



SPA MDR CDR SCE

ML11: Reimagining CSR: From TFLs to Dynamic Text with Generative AI

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- **Implementation Playbook**
- **Risk Register and Mitigations**



INTRODUCTION

What is a Clinical Study Report?

DEFINITION

A Clinical Study Report (CSR) is the comprehensive written document presenting the complete results, methodology, and analysis of a clinical trial to regulatory agencies.

Think of it as: The official trial report card submitted to FDA/EMA to prove a drug works and is safe.

100s to 1000s

Pages per CSR

ICH E3

Global Standard

KEY PURPOSE

Document Trial Results

Complete record of efficacy and safety findings from the clinical trial

Support Regulatory Decisions

Primary evidence package for drug approval and labeling claims

Enable Scientific Review

Allow regulators to independently evaluate benefit-risk profile

Ensure Transparency

Full disclosure of methods, results, and statistical analyses



Role of CSRs in Regulatory Submissions

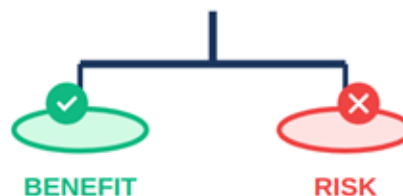


REGULATORY REVIEW



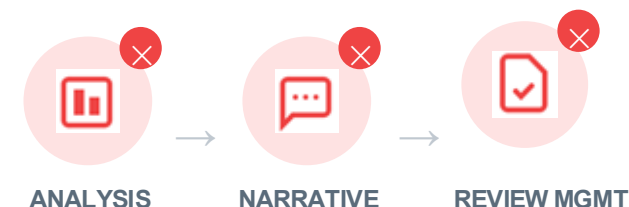
REGULATORY REVIEW

CSR: VITAL DECISIONS



LABELING DECISIONS

LENGTHY & ERROR-PRONE PROCESS



LATE-STAGE FINDINGS /
RE-WORK & DELAY



Anatomy of a CSR

CSR STRUCTURE (ICH E3)

Title Page and Synopsis

Study Design and Methods

Study Patients

Efficacy Results

Safety Results

Conclusions

Appendices and TFLs

KEY COMPONENTS

Tables, Figures, Listings

Statistical outputs presenting quantitative trial data — the foundation of CSR content

Protocol Alignment

CSR must align with pre-specified objectives, endpoints, and statistical analysis plan

Written Narratives

Medical writing that interprets and contextualizes the data for regulators

Cross-References

Internal linking between sections, tables, and source datasets for traceability



THE CHALLENGE

CSR creation requires manual synthesis of TFLs into narratives, ensuring consistency across 100s - 1000s pages while maintaining alignment with protocol. This is where AI can help.

Challenges in Traditional CSR Life Cycle

Current workflows require **manual extraction and interpretation** of tables, figures, and listings (TLFs), alignment with protocol/SAP, and harmonization of cross-references across sections.

