EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

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

28 August 2019

Reporting period: 05/8/2019 - 13/9/2019
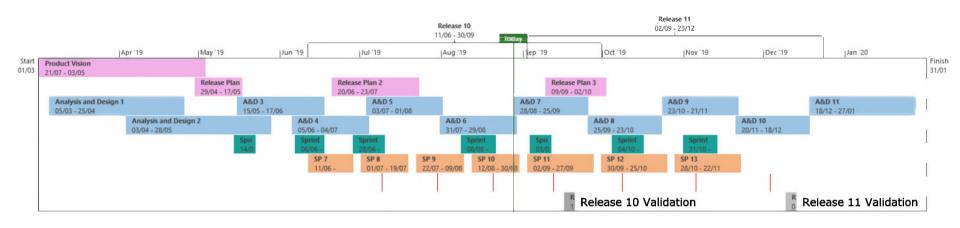
Content

- Executive Summary
  - Integrated planning
  - Overall progress status update for the past three weeks and next three weeks
- Progress status Release 10
- KPIs results
  - Sprint 9: Root causes of items not delivered
  - Short term plan: Status
- Release 10: Forecast of items to be delivered
- Main milestones
- Annexes

Integrated short term planning

Plan considering 3 to 4 weeks from Sprints 11 onwards

General status of implementation of New Delivery Model

For the past three weeks (05/8/2019 - 23/8/2019)

- Sprint implementation and testing activities:
  - Sprint 9 Closed
  - Sprint 10 development is on-going, corrective actions on-going
- Release and Sprint planning activities:
  - Release 11 plan was approved
  - Sprint 11 plan was discussed and agreed with POs
- Analysis & Design:
  - Finishing iteration 6
  - Defining the scope of iteration 7
- Backlog Management:
  - Feedback received from MS and Sponsor POs was analysed, consolidated and added to JIRA
  - Solutions were specified and agreed with POs for Fast-Track tickets
- Change management:
  - Actions from the Delivery Communication Plan have been implemented
  - The approach to the master reports has been agreed upon
  - Internal IT4U meetings to agree actions to improve on the lessons learned have taken place

In the next three weeks (26/8/2019 - 13/9/2019)

- Sprint implementation and testing activities:
  - Close Sprint 10 development and testing
  - Start implementation of Sprint 11
  - Preparation of the Release Validation
- Release and Sprint planning activities:
  - Define Sprint 12 plan proposal
- Analysis & Design:
  - Complete iteration 6
  - Iteration 7 is on-going
- Backlog Management:
  - Regular backlog management activities (review tickets with POs, enhance and create tickets,…)
  - Identify and specify solutions for Fast Track tickets identified as Business Blockers by the MS POs
- Change management:
  - Finalise Onboarding Package
  - Identify training needs for POs and rapporteurs
  - Prepare concept for future UAT in alignment to NDM

General status

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Sprint Implementation and Testing

(*) ▮ items validated and ▮ issue pending for POs feedback

Sprint 7 – Closed

- **Scope:** ▮ Items
  - ▮ fresh in the original scope
- **Status**
  - Items delivered to FAT: ▮ ▮
  - Items delivered to SAT: ▮ ▮
  - Items delivered to BV: ▮ ▮
  - **Items validated:** ▮ ▮
  - Items not delivered: ▮ ▮
- **Timing**
  - Starting date: 11/06
  - Business Validation: 09/07

Sprint 8 – Closed

- **Scope:** ▮ Items
  - ▮ fresh in the original scope
  - ▮ carryover items
- **Status**
  - Items delivered to FAT: ▮
  - Items delivered to SAT: ▮
  - Items delivered to BV: ▮
  - **Items validated:** ▮
    - Original scope: ▮
    - Carryover: ▮
  - Items not delivered: ▮
- **Timing**
  - Starting date: 01/07
  - Business Validation: 30/07

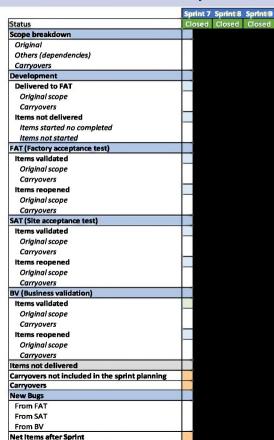### Sprint 9 – Closed

- **Scope:** ▮ Items
  - ▮ fresh in the original scope
  - ▮ dependency
  - ▮ carryover item
- **Status**
  - Items delivered to FAT: ▮
  - Items delivered to SAT: ▮
  - Items delivered to BV: ▮
  - **Items validated:** ▮
    - Original scope: ▮
    - Dependency ▮
    - Carryover: ▮
  - Items not delivered: ▮
- **Timing**
  - Starting date: 22/07
  - Business Validation: 20/08

