

Friday 1st of February

**Minutes of the 2nd Meeting of the monitoring sub-group of the Coordination
Group**

EU Clinical Trials Regulation

Date:

- **Wednesday 30 January 19**
 - Audioconference 4 -5 pm (Brussels time)

Chair :

- [REDACTED], European Commission

Participants:

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

Minutes of the meeting

Adoption of the agenda

- Minutes were adopted taking into account some clarifications on backlog and actors in the group

1st Topic: Project update by EMA

- Present Priority is consolidation of Backlog:
 - Backlog includes UAT 6, pre-UAT 7 & several Test & Verification and workshop feed backs as well as CTFG priority list post UAT6
- Consolidation has to be regarded as a high-level process in 3 steps:
 - 1 Clarification of themes and complete minimum data in Jira
 - 2 Fixing strategic objectives for each further release
 - Design, estimation & endorsement of scope, will require a couple of weeks ...
 - 3 Iterative developments will integrate several levels of prioritisations
 - Release planning will be built up as an iterative development including sequential sprints, in line with agile development:
 - Scope will be defined and endorsed at each sprint
- There will be continuous involvement of stakeholders through workshops

- Task is huge as there are ± 2.500 “items” to be allocated in Jira
 - Therefore, Task force & EMA are “bucketing” items in to 12 Themes
 - Agenda:
 - Fixing priority themes:
 - Start date is fixed: 1 Feb 19; End date: within February
 - Further analysis & design: in February & march
 - **Handover, backlog management & release planning: 1 April 19**
- Questions & remarks in line with evaluation of ownership, amount of work, accurate time planning
- Answers:
 - At present we get a high-level overview: strategy but not details
 - Need to get clarity on Real Bugs or “Improvements”
 - Time line is much dependent on signature of contract
- Further remarks:
 - Priorities of themes need to be verified with MS experts (UAT champions).
- There needs to be a verification feedback loop with MS experts prior coding.

2nd Topic: Recommendations from the external review

- Change Management process will require more resources, training & communication
- Recruitment External PMO support: option is to employ an EMA manager
- Timing:
 - Contract initially planned for January 2019 should be concluded with IT4U mid or end February: at least 2 additional weeks.
 - Major reasons of delays:
 - Scope of outstanding BCM not agreed yet
 - Merging CT1 and CT2 has an impact on overall project plan
 - Still some more time needed for formal penalty process
- Objective is
 - to ensure that Everis has a clear understanding of state of play
 - to safe knowledge transfer
- Questions & remarks on start of monitoring, on transfer plan or handover plan, metrics
- Answers:
 - Monitoring will start for a period of 6 months from the signature of contract:
 - *Expected & most probable date for signature: **second period of February***
 - *There will be a kick off meeting in Sevilla (including MS business)*
 - Sprints will run from this date in a cascade effect
 - Activities are running for next 2 weeks:
 - Backlog consolidation with champions
 - Teleconference on issues raised by EFPIA with sponsor stakeholders (PM note and CTFG CoChairs)

Progress Report – January 2019 by IT4U

- Presentation by Contract Manager of Consortium reporting directly to CEO

Programme Plan is at present “high level”

- Timeline:
 - Iterations 1 & 2 of R0.9 were delivered as per plan
 - SAT acceptance R0.7 ongoing till end of February for Handover and contract Closure

- CT Reconstruction impact might affect R0.9 Plan!
- Merge Plan – R0.9 and pre-UAT R0.7 bug fixing - does include:
 - 2 full regression cycles to secure complete functionality
 - At start and end of Merge
 - Sprint 1 and iterative delivery will start after 2nd regression test
 - Thanks to Merge, there will be 1 System
 - Unified CT code base and single delivery team
 - All Everis Managers will have the same focus
- Willingness to have close collaboration with stakeholders in agile way
- Planning for 2019:
 - Merge should be finalised in ± June 19
 - Change Requests & Bugs will be treated sequentially to ensure UAT readiness
 - Process to start, after Merge, in ± 5 Sprints, from ±June 19 till ± November 19,

R0.7 Handover:

- Emphasis on close collaboration between Everis, CT1 Team (Unisystem) & key EMA staff
- Purpose is to enhance acumen of the whole Clinical Trials platform
 - Everis previous main focus was “Safety Reporting” functionality

IT4U

- [Redacted]
- [Redacted]
- [Redacted]
- Answers:
 - [Redacted] are and will be key contact persons.
 - Exact governance has still to be defined. PM Note: what does this mean?

Summary

- “High level” Presentations were much valuable
 - Overall strategy for agile & iterative process was described
- Baseline for timing is highly dependent of signature of contract
- Contract will be finalised later than planned:
 - End February in place of end January
- Fixing metrics reflecting project progress once contract has been kicked off
- Iterative delivery, fixing CR’s & bugs, will ensure next UAT readiness
 - High level plan, IT4U slide 5, indicates end of iterative delivery in ± Oct 19
- More clarity on knowledge transfer plan in coming weeks:
 - It will better be defined and understood
- There is a need to get more clarity or details on:
 - Present N of bugs, “items”, and on performances of CT1
- Coordination group has the responsibility to determine relevant iterations for UAT- 7 and Audit
- Coordination group will endorse the date for launching the UAT