TYPICAL PAIN POINTS



DUPLICATIVE EFFORT

Redundant manual work across multiple document sections



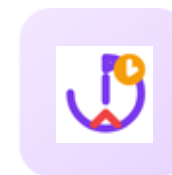
INCONSISTENCIES

TLF data misaligned with narrative text



HIGH REVIEW BURDEN

Extensive manual QC and reconciliation cycles



RE-WORK & DELAY

Late-stage findings cause timeline slippage

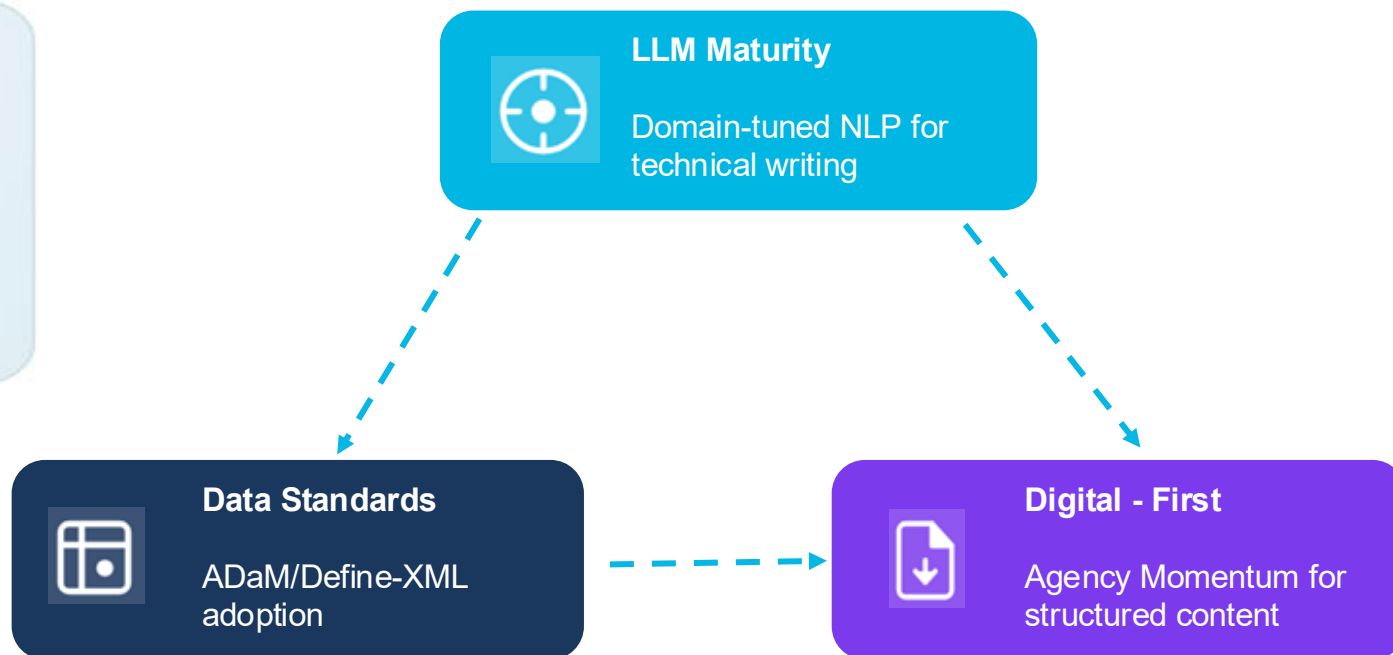


Why Now? Drivers for Change

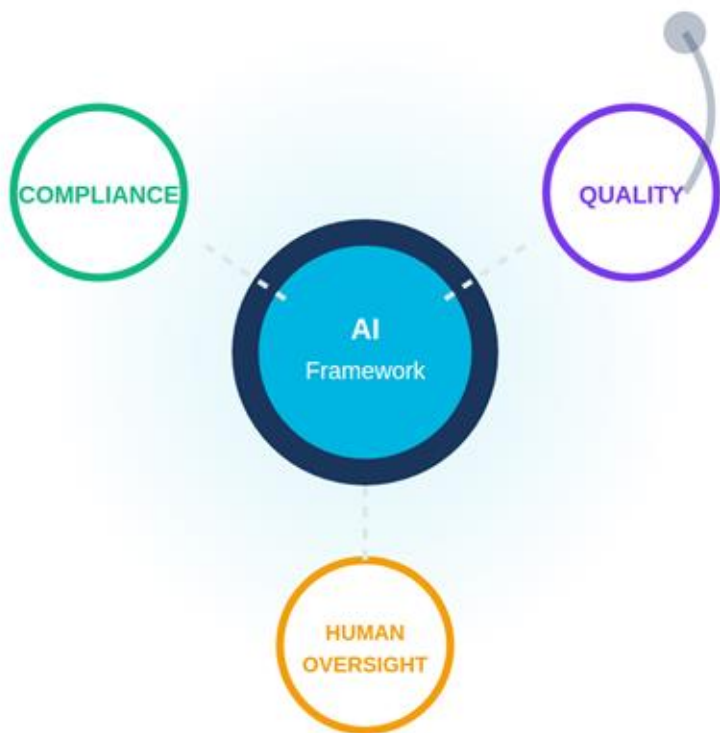
Three trends make CSR automation timely — together, these enable a shift from **manual drafting** to **augmented authoring**.



