

Single Day Event

Advancing Regulatory Submission
Readiness through Role Rotation
and Cross-Functional Integration

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Biostatistician I - Biostatistics

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Biostatistician I - Biostatistics

Precision for Medicine

Sarika Selvaraj

Biostatistician I, Biostatistics, Precision for Medicine

Sarika is currently associated with Precision as Biostatistician I, with a background of 4 years in the field of clinical research.

In Statistical Programming, she has made significant contributions to both CDISC and non-CDISC studies. She has worked on multiple therapeutic areas with end-to-end projects as a programmer.

She is passionate about the nuances of clinical data and has consistently demonstrated a remarkable ability to handle diverse datasets effectively.

Sarika holds a Master of Science (MSc) degree in Statistics.



Rubha Raghu

Biostatistician I, Biostatistics, Precision for Medicine

Rubha has been associated with Precision for medicine since 2021 across roles in Biostatistics and Statistical Programming. In her role as a Programmer, she has been actively involved in supporting the end-to-end programming process. In her current role as a Biostatistician I, she has made note-worthy contributions to writing SAPs and Creating Mockshells. She has also worked on reviewing TLF's output and actively addressed sponsor comments.

In addition, she has a keen interest in the identification of solutions through the application of AI/ML.

Rubha holds a Master's degree in Statistics.





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Agenda

Farming vs Clinical Trial

Regulatory Submissions

Roadblocks & Scenarios

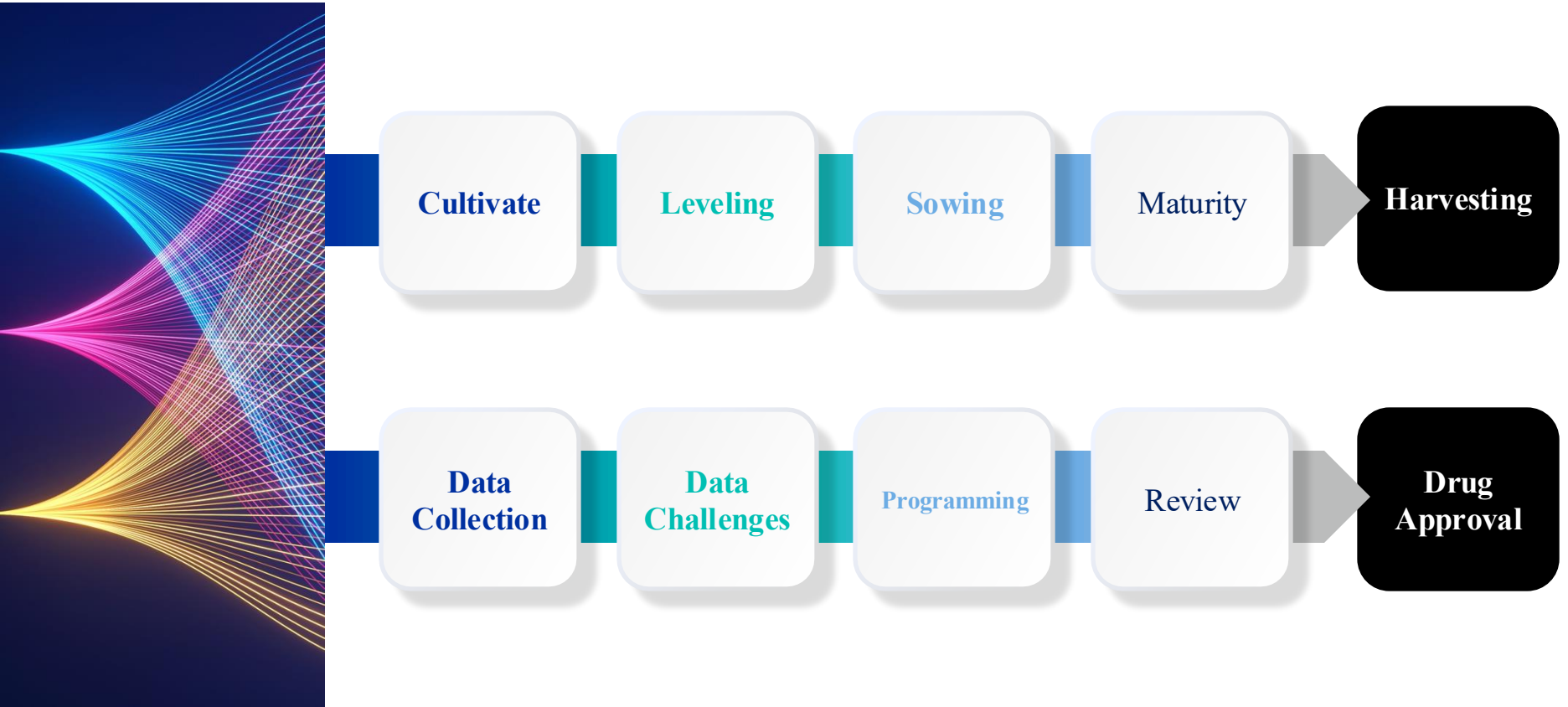
Role Rotation Model (RRM)

