

Powering Up Programming Milestones: From Chaos to Cohesion

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ABSTRACT

Join us to explore a transformative approach to simplify management of programming milestones in clinical trials. We address the need for precise programming milestones data, which can counter inefficiencies from fragmented, manual processes as these often lead to poor resource utilization. Our team drives this change through standardization, automation and streamlined communication by employing latest tools that are readily available.

Our demo showcases how we use SharePoint, Power Automate and Power BI to collect, store and track programming milestones data with automation. We illustrate how operational dashboards support leadership reviews and decision-making, alongside integrating these tools with other databases for enhanced functionality. We'll also share insights into the new skills our team developed throughout this process.

Our approach can be used as a template for future innovations and expanded upon to meet the needs of other departments beyond programming.

Introduction

In the dynamic landscape of clinical research, programming milestones such as Clinical Study Report (CSR) delivery, Dry-run readiness, Case Report Tabulations (CRT) submission, Study Data Tabulation Model (SDTM)/Analysis Data Model (ADaM) set-up, and Investigators Brochure (IB) outputs represent fundamental checkpoints throughout the study lifecycle. These definitions and examples are not only prevalent within organizations but also well-established across the pharmaceutical industry. The coordinated tracking and reporting of these milestones form the backbone of efficient resource planning, portfolio management, and team performance evaluation.

Utilization of Programming Milestone Data

Throughout various programming line functions, milestone data assumes a central role, guiding workflows and resource allocation. Its usage spans a spectrum from granular activity tracking to high-level project planning. For example, teams utilize CSR milestones to forecast resource needs for data cleaning and output generation, whereas dry-run milestones help assess readiness for regulatory submissions. In turn, CRT, SDTM, and ADaM milestones serve as benchmarks for data quality and analysis set handovers.

Processing and sharing milestone data is executed in numerous fashions: some teams favor detailed spreadsheets, others prefer visual presentations, and still others rely on bespoke tracking tools. The methodology is often influenced by end-user requirements, the chosen project management style, and specific team traditions. As a result, the way milestone data is absorbed, processed, and disseminated can vary widely across organizations and even within functions.

Variability in Milestone Data Handling: Teams and Methods

Each team engages with milestone data differently, depending on their responsibility and project focus. Data management teams might aggregate milestones to monitor data collection and verification activities. Statistical programming team frequently use milestone information for timeline management and resource forecasting to produce required programming deliverables. Operations team reference milestones to coordinate deliverable with various vendors, Regulatory team supports submissions and ensure compliance with regulatory timelines. These diverse applications underscore the importance of flexible yet robust milestone data handling procedures.

Manual methods of presenting milestone data—such as static presentations and Excel spreadsheets—are still widely used for sharing and reviewing progress across teams. However, these methods offer limited capability to validate or automate critical process steps. The format can be customized per the end-users' needs, but what is gained in flexibility may be lost in consistency, accuracy, and reproducibility.

The Role of the End User in Data Structure

User requirements are pivotal in determining how milestone data is structured and presented. The way programming milestones are documented must be tailored for optimal utility—whether dashboards for line managers, timelines for resource planners, or summaries for leadership review. This makes the structure of milestone data highly context-dependent, reflecting both the nature of the work and the decision-making priorities of its consumers.

Problem Statement: Limitations of Traditional Approaches

Despite the widespread recognition of programming milestones, meeting organizational goals is hampered by reliance on manual, ad hoc methods for collection, tracking and reporting. Spreadsheets and slide-based presentations, while accessible, introduce several drawbacks: inconsistencies arise from non-standard formats, data validation is difficult to enforce, and updating information is tedious and error-prone. Consequently, estimations related to resource forecasts, KPIs, and future programming activities often lack precision, leading to vague or incomplete insights. These inconsistencies can hinder not only team-level planning and risk assessment but also strategic portfolio management by leadership.

