Meeting of the monitoring sub-group of the Coordination Group

EU Clinical Trials Regulation

Date:
- Thursday 15th May 2019

Chair:
- [Name], European Commission

Participants:
- EC:
- EMA:
- AT:
- BE:
- DE:
- DK:
- SE:

Adoption of the previous minutes
Comments to the minutes should be sent directly by email to [Email].

Introduction
- It was agreed not to invite the service provider to this meeting and not to discuss the Project update in order to focus on KPI’s and Success criteria

1st topic: KPI’s

Preliminary work
- KPI’s and success criteria have already been widely discussed between the Agency, EC and participants
  - Most of the KPI’s have not been significantly modified

Basic principles on KPI’s
- These KPI’s must not be reductive:
  - The service provider will work as efficiently as possible to be able to solve additional items in a sprint if time permits
- All these KPI’s make it possible to objectify and evaluate progress:
  - In this process the focus is on each sprint in particular
  - The analysis & design process makes it possible to best meet the needs of users
- Main purpose of KPI’s is to monitor the performance of the service provider and not to evaluate the entire process
Prioritization of work

- It is important to ensure that all complex items are processed in a timely manner:
  - Sprint or items can vary in complexity
  - New and revised tickets will be included in each consecutive sprint
- The content of each sprint is widely discussed in partnership with PO’s:
  - The service provider will execute what is agreed
- Product Owners have an important role to play in the preparation of the sprint as well as in the analysis & design:
  - They have the ability before each sprint to define the content of the sprint so that the service provider works efficiently

Clarification

- The term "resolved" has been clarified:
  - this term means that the items have been fixed by the service provider but must still be subject to further verification through FAT and SAT
- The data breakdown will reflect all the work done in each of the sprints and at the end of release plan

Holistic resolution of items

- It is essential to be able to group certain items in a cluster:
  - The resolution of an item should not be considered in isolation
  - There is a strong interdependence between the different items:
    - Some items are validated under the condition that others are resolved
  - In some cases, there is resolution of a cluster of items
    - This has been demonstrated in the different bug validation sessions

Automation

- The automation of tests will be implemented and will make it possible to check the quality
  - Ideally, objective is to have ±100% automation

Conclusion

- concludes that there is broad support from participants for these KPI’s:
  - It is necessary to ensure during the next few months that there is a good distribution of items according to their complexity in each sprint and in Release plan.
- These KPI’s have been sufficiently discussed and provide a solid basis for performance analysis for the MB
- will still exchange by email with some consideration in order to finalize the document
  - These considerations focus mainly on form and will help to finalize the document

Part 2: Measuring Success

Preliminary question supporting the measurement of success

- What can be expected objectively or reasonably from Everis?

Progress assessment

- Purpose is that participants in the monitoring group have the perception over time that the progress of the Release is effective.
The annexed table of tasks was widely discussed between EC and Agency:
- The 1st, 2nd and 4th items are already part of sprints 5 and 6 of the contract
- These criteria are already part of the contract
- The only point that remains to be defined: security-related metrics

Different levels of tolerance
- Levels of tolerance are progressive throughout the execution of the sprints
- wants that at the end of the release there are no more blockers that would hinder a general demonstration or a UAT

Weighting
- The success criteria presented to Everis are not necessarily the same as those presented to coordination group or MB
  - The criteria for Everis will be more demanding

Conclusion
- concluded that the success criteria are still being discussed at the next meeting in 14 days
  - In the meantime, participants will have the opportunity to look at the different criteria

Management Board meeting
- It is only in mid-September, at the end of the monitoring period and release plan 1, that an objective picture of the progress and of the work provided by the service provider can be obtained in a factual way.
- Nevertheless, asked that the KPI are presented to the EMA management board in June