Implementation

Benefits of RRM

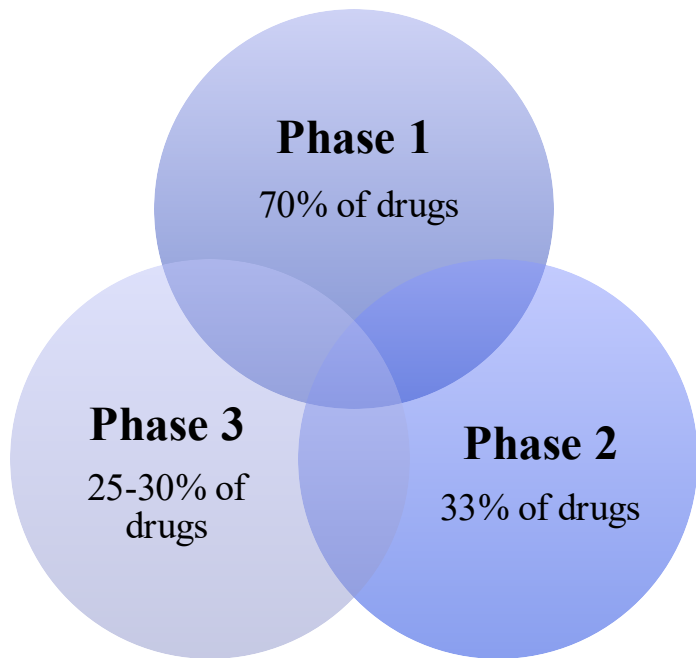
ONE Delivery

Farming vs Clinical Trial





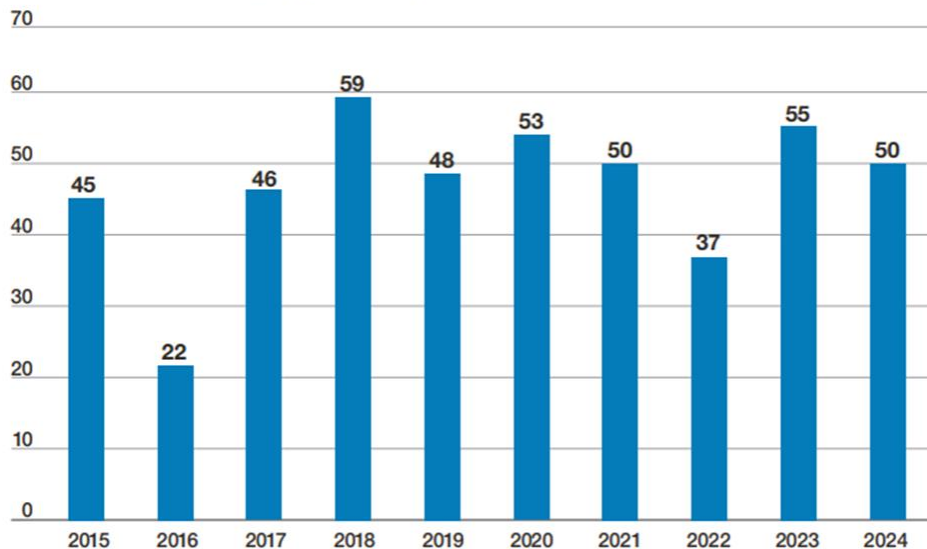
Regulatory Submissions

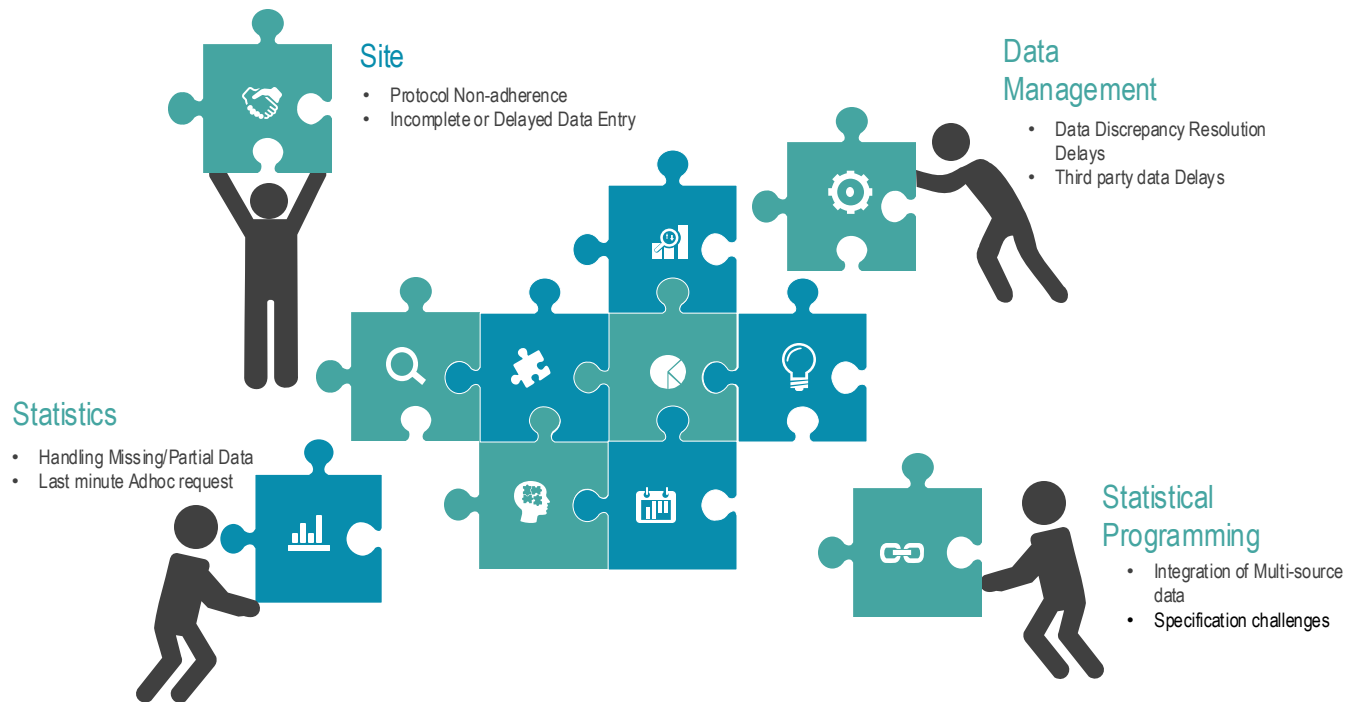


CDER's Annual Novel Drug Approvals: 2015 – 2024

The 10-year graph below shows that from 2015 through 2024, CDER has averaged about 47 novel drug approvals per year.

CDER's Novel Drug Approvals By Year







Scenario: Site $\leftrightarrow$ Data Management



Subject	Folder	BMKYN	BMKDAT1	BMKTIM1
5118001	W1D1	Yes	27 JAN 2025	11:30
5118001	W2	Yes	3 FEB 2025	09:58
5118001	W3	Yes	10 FEB 2025	11:35
5118001	W4	Yes	17 FEB 2025	11:05
5118001	W5	Yes	24 FEB 2025	11:03
5118001	W6	Yes	3 MAR 2025	11:00

