ABSTRACT

Have you ever asked the question: "How are study programming tasks progressing?" When working on programming or filing activities for a study, a lot of time is spent planning what datasets & variables will be required to create the TLGs for a reporting activity. Upfront planning is good; however, keeping track of the progress of the different deliverables such as SDTM/ADaM including conformance, aCRF and Define.xml generation, reviewers guide completion, and TLG creation, proves challenging, especially when there are a lot of data science members involved. The reliance for gauging progress often is on 'word of mouth,' 'guesstimates,' and a 'gut' feeling. This drove us to explore a better approach to assess Filing and FAIR (Findable, Accessible, Interoperable and Re-usable) progress which resulted in the creation of an R Shiny application. The F2 dashboard, as we call it, creates a color coded visual to demonstrate how the study is progressing - the colors indicate where progress is going well and identify areas where teams may need to place greater emphasis on. The assessment is based on tangible evidence provided by the study team.

The F2 dashboard helps gauge the progress of study deliverables at any point of time. It could help understand how the team is FAIRing, help have conversations to know the road blocks and triage the issues that the team is facing. Our overall objective is to be Filing and FAIR ready by database lock.

INTRODUCTION

Submission activities in the pharmaceutical industry require a lot of effort and planning. There are several components to be considered – number of studies to be submitted, deliverables within the submission, the standards to be used, regulatory requirements and quality to top it off.

The greater use of the study data beyond CSR reporting and Filings is required to generate scientific insights and make more informed clinical decisions. Abiding to global data standards and proactively preparing data for reuse enables efficient data sharing both internally and externally, which means additional insights can easily be generated. The lifespan of our data far exceeds our time with it, so it’s our responsibility to make sure that others can easily see how we handled it and the decisions that were made. Remembering this whilst carrying out our project work is crucial for our studies to be FAIR. Having the data in a FAIR (Findable, Accessible, Interoperable and Reusable) state allows us to maximize the value of our data, sharing it across could help explore new avenues in drug discovery and development activities.

A proactive approach and a mindset shift is required when developing study deliverables, be it for a reporting event or a submission. At Roche-Genentech our aim is to ensure study teams are submission and FAIR ready by the Database Lock (DBL). In an endeavor to achieve this the eSubmission (eSub) team has developed several guidance documents and tools.

E-SUBMISSION TOOLS

READINESS CHECKLIST

The Readiness Checklist has been developed to aid the incorporation of FAIR principles and submission requirements as part of the study development process. The Readiness checklist provides details on all the front loading activities that need to happen during study conduct to ensure generation of good FAIR and filing deliverables leading to DBL. It provides a logical flow of the activities that the team would need to do in order to prepare a good quality submission package; a large portion of which are already being done as a part of CSR reporting activities. The checklist calls out the different deliverables leading to a filing, the dependencies between them, the timings for generating and refreshing the deliverables – the different time points at which these should be generated / refreshed during the study life cycle.
In the screenshots below you can see the readiness checklist and how it emphasizes on frontloading.

**Figure 1. Screenshot of Readiness Checklist**

![Readiness Checklist](image)

**Figure 2. Timeframe for generating FAIR and Submission Deliverables**

![Timeframe Diagram](image)
QUALITY ASSURANCE (QA) CHECKS

In order to address the common issues repeating across studies, molecules and therapeutic areas (TA's), resulting in variations in quality of submission deliverables, the QA checks were developed. These checks help teams validate their own submission deliverables and produce good quality packages. The QA checks are embedded within an excel file with a tab each for SDTM and ADaM related deliverables; with a column to check mark or add comments during the validation process. These checks serve as reminders to improve quality. The checks will help reduce the back and forth between study teams and eSub team reviewers. Implementing them right from the very beginning could help save resources be it time or personnel.

Below is a screenshot of the QA checks that help understand the issues to be looked into from a quality perspective in SDTM data package. It lists out contents to be checked in order to ensure the deliverables adhere to Health Authority requirements and will avoid failing any Technical Rejection Criteria.

![Figure 3. Screenshot of SDTM QA Checks](image)

While the screenshot highlights the SDTM checks, similar ones are available for ADaM data and related deliverables as well (ADaM QA Checks in screenshot above).

F2 DASHBOARD (F2DB)

As part of our submission activities to the Health Authorities, we had to evolve our approach to create and deliver CDISC compliant eSub data packages. While the readiness and QA checks were helping teams develop quality packages, we never really could gauge or assess the progress of eSub activities. We needed a tangible way to help track progress and identify areas to prioritize and focus on. To address this issue the F2 Dashboard was developed.

