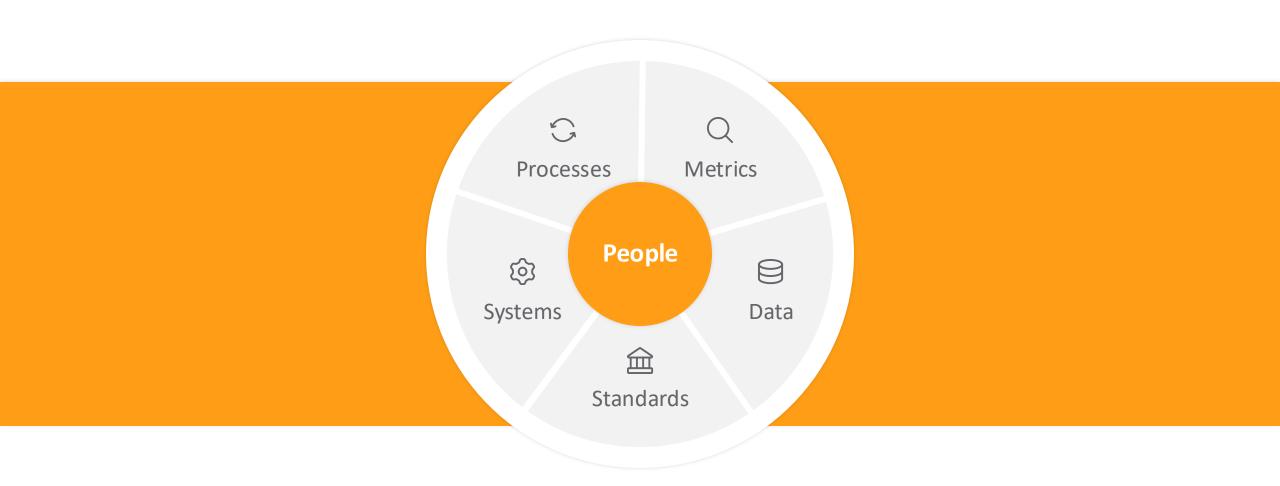


UNIFYING CLINICAL PROCESSES AND TEAMS WITH TMF

Annette Bugno — *Biomea Fusion*Ashley Sawaf — *Dren Bio*

The Human Element of TMF Efficiency





The Human Element of TMF Efficiency









Annette Bugno

Associate Director, Clinical Records Management (TMF)



dren bio

Ashley Sawaf

Senior Manager, TMF Operations

By the Numbers



2 TMF staff

4 CROs

5 Studies

dren bio

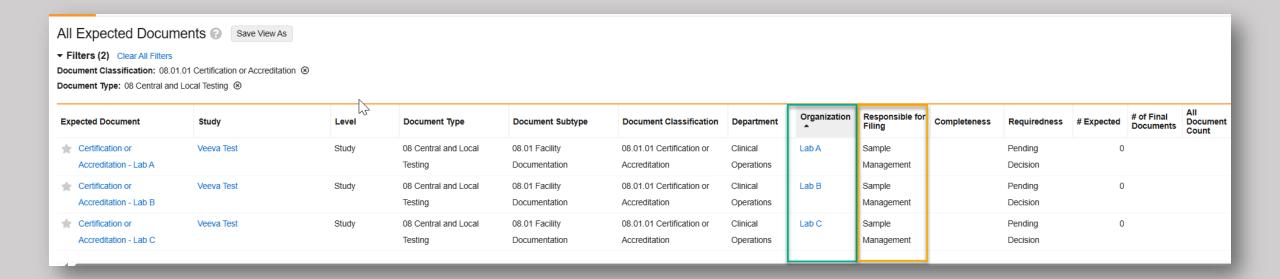
2.25 TMF staff

2 CROs

7 Studies



Organization Specific EDLs





Role-Specific Reports

* CRA Report - John Smith

PROPERTIES

Report Type Milestone with ED, Matched Doc with QI by CRA

Flash Report Runs monthly on the first Monday at 12:00 AM Runs as Ashley Sawaf Last ran 03 Mar 2025

Advanced Options Multi-Pass

- ▼ FILTERS (4)
 - » Expected Document > Requiredness in "Pending Decision, Required"
 - » Document > Document Status is not equal to "Approved"
 - » Document > Document Status is not equal to "In QC Review"
 - » Study Site > CRA in "John Smith"



Multi-Pass Reports

Milestone with Expected Document		Expected Document with Matched Document			
Milestone > Milestone -	Expected Document > Owning Milestone	Expected Document > Expected Document	Document > Document Name	Document > Document Status	
✓ Milestone > Study Site: 001-102(5)					
▼ Milestone > Study: DR-01-O NC-001 (5)					
IMV29_DR-01-ONC-001 - United States - 001-102	IMV29_DR-01-ONC-001 - United States - 0 01-102	Monitoring Visit Report (Monitoring Visit)			
IR - Site Initiated (DR-01-O NC-001 - United States - 00 1-102)		informed consent Form (for)	DR-01-ONC-001_NXVIR22.10_Pro tocol Amend. 7.0 + Non-Substantial Amend + Revised ICF Approval_20 Mar25 (v0.1)	00 D-itd	
IR - Site Initiated (DR-01-O			DD04 ONC 004 004 402 NTE ID		



Quality Issues Report

Quality Issue with Documents						
Quality Issue > Quality Issue ID	Quality Issue > QC Issue Type	Quality Issue > QC Issue Comments	Quality Issue > Status	Quality Issue > Assigned To	Quality Issue > Due Date	
QI-004320	Inaccurate Content	Both IRB approval and ICF filed int o one placeholder. Please separate into separate PHs and rename acc ordingly.	Active	Jane Johnson	24 Apr 2025	
		Diagon re file under Site Evidence				

- Quality issues and incomplete EDLs
- Multi-pass reports for QI assignment

Study Site CRA				
Study Site > Study Site Number	Study Site > CRA			
001-102	John Smith			
001-102	John Smith			