SUBJID	VISIT	LBDAT	LBTIM	ASSAY	Unit
5118001	W1D1	01/27/1945	11:30:00.000	CSF2	pg/mL
5118001	W1D5	01/31/2025	11:15:00.000	CSF2	pg/mL
5118001	W2	02/03/2025	10:18:00.000	CSF2	pg/mL
5118001	W2D2	02/04/2025	11:08:00.000	CSF2	pg/mL
5118001	W2D5	02/07/2025	11:16:00.000	CSF2	pg/mL
5118001	W3 PREDOSE	02/10/2025	11:45:00.000	CSF2	pg/mL
5118001	W4 PREDOSE	02/17/2025	11:22:00.000	CSF2	pg/mL
5118001	W5 PREDOSE	02/24/2025	11:15:00.000	CSF2	pg/mL
5118001	W6 PREDOSE	03/03/2025	11:23:00.000	CSF2	pg/mL



DM $\leftrightarrow$ Programming

SUBJID	VISIT	▲ LBDAT	LBTIM	ASSAY	Unit
5118001	W1D1	01/27/1945	11:30:00.000	CSF2	pg/mL
5118001	W1D5	01/31/2025	11:15:00.000	CSF2	pg/mL
5118001	W2	02/03/2025	10:18:00.000	CSF2	pg/mL
5118001	W2D2	02/04/2025	11:08:00.000	CSF2	pg/mL
5118001	W2D5	02/07/2025	11:16:00.000	CSF2	pg/mL
5118001	W3 PREDOSE	02/10/2025	11:45:00.000	CSF2	pg/mL
5118001	W4 PREDOSE	02/17/2025	11:22:00.000	CSF2	pg/mL
5118001	W5 PREDOSE	02/24/2025	11:15:00.000	CSF2	pg/mL
5118001	W6 PREDOSE	03/03/2025	11:23:00.000	CSF2	pg/mL





Programming ↔ Statistics

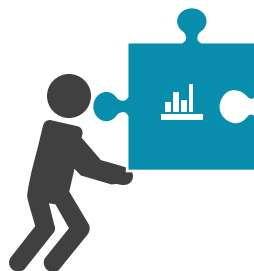
USUBJID	LBTEST	LBORRES	LBORRESU	LBORNALO	LBORNAHI	VISIT	LBOTC
-5118-001	Urea Nitrogen	27	mg/dL	8	23	Week 1 Day 1	2025-01-27
-5118-001	Hematocrit	45.7	%	37	50	Week 1 Day 1	2025-01-27
-5118-001	Hemoglobin	15.5	g/dL	13	17.7	Week 1 Day 1	2025-01-27
-5118-001	Ery. Mean Corpuscular Volume	98.1	fL	79	97	Week 1 Day 1	2025-01-27
-5118-001	Platelets	205	10 ³ /uL	140	450	Week 1 Day 1	2025-01-27
-5118-001	Erythrocytes	4.66	10 ⁶ /uL	4	5.8	Week 1 Day 1	2025-01-27
-5118-001	Leukocytes	5.2	10 ³ /uL	4.1	12.3	Week 1 Day 1	2025-01-27
-5118-001	Bacteria	N/A				Week 1 Day 1	2025-01-27
-5118-001	Casts	N/A				Week 1 Day 1	2025-01-27
-5118-001	Crystals	N/A				Week 1 Day 1	2025-01-27
-5118-001	Epithelial Cells	N/A	/HPF			Week 1 Day 1	2025-01-27
-5118-001	Glucose	NEGATIVE				Week 1 Day 1	2025-01-27
-5118-001	Ketones	NEGATIVE				Week 1 Day 1	2025-01-27
-5118-001	Leukocyte Esterase	NEGATIVE				Week 1 Day 1	2025-01-27
-5118-001	Nitrite	NEGATIVE				Week 1 Day 1	2025-01-27
-5118-001	Occult Blood	TRACE				Week 1 Day 1	2025-01-27
-5118-001	Protein	NEGATIVE				Week 1 Day 1	2025-01-27
-5118-001	Erythrocytes	0	/HPF			Week 1 Day 1	2025-01-27
-5118-001	Renal Tubular Cells	N/A				Week 1 Day 1	2025-01-27
-5118-001	Leukocytes	0	/HPF			Week 1 Day 1	2025-01-27
-5118-001	Yeast Cells	N/A				Week 1 Day 1	2025-01-27