The F2DB is an R Shiny app developed internally by Roche-Genentech eSub team. It helps study teams assess their progress towards being FAIR and submission ready by DBL. We first prototyped this tool in excel before making it an R shiny app. The app creates a color coded visual to demonstrate how the study is progressing.
The app requires teams to input study information and further provide details on the deliverables. At Roche-Genentech the app has been linked to an internal portfolio report to get basic study information like study name, study number, and milestone dates. This along with study specific deliverable information helps generate a color coded report as seen in the screenshot below (Figure 5). The color coding is determined by a backend formula that evaluates the progress of the deliverables relative to the DBL date and assigns colors accordingly. The colors indicate if you are on track, off track or need attention.
READINESS – TOOL INPUT AND METRICS

The F2 dashboard consists of windows that require user input. Described below are details about each of them.

STUDY INPUT or READINESS CHECK

This panel displays basic study information. It is linked with Roche-Genentech’s internal portfolio report that helps populate the basic study information like study number, molecule, study description, and DBL date. Users can check the readiness of either SDTM or ADaM by choosing one of them. The orange panel in the screenshot below displays the study input information.

![Figure 6. F2DB – Input information panels screenshot](image)

SDTM / ADaM READINESS INPUT

This panel includes a series of questions about the status and extent of completion of deliverables that contribute to the SDTM and ADaM packages respectively. Users would need to provide input on each of the listed fields. Alternatively, they could enter all the relevant information into an EXCEL file and use the upload functionality to input the information for generating the reports. The above screenshot in blue shows this panel’s contents (readiness criteria of the FAIR and Filing).
OVERALL PACKAGE STATUS

Once the study and deliverable status input is provided in the previous two panels, an OVERALL package status report is generated and displayed in the SDTM/ADaM Status package panel. A color coded visual showing the status of readiness of each of the fields suggested in the readiness panel is output. The report visually provides tangible evidence on the progress of tasks in relation to the DBL date. It highlights areas where -

- **Progress is good (ON-TRACK)**
- **Average (NEEDS ATTENTION)**
- **Poor (OFF-TRACK)**

The screenshot below displays the Overall status of the SDTM and ADaM deliverables for an example study.

![SDTM and ADaM Status Report](image)

**Figure 7. Example - F2DB Overall SDTM and ADaM Status Report**

The tool can be used multiple times, as many time as the team would like to gauge their progress during the study life cycle. Managers and study / programming leads could look at the overall status report to understand the progress and address potential road blocks to help the teams be FAIR and filing ready in time. In addition to studies, summary level reports could be generated and reviewed from a molecule perspective to understand patterns and trends.

**QR CODE to F2DB**

Please find below a QR Code that will give you access to try out the F2DB that has been developed by Roche-Genentech
PLANNED FUTURE ENHANCEMENTS
While the F2DB is completely functional and is helping us gauge the progress of our deliverables, we intend to evolve this tool to make it more user friendly based on the initial feedback received. We plan to add more options to improve the visualizations, bring in some automation to avoid manually entering fields, and also have a similar dashboard for non-filing studies, to name a few.

CONCLUSION
The F2 dashboard is the first of its kind within our function that will help teams gauge their progress, a tangible way to assess the completeness of their deliverables at any point of time. The dashboard is particularly helpful to know how the team is faring, understand the bottlenecks and triage the issues that the team is facing due to resourcing, time or any other constraints. The color coded user friendly visuals help understand areas to focus on. Timely and regular use of F2DB, along with the rest of the tools listed, could help avoid panic situations and last minute fire-fighting and ensure creation and delivery of good quality packages.

ACKNOWLEDGEMENTS
The authors would like to thank the Analytical Data Sciences eSub Chapter and management teams from Roche-Genentech, for their advice and support on this paper/presentation.

CONTACT INFORMATION
Your comments and questions are valued and encouraged. Contact the author at:

Bidhya Basnet
Roche-Genentech, 1 DNA Way, South San Francisco, CA - 94080
e-mail: basnet.bidhya@gene.com

Dyuthi Yellamraju
Roche-Genentech, 1 DNA Way, South San Francisco, CA - 94080
e-mail: yellamraju.dyuthi@gene.com

Any brand and product names are trademarks of their respective companies.