Convergence of technology, standards, and regulatory direction



Scope and Contributions



Proposed AI Framework



AI-assisted CSR authoring framework

Leveraging LLMs for structured regulatory document generation



Grounded in compliance, quality, and human oversight

Regulatory-ready with built-in validation controls



Technical architecture and workflows detailed

End-to-end process from data to publication



Includes validation controls and implementation playbook

Practical guidance for organizational adoption



Inputs to Automation



Structured Data and Metadata



ADaM Datasets, TLFs

Standardized analysis datasets and tables, figures, listings that form the quantitative foundation



Study Documentation



Protocol / Amendments

Study design, objectives, endpoints, and statistical analysis plan (SAP) specifications



Templates and Guidance



ICH E3 Structure

Section outlines aligned to international regulatory guideline structure



Mapping to ICH E3 Guidelines

1 Efficacy Results

- Disposition summaries
- Protocol deviations
- Endpoint analysis summaries

12 Safety Results

- TEAEs and serious AEs
- Deaths and discontinuations
- Lab/vital sign shifts

9-10 Methods

- Study population
- Analysis sets definitions
- Statistical methods



Human-Authored Sections

Free-text sections for clinical relevance remain human-authored



AI Assistance Available

Phrasing options and cross-reference verification

Model Capabilities and Guardrails

LLM/NLP FOR CSRs

CAPABILITIES



Table Understanding

Structured-to-Text conversion



Consistency Checks

Templated Drafting



Style Enforcement

Regulatory tone compliance

GUARDRAILS



Strict Source-Linking

Every claim traced to data



Deterministic Prompting

Reproducible outputs

POLICY CONSTRAINTS



