

Are Study Deliverables Under Your RADAR?

Deepak Pandarivasagan, AstraZeneca, Cambridge, UK

Piotr Karasiewicz, AstraZeneca, Warsaw, Poland

ABSTRACT

The Risk Assessment of Deliverables in Analysis and Reporting (RADAR) tool enhances early risk assessment and mitigation for analysis and reporting deliverables, aligning with submission excellence and next-generation submission strategies. By providing a standardized method for tracking progress, it facilitates rapid decision-making and minimizes manual effort and typographical errors. This is achieved using source data inputs with minimal team intervention, employing a validation tracker (also referred to as QC/Efforts tracker) to capture deliverables, effort hours, and overall study milestone dates, thus streamlining business processes. Specifically designed to support the Biometrics team, the tool simplifies decision-making processes and addresses resource gaps and delivery risks within the Biometrics scope. Developed using SAS and Power BI, it offers a user-friendly front-end for easier navigation and improved project management. The integration of these technologies enhances the efficiency and accuracy of deliverable tracking, significantly benefiting resource-intensive activities and mitigating potential risks in the project pipeline.

INTRODUCTION

RADAR Tool was developed within AstraZeneca to enhance early risk assessment and mitigation for analysis and reporting deliverables, aligning with submission excellence and next-generation submission strategies.

This tool allows...

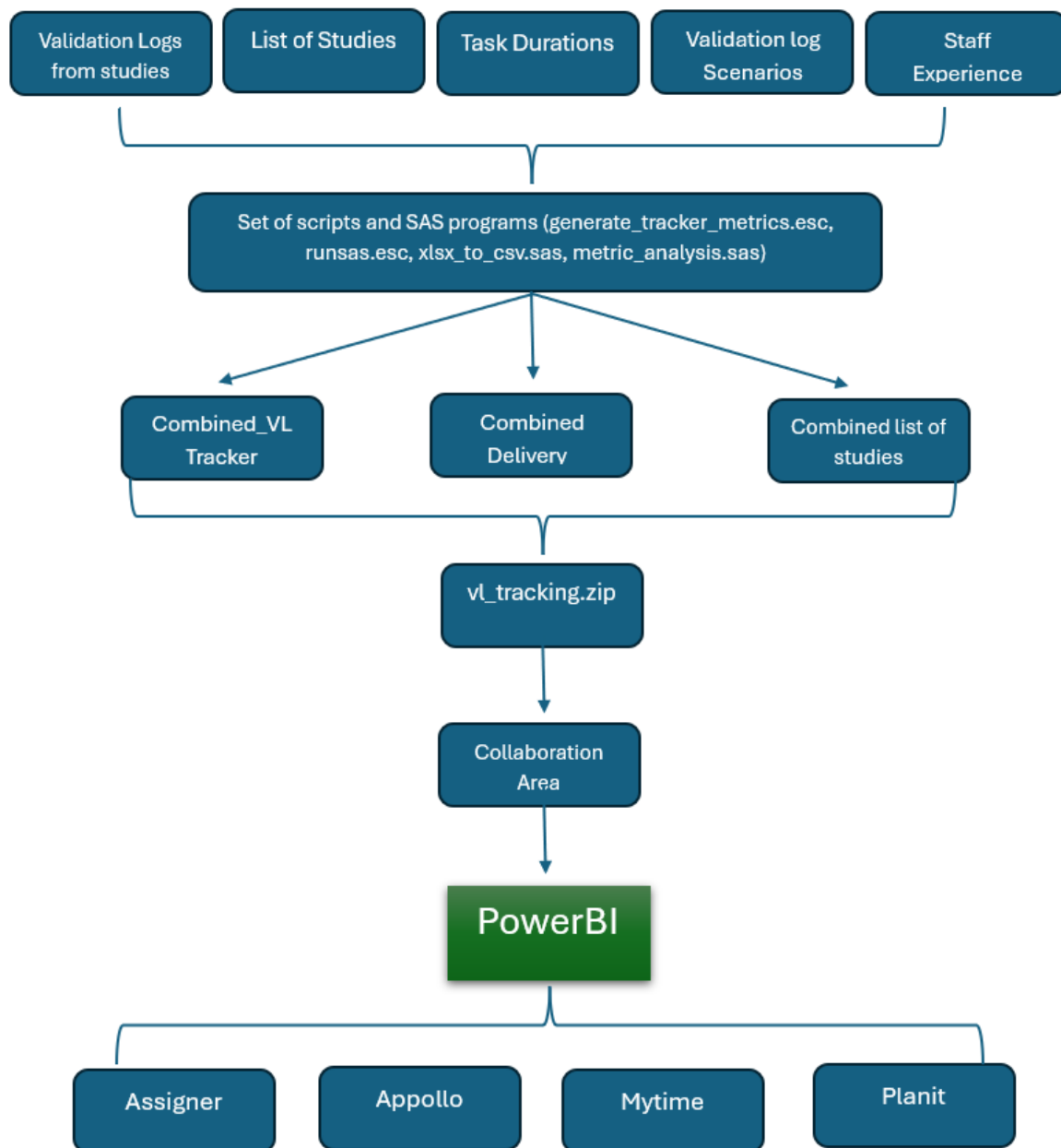
- Instant visibility of progress across studies and milestones, removing the guesswork from deliverable tracking.
- Automated integration of key data sources - no more chasing updates in multiple files.
- Flagging potential delays early (earlier) so teams can prioritize, adjust plans and request support where genuinely needed.
- Improved collaboration - everyone sees the same status in real time, strengthening transparency and collective problem solving.