Crucially, inadequate or non-validated programming milestone tracking can distort financial projections, stress budget constraints, and inadvertently provoke over- or under-allocation of resources. The ripple effect may result in diminished programming efficiency and compromised project team outputs at a senior leadership level.

Call for Unified Solutions

There is a compelling need to implement standardized, robust, and efficient solutions to harmonize programming milestone data handling. Transitioning away from manual and inconsistent tools toward centralized, automated systems would facilitate better tracking, validation, and reporting of programming milestones. Such systems would support leadership in making well-informed decisions, optimizing resource allocation, and positioning teams to meet the challenges of an ever-evolving project portfolio.

A unified strategy would not only improve data quality and program transparency but also empower teams with actionable insights, driving operational efficiency and supporting long-term organizational success. As part of this transformation, identifying the ideal balance between automation, customization, and user-centric design will be essential to ensure broad adoption and sustained impact.

Platform Selection and Key Requirements

In developing our solution, we sought a platform that would encourage user engagement with data entry by providing a visually appealing and intuitive interface. A principal requirement was moving away from conventional spreadsheets such as Excel, opting instead for an online, shareable environment that supports data import/export and version control. It was crucial for the platform to offer flexibility for evolving data structures and features, including multi-select columns.

The primary aim was to reduce manual effort and repetitive tasks by automating processes, such as sending emails to predefined user groups and dynamically updating contact records in trackers based on changes to the Leads Database, the master contact list for all study-associated personnel. We focused on developing an online tool-based presentation layer that would be both readable and familiar to end users, ensuring ease of learning and intuitive use throughout the organization.

Integration and Adoption Strategy

Given our requirements, we selected tools that enabled seamless integration with minimal or no coding, leveraging existing Microsoft licenses within the organization. This approach ensured broad accessibility for users and simplified the adoption process.

The goal was to enable a seamless information flow from Lead Programmers to the Leadership team, minimizing delays and reducing or eliminating manual effort.

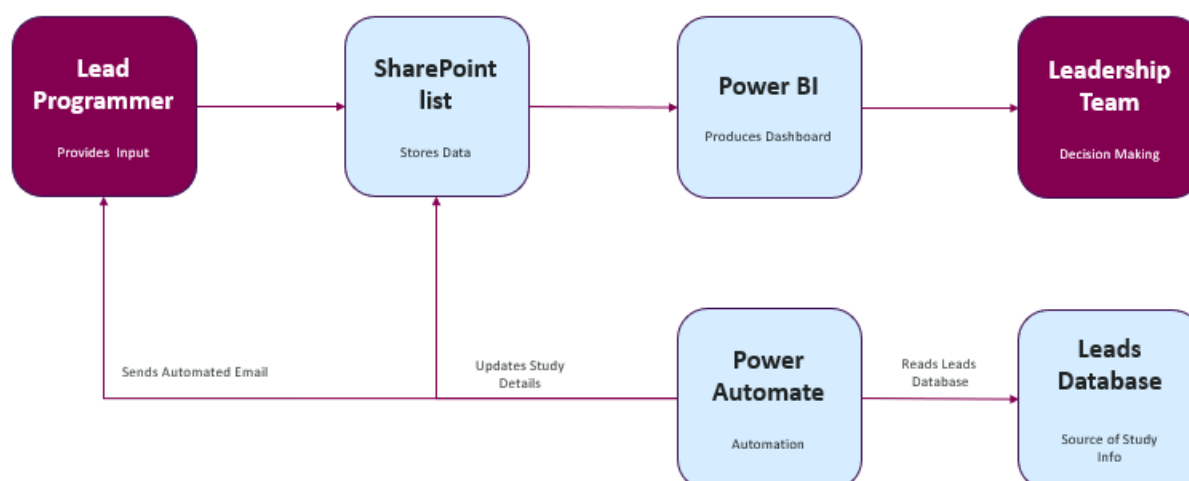


Figure 1. Overall process

Implementation: SharePoint List for Milestone Tracking

A Microsoft SharePoint List was used to store information related to programming milestones, offering a web-based, collaborative environment for efficient data sharing. The customizable data structure adapts readily to evolving project needs, and built-in version control provides comprehensive tracking of changes. SharePoint Lists' integration with other Microsoft services, such as Power Automate, further enhances workflow efficiency.

