

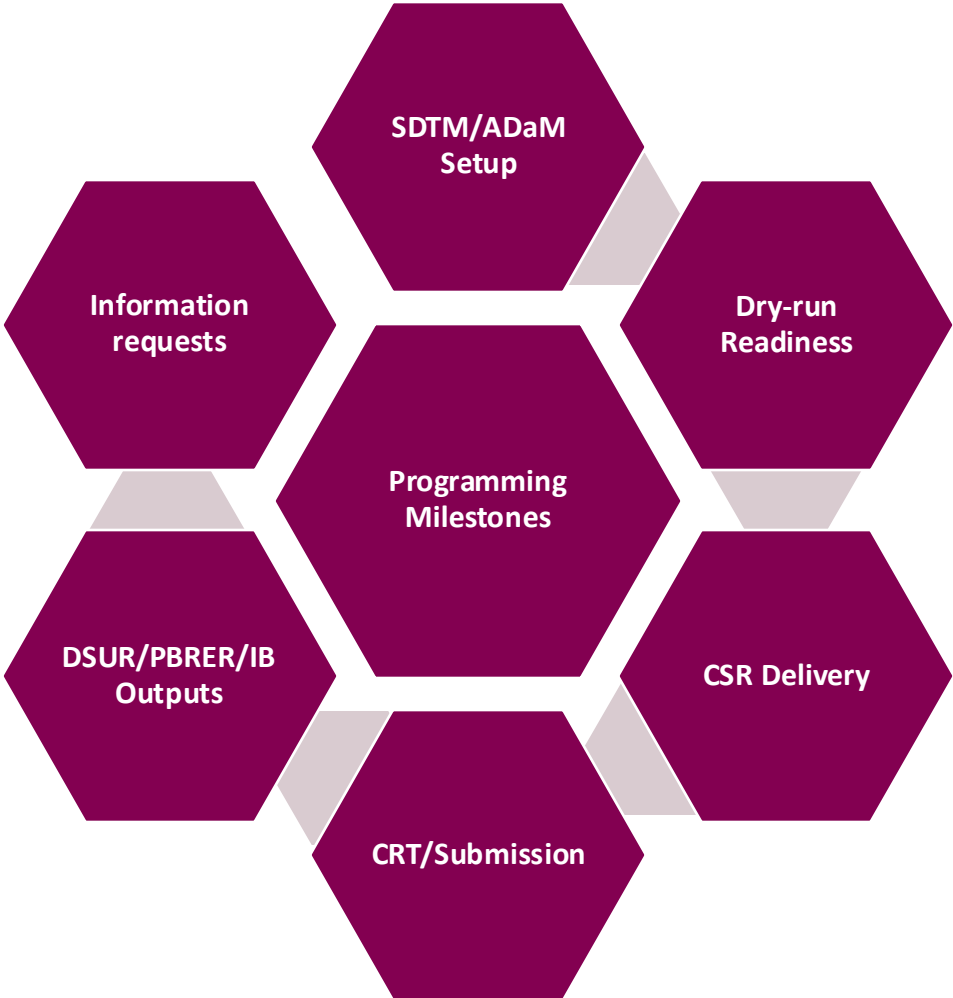
Trends & Technology(TT03)

Powering Up Programming Milestones: From Chaos to Cohesion

Maciej Wysokiński | AstraZeneca, Warsaw, Poland
Hitesh Thacker | AstraZeneca, Cambridge, UK

Programming Milestones Ecosystem

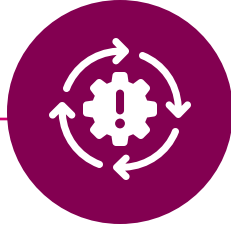
Programming Activity Milestone
eCRF
CSP/SAP
Study setup
TLF Shell/TOC
SDTM setup
ADaM setup
TLF Setup
IDMC
EXPL
IB
DSUR
DRYRUN1
DRYRUN2
MINI DRYRUN
PUBLICATIONS
EVENT PREDICTION
INTERIM ANALYSIS