Data Flow

Below Flowchart (Figure1) describes how data from different sources is integrated, processed, and feed into Power-BI for visualization. Data sources Include validation logs, task durations derived from historical data, global and Biometrics Study milestones, actuals from timesheet data, demand predictions and planned FTEs among the others.

We have used SAS Programming for data analysis and pooling in the backend. Power-BI used for front end Graphical interface. Also, we used Groovy script for some of utility activities like pooling validation logs from on-going studies.

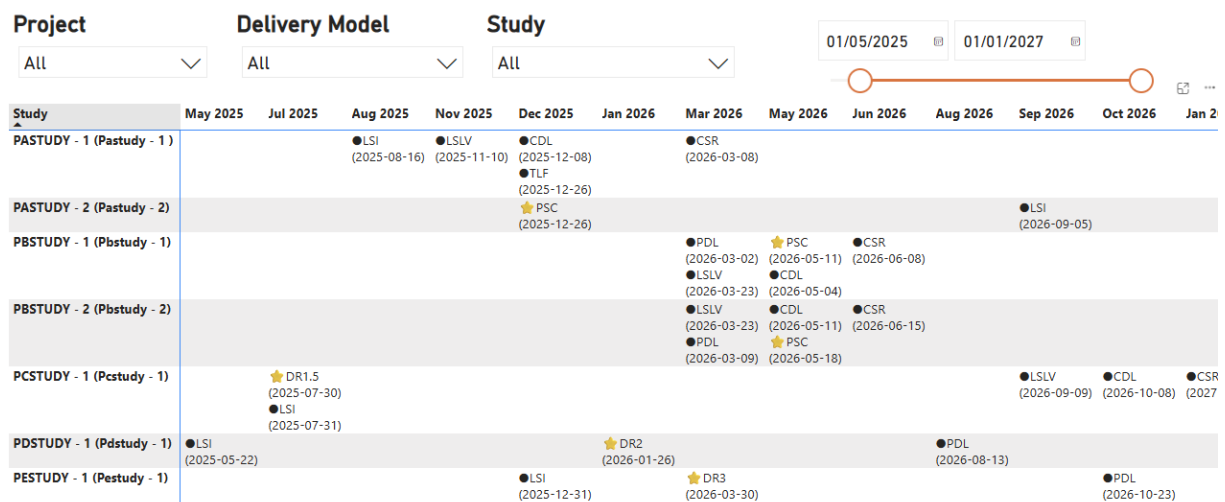
Figure 1: Data Flow Illustration



Project Timelines

This dashboard offers a comprehensive comparison of projects and detailed tracking of individual study milestones. They enable all members of Biometrics to view all milestones on a single dashboard in very easy and visual way. It became standing agenda point for Biometrics Team meetings. The dashboard integrates data from multiple inhouse applications & RADAR metadata and supports effective comparison of upcoming milestones across projects & studies.