PTL	GPP	Project	Study Dcode	Study Name	Delivery Model	Status	JAN 26	FEB 26	MAR 26	APR 26	MAY 26	JUN 26
Wysocki, Maci	Wysocki, Maci	Project A	Study00001	Orange	Internal	Green		SRC		DSUR	IB	DSUR
Wysocki, Maci	Wysocki, Maci	Project A	Study00002	Apple	Internal	Green		DSUR	IB	DSUR	IB	DSUR
Wysocki, Maci	Wysocki, Maci	Project B	Study00003	Banana	External 1	Green	SRC	DSUR	DSUR	IB		
							PUBLICATIONS	PUBLICATIONS				
Wysocki, Maci	Wysocki, Maci	Project C	Study00004	Cherry	External 1	Green		IB				
Wysocki, Maci	Wysocki, Maci	Project C	Study00004	Cherry	External 1	Green	PUBLICATIONS	PUBLICATIONS				
Wysocki, Maci	Wysocki, Maci	Project D	Study00005	Pear	Internal	Green	eCRF	CSP/ASAP	Study setup	SOTM setup	ADaM setup	ADaM setup
							Study setup	SOTM setup	FSD	FSI	SRC	SRC
							TLF Shell/TDOC	eCRF	SOTM setup			
Wysocki, Maci	Wysocki, Maci	Project D	Study00006	Strawberry	Internal	Green	PATIENT PROFILES	SRC	PATIENT PROFILES	SRC	DRYRUN	ADaM setup
							ADaM setup	PATIENT PROFILES	TLF Setup	SRC	PATIENT PROFILES	TLF Setup
							DSUR	ADaM setup		TLF Setup		SOTM setup
Wysocki, Maci	Wysocki, Maci	Project E	Study00007	Blueberry	External 2	Green	PRIMARY ANALYSIS	CRT				

Figure 2. Programming milestone tracker based as Sharepoint list

Automating Workflows: Power Automate

Microsoft Power Automate was adopted to minimize manual tasks. This cloud-based service streamlines the automation of workflows and processes across platforms, requiring little to no programming expertise. Although developing and testing more complex functionalities could be time-consuming for fresh Power Automate users, overall automation improvements outweighed these challenges.