Programming Activity Milestone
CDL
HLR GLOBAL
HLR REGIONAL
PRIMARY ANALYSIS
FINAL ANALYSIS
TLF Global
TLF Regional
CSR
NARRATIVES
OSI/BIMO
CRT
SUBMISSION
REG REQ
POOLING
FUP ANALYSIS
120 DSU
CLOSE OUT

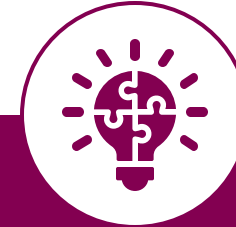
Programming Milestones Puzzle

Collection, Storage and Tracking



Chaos

- ❖ Excel spreadsheets
- ❖ Email chains
- ❖ Manual tracking
- ❖ Inconsistent formats

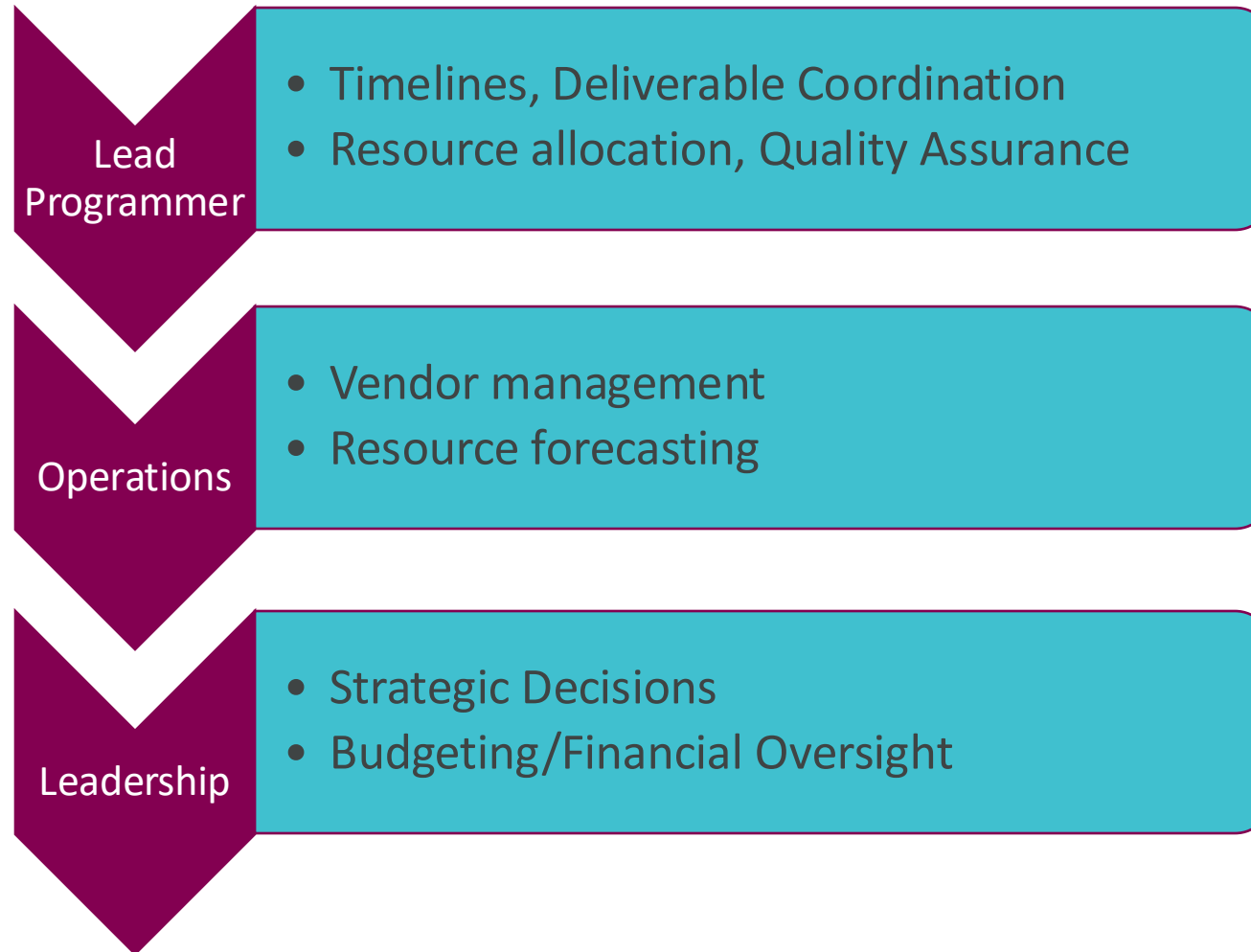


Impact

- ❖ Poor Resource Utilization
- ❖ Inaccurate Forecasting
- ❖ Risk to Project Timelines
- ❖ Compromised Decision Making