Statistical Programming



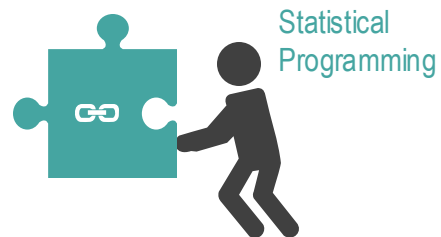
Matrix	Arm A	Arm B	Arm C
Visit/ Timepoint	(N = 54)	(N = 27)	(N = 27)
Urine			
Week 1 Day 1/ Predose			
n	28	13	15
Mean (SD)	0.43 (0.394)	0.55 (0.504)	0.32 (0.236)
Geometric Mean	0.29	0.36	0.25
Median	0.30	0.45	0.28
Min, Max	0.1, 1.8	0.1, 1.8	0.1, 0.8
Week 1 Day 2/ Postdose			
n	27	10	17
Mean (SD)	3294.13 (2161.706)	3945.91 (2151.657)	2910.72 (2137.221)
Geometric Mean	2223.44	3093.87	1830.75
Median	2710.53	5369.22	1938.90
Min, Max	59.1, 5648.6	528.7, 5648.6	59.1, 5648.6
Week 1 Day 5/ Postdose			
n	28	13	15
Mean (SD)	339.35 (706.891)	183.57 (271.047)	474.36 (926.640)
Geometric Mean	71.36	63.14	79.35
Median	75.74	67.90	92.15
Min, Max	0.2, 3493.2	4.3, 822.3	0.2, 3493.2