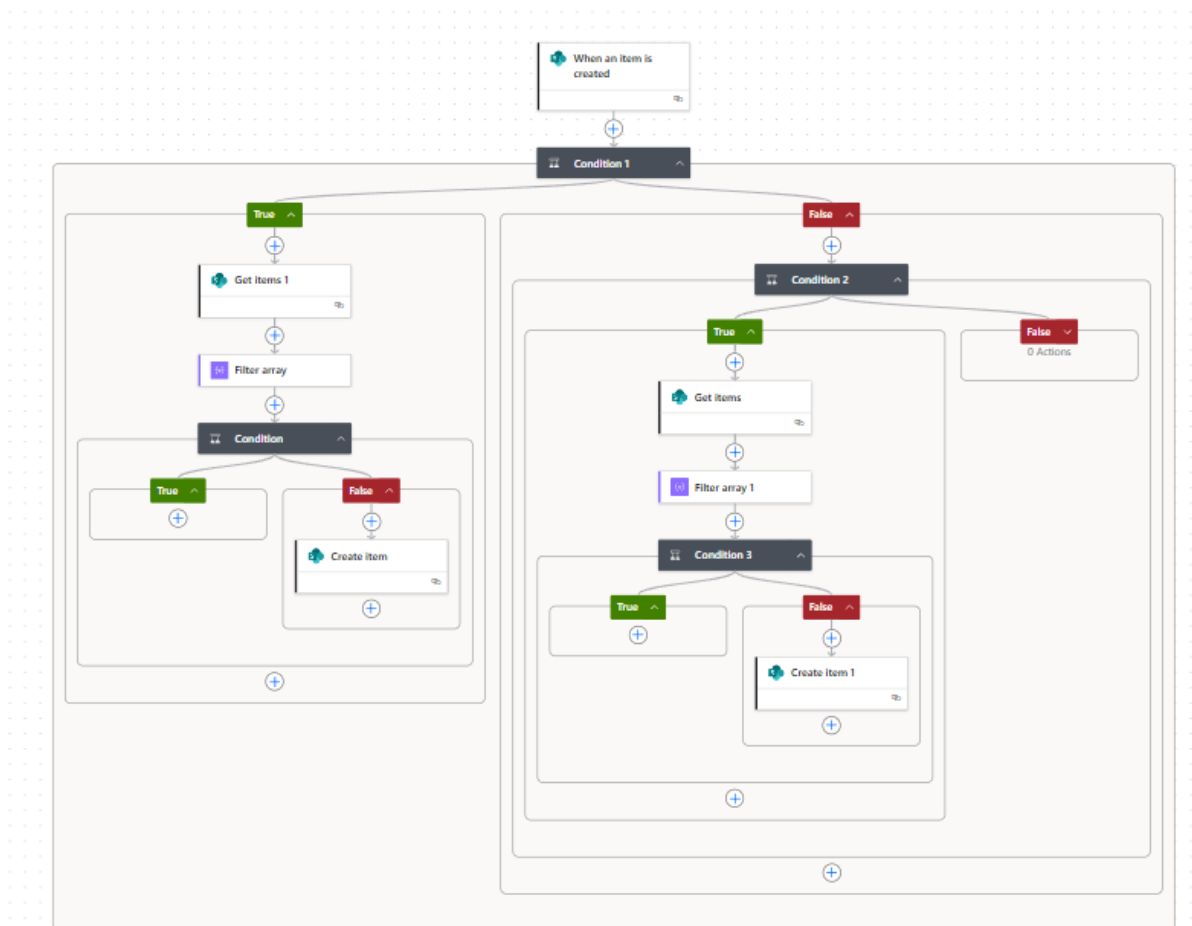


Figure 3. Power Automate flow to update tracker with new studies or contact details changes

Reporting and Visualization: Power BI

For reporting and data visualization, Microsoft Power BI was selected due to its direct compatibility with SharePoint Lists. Power BI enables the development of interactive dashboards and reports, facilitating efficient information sharing and supporting data-driven decision-making across the organization.

Programming Milestones											
Senior Director			PTL								
All			All								
Senior Director	PTL	GPP	Project	Study Dcode	Study Name	Delivery Model	Status	Q1 26	Q2 26	Q3 26	Q4 26
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project A	Study00001	Orange	Internal	Green		SRC		DSUR IB
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project A	Study00002	Apple	Internal	Green		DSUR IB	DSUR IB	DSUR
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project B	Study00003	Banana	External 1	Green	SRC PUBLICATIONS	DSUR PUBLICATIONS IB	DSUR IB	
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project C	Study00004	Cherry	External 1	Green	PUBLICATIONS CLOSE OUT	PUBLICATIONS		
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project E	Study00007	Blueberry	External 2	Green	PRIMARY ANALYSIS	CRT		
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project E	Study00008	Pear	Internal	Green				
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project E	Study00008	Watermelon	External 2	Green		CDL PRIMARY ANALYSIS		
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project E	Study00009	Plum	External 2	Green	CDL	FINAL ANALYSIS CSR		
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project E	Study00009	Strawberry	Internal	Green			FSI	
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project E	Study00010	Melon	Internal	Green				

Figure 4. Power Point report on aggregate programming milestones data

User Access and Data Synchronization

Lead Programmers were granted access to the Programming Milestones Tracker via a SharePoint List. Within this system, users can locate their studies and update programming milestone details. Access instructions, milestone definitions, and user expectations are communicated through automated emails generated by Power Automate.