Block Unsupported Claims

No data = no statement



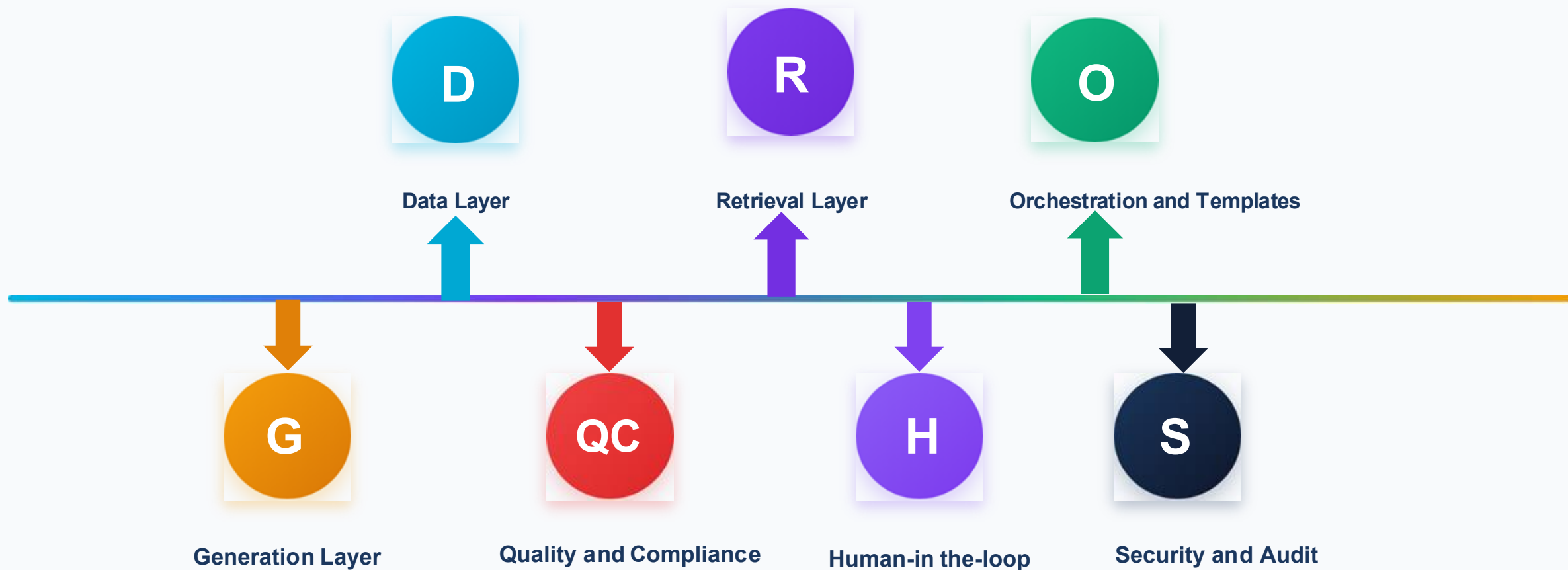
Block Hallucinations

Prevent fabricated data

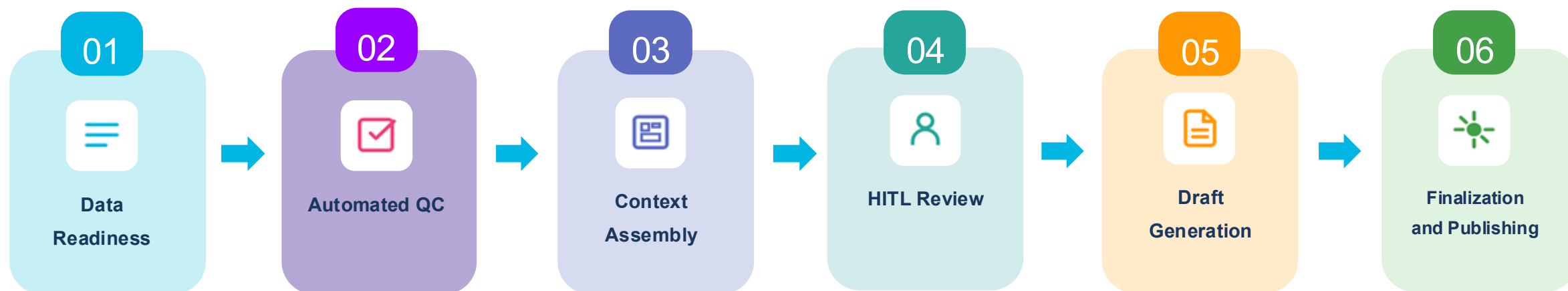


FRAMEWORK ARCHITECTURE

Components



End-to-End Workflow



Template-Driven Drafting

TEMPLATE PATTERN

"A total of `{N_treated}` participants received `{drug}` (`{dose_regimen}`). The overall incidence of TEAEs was `{teae_pct}`%."

EXAMPLE OUTPUT:

"A total of 120 participants received Drug A (100 mg once daily). The overall incidence of TEAEs was 23.5%."

TEMPLATE PATTERN

"The most frequently reported TEAEs (`{threshold}`%) were `{pt_list}`. Serious AEs occurred in `{sae_pct}`% of participants."

EXAMPLE OUTPUT:

"The most frequently reported TEAEs (5%) were headache (8.0%), nausea (6.7%), and fatigue (5.3%)."



Consistent structure



Dynamic data population



Traceable to source TLFs



Quality, Validation and Compliance

Source–Narrative Traceability & Automated Checks

TRACEABILITY

Source–Narrative Linking

Each generated sentence retains pointers to originating sources (TLF ID, ADaM variable, Define-XML VLM record). Lineage metadata is preserved through edits, enabling auditors to reconstruct evidence chains.

Automated Consistency Checks

NUMERIC CONCORDANCE

Percentages recomputed from counts;
discrepancies flagged beyond tolerance

TERMINOLOGY ALIGNMENT

Preferred terms and MedDRA levels checked;
spellings/style harmonized

CROSS-SECTION COHERENCE

Population counts and denominators
reconciled across Efficacy and Safety

TLF Source



Generated Text



QC Validation



Audit Trail



Quality, Validation and Compliance

GxP Controls & Human Oversight

GxP Controls

CHANGE CONTROL

Audit trail

ACCESS CONTROL

Role-based

E-SIGNATURES

21 CFR Part 11

VALIDATION

IQ/OQ/PQ



Human Oