

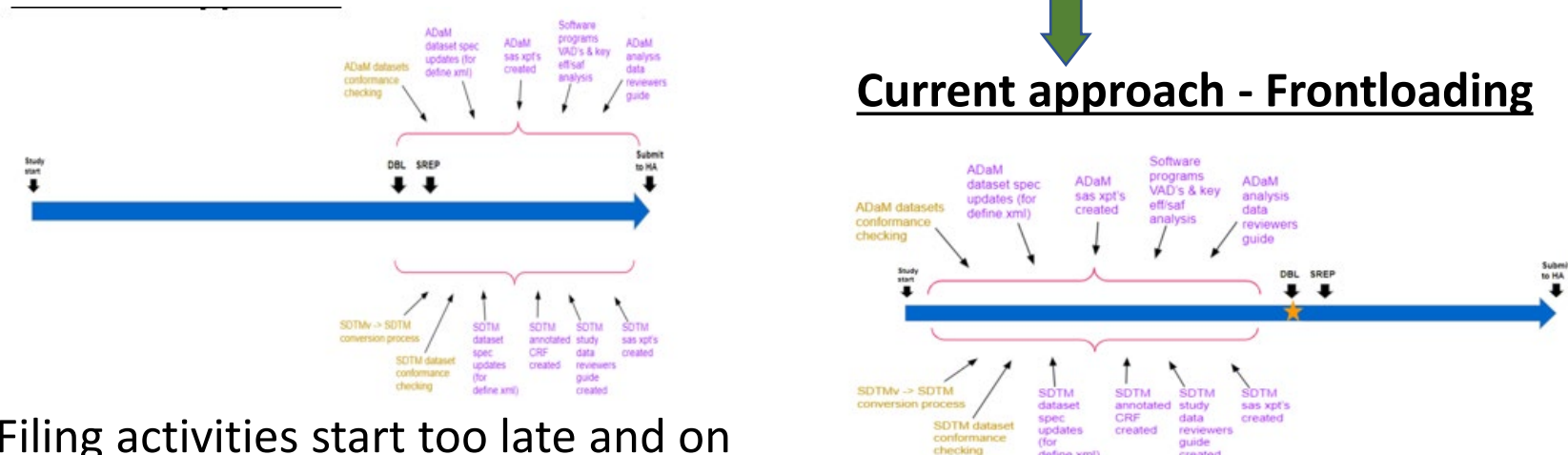
Background:

As part of our submissions activities to Health Authorities (i.e. FDA), we had to evolve our approach in order to be better prepared to create and delivery CDISC compliant eSub data packages. Our aim was to be submission ready by the time we reached the Database Lock Date. Given the greater use of the study data beyond CSR reporting and Filings in the future, we want to use this approach for all reporting events in order to allow for the FAIR principles (Findable Accessible Interoperable Re-usable).

As you will see in this poster, we changed our programming activities to be more front loading instead of being retrospective, tools and guidances were created (& are still evolving) to reduce manual work, a checklist guidance is provided to guide teams when certain activities should be done in order to achieve eSub readiness by DBL, and also a Quality Assurance aid was created in order to ensure the deliverables were of high quality.

With all these tools and guidances provided, we wanted to extend this to help team track how they are progressing, hence the creation of **the Filing & FAIR (F²) Dashboard** . The aim was to create visuals to easily show if their progress was 'Off Track' [red] 'Needs more attention' [yellow] or 'On Track' [green]