Statistics



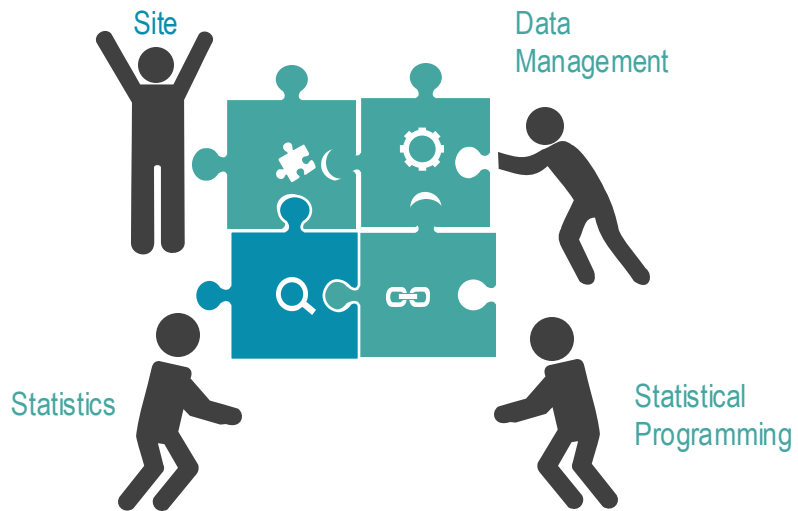


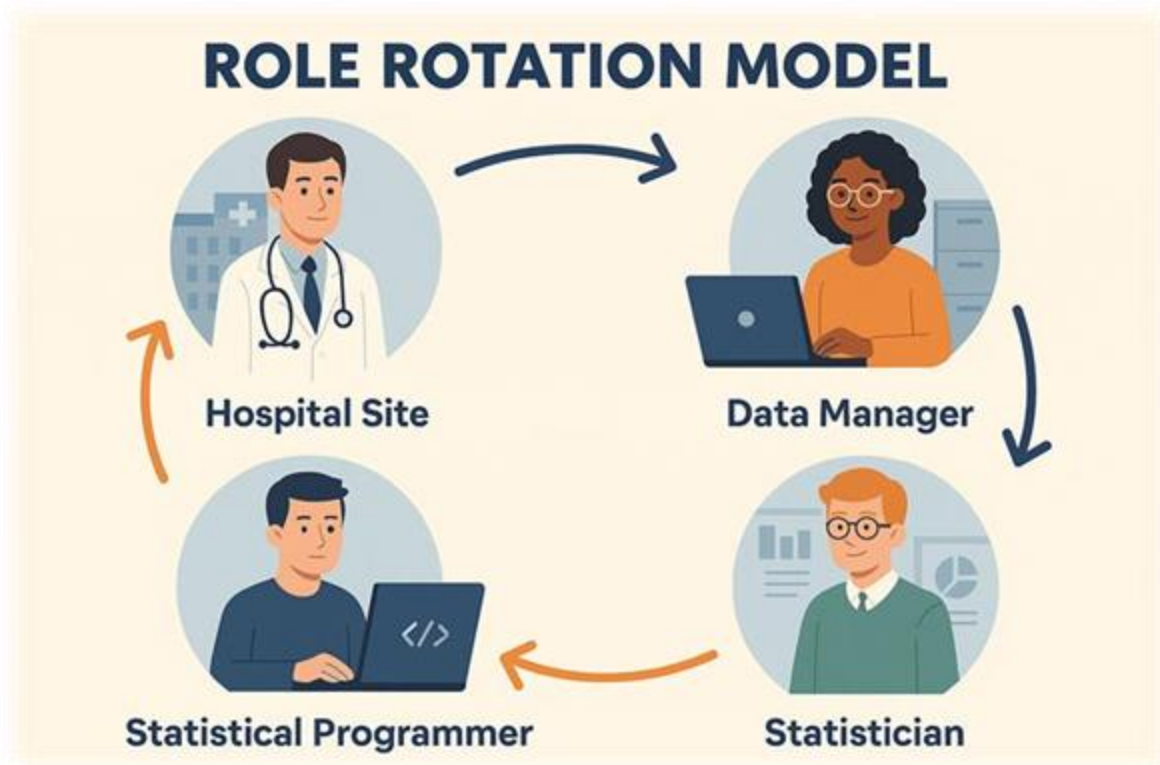
Collaboration?





Mutual Collaboration







Role Rotation Model (RRM)

- **Fosters Cross-Functional Understanding**
 - Enables team members to experience adjacent roles (e.g., Data Management, Biostatistics, Programming), building empathy and reducing misalignment.
- **Improves Submission Quality and Timeliness**
 - Early involvement in feasibility reviews and mock TLFs helps identify issues before final CSR delivery, minimizing rework and delays.
- **Promotes Shared Ownership of Data Integrity**
 - Encourages accountability across functions, ensuring consistent data quality and traceability throughout the submission lifecycle.
- **Supports Agile Resource Management**
 - Cross-trained staff can flexibly support high-demand areas, reducing dependency on specific individuals and avoiding burnout.
- **Drives Continuous Process Improvement**
 - Real-time feedback from rotators helps refine SOPs, streamline workflows, and foster a culture of operational excellence.



Implementation



Trainings

- SOP
- Practical Exposure



Meetings

- From KoM to LLT
- Shared Repository



Batch Run

- Assign new resources
- Use Cross Departmental



Dashboards

- Graphical Output
- Resource Management
- Alert Management

Clinical Trial Dashboard

An integrated dashboard for tracking project status.

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Reset All Data

Dashboard Data Management Stat Programming Stat Review

SDTM Datasets

Domain	Status	Start Date	Complete Date	Issue?	Issue Status
DM	Ongoing	08/10/2025	08/24/2025	Yes	Ongoing
DS	Completed	08/17/2025	08/24/2025	No	Completed
VS	Not Started	mm/dd/yyyy	mm/dd/yyyy	No	N/A
AE	Not Started	mm/dd/yyyy	mm/dd/yyyy	No	N/A
LB	Not Started	mm/dd/yyyy	mm/dd/yyyy	No	N/A

ADaM Datasets

Domain	Status	Start Date	Complete Date	Issue?	Issue Status
ADSL	Not Started	mm/dd/yyyy	mm/dd/yyyy	No	N/A
ADAE	Not Started	mm/dd/yyyy	mm/dd/yyyy	No	N/A
ADSV	Not Started	mm/dd/yyyy	mm/dd/yyyy	No	N/A
ADVS	Not Started	mm/dd/yyyy	mm/dd/yyyy	No	N/A
ADLB	Not Started	mm/dd/yyyy	mm/dd/yyyy	No	N/A
ADMH	Not Started	mm/dd/yyyy	mm/dd/yyyy	No	N/A

Clinical Trial Dashboard

An integrated dashboard for tracking project status.

