

*Draft*

## Meeting of the monitoring sub-group of the Coordination Group

### EU Clinical Trials Regulation

Date:

- Thursday 15<sup>th</sup> May 2019

Chair :

- [REDACTED], European Commission

Participants:

- EC : [REDACTED]
- EMA : [REDACTED]  
[REDACTED] ;
- AT : [REDACTED] ;
- BE: [REDACTED]
- DE: [REDACTED]
- DK: [REDACTED]
- SE : [REDACTED]

### Adoption of the previous minutes

Comments to the minutes should be sent directly by email to [REDACTED].

### 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

### 1<sup>st</sup> 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 1

## 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  $\pm 100\%$  automation

## Conclusion

- [REDACTED] 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
- [REDACTED] will still exchange by email with [REDACTED] 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 assesment

- 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 [REDACTED]
    - 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
- [REDACTED] 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

- [REDACTED] 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, [REDACTED] asked that the KPI are presented to the EMA management board in June