Old approach - Retrospective

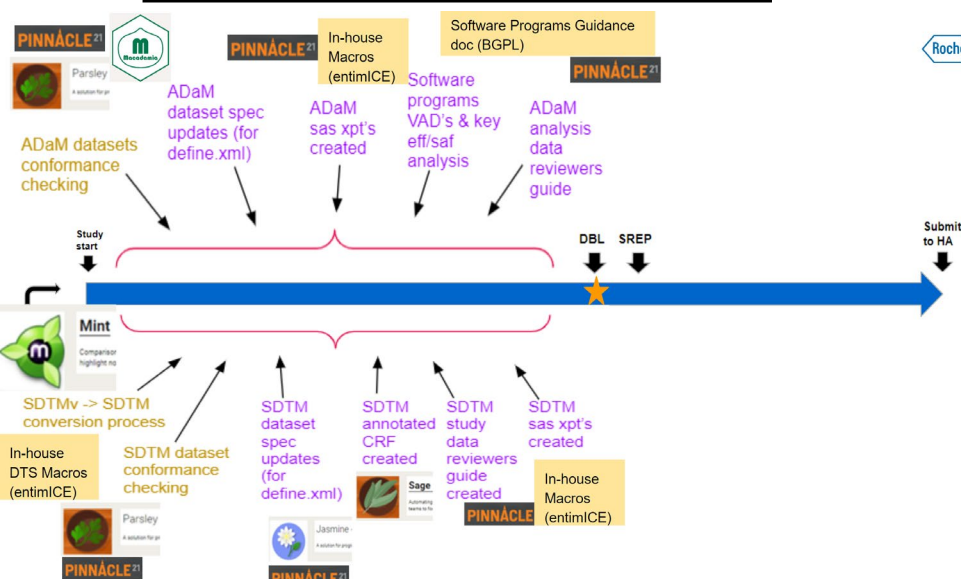


Filing activities start too late and on the critical path which leads to time constraints, frustration and delays

Incorporating eSub activities into the programming life cycle early

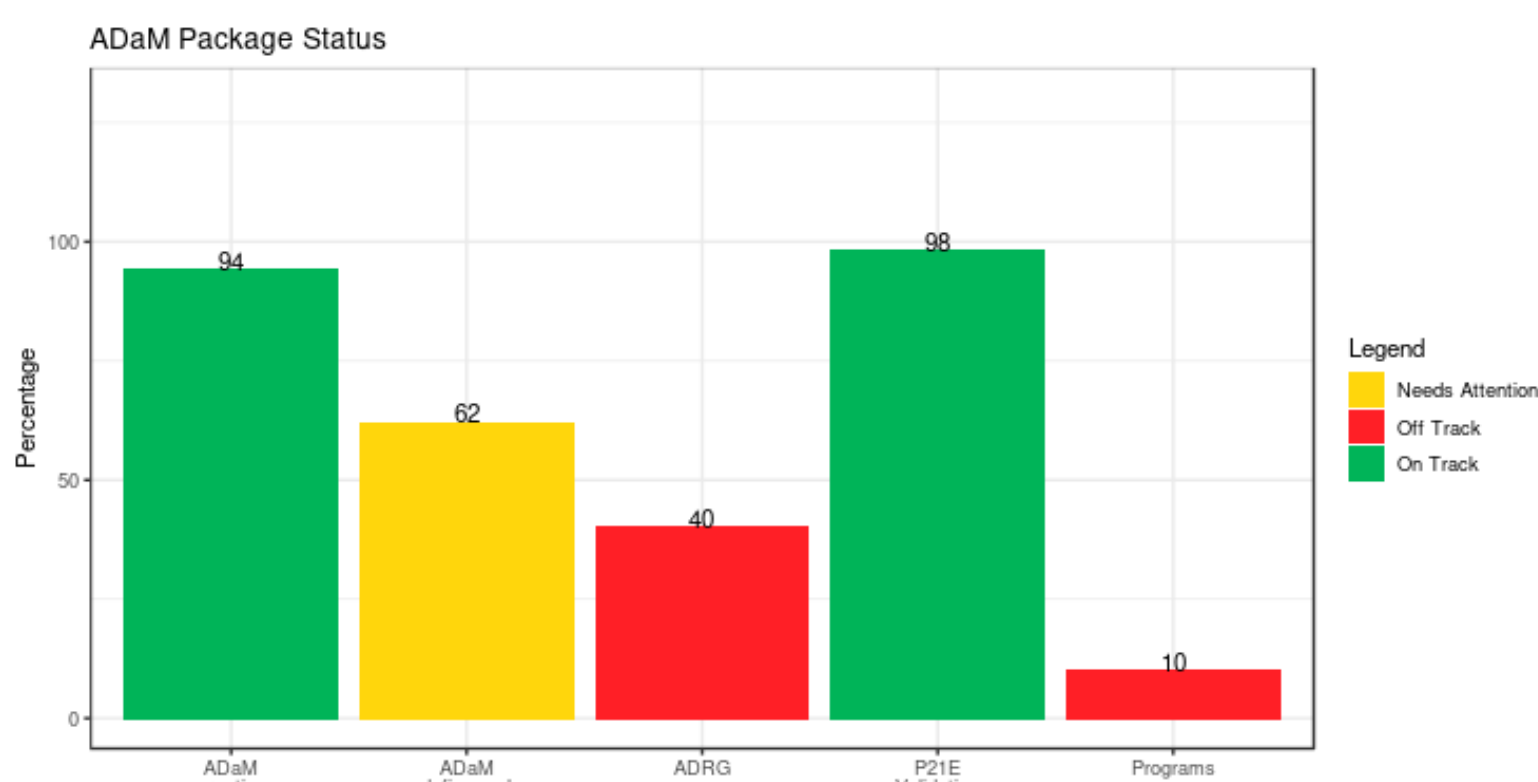
Provide resources to help study teams conduct the work more efficiently, save time, reduce manual work, bring consistency across molecules, and gives more scope to create better tools