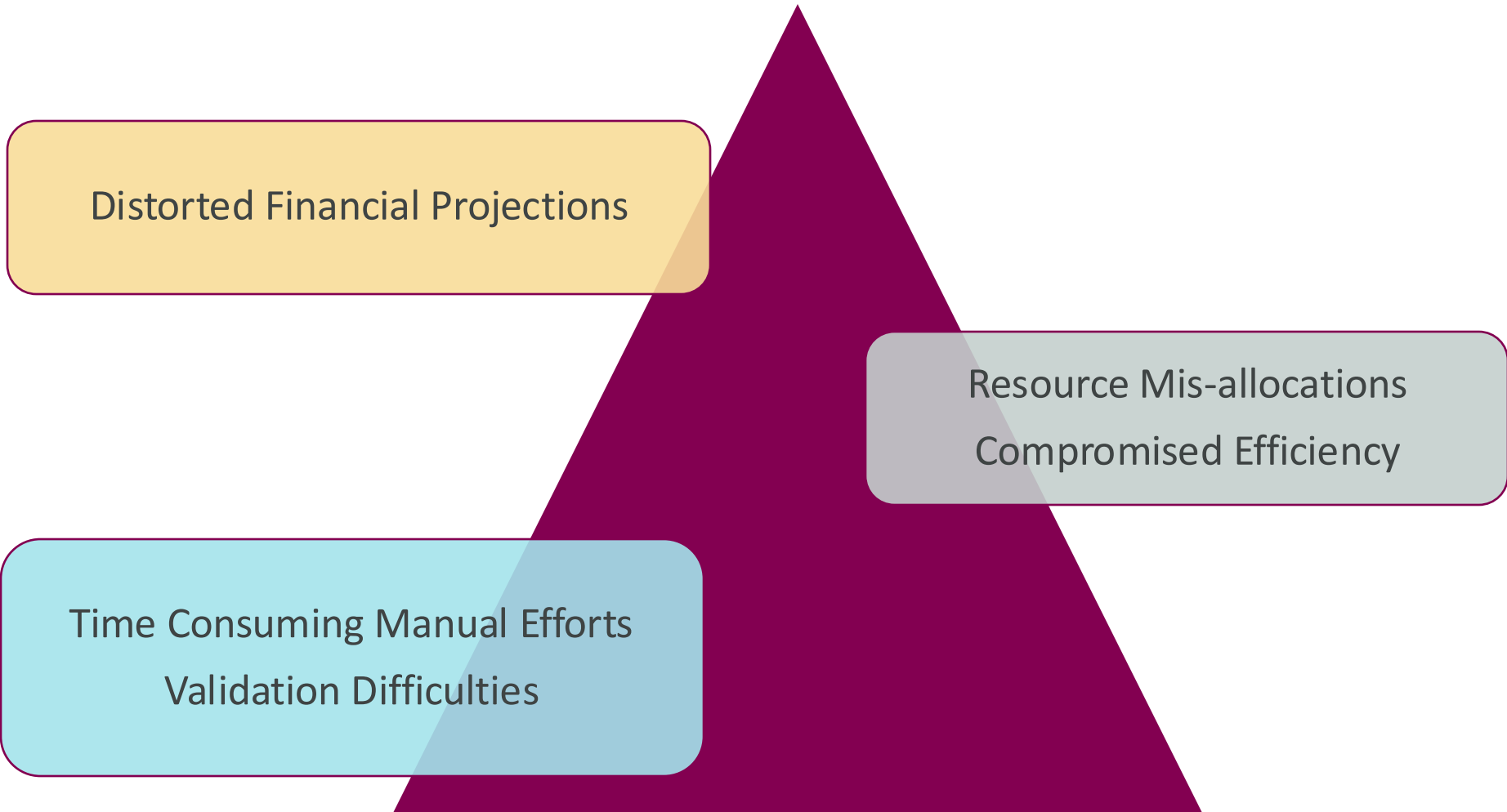


The Ripple Effect



The Pain Points

Why Traditional Methods Fall Short



Distorted Financial Projections

Resource Mis-allocations
Compromised Efficiency

Time Consuming Manual Efforts
Validation Difficulties

Call for Unified Solutions

Automated Workflow

- ✓ Dynamic Updates
- ✓ Automated Communications

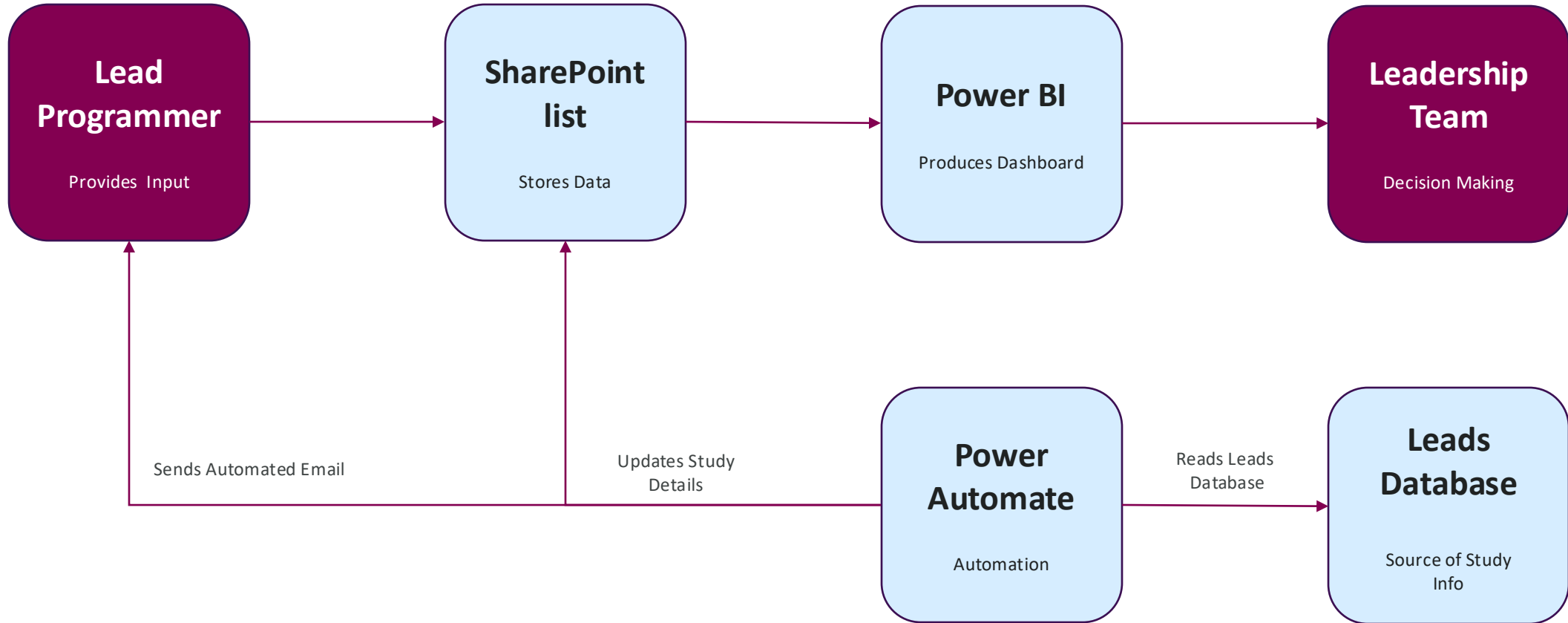
Unified Process

- ✓ Definitions, timelines communicated
- ✓ Seamless Tools Connectivity

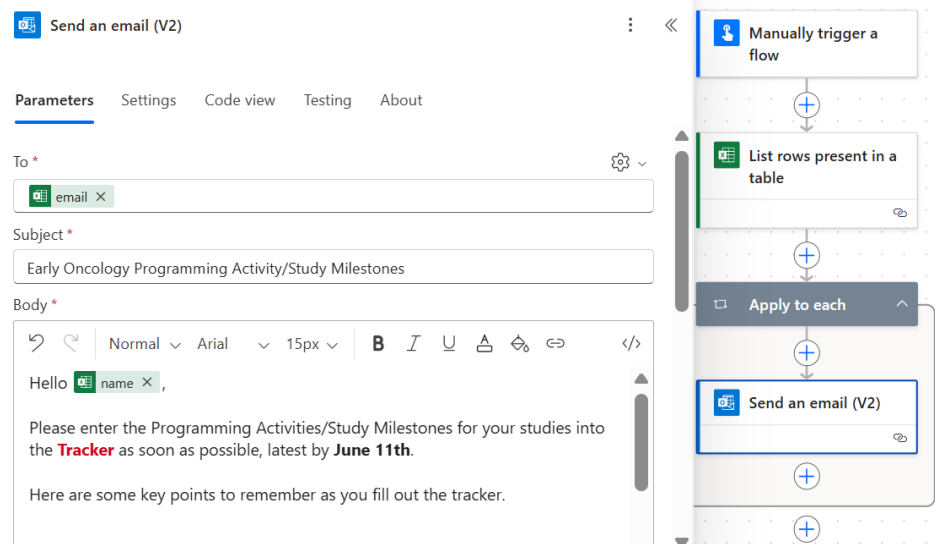
User Experience

- ✓ Easy data entry and update
- ✓ Familiar Tools

