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F2: FAIR and Filing **Assessing Data Fitness for FAIR and Filing**

Presented by Siye Liu, Roche (China) Holding Ltd.



Meet the Speaker

Siye Liu

Title: Principal Data Scientist

Organization: Roche (China) Holding Ltd.

Siye Liu worked in the pharmaceutical industry for 14 years and took on several roles in the data sciences department, namely data Manager, clinical programmer, and he became a member of data science acceleration department, mainly supporting tool development which secures the business success for SAS programming. Siye is also a key contributor to the eSub translation process and his experience in multiple roles allow him to support China filling for many studies.



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Agenda

1. FAIR and Filing (F2) Dashboard Overview
2. F2 Dashboard Demo
3. Future Enhancements to F2 Dashboard
4. Summary

F2 Dashboard Overview



What is F2 Dashboard?

- A tool for gauging the progress of study level deliverables
- The F2 Dashboard is an R shiny app that has been developed internally by Roche-Genentech eSubmission team
- It visually provides tangible evidence on the progress of tasks in relation to the Database Lock date
- The tool can be used multiple times during the study life cycle to ensure completeness of the deliverables
- It generates reports or summaries by study, molecule or therapeutic areas

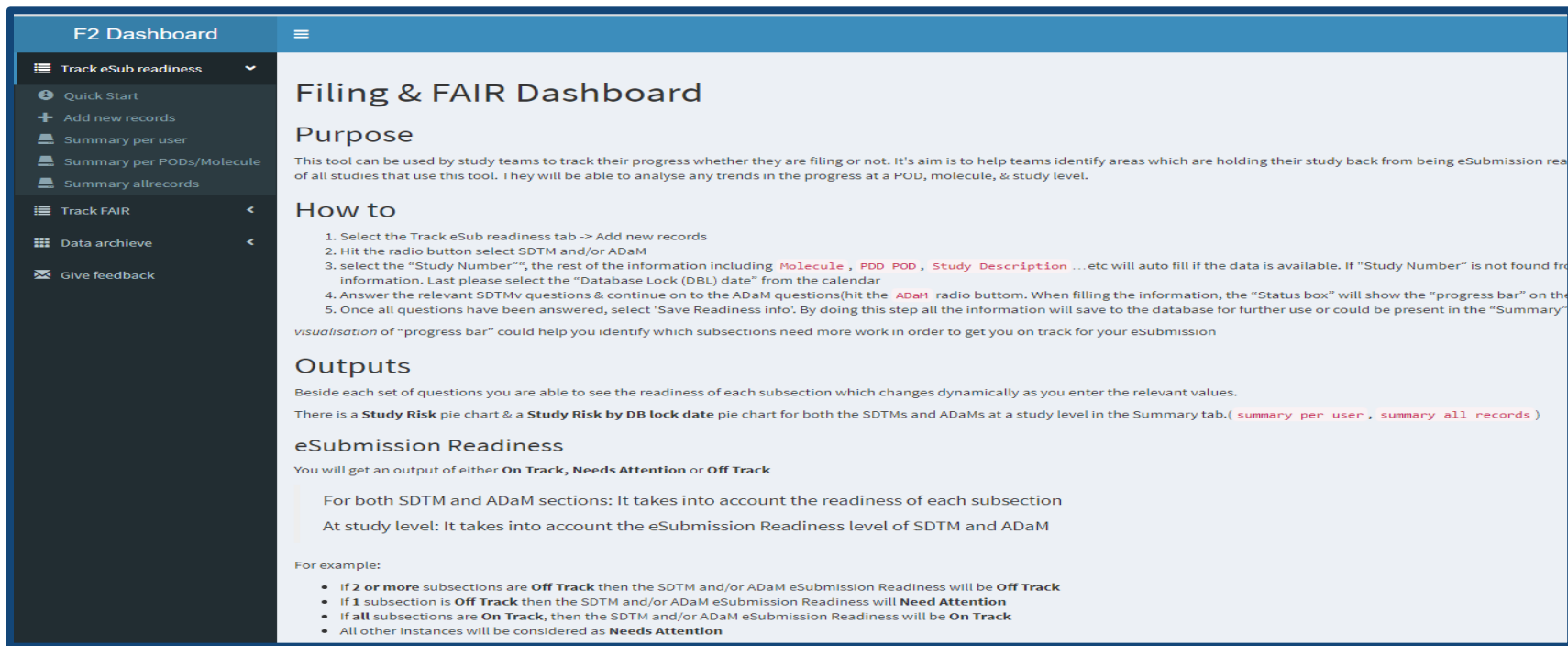


Why F2 Dashboard?

- At Roche-Genentech we did not have any way of gauging the progress of the FAIR & Filing deliverables
- Lack of having any mechanisms to evaluate the progress of deliverables on a study or molecule was posing to be a challenge for the eSubmission team
- While the available tools and submission checklists were helping teams develop quality packages, we could not assess the progress of the deliverables
- We needed a tangible way to help track progress and identify areas for study teams to prioritize and focus on. To address this issue the F2 Dashboard was developed



F2 Dashboard Overview



The screenshot shows a web application interface for the 'F2 Dashboard'. On the left is a dark sidebar with navigation options: 'Track eSub readiness' (selected), 'Quick Start', 'Add new records', 'Summary per user', 'Summary per PODs/Molecule', 'Summary allrecords', 'Track FAIR', 'Data archive', and 'Give feedback'. The main content area is titled 'Filing & FAIR Dashboard' and contains the following sections:

Purpose

This tool can be used by study teams to track their progress whether they are filing or not. It's aim is to help teams identify areas which are holding their study back from being eSubmission ready of all studies that use this tool. They will be able to analyse any trends in the progress at a POD, molecule, & study level.

How to

1. Select the Track eSub readiness tab -> Add new records
2. Hit the radio button select SDTM and/or ADaM
3. select the "Study Number", the rest of the information including **Molecule** , **POD** , **Study Description** ... etc will auto fill if the data is available. If "Study Number" is not found from information. Last please select the "Database Lock (DBL) date" from the calendar
4. Answer the relevant SDTMv questions & continue on to the ADaM questions(hit the **ADaM** radio button. When filling the information, the "Status box" will show the "progress bar" on the
5. Once all questions have been answered, select 'Save Readiness info'. By doing this step all the information will save to the database for further use or could be present in the "Summary"

visualisation of "progress bar" could help you identify which subsections need more work in order to get you on track for your eSubmission

Outputs

Beside each set of questions you are able to see the readiness of each subsection which changes dynamically as you enter the relevant values.

There is a **Study Risk** pie chart & a **Study Risk by DB lock date** pie chart for both the SDTMs and ADaMs at a study level in the Summary tab.(**summary per user** , **summary all records**)

eSubmission Readiness

You will get an output of either **On Track**, **Needs Attention** or **Off Track**

For both SDTM and ADaM sections: It takes into account the readiness of each subsection

At study level: It takes into account the eSubmission Readiness level of SDTM and ADaM

For example:

- If **2 or more** subsections are **Off Track** then the SDTM and/or ADaM eSubmission Readiness will be **Off Track**
- If **1** subsection is **Off Track** then the SDTM and/or ADaM eSubmission Readiness will **Need Attention**
- If **all** subsections are **On Track**, then the SDTM and/or ADaM eSubmission Readiness will be **On Track**
- All other instances will be considered as **Needs Attention**

SDTM Readiness - Input

Study and Package details

SDTM
 ADaM

Please enter the study number

ABC12345

Molecule

Pharma Drug

PDD POD

Onco

Study Description

Mega Drug

Primary end point db lock / snapshot date.

2023-05-14

SDTM Readiness

SDTM aCRF Creation Progress

NOTE: Your study should have used Project Botany tools, Mint & Sage, when creating the aCRF

Have all GDSR standard variables been annotated?

Yes
 No

Have all non-standard variables been annotated?

Yes
 No

Has the bookmarking been completed?

Yes
 No

SDTMv to SDTM Conversion Progress

Total no. of SDTMv datasets planned to be created:

0

No. of datasets programmed, validated & specification updated:

0

SDTMv to SDTM Conversion Progress

SDTMv to SDTM Conversion:

Activity not started
 In-Progress
 Completed

SDTMv to SDTM Conversion:

Activity not started
 In-Progress
 Completed

SDTM Conformance Checking

SDTM Pinnacle 21 XPT Validation Score

0 100

0 10 20 30 40 50 60 70 80 90 100

SDTM Define.xml Creation Progress

Have you started creating the Define.xml?:

Yes
 No

SDTM cSDRG Creation Progress

How much of the cSDRG has been completed?

<=50%
 51-80%
 >80%

Have all conformance issues been documented?

Yes
 No

ADaM Readiness - Input

Study and Package details

SDTM
 ADaM

Please enter the study number

ABC12345

Molecule

Pharma Drug

PDD POD

Onco

Study Description

Mega Drug

Primary end point db lock / snapshot date.

2023-04-13

ADaM Readiness

ADaM Progress

ADaM Dataset Creation Progress

Total no. of ADaM datasets planned to be created:
19

No. of datasets programmed, validated & specs updated:
017

ADaM Conformance Checking

ADaM Pinnacle 21 XPT Validation Score

0 81 100

ADaM Define.xml Creation Progress

Have you started creating the Define.xml?
 Yes
 No

ADaM Pinnacle 21 define.xml issues:

0-10 issues
 11-30 issues
 >30 issues

ADaM Datasets Readable Programs & program TOC

Have all the relevant ADaM programs been converted to txt files?
 No
 Yes

ADaM Datasets Readable Programs & program TOC

Have all the relevant ADaM programs been converted to txt files?
 Yes
 No

Have all the relevant TLG programs been converted to txt files?
 Yes
 No

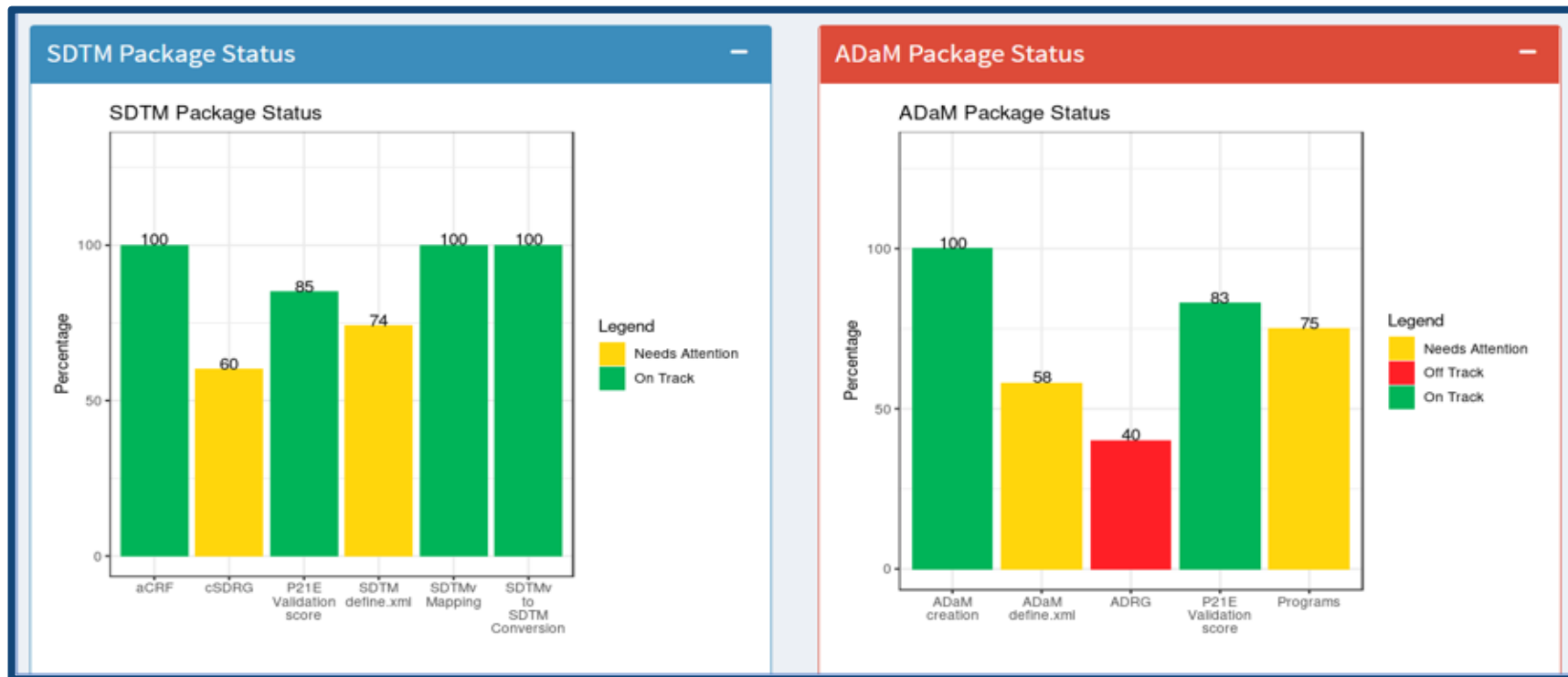
How much of the programtoc has been completed?
 <=50%
 51-80%
 >80%

