to CTIS?
    - Who will manage permissions as staff are recruited or leave?
    - How will we interact with CROs in future?
      - Increased complexity
  - Who will manage OMS, EMAs IAM, xEVMPD update related to CTIS?

- **How will we handle HA/IRB interactions through CTIS:**
  - "Ad hoc" communication via CTIS or can we still pick up the phone and call the HA or IRB Chair if there is a problem?
  - Can we contact a CMS or only the rMS if we have a problem in a CMS?

Managing the complexity of harmonisation/CTIS

New challenges continued

- **New processes in CTIS:**
  - Multiple RFIs in the same timescale?
    - Update a protocol and associated patient facing materials for 15 countries in 15 languages within 12 days?
    - No option to extend deadline
    - Limited approval with conditions
  - Transparency?
    - Redaction of PPD – documents possibly in 15 languages?
    - Will our processes (and people) be able to handle “for publication” and “not for publication” versions?
    - Coordinating translation needs
    - Do we have an internal process for dealing with deferrals?
  - Coordinating event notifications from all countries

Managing the complexity of harmonisation/CTIS

Lifecycle management

- **Accommodating lack of flexibility in the Regulation**
  - Coordinating changes in large trials and across trials using the same IMP to manage sequential SMs
    - Grouping together, delaying some changes ….
- **Handling complex trial designs:**
  - Processes for submitting a master protocol in CTIS?
  - Coping with rapid, multiple changes?
  - Publishing results when one arm closes?
- **Transitioning a large trial from the Directive to the Regulation:**
  - Determine trials needing transition and documentation requirements
  - Ensure existing TMF/data are electronically stored
  - Consolidating your protocol!
  - Prepare ahead for a time with no changes ongoing and submit
  - Do not forget your VHPs

Summary

- **CTIS is an IT tool designed to implement the Regulation**
- **Challenges due to adopting such a new tool**
  - Sponsor Handbook
  - EMA training program
- **Many come from the Regulation itself**
- **Sponsors must:**
  - Prepare for what we know is coming; and
  - Remain flexible enough to adjust when CTIS goes live

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Thank you