Is Industry Ready for the Regulation? Latest Status

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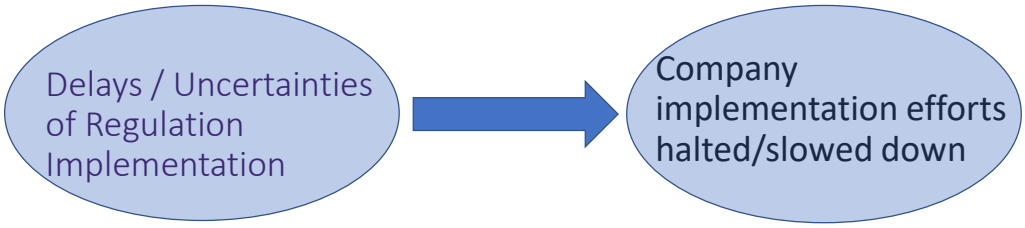
1

Is Industry Ready for the CT Regulation?

Overall Message:



Does not mean we are not driving towards CTRegulation implementation

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2

Industry Priorities to Drive Towards CTReg Implementation

Balanced regulatory procedures, systems and requirements to support an enhanced European clinical trials environment

- Working with EMA, Member States (CTFG), other stakeholders, to ensure development of the CT information system (CTIS) supports clinical trials in Europe
- Address specific technical issues to ensure implementation of the CTRegulation does not hinder the conduct of clinical trials in Europe. In particular:
  - Annex VI / Labelling
  - Complex Innovative Design trials
  - Multiple substantial modifications
- Work to establish a cross-MS platform to assist in addressing regulatory, procedural clinical trial issues
- Input to development of Delegated Acts, Guidance, Q&A, etc needed for the efficient operation of the CTRegulation
- Analysis of the state of national implementation of the Regulation via EFPIA CTiMonitor

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3

CTIS New Delivery Model - Sponsor PO team

Lead Product owner: Pierre Omnes, ACRO

Product owners:

- Ingeborg Boddeke, EUCROF
- Milagros Blazquez, EFPIA
- Stephanie Kromar, EORTC
- Ruediger Pankow, ACRO
- Marta Pavia, ECRIN

Product Owner Back ups

- Gaby Di Matteo, EFPIA
- Lidya Dominguez, EUCROF
- Marianne Andersson, EFPIA
- Tuula Ikonen, EORTC
- Chris Price, EuropaBio

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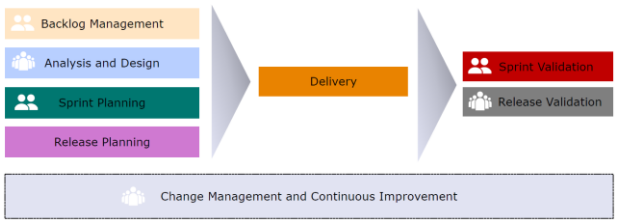
Sprint and Release: current model



Key dates

02-03 Jul 2019: New delivey Model KOM, Seville, Spain including presentation of Product Vision

17 Jul 2019: Delivery Communication Plan presented to POs

4

Release Validation 10: Sponsor PO impression

- Sponsor access to sandbox and other tools confirmed from Sep 2019
- Positive outcomes in terms of increased collaboration with Member States and more focus on operational assessment to baseline the CTIS functionalities compared to our real life needs
- The side discussions and discussions on needed improvements to the Model were in the end more important than the actual testing
- Further proposed adjustments also go in the right direction

Sponsor PO Concerns include:

- Scalability and oversight
  - User management (e.g. bulk user management)
  - Lack of dashboard or alternative Business Intelligence reports
  - Download functionality (e.g. format of download output)
- Registration of organizations and trial management
- Flexibility in managing users
  - Role matrix and associated permissions (e.g. product specific IMPD-Q user role and assessment report)
- Documentation - Naming and versioning of documents, redaction

Future considerations

- Whole concept of business blocker has been developed mainly by Member States for their workflows - need to ensure that the Sponsor side is addressed (less workflow oriented, more operational implementation)
  - Business blocker definition: issue where work-around is either not possible or too difficult to implement operationally (impact on GO Live)
- Further adjustments to the New Delivery Model and the Commission Q&A
- A need to focus not only of audit milestone, but also on Go Live (possibly more important for Industry Stakeholders)
  - Assess and communicate the impact of a failed "go live"

Multiple Substantial Modifications

Issue: Unable to have more than one substantial modification under assessment at any one time

- Commission interpretation of Art 2(13) of CTReg:
  - *'Substantial modification' means any change to any aspect of the clinical trial which is made after notification of a decision referred to in Articles 8, 14, 19, 20 or 23 and which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial*
- Willing to discuss solutions but 'respecting the legislation'

Other Issues to be Addressed

- Annex VI / Labelling
  - Expiry date on outer and immediate packaging
- Complex Innovative Design trials
  - Approach to take with Master Protocols and sub-protocols
- Establish a cross-MS platform to assist in addressing regulatory, procedural clinical trial issues
  - Discussions with CTFG
- Implementation at the Member State level

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9

A Quick Recap….

1. Industry implementation efforts have slowed
2. We are taking a proactive approach to CTIS development
3. A major concern is inability to submit multiple substantial modifications

Keep in Touch:

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10