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

11 June 2019
Table of Contents

- Progress Status update – Reporting period
- Planned work and activities – Next period
- CT Programme Plan – Timeline overview
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

KEY HIGHLIGHTS

• [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)

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Actual % completion</th>
<th>Expected % completion</th>
<th>SPI</th>
<th>Forecast end date</th>
<th>Baselined end date</th>
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<tbody>
<tr>
<td><strong>Iteration 4 (Development phase)</strong></td>
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<td>Implementation and testing</td>
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<td>Regression testing cycle 1</td>
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<td>Sandbox environment preparation</td>
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<td>Sprint 5</td>
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<td>Development</td>
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<tr>
<td>FAT of Sprint 6</td>
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<td>SAT of Iteration 4</td>
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<td>Interactive session on Sprint 5</td>
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<td>Interactive session on Sprint 6</td>
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<td>Demo on Iteration 4</td>
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<td><strong>Regression testing cycle 2</strong></td>
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### R0.7 (52) bug fixing Status Update – Reporting Period (27/05 - 07/06)

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Actual % completion</th>
<th>Expected % completion</th>
<th>SPI</th>
<th>Forecast end date</th>
<th>Baseline end date</th>
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<td>Implementation and testing</td>
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<td>FAT of Sprint 6</td>
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<td>1st batch</td>
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<td>3rd batch</td>
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<td>4th batch</td>
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<td>Demos of the reopened ones</td>
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</tbody>
</table>
Progress Status Update – preUAT7 Bug Fixing

- 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.

<table>
<thead>
<tr>
<th>Priority</th>
<th>IN PROGRESS</th>
<th>VALIDATE</th>
<th>CLOSED</th>
<th>T.</th>
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<tbody>
<tr>
<td>Blocker</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<tr>
<td>Critical</td>
<td>0</td>
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<td>7</td>
<td>7</td>
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<tr>
<td>Major</td>
<td>1</td>
<td>1</td>
<td>24</td>
<td>26</td>
</tr>
<tr>
<td>Minor</td>
<td>0</td>
<td>0</td>
<td>15</td>
<td>15</td>
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<tr>
<td>Trivial</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>3</td>
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<tr>
<td>Total Unique Issues:</td>
<td>1</td>
<td>2</td>
<td>49</td>
<td>52</td>
</tr>
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</table>
Progress Status Update – preUAT7 Bug Fixing

- Net progress of the period

![Bar chart showing progress status over time]

- Fixed (closed)
- Validate (pending verification by the POs)
- In development
- Open

CTIS project update 11 June 2019
**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).
Work plan for the next 2 weeks

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*

CTIS project update 11 June 2019
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]

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 [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:
- 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)

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

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

14  CTIS project update 11 June 2019
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).