EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

24 June 2019

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Status on Safety Reporting and CT2 Extension

KEY HIGHLIGHTS - Reporting period: 10/06/2019 - 21/06/2019

- **Safety Reporting**
  - All deliverables have been submitted to EMA. The 2nd review cycle is on-going.
  - The acceptance period finishes on 02/07.

- **CT1 Extension (fixing 52 pre-UAT bugs)**
  - 49 items have been shown to the POs and all of them were closed.
  - One bug was reopened by EMA, but fixed already. It has been deployed within the first development version of Release 1 - Sprint 7. Planned to be validated with EMA in IT4U environments in Release 1 - Sprint 7.
  - Two are pending to be shown due to liferay issues, the technical analysis is on-going to reach the solution.

- **Regression Testing 2**
  - Regression testing 2 completed by IT4U.
    - ███ out of █████ test cases are blocked by an issue ███████████
  - Approximately ████ items identified between regression testing 1 and 2. Out of them, ███ items were unknown from regression testing 1 (categorization are under review).
  - IT4U and EMA working together to validate (and improve if applicable) testing coverage

KEY HIGHLIGHTS - Reporting period: 10/06/2019 - 21/06/2019

- **Release Management (planning, development and testing) activities**
  - Release 1 - Sprint 7 implementation started on 11/06, it is going as planned.
  - Release 1 - Sprint 8 scope has been approved by Product Owners, EMA and IT4U. Focus on application creation and evaluation, and RMS selection. The proposal includes 4 technical issues and 27 functional issues.

- **Backlog management activities**
  - 463 items (from Member States POs) and 455 items (from Sponsors POs) have been received and are "open*". Currently, 90% of the total functional historical backlog (1022 items*) have been reviewed. From those items reviewed, 97% of them have business value and of which, at least, 444 items have business value 3**.
  - Currently, the IT4U team is starting the consolidation of these items (i.e. reviewing items that have different business value from MS and Sponsors POs) and updating JIRA.
  - The assignment of the Technical Value to technical debt items is on-going by Technical Team

- **Analysis and Design activities**
  - A&D 3: the activities are completed as planned (35 items fully analysed and designed)
  - A&D 4: analysis of the items is on-going (expecting 38 items to be analysed and designed)

*Only considering the items that are open in JIRA. Up to now, POs have reviewed a total of 1134 items, from those 1022 are open in JIRA.
** Provisional number depending on the consolidation analysis being performed by IT4U.

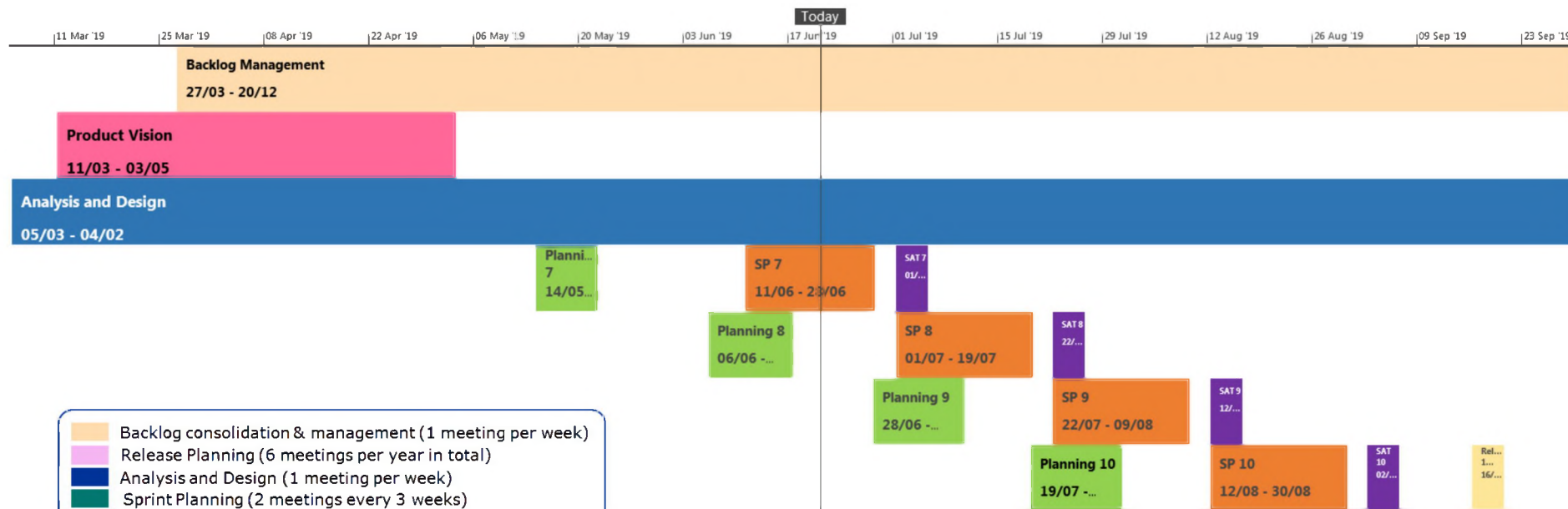## KEY HIGHLIGHTS - Reporting period: 10/06/2019 - 21/06/2019