The Lead Programmers list is sourced directly from the Leads Database. Any changes in Lead Programmers' assignments or the addition of new studies in the Leads Database are automatically reflected in the Programming Milestones Tracker. These data synchronization procedures are securely managed through Power Automate workflows.

Data Entry and Reporting Procedures

Milestone information is entered at a monthly granularity. If a programming milestone spans multiple months, it is recorded for each relevant month, and the system also supports entering multiple milestones for a single study within the same month. All milestone data are made accessible to Power BI through a dedicated connection, transformed as dashboard to support Leadership team's specific visualization and analytical requirements.

Benefits of a Unified Vendor Approach

Using a suite of tools from a single vendor enabled smooth integration between components. Relying solely on internally available Microsoft software eliminated additional licensing expenses. Familiarity among end users with SharePoint and Power BI significantly reduced onboarding time and minimized user errors. The widespread adoption of Microsoft services and the availability of extensive documentation and community resources contributed to smoother development and faster resolution of technical issues.

Implementation Results, Impact and User Adoption

Following a staged deployment approach—initial pilot with the Early Oncology team followed by full implementation across the Late Oncology portfolio—comprehensive user experience evaluations were conducted with Lead Programmers and Programming Managers to assess system impact and adoption effectiveness. The results demonstrated exceptional user acceptance with a 92% satisfaction rate and unanimous positive feedback across all user groups. Users reported significant improvements (70%) in interface usability and workflow efficiency compared to legacy manual processes, with measurable enhancements (62%) in data accuracy and consistency that increased confidence in milestone tracking precision. The

Programming Dashboards were successfully integrated into executive portfolio review processes, enabling senior leadership to make data-driven resource allocation and strategic planning decisions with real-time visibility into programming milestones across multiple studies. This provided better insights for capacity planning and timeline optimization, transforming how strategic decisions are made at the organizational level. Both individual contributors and executive stakeholders embraced the digital transformation, citing improved operational efficiency, enhanced decision-making capabilities, and reduced administrative burden as key benefits.

Lessons Learned and Future Steps

We implemented a modular SharePoint information architecture anchored by a redesigned home page and governed SharePoint lists. SharePoint lists were normalized with typed columns, lookup relationships, unique index constraints, and Power Apps forms for consistent data entry. Data flows from SharePoint List to KPI dashboards were standardized via scheduled automated refresh methods. Together, these capabilities enabled enhanced collaboration and communication across roles and leadership levels, aligning stakeholders around a single source of information and accelerating progress toward expected outcomes. In this entire new approach, we were able to get inputs from Study lead programmers, Managers and Senior Leadership team which helped us understand the criticality of accuracy of milestone activity reporting. Not only we learned new Power BI specific technological tools, but we also increased our knowledge base having constant dialogue and improved both collaboration and communication in our respective role. Building upon the successful implementation outcomes, the next phase involves strategic consultation with cross-functional teams and senior leadership to evaluate expansion opportunities leveraging the solution's modular architecture and artificial intelligence capabilities. A systematic rollout of periodic user feedback surveys will be implemented to capture enhancement requirements and identify optimization opportunities for continuous improvement. Priority will be placed on developing comprehensive user documentation, training materials, and knowledge management resources for all new and existing users.

CONCLUSION

The introduction of a unified, automated programming milestone tracking framework using SharePoint, Power Automate, and Power BI has enhanced operational efficiency and data accuracy in statistical programming at AstraZeneca Oncology. By unifying definitions and processes, streamlining resource tracking, enhancing visibility, this approach not only resolves challenges posed by manual processes but also creates a scalable template for organizational innovation. As industry expectations evolve, such advancements offer significant potential for further expansion and adoption across research functions, inviting teams to rethink traditional workflows and harness collective insights for sustained progress.

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