EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Document 59

CTIS project update for the Monitoring sub-group of the EU CTR Coordination Group

11 June 2019

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Progress Status Update – Reporting Period

KEY HIGHLIGHTS

- **[Implementation team]** The list below shows the key activities undertaken by the implementation team during the reporting period:

Safety Reporting:
- The last Interactive Session on Sprint 6 was held on 28/05, where the 17 improvements were shown to the CT Champions. One feedback was received and recorded in JIRA.
- The SAT testing of the Iteration 4 development has been completed, functional testing is closed with 0 BCMs. However the performance testing results need to be analysed and validated.
- The regression testing started on 03/06, right after the SAT completion. Duration of testing is 2 weeks.
- Complete set of deliverables, including the testing reports were sent to EMA for review. The feedback of the first review was received on 05/06. The acceptance of Iteration 4 (Sprint 5 and 6) milestone is 02/07.
- In the R0.7 bug fixing scope: 52 bugs have completed development, 49 of 52 have been validated by Product Owners and closed, one has been re-opened during validation with EMA and two are awaiting for environment issues to be resolved.
- The meeting to demo the next batch of pre-UAT bugs from the R0.7 patching scope (Dec '18) (37+16) was cancelled last week. In total 5 issues have been validated and closed. Three sessions are scheduled for the next weeks to close the rest of the issues by the Product Owners.

- **NDM:**
  - The technical team started working on the Sprint 7 preparation and the clarification of the 38 issues in scope.

Progress Status Update – Reporting Period

- **[Feature Backlog Management team]**
  - **Analysis & Design**:
    - Iteration 3: ongoing with 43 items analysed, 34 items expected to be completed. Expected delivery date: 11th of June
    - Iteration 4: launched on the 5th of June. Probably: 43 items in the scope
  - **Release Plan:** endorsed by CTIS Expert Group and sent to the Coordination Group for information
  - **Sprint Plan:** Sprint plan 7 agreed and ready to be implemented starting on the 11th of June.
  - **Backlog Management**: - Continue with backlog grooming sessions.
    - Continue providing Business Value on the historical backlog. 71% of the backlog is processed.
      - 7th of June: receive all remaining business value from MS POs
      - 14th of June: receive all remaining business value from Sponsors POs.
    - Review new and re-open backlog items
    - Process defined on how to manage technical backlog items.
  - **Overall and change management:**
    - Continue setting up the New Delivery Model:
      - Prepare the implementation of KPIs
      - Support to Seville's meeting
    - Improve communication and training:
      - Finish the As-Is of the current communication channels and tools related to the NDM
    - Propose continuous improvement actions:
      - Lead and conduct lesson learned session with MS PO and EMA and make a summary report.

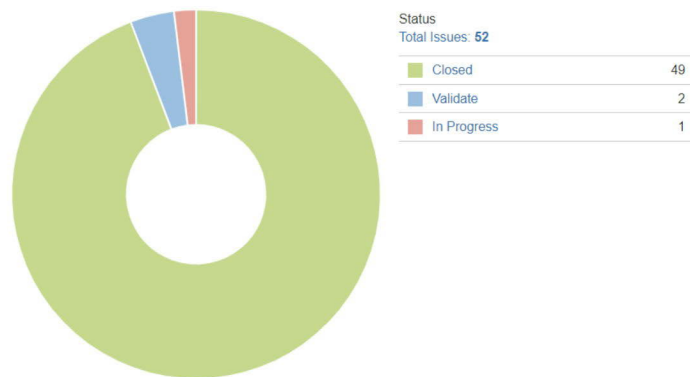# Safety Reporting Progress Status Update – Reporting Period (27/05 - 07/06)

Tasks	Actual % completion	Expected % completion	SPI	Forecast end date	Baselined end date
Iteration 4 (Development phase)					
Implementation and testing					
Regression testing cycle 1					
Sandbox environment preparation					
Sprint 5					
Sprint 6					
Development					
FAT of Sprint 6					
SAT of Iteration 4					
Interactive session on Sprint 5					
Interactive session on Sprint 6					
Demo on Iteration 4					
Regression testing cycle 2					

R0.7 (52) bug fixing Status Update – Reporting Period (27/05 - 07/06)

Tasks	Actual % completion	Expected % completion	SPI	Forecast end date	Baselined end date
R0.7 bug fixing in Iteration 4					
Implementation and testing					
Sprint 5					
Sprint 6					
Development					
FAT of Sprint 6					
SAT of Iteration 4					
Bug fixing validation					
1st batch					
2nd batch					
3rd batch					
4th batch					
Demos of the reopened ones					

