How Sponsors are Preparing for CTIS: Large Sponsor Perspective

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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
Thank you