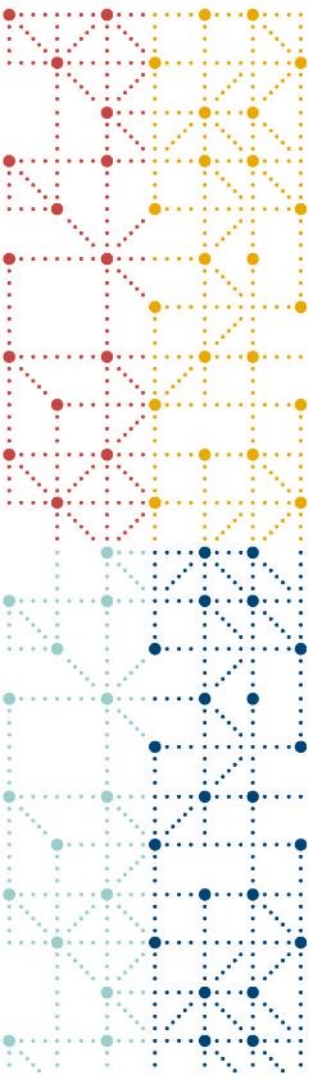
ADaM ADRG Creation Progress

How much of the ADRG has been completed?
 <=50%
 51-80%
 >80%

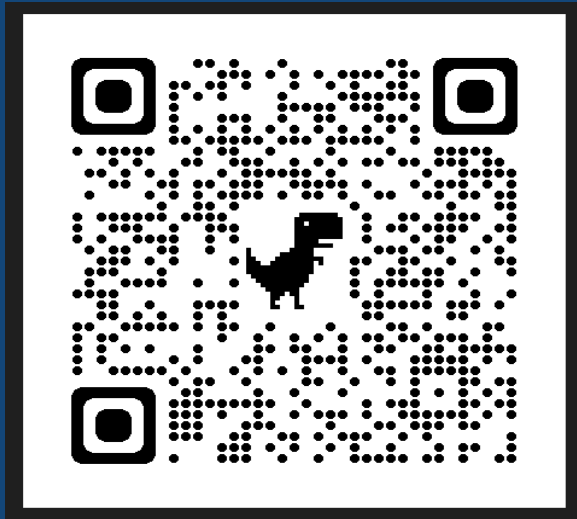
Have all conformance issues been documented?
 Yes
 No

SDTM and ADaM - Progress Visual





F2 Dashboard DEMO



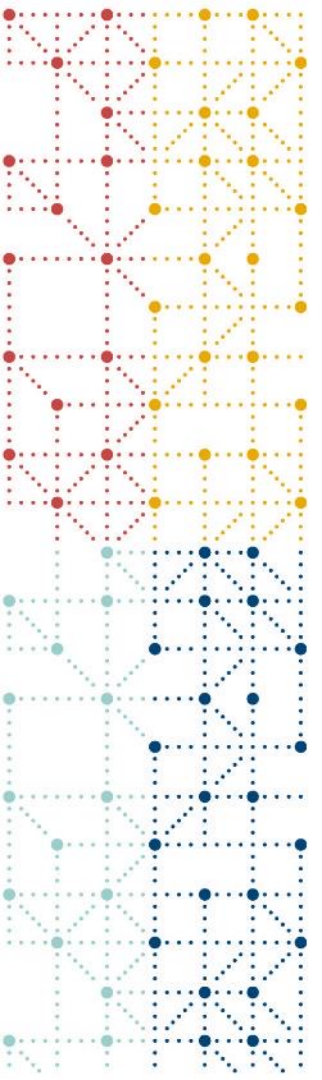


Future Enhancements to F2 Dashboard

Future Enhancements to F2 Dashboard

- Improve visualizations
- Evolve the tool based on user feedback
- Bring in automation – reduce manual input entry



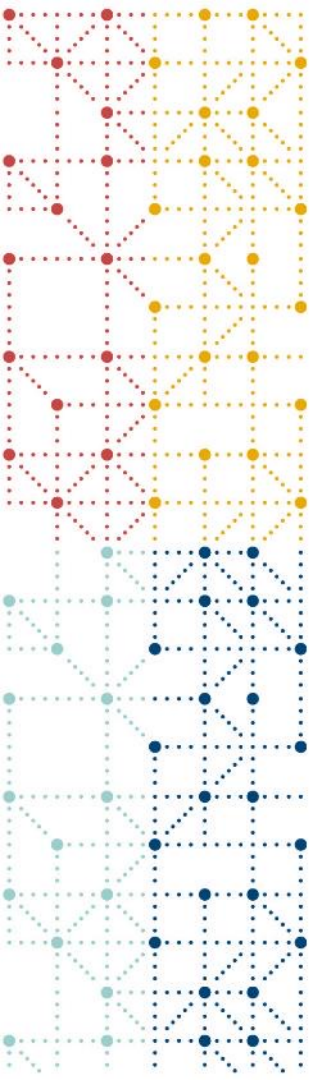


Summary

Summary

- The F2 dashboard is Roche-Genentech's first tool of its kind that provides a tangible way to gauge progress to assess FAIR and filing readiness
- The tools functionality and the color coded visuals help identify the areas to focus on
- The dashboard helps identify bottlenecks and triage the issues
- Regular use of the F2 Dashboard could help avoid panic situations, stress and last minute firefighting





Thank You!

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