Progress Status Update – preUAT7 Bug Fixing ████████████

Status
Total Issues: **52**

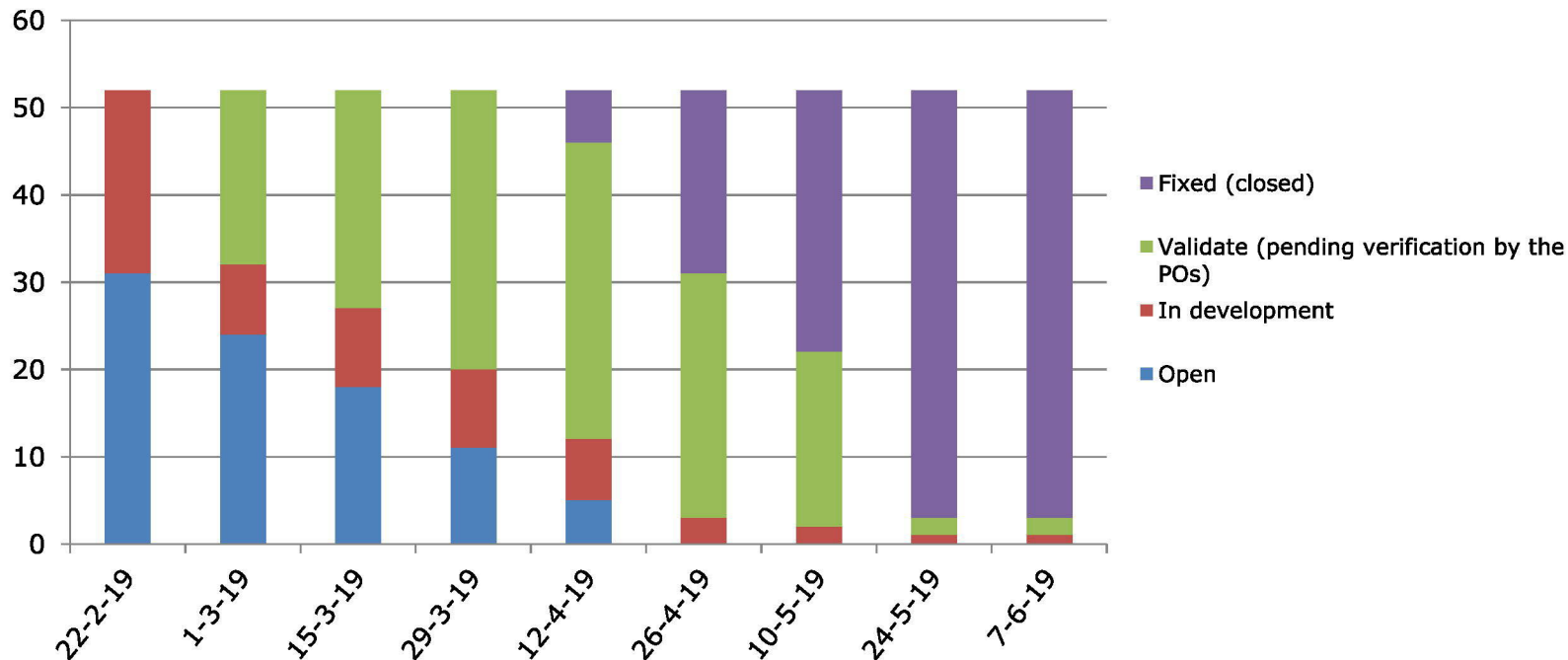|		
🟩	Closed	49
🟦	Validate	2
🟥	In Progress	1

- 52 bugs have completed development,
- 49 have been validated by Product Owners,
- 1 has been re-opened during validation with EMA,
- 2 are awaiting for Liferay environment issues to be resolved.

Priority	IN PROGRESS	VALIDATE	CLOSED	T:
⊘ Blocker	0	1	0	1
↑ Critical	0	0	7	7
⌃ Major	1	1	24	26
⌄ Minor	0	0	15	15
↓ Trivial	0	0	3	3
Total Unique Issues:	1	2	49	52

Progress Status Update – preUAT7 Bug Fixing

- Net progress of the period

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Work plan for the next 2 weeks

KEY HIGHLIGHTS

- **[Sandbox environment]**
  - The SAT testing completed on the 03/06 with version v0.9.6.11. This version can be deployed into the Sandbox environment. The deployment date to be confirmed and communicated to EMA.

- **[Implementation team]**
  - Iteration 4 development/testing scope:
    - Update the official deliverables according to EMA`s comments in the review cycles.
    - Review and analyse the performance testing results.
    - Perform and complete Regression Testing Cycle 2 with the improved Test Suite.