Sprint Implementation and Testing

Status	Sprint 7	Sprint 8	Sprint 9
	Closed	Closed	Closed
Scope breakdown			
Original			
Others (dependencies)			
Carryovers			
Development			
Delivered to FAT			
Original scope			
Carryovers			
Items not delivered			
Items started no completed			
Items not started			
FAT (Factory acceptance test)			
Items validated			
Original scope			
Carryovers			
Items reopened			
Original scope			
Carryovers			
SAT (Site acceptance test)			
Items validated			
Original scope			
Carryovers			
Items reopened			
Original scope			
Carryovers			
BV (Business validation)			
Items validated			
Original scope			
Carryovers			
Items reopened			
Original scope			
Carryovers			
Items not delivered			
Carryovers not included in the sprint planning			
Carryovers			
New Bugs			
From FAT			
From SAT			
From BV			
Net Items after Sprint			

Summary of sprints completed:

Sprint 10 – On-going

- **Scope:** ▉ **Items**
  - ▉ fresh in the original scope
  - ▉ carryover items

- **Summary Status at (23/08/2019)**
  - Items being developed/tested: ▉
  - Items to *descope: ▉
  - **Items validated on August 20:** ▉
    These items were developed and tested in parallel with Sprint 9

- **Timing:** Starting date: 12/08, BV: 12/09

*More details in slide 12

The table below compares the agreed thresholds with the actual results of the m

KPI	Formula	Most recently ended Sprint (S9)	EMA threshold for S9	Comments	Status

(*) ▮ items validated and ▮ issue pending for POs feedback

The table below compares these thresholds with the results of the most recently closed Sprint.

KPI	Formula	Most recently ended Sprint (S9)	EMA threshold for S9	Comments	Status

7
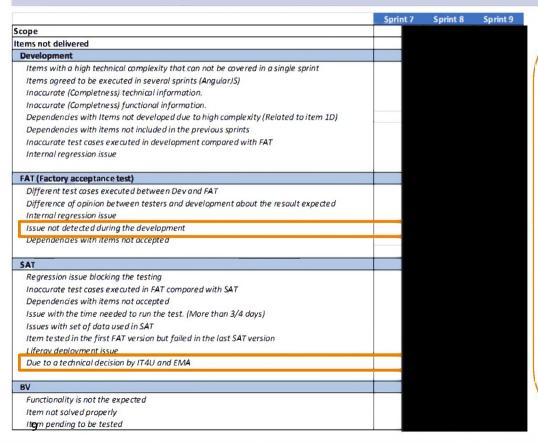
The table below compares these thresholds with the results of the most recently closed Sprint.

KPI	Formula	Most recently ended Sprint (S9)	EMA threshold for S9	Comments	Status

IT4U has analysed the root causes to define an action plan in the short and medium term

	Sprint 7	Sprint 8	Sprint 9
Scope			
Items not delivered			
Development			
Items with a high technical complexity that can not be covered in a single sprint			
Items agreed to be executed in several sprints (AngularJS)			
Inaccurate (Completness) technical information.			
Inaccurate (Completness) functional information.			
Dependencies with Items not developed due to high complexity (Related to item 1D)			
Dependencies with items not included in the previous sprints			
Inaccurate test cases executed in development compared with FAT			
Internal regression issue			
FAT (Factory acceptance test)			
Different test cases executed between Dev and FAT			
Difference of opinion between testers and development about the resault expected			
Internal regression issue			
Issue not detected during the development			
Dependencies with items not accepted			
SAT			
Regression issue blocking the testing			
Inaccurate test cases executed in FAT compared with SAT			
Dependencies with items not accepted			
Issue with the time needed to run the test. (More than 3/4 days)			
Issues with set of data used in SAT			
Item tested in the first FAT version but failed in the last SAT version			
Liferay deployment issue			
Due to a technical decision by IT4U and EMA			
BV			
Functionality is not the expected			
Item not solved properly			
Item pending to be tested			

Main Root Causes

- ▮Issues not detected during development, the detailed test cases were only available in the late stage of development

- ▮Due to a management decision in order to avoid introducing risk in the delivery of Sprint 9

Root cause of the regression metrics

- ▮ of the test cases in the regression suite couldn`t be executed in Sprint 9. Performance issue was raised during SAT and automated test cases fail. Notices and alerts page takes 2 mins to load

Action Plan: Short Term

Status of the actions implemented in sprints 8 and 9

- Two types of **action plans** were **implemented** during sprints 8 and 9 to increase the amount of net items validated per sprint

  - Focus on **capacity**: The objective was to keep the development capacity during the summer period and take over the development of the items not delivered in sprint 7 and 8.

