

A Day in the Life of Working in a CRO-Oversight Role within a Sponsor

07Nov2025





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A closer look at my day at work

Meet

Meet with partners to discuss timelines, progress, and budget

Share

Share sponsor standards (Raw, SDTM, ADaM, TLF) with vendors

Review

Review annotated CRFs, SAP, and TLF shells prior to finalization

Review

Review deliverables: SDTM/ADaM specs and datasets, and TLFs

Guide

Guide vendor on TA-specific (ADRE, ADXA) for respiratory and efficacy (ADEFF, ADTTE) datasets

What to I need to understand to enable my work?

Raw Data Standards: define output structure aligned to CRFs; used for EDC extracts and data mapping

SDTM Data Standards: domain models, controlled terminology, compliance expectations, submission readiness

ADaM Principles: analysis readiness, traceability to SDTM/raw, standard derivations and variable roles

TLF Standards: standardized shells, parameter conventions, footnotes, and pagination rules

Why standards matter in sponsor oversight



Efficiency: reduce rework and enable repeatable processes across studies



Consistency: harmonized derivations and outputs drive comparability and faster review



Quality: predefined rules and checks minimize ambiguity and defects



Scalability: standards are the foundation for automation and re-use

Sponsor-defined programming standards

Therapeutic Area CRFs: TA-specific pages improve data quality and alignment

Dynamic ADaM templates: reusable patterns for efficacy/safety endpoints

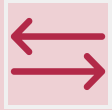
Standard derivation libraries: common functions for dates, visits, censoring, event detection

Output shells: parameterized TLFs with consistent titles, footnotes, and layouts

Accelerating endpoints via templates



Approach: pre-specify endpoint logic (e.g., exacerbation, responder, time-to-event)



Benefits: faster derivation, fewer ambiguities, robust traceability



Example (Respiratory): ADRE/ADXA template variables (event dates, severity, censoring flags)



Governance: versioning, change control, and documented assumptions

Oversight role: responsibilities and cadence



Requirement alignment: interpret SAPs and standards; confirm vendor implementation plans



Deliverable review: structured feedback on SDTM, ADaM, and TLFs; track issues to closure



Risk and timeline monitoring: milestones, slippage signals, and remediation plans



Budget oversight: scope alignment, change orders, and effort drivers



Representation: present sponsor positions in study meetings; resolve cross-functional questions

Quality framework and review strategy



Entry criteria: checklists for CRFs, specs, and mapping plans



SDTM checks: domain integrity, CDISC conformance, metadata alignment



ADaM checks: variable roles, traceability to SDTM, derivation reproducibility



TLF checks: shell adherence, statistical requirements, consistency across outputs



Feedback: structured comment logs, action owners, timelines

Enablers for automation and re-use



Standardized metadata:
machine-readable specs (e.g.,
define.xml, variable catalogs)



Parameterized pipelines: code
templates drive consistent
derivations and outputs



Auto-QC: rules-based validators
for SDTM/ADaM and TLF
discrepancies



Reproducible environments:
version-controlled code and
datasets

Technology advances shaping oversight

Remote informed consent:
streamlined enrollment and
audit trails

ePRO and digital health:
richer longitudinal data;
device integration patterns

Patient tokenization: secure
linkage across sources;
privacy-by-design

Data integration:
interoperability standards
and master data alignment

Collaboration model with CROs

01

Onboarding: share standards, examples, and acceptance criteria early.

02

Working agreements: SLAs for responses, defect thresholds, and escalation paths.

03

Transparency: joint dashboards for timelines, quality metrics, and risks.

04

Continuous improvement: retrospectives and lessons learned to refine standards



Metrics that matter



Timeliness: milestone adherence;
cycle time from draft to approval



Quality: defect rates per deliverable;
rework percentages



Consistency: standards adherence;
variance from shells and templates



Efficiency: automation coverage;
code re-use rate; time saved

Case vignette-Respiratory study

Context: Phase III, multicenter, randomized, double-blind study in moderate-to-severe COPD; primary endpoint: annualized rate of moderate/severe exacerbations; key secondary endpoints: change from baseline in FEV1, SGRQ, and time-to-first exacerbation.

Standards applied: Therapeutic area CRFs for respiratory (exacerbation event page, rescue medication, spirometry), sponsor ADaM templates for ADRE (respiratory events) and ADXA (exacerbations), and standardized TLF shells for rate models, Kaplan–Meier, and responder analyses.

Implementation highlights: Pre-specified censoring and event severity rules, parameterized ADaM derivations (visit windows, partial dates, tokenized patient IDs for device/ePRO linkage), and reusable TLF macros aligned to shells.

Outcome: Derivation cycle time reduced by ~35% vs prior studies (from 10 to 6.5 weeks); SDTM conformance findings decreased by ~40%; TLF discrepancy rate down to 1.8 per 100 outputs; SAP amendment accommodated in 4 days without re-architecting datasets due to template flexibility.

Lessons learned: Early alignment on exacerbation definitions prevents downstream rework; dynamic templates with version control enable rapid change management; shared acceptance criteria and joint review checkpoints with the CRO sustain quality and timeline adherence.

Challenges and how we address them



Evolving requirements: manage via change control and flexible templates



Data heterogeneity: harmonize with robust mapping and tokenization strategies



Ambiguity in SAPs: resolve through clarifying assumptions and examples



Vendor variability: mitigate with clear acceptance criteria and joint reviews

Key takeaways



Standards are the backbone for agility, consistency, and automation



Oversight programming ensures requirements are understood and implemented correctly



Technology advances enrich data capture and integration; oversight must adapt



Structured feedback and metrics drive continuous improvement