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Reset All Data

Dashboard Data Management Stat Programming Stat Review

SDTM Review

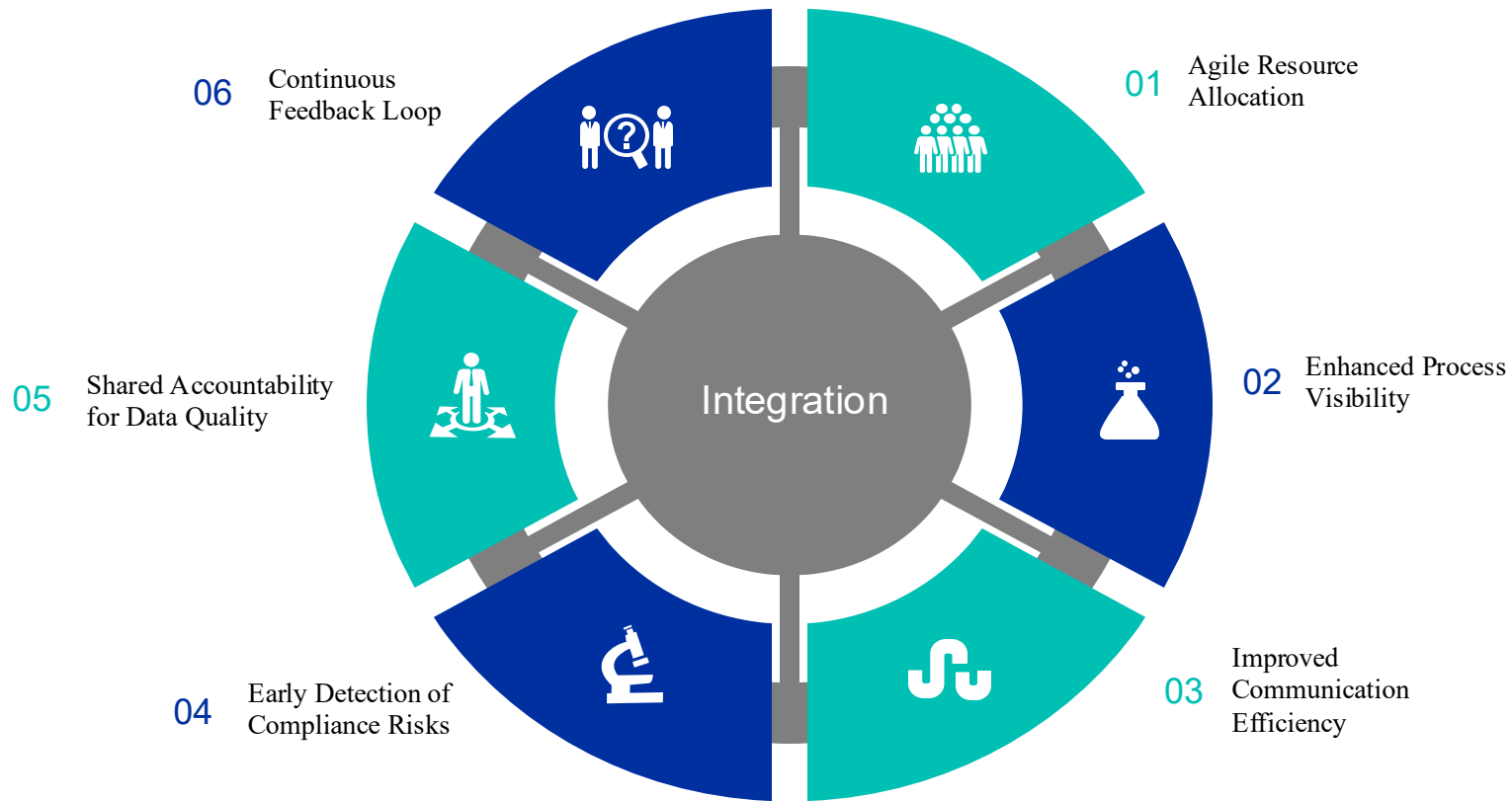
Domain	Start Date	End Date	Comments Given?	Comments Resolved?	Status	Any Issue?
DM	08/11/2025	08/26/2025	No	No	Open	not updated
DS	mm/dd/yyyy	mm/dd/yyyy	No	No	Closed	test issue
VS	mm/dd/yyyy	mm/dd/yyyy	No	No	Ongoing	
AE	mm/dd/yyyy	mm/dd/yyyy	No	No	Closed	
LB	mm/dd/yyyy	mm/dd/yyyy	No	No	Open	