- **Change management:**
    - **KPIs:** Formulas validated.
    - **Set-up:** Seville's agenda defined (Kick-off meeting at supplier's premises).

Work plan for the next 3 weeks

KEY HIGHLIGHTS - Reporting period: 24/06/2019 - 17/07/2019

- **Release Management (planning, development and testing) activities**
  - Release 1 - Sprint 7 will be completed, including FATA, SAT and business validation (09/07)
  - Release 1 - Sprint 8 the development will be completed (16/07) and the SAT will be starting
  - Release 1 - Sprint 9 scope to be agreed with Product Owners, EMA and IT4U (08-10/07).
  - Release 2 meeting to take place with Expert Group (05/07) and the Release Plan 2 to be endorsed.

- **Backlog management activities**
  - A consolidate view of the functional historical backlog to be shared with EMA and POs
  - New and re-open backlog items will be analysed in 3 grooming sessions foreseen
  - 30 items more will have Technical Value (assuming 10 per week)
  - A projection on when the audit could take place will be presented.

- **Analysis and Design activities**
  - A&D 4 will be finished
  - Scope of A&D 5 and A&D 6 to be presented.
  - A&D5 will be starting

- **Change management:**
  - **Reporting:** Provide analysis of the KPIs for Release 1 - Sprint 7 and on-going on streamiline of reporting
  - **Set-up:** Provide highlights of the meeting at supplier's premise and identify improvements in the A&D process with Pos.
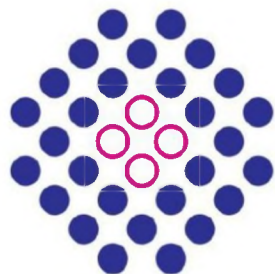
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Today

|11 Mar '19 |25 Mar '19 |08 Apr '19 |22 Apr '19 |06 May '19 |20 May '19 |03 Jun '19 |17 Jun '19 |01 Jul '19 |15 Jul '19 |29 Jul '19 |12 Aug '19 |26 Aug '19 |09 Sep '19 |23 Sep '19

Backlog Management
27/03 - 20/12

Product Vision
11/03 - 03/05

Analysis and Design
05/03 - 04/02

Planni...
7
14/05...

SP 7
11/06 - 23/06

SAT 7
01/...

Planning 8
06/06 -...

SP 8
01/07 - 19/07

SAT 8
22/...

Planning 9
28/06 -...

SP 9
22/07 - 09/08

SAT 9
12/...

Planning 10
19/07 -...

SP 10
12/08 - 30/08

SAT 10
02/...

Rel...
1...
16/...

Backlog consolidation & management (1 meeting per week)
Release Planning (6 meetings per year in total)
Analysis and Design (1 meeting per week)
Sprint Planning (2 meetings every 3 weeks)
Development
SAT
Sprint Validation (1 day every 3 weeks)
Release Validation (1 week every 3 months)
Envisaged meeting (onsite or offsite)

Thank you for your attention