  - NDM:
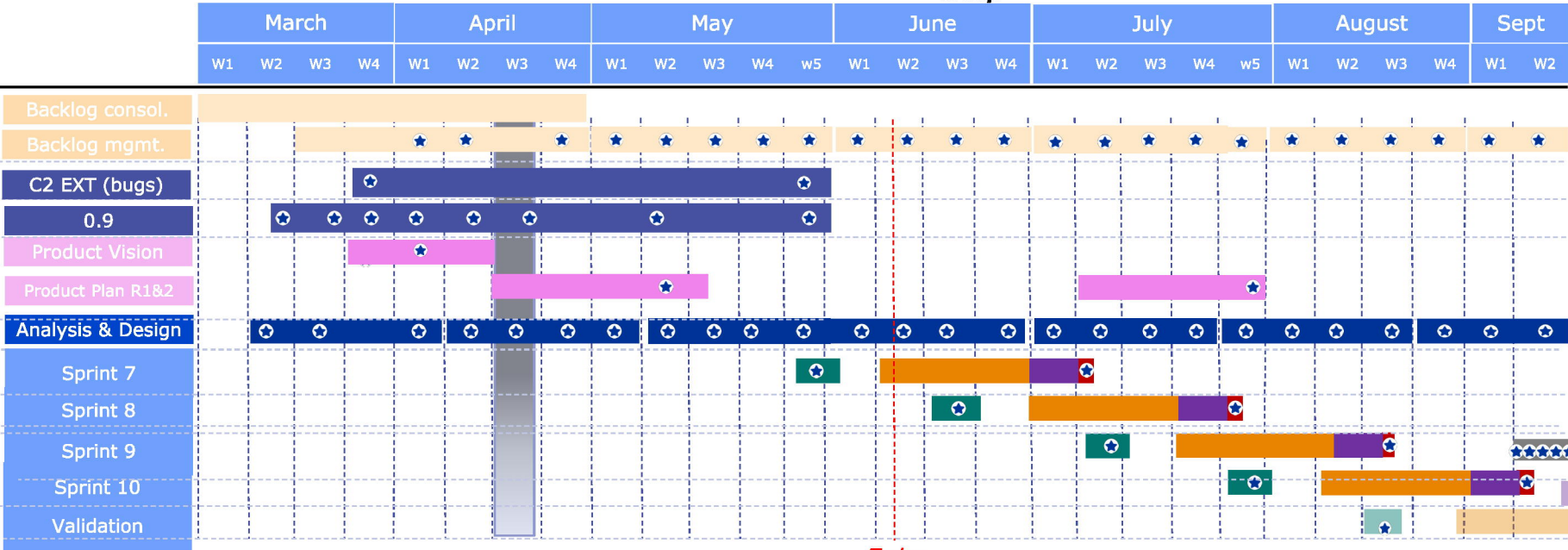   - Start the development of Sprint 7 (38 items in scope).

KEY HIGHLIGHTS

- **[Feature Backlog Management team]**
  - **Analysis & Design**:
    - Iteration 3: Closed Expected delivery date: 11th of June
    - Iteration 4: On-going
  - **Sprint Plan:**
    - Sprint plan 7 agreed and ready to be implemented starting on the 11th of June.
    - Sprint plan 8: preparation on-going. Meeting scheduled to the 17th of June to agree on the Sprint 8 scope.
  - **Development:**
    - Sprint 7: on-going
    - Sprint 7 – validation 9th of July
  - **Backlog Management**: - Continue with backlog grooming sessions.
    - Consolidate and review Business Value on the historical backlog provided
    - Review new and re-open backlog items
    - Start providing Technical Value
    - Start providing Very High Level Effort Estimations for auditable items.
  - **Overall and change management:**
    - Continue setting up the New Delivery Model:
      - Provide first of KPIs
      - Support the Kick-off meeting at supplier`s premises
    - Improve communication and training:
      - Finish the To-Be of the current communication channels and tools related to the NDM
    - Propose continuous improvement actions:
      - Define continuous improvement actions based on Lesson Learnt sessions

Preparations for new delivery model

Please note: **Audit dates will depend on the decision on scope of the auditable release by the EU CTR Coordination Group**

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Legend:
- Backlog consolidation & management (1 meeting per week)
- Release Planning (5 meetings per year in total)
- Analysis and Design (1 meeting per week)
- Sprint Planning (1 meeting per week)
- Development
- SAT
- Sprint Validation (1 day)
- Release Validation (1 week)
- Envisaged meeting (onsite or offsite)

ANNEX

Progress Status Update – Regression Testing

Regression Test Cycle 1:

- After the code merge of releases R0.7 and R0.9 (Safety Reporting), the Regression Test Cycle 1 was performed in February
- The Safety Reporting regression bugs that were identified within this cycle (21) have been fixed in the context of the Safety Reporting delivery
- The other outstanding issues have been catalogued in the backlog to allow easy identification and management

Regression Test Cycle 2:

- A second regression cycle is planned after the successful delivery of Safety Reporting in order to identify regression issues caused since the Regression Test Cycle 1 was run and make sure that the quality has not decreased. The findings of this second cycle will be added to the existing cycle 1 issues, to come up with a final "Regression backlog" to be fixed during the forthcoming iterations
- The Suite for cycle 2 will be improved as compared to the one used in cycle 1 by reviewing:
    - ➢ The findings from pre-UAT activities, including the 52 R0.7 bugs in scope of the ████████
    - ➢ The focus areas with EMA Business Team and adjust the test coverage accordingly.

