

*Draft*

## **Report of the 7th meeting of the monitoring sub-group of the Coordination Group**

### **EU Clinical Trials Regulation**

#### **Date:**

- **Wednesday 17 April 2019**

#### **Chair :**

- [REDACTED], European Commission

#### **Participants:**

- EC : [REDACTED]
- EMA : [REDACTED] ;
- Everis : [REDACTED]
- BE: [REDACTED]
- DE : [REDACTED]
- DK: [REDACTED] ;

#### **Meeting of the monitoring sub-group of the Coordination Group on the EU clinical trials Regulation**

**Aims:** (1) to receive a progress report from Everis and EMA and (2) to review key performance indicators (KPIs) proposed by EMA for the quantitative monitoring of the progress

#### **Discussion:**

- backlog consolidation team: champions have done a great job with the review: up till now they reviewed 680/1634 open items; attached business value to 501/680 items; 258/501 are with high business value. Backlog consolidation will soon be closed with a final report. Identified items will be moved to backlog management. New volunteer from BG as first responder to joint letter.
- implementation team: finished the development and testing of the Safety Reporting functionality; closed 6/25 bugs in sprint 5 (15 more is scheduled for review later this week); completed the analysis of the [REDACTED] after merging R07 and R09; agreed on the scope of Sprint 6
- development team: released the Sandbox environment
- backlog management team: completed first iteration; developed a draft vision; set up 2019 activity calendar;

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- A [REDACTED] was identified in the completion of sprint 5, Everis explained that this delay was due to the different demos and other unforeseen activities, and should not jeopardize the overall timelines for this iteration (iteration 4) nor for the delivery of the project. On the other hand, Everis has made good progress on the preUAT 7 bug fixing (6 bugs closed)
- [REDACTED] (after the merge of R0.7 and R0.9) identified [REDACTED] new bugs (59 previously unidentified bugs existing in R0.7) on top of the [REDACTED] existing bugs



**Outcome: Group members are invited to submit additional comments on the KPIs by eob Wednesday (April 24) directly to EMA (keeping the rest of the team in the loop of communication).** EMA on the basis of the comments from today will already update the draft on KPIs so that this new version can be discussed at the next monitoring meeting on May 2. Commission suggested to take into account those KPIs that are currently used for internal progress reports. [REDACTED] also proposed to draft by April 30 a high-level paper to assess the expectations vis a vis Everis in 6 months as requested by the coordination group. EMA will send exact deliverables of the contract. The Group members and EMA agreed to provide assistance with this work.