



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)



**Ashley
Sawaf**

Senior Manager,
TMF Operations

By the Numbers



2 TMF staff

4 CROs

5 Studies



2.25 TMF staff

2 CROs

7 Studies

Organization Specific EDLs

All Expected Documents ? Save View As

▼ **Filters (2)** [Clear All Filters](#)

Document Classification: 08.01.01 Certification or Accreditation ⊗

Document Type: 08 Central and Local Testing ⊗

Expected Document	Study	Level	Document Type	Document Subtype	Document Classification	Department	Organization	Responsible for Filing	Completeness	Requiredness	# Expected	# of Final Documents	All Document Count
★ Certification or Accreditation - Lab A	Veeva Test	Study	08 Central and Local Testing	08.01 Facility Documentation	08.01.01 Certification or Accreditation	Clinical Operations	Lab A	Sample Management		Pending Decision	0		
★ Certification or Accreditation - Lab B	Veeva Test	Study	08 Central and Local Testing	08.01 Facility Documentation	08.01.01 Certification or Accreditation	Clinical Operations	Lab B	Sample Management		Pending Decision	0		
★ Certification or Accreditation - Lab C	Veeva Test	Study	08 Central and Local Testing	08.01 Facility Documentation	08.01.01 Certification or Accreditation	Clinical Operations	Lab C	Sample Management		Pending Decision	0		



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 > Owing 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 - 001-102	Monitoring Visit Report (Monitoring Visit)		
IR - Site Initiated (DR-01-O NC-001 - United States - 001-102)		Informed Consent Form (ICF)	DR-01-ONC-001_NXVIR22.10_Protocol Amend. 7.0 + Non-Substantial Amend + Revised ICF Approval_20 Mar25 (v0.1)	QC Rejected
IR - Site Initiated (DR-01-O			DR01-ONC-001-001-102-NTE-IP	



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 into one placeholder. Please separate into separate PHs and rename accordingly.	Active	Jane Johnson	24 Apr 2025
		Please 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