Tools & Guidances resources

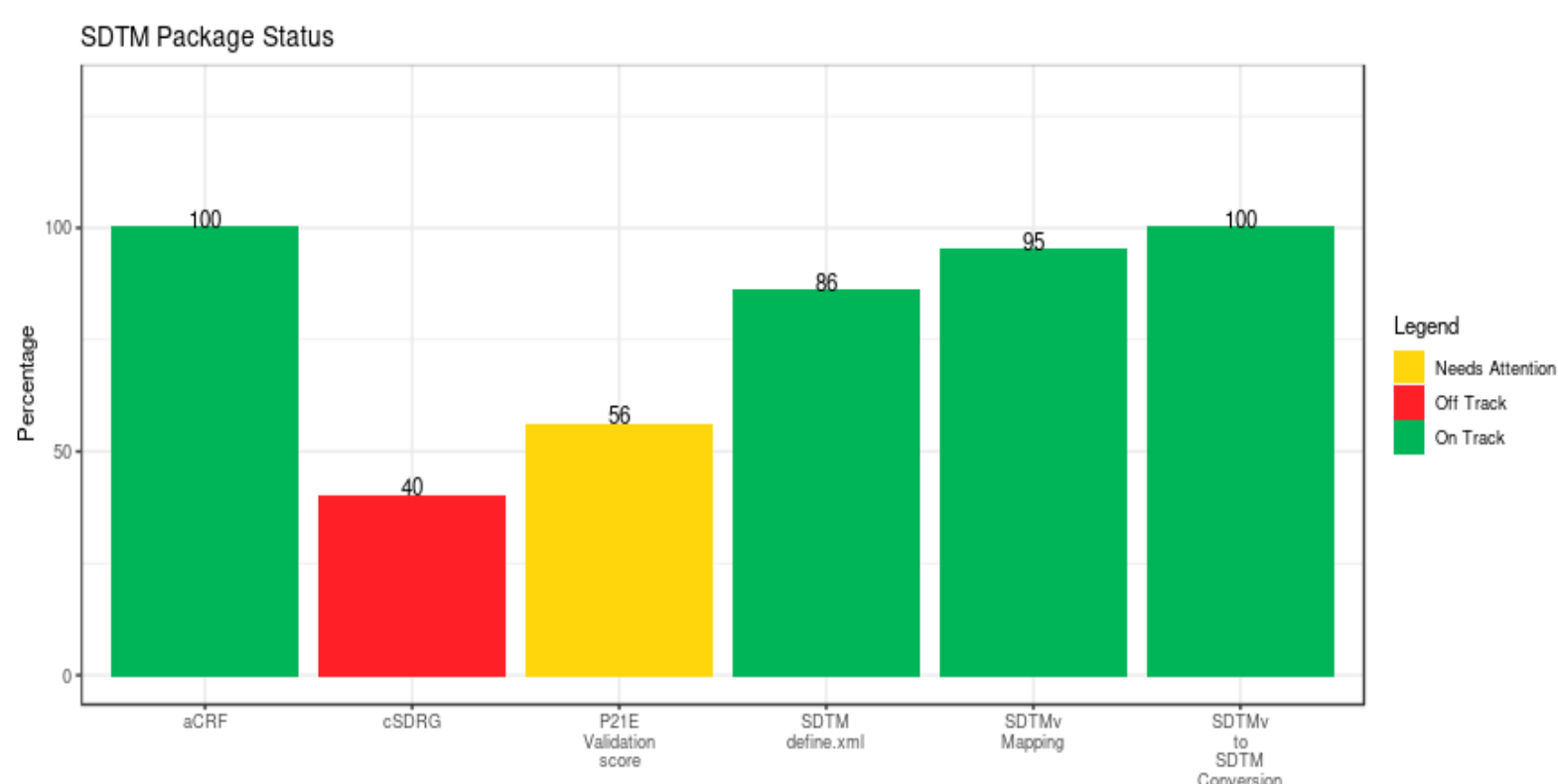


Guidance on when the different activities should be done in order to be submission ready by DBL.
Note: All are repeat cycles during the study conduct and not just to be done once.