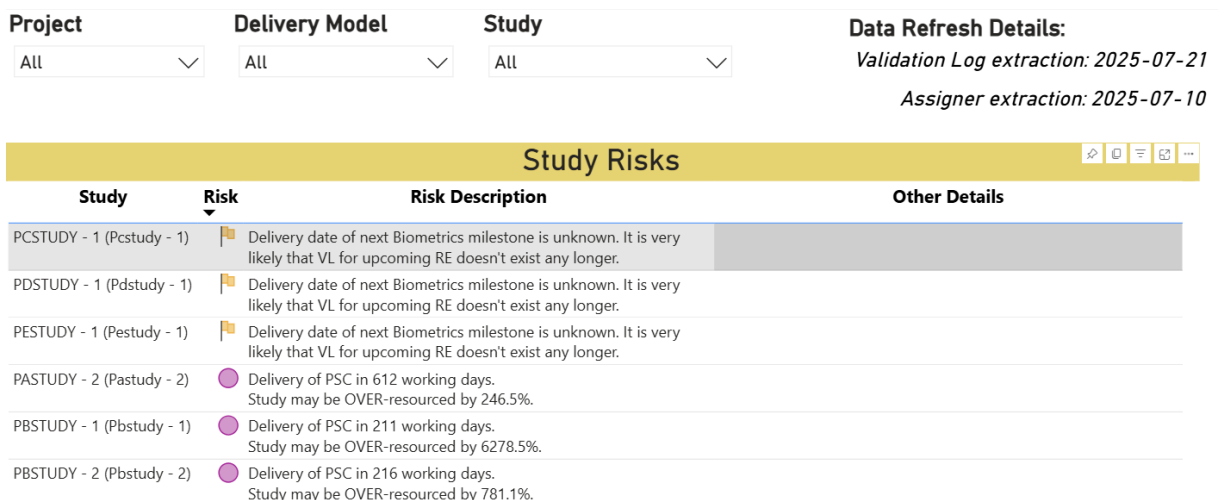
Figure 2: Project Timeline View



Project Risks

This dashboard enables easy identification of resourcing risks associated with upcoming milestones as well as it helps in identifying opportunities to move resource from one project to other. Timely & accurate risk identification unlocks early support - you get WHAT you need and WHEN you need - firefighting reduced.

