

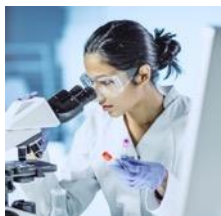


European Federation of Pharmaceutical
Industries and Associations



How Sponsors are Preparing for CTIS: Large Sponsor Perspective

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Presentation



Introductions

* Rose-Marie Swallow

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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