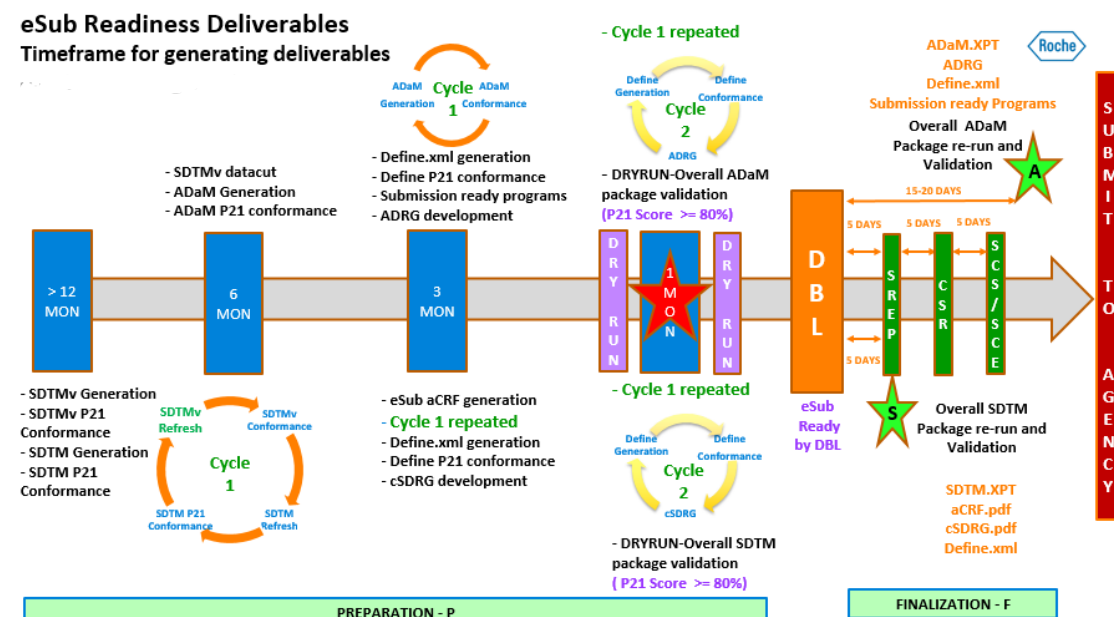
ADaM Package Status ADaM eSub Package Progress



Input (directly or via uploading a spreadsheet) the relevant SDTM and ADaM processing components into the R application with the current progress. Repeat regularly in order to see the trend in progress as you approach DBL.

SDTM Package Status **SDTM eSub Package Progress**

eSub Readiness Deliverables
Timeframe for generating deliverables



Aid to Improve Quality

Quality Assurance Checks

Category	QA Check	Why?	Click if Check Complete	Click if Check Not complete	Reason check Not completed?
	1. ICM prepared and review must be submitted	This is FDA Technical Inspection Criteria and if not met, NIA will reject the package	☐	☐	
TRC	TRC T3 exists with T3 DOTCOT provided with the nearest Informal Consent Date in the current format (yy-mm-dd)	This is FDA Technical Inspection Criteria and if not met, NIA will reject the package	☐	☐	
TRC	Ensure the links CIP used to be the annotations connected to your draft date, if should be none		☐	☐	
ACRF	Are there any watermarks (Copyright with your Data Manager)	IA requirement for findings	☐	☐	
	Are biomarkers are a defining a separate decision		☐	☐	
	All forms (or pages) should be presented if a version is not submitted otherwise with (NOT SUBMITTED)	Ensure functionality and present potential information requires from Health Authorities	☐	☐	
ACRF	Has Regulatory (R) Review and DONALD should be present for the ACRF	IA requirement for findings	☐	☐	
	Is verification is finished, Missing CIP for use of off the page		☐	☐	
ACRF	Each entry in final biomarker menu and reflecting to T3r page	IA requirement for findings	☐	☐	
	Approved screen label on ACRF should be aligned	IA requirement for findings	☐	☐	

Pre-finalisation quality check to be conducted. It lists out contents to be checked in order to ensure the deliverables adhere to HA requirements and will avoid failing any Technical Rejection Criteria