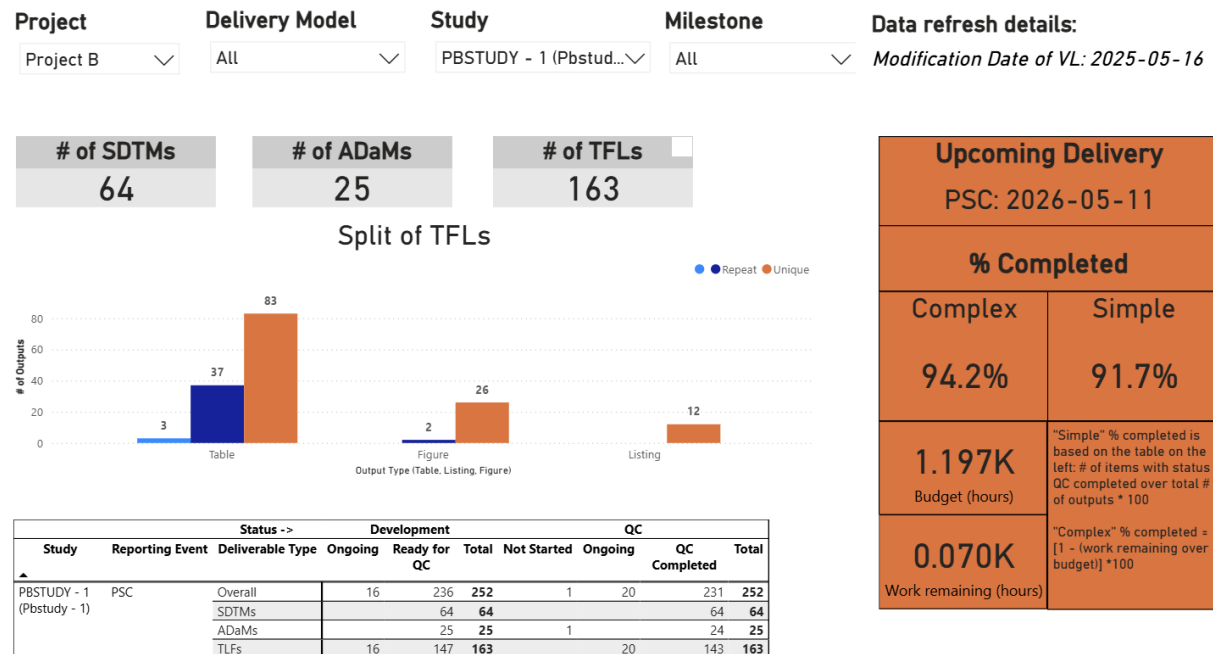
Figure 3: Project Risks



Study Status Dashboard

This dashboard present detailed summary of effort including two KPIs for % completion for key programming activities, including SDTM, ADaM, and TLFs. It provides a comprehensive breakdown of progress by Main and QC effort. Project leads use these dashboard reports to efficiently plan studies and allocate resources as needed. The dashboards utilize data from the validation trackers and calculate metrics using an algorithm built in SAS, allowing for reliable and timely decision-making.

Figure 4: Study Status Dashboard



Study Progress Reports

This Dashboard presents monthly progress achieved – overall and by specific artifacts SDTM, ADaM and TLF's. It enables comparisons of monthly study progress and FTE utilization. Reports can be broken-down by milestones, such as Dry-run and CSR activities, providing a clear overview of study progress. Dashboards provides handy access to progress across all projects and studies in the portfolio and helps in early detection of risks which optimizes decision making process in more efficient resource utilization.

Figure 5: Study Progress reports

Project

All

Delivery Model

All

Study

All

Milestone

PSC

Deliverable

All

Project	Study	MyTime FTE	Reporting Event	Reporting Event Date	Deliverable Type	Snapshot Date	30-May-25		30-Jun-25	
						delta [%]	Total #	% Completed	Total #	% Completed
Project B	PBSTUDY - 1 (Pbstudy - 1)	0.27	PSC	2026-05-11	Overall	0.0%	252	91.7%	252	91.7%
					SDTMs	0.0%	64	100.0%	64	100.0%
					ADaMs	0.0%	25	96.0%	25	96.0%
					TLFs	0.0%	163	87.7%	163	87.7%
		1.15	PSC	2026-05-11	Overall	0.0%	252	91.7%	252	91.7%
					SDTMs	0.0%	64	100.0%	64	100.0%
					ADaMs	0.0%	25	96.0%	25	96.0%
					TLFs	0.0%	163	87.7%	163	87.7%
	PBSTUDY - 2 (Pbstudy - 2)	0.23	PSC	2026-05-18	Overall	0.0%	240	87.5%	240	87.5%
					SDTMs	0.0%	66	93.9%	66	93.9%
					ADaMs	0.0%	25	88.0%	25	88.0%
					TLFs	0.0%	149	84.6%	149	84.6%
		0.78	PSC	2026-05-18	Overall	0.0%	240	87.5%	240	87.5%
					SDTMs	0.0%	66	93.9%	66	93.9%
					ADaMs	0.0%	25	88.0%	25	88.0%
					TLFs	0.0%	149	84.6%	149	84.6%

CONCLUSION

The implementation of the RADAR tool within AstraZeneca marks a significant advancement in the proactive management of analysis and reporting deliverables by automating progress & effort tracking for both in-house and outsourced studies, RADAR streamlines operational workflows for the Biometrics team and supports submission excellence. The combination of SAS-powered back-end analytics and Power BI interactive dashboards ensures data accuracy, enhances visibility across projects and facilitates timely, informed decision-making. Ultimately, RADAR delivers greater efficiency, reduces resource gaps, and Strengthens risk mitigation supporting AstraZeneca's commitment to robust, next- generation submission strategies and operational excellence in clinical research.

ACKNOWLEDGEMENT

We would like to thank the AstraZeneca R&I Biometrics Leadership Team for sponsoring and supporting this Initiative and workstream.

CONTACT INFORMATION, AFFILIATIONS, FUNDING, DISCLAIMER

Your comments and questions are valued and encouraged.

Author: Deepak Pandarivasagan, Biometrics, Late-stage Development, Respiratory and Immunology (R&I), Biopharmaceuticals R&D, AstraZeneca, Cambridge, UK, Email: deepak.pandarivasagan@astrazeneca.com.

Author: Piotr Karasiewicz, Biometrics, Late-stage Development, Respiratory and Immunology (R&I), Biopharmaceuticals R&D, AstraZeneca, Warsaw, Poland, Email: piotr.karasiewicz@astrazeneca.com.

The authors are AstraZeneca employees and may hold stocks or stock options in AstraZeneca entities. This paper was authored using funding from AstraZeneca. Brand and product names are trademarks of their respective companies.