ADaM Review

Domain	Start Date	End Date	Comments Given?	Comments Resolved?	Status	Any Issue?
ADSL	08/27/2025	08/29/2025	Yes	Yes	Closed	
ADAE	mm/dd/yyyy	mm/dd/yyyy	No	No	Closed	sample issue
ADSV	mm/dd/yyyy	mm/dd/yyyy	No	No	Closed	
ADVS	mm/dd/yyyy	mm/dd/yyyy	No	No	Open	
ADLB	mm/dd/yyyy	mm/dd/yyyy	No	No	Ongoing	
ADMH	mm/dd/yyyy	mm/dd/yyyy	No	No	Open	



Benefits of RRM





ONE DELIVERY

Role Awareness

Encouraging cross-functional understanding through rotation builds empathy and reduces silos.

Shared Ownership

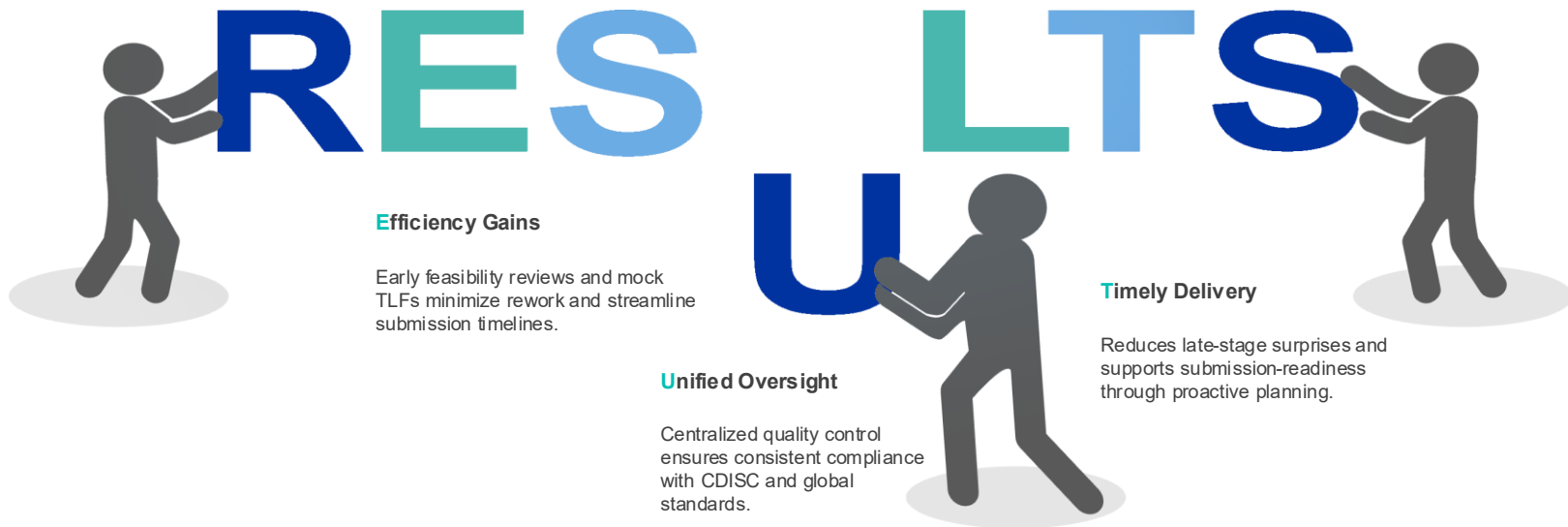
Promotes accountability for data quality across functions, not just within silos.

Learning Culture

Hands-on exposure to adjacent roles fosters continuous improvement and skill development.

Strategic Collaboration

Enhances teamwork and communication, aligning efforts from dry runs to CSR delivery.



Efficiency Gains

Early feasibility reviews and mock TLFs minimize rework and streamline submission timelines.

Timely Delivery

Reduces late-stage surprises and supports submission-readiness through proactive planning.

Unified Oversight

Centralized quality control ensures consistent compliance with CDISC and global standards.



References

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thank
YOU:-)

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