Our Solution



Step 1: Data Integration and Automated Communication



Early Oncology Programming Activity/Study Milestones



OBM KPI Metrics
To Wysokiński, Maciej



Hello Maciej,

Please enter the Programming Activities/Study Milestones for your studies into the [Tracker](#) as soon as possible, latest by **June 11th**.

Here are some key points to remember as you fill out the tracker.

Step 2: Filling in Programming Activity Milestones

PTL	GPP	Project	Study Dcode	Study Name	Delivery Model	Status	JAN 26	FEB 26	MAR 26	APR 26
 Wysokiński, Maciej	 Wysokiński, Maciej	Project A	Study00001	Orange	Internal	Green		SRC		DSUR IB
 Wysokiński, Maciej	 Wysokiński, Maciej	Project A	Study00002	Apple	Internal	Green		DSUR IB	DSUR IB	IB DSUR
 Wysokiński, Maciej	 Wysokiński, Maciej	Project B	Study00003	Banana	External 1	Green	SRC PUBLICATIONS	DSUR PUBLICATIONS IB	DSUR IB	
 Wysokiński, Maciej	 Wysokiński, Maciej	Project C	Study00004	Cherry	External 1	Green	PUBLICATIONS CLOSE OUT	PUBLICATIONS		
 Wysokiński, Maciej	 Wysokiński, Maciej	Project D	Study00005	Pear	Internal	Green	eCRF Study setup TLF Shell/TOC	CSP/SAP Study setup SDTM setup eCRF	SDTM setup FSD FSI	ADaM setup SRC SDTM setup