  - Focus on **quality**: The main objective was to improve the sanity check and acceptance criteria of the test performed during the development as well as in FAT to avoid items not validated in FAT and SAT.

- As a **first result** of these actions:

Status of the actions implemented in sprints 8 and 9

- A new action has been defined and implemented in the last weeks.

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- Despite the positive trend of S9, the best-case scenario for the Release 10 is to deliver ███ Items to FAT out of ████ estimated items in the original scope.

- Based on the outcome of S9 and the remaining time available to complete the implementation of S10, 11 items are not developed. Complexity and reasons are as follow:

	Items included in the scope of Sprint 10	Number of items Not Developed	Ground for decision are the following
Complex			
High			- Items reopen in BV (SP8): ██
Medium			- Technical complexity or pending functional clarifications: ██
Low			- Dependency on incomplete item: ██
Trivial			- Remaining effort needed does not allow to complete the item before the end of Sprint 10: ██
Items with 0 estimates			
TOTAL			

- The accurate estimation of the actual items to be delivered for BV at the end of R10 will be shared on 04/09.

12   * Final number to be confirmed by 04/09

- **2nd of September**: Start the implementation of Release 11 by applying 4 weeks Sprints in order to improve the New Delivery Model

- **13th September:** End of Release 10

- **$16-20^{th}$ of September**: First Release Validation at EMA

Any questions?

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Annex
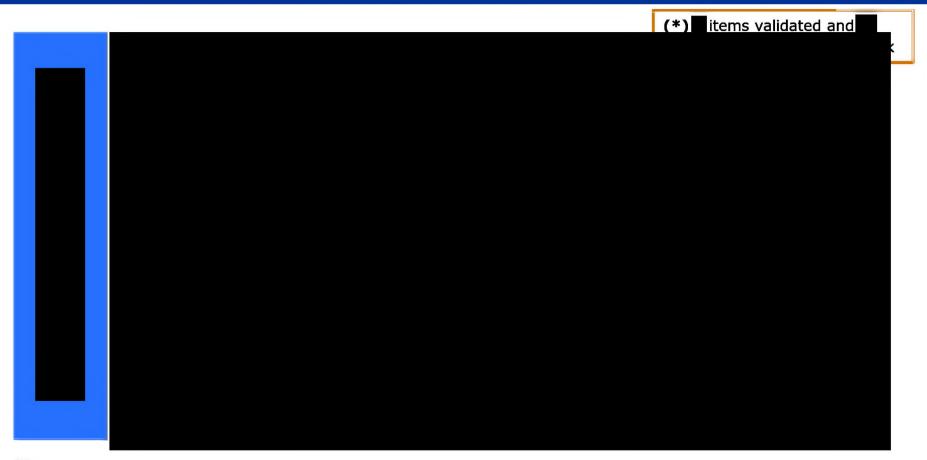
(*) ▮ items validated and ▮ issue pending for POs feedback

Data breakdown. In addition to showing the percentage of items resolved in each Sprint, we will specify the items' complexity (classified from high to low).

	Number of items in Sprint scope	Number of items validate in the Sprint (after FAT)	Number of items validate in the Sprint (after SAT)	Number of items validate in the Sprint (after BV)
Complex				
High				
Medium				
Low				
Trivial				
Items with 0 estimates				
TOTAL				

(*) items validated and

(*) ███ items validated and ███ issue pending for POs feedback

Data breakdown.

- Within this KPI, further data will be available on the nature of the items that have been addressed during each milestone.

Release 10		Ready (after A&D)	Validate (after FAT)	Verify (after SAT)	Closed (after Business Validation)
	Sprint 9	███████	███████	███████	█████

Action Plan: Medium Term

Following actions will be implemented along Release 11

Action	Status
A&D **functional analysis** will be perform in an **holistic way** and technical analysis will break down the items to ensure the parallel implementation. The **benefits** of this action are: • Grouping items by functionality (Clustering). • Better understanding about how the application operates. • Earlier detection of functionality missing. • Better sprint planning in the way the items included in the scope can be selected with more complete and accurate information • To detect dependencies between items before including them in the scope of each sprint. The main **consequence**, in the short term, is: • Limited A/D capacity will be working on items with non-auditable functionality (Less than Business value 3)	To be implemented in Release 11
Extend sprint duration (testing period), from 3 to 4 weeks. The **benefits** of this action are: • More time to update test cases of run in each sprint. • To extend the FAT duration to fix and re test issues founded during FAT. • To increase the number of net items delivered to be approved. The main **consequence** is: • Release 11 will have same duration (12 weeks) but will contain 1 sprint less	To be implemented by September 2

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