Progress Status Update – ███████████████████████

Existing Bugs (raised before Regression Testing Cycle 1): ███ **(Not Closed)**

Blocker	Critical	Major	Minor	Trivial
████████████████████████████████				

- Sources:
  - Backlog of R0.7 Minor and Trivial issues (to be prioritized and implemented throughout the Iterative Delivery - June 2019 onwards)
  - R0.7 Bugs identified as part of R0.9 Testing cycles (to be prioritized and implemented throughout the Iterative Delivery - June 2019 onwards)
  - R0.7 Tolerance List bugs: to be delivered with the ████████ - May 2019
  - preUAT7 bugs under ██: to be delivered with the ████████ - May 2019
  - The nature and categories of these bugs will be analyzed as part of the Backlog grooming activities
- **New Bugs** (these issues are under analysis to be properly typified): ███ **(Not Closed)**
  - Sources:

Blocker	Critical	Major	Minor	Trivial
█████████████████████████████				

  - ██ R0.7 codebase merge bugs
  - **R0.9 codebase merge bugs**
  - unidentified R0.7 bugs
  - bugs requiring additional testing to verify their source
  - These bugs, alongside with other new bugs that will be found in ████████████████ (May 2019), are to be addressed throughout the Iterative Delivery (June 2019 onwards)

Progress Status Update – preUAT7 Bug Fixing ████████████

- 9 Issues have been closed after preUAT7 Business Validation (07/05/2019)

Issue Type	Key	Summary	Priority	Status
Bug	CTCS-9112	1018_no MSC have expressed willingness by day 3_the system asssigned the RMS candidate by default this is incorrect	Critical	Closed
Bug	CTCS-9317	151. 1) default candidate in scenario 5b (assignor is proposed rms)	Minor	Closed
Bug	CTCS-8893	UC1026 - Additional MSC accessing the part I evaluation folder	Critical	Closed
Bug	CTCS-9223	102. 'SM Document considerations on Part I' task displays as completed and does not navigate to the Evaluation page	Major	Closed
Bug	CTCS-9053	New user creates trial via CT Centric approach and does not have appropriate CT Admin tabs or ability to lock certain sections of the Part I	Major	Closed
Bug	CTCS-9243	113. Corrective measures sorting dysfunctional.	Minor	Closed
Bug	CTCS-9311	170. important clarifications in disagreement - RMS candidate	Major	Closed
Bug	CTCS-9197	074. Name of 'Response to RFI Submitted' notice should be updated to specify Part I or Part II	Trivial	Closed
Bug	CTCS-9316	150. 1) not possible switch several times willing/unwilling	Critical	Closed

(*) Bug Workflow Status: Open -> In Progress -> Resolved -> Validate -> Closed (*Issues to be Closed by the end of Sprint)

Scope of Sprint 5

Sprint 5

- **Development of Safety reporting business functionalities:**
  - View ASR summary by MS.
  - Request additional information (MS): all functionalities
  - View alerts and notices related to RFIs
  - Assess additional information: all functionalities:
    - Save, share, cancel
    - Create, edit, submit an RFI
    - Create a discussion on an RFI.
  - View RFI and Respond to RFI: all functionalities
  - Search for RFI.
  - Download ASR details.
  - Search & View ad-hoc assessment details: search and display information.
  - Display ASR Assessment.
  - Download ASR Assessment attached documents.
  - Display ASR Submission with RFI information.
  - Download ASR Submission attached documents.
  - Search & View ad-hoc assessment details: download and clear search results

- **Addressing regression testing findings** that block execution of other test cases and impact demo paths.

- Within the **R0.7 bug fixing** stream, fixing **26 bugs** (out of 52).

Scope of Sprint 6

Sprint 6

- Development of **17 improvements** that agreed with EMA and shared with the R0.9 Champions. The source of 9 improvements (out of the 17) are previous R0.9 Interactive sessions and 2 are from other feedback of Stakeholders (like R0.7 preUAT).

- **Implementation of bug fixes** from previous sprints.

- Addressing **R0.7 performance related issues**.

- **Improvement** of the current the **front end unit testing coverage**.

- **Fixing quality findings** identified by the **Sonarqube**, the quality tool used by EMA.

- **Addressing SR bugs** that were introduced **by the code merge** between R0.7 and R0.9.

- Within the **R0.7 bug fixing** stream, fixing the remaining **26 bugs** (out of 52).