Study Milestone	Programming Activity Milestone (PAM)	PAM - Description	Examples of activities
	eCRF	eCRF development and review	eCRF review, DTS review
	CSP/SAP	Date on which all required signatures are obtained for the approval of the Clinical Study Protocol (CSP) and finalised CSP is published. Same for SAP.	CSP/SAP, Final CSP, Study Design
	Study setup	Establishing teams, committees, and suppliers, agreeing to deliverables, setting up operational tools and global study systems, and providing study-specific training as needed.	Kick off meetings (KOM), EntimICE set up, change requests, create validation logs, setting up raw, TPV (Third Party Vendor) data transfer agreements
	TLF Shell/TOC	TLF Table of contents and TLF shell review	TLF shell review, mock shell review
FSI (First Subject In)	FSI	Date the first participant is Consented/Screened and provided with a Subject ID (previously referred to as Enrolment Code)	FSI (not a programming activity milestone)
FSD (First Subject Dosed)	FSD	First Subject Dosed	FSD (not a programming activity milestone)
	SDTM setup	SDTM spec development/review and programming setup	Annotation eCRF, SDTM, SDTM preparation, SDTM set up, mapping Specifications Review, SDTM specification
	ADaM setup	ADaM spec development/review and programming setup	ADaM, ADaM preparation, ADaM set up, ADaM specification, Efficacy ADaM, ADaM batch n
	TLF Setup	CSR TLFs programming setup	TLF Programming, TLF set up, TLF preparation, IA TLF

Step 3: Real-Time Dashboard

APPLIED STEPS

Custom33

Custom34

Custom35

Custom36

Custom37

Custom38

Custom39

Custom40

Merged1

Custom41

Custom42

File

Refresh

Share

Explore

Refresh now

Schedule refresh

Refresh history

Create advanced refresh (preview)

```
= Table.CombineColumns("#Custom40",{ "MAY 25", "JUN 25"},
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```

Leads Database

App Created By

App Modified By

Attachments

AZP_ID

BTL

Color Tag

Comments

Compliance Asset Id

Content Type

Collapse

Early Oncology Program...

A&R Vendor

BTL

Delivery Model

GPP

Project

PTL

Q1 2025

Q1 2026

Q2 2025

Collapse

Programming Milestones

Senior Director

All

PTL

All

Senior Director	PTL	GPP	Project	Study Dcode	Study Name	Delivery Model	Status	Q1 26	Q2 26	Q3 26
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project A	Study00001	Orange	Internal	Green		SRC	
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project A	Study00002	Apple	Internal	Green		DSUR IB	DSUR IB
Thacker, Hitesh	Wysokiński, Maciej	Wysokiński, Maciej	Project B	Study00003	Banana	External 1	Green	SRC PUBLICATIONS	DSUR PUBLICATIONS IB	DSUR IB
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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	

User Satisfaction Results and Impact

92%

Overall
Experience

70%

Liked New
Interface

62%

Increased
Data
Accuracy

Use of AI,
Training,
Expansion

Enhanced Decision Making

Improved User
Satisfaction

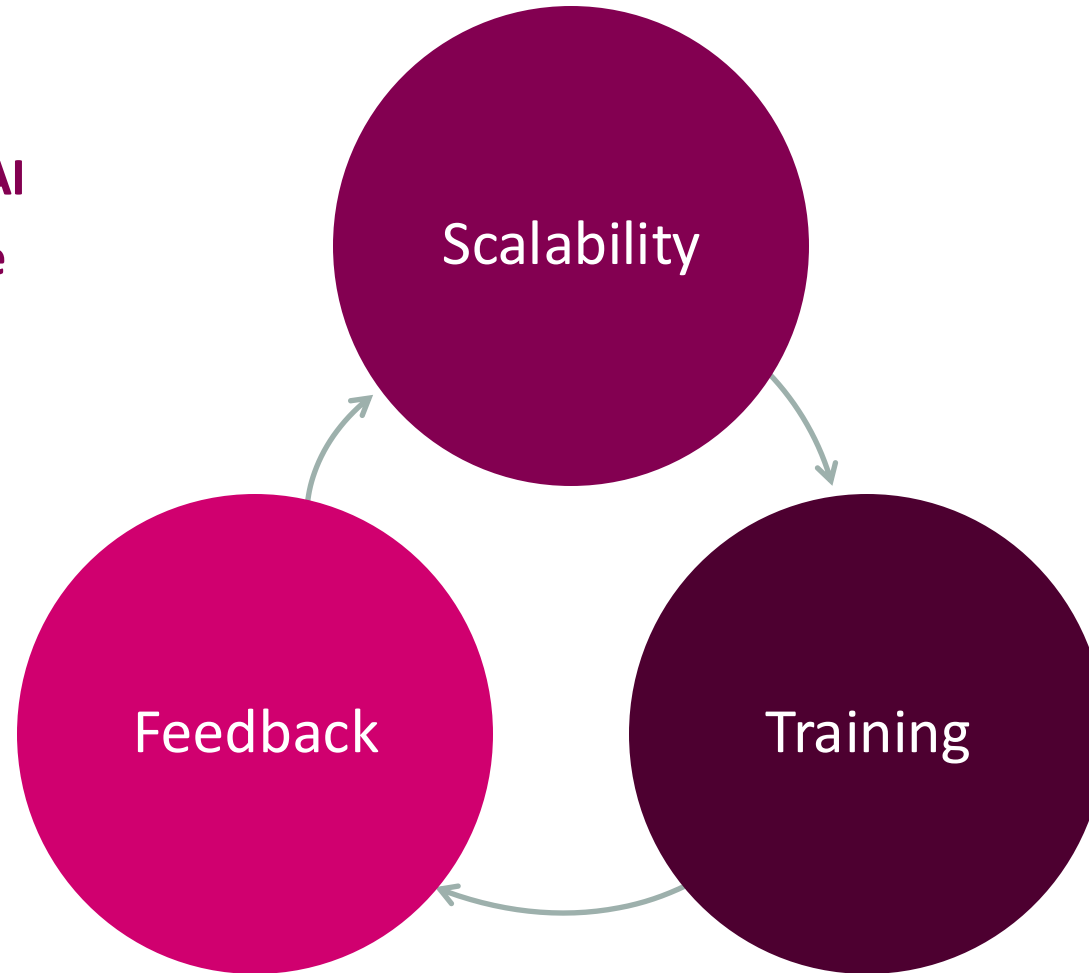
Better Resource
Allocation, Forecasting
Accuracy

Increased Team
Collaboration

Lessons Learnt and Future Vision

- **Modular Architecture, AI**
- **Consult and Collaborate**

- **Continuous, Periodic**
- **Data Quality**



- **Extensive Documentation**
- **Audience Targeting**

References and Acknowledgement

- Microsoft. “Power BI Documentation.”
<https://docs.microsoft.com/en-us/power-bi/>.
- Microsoft. “SharePoint Lists Documentation.”
<https://docs.microsoft.com/en-us/sharepoint/>.



Goutham Ghanta, Dana Soloff



Mark Reynolds, Justine Eastman



Rafał Kolasa, Milena Balcerzak-Zych, Mei Dey



Korak Datta, Zach Dorman, Jinesh Patel



OBM KPI Metrics and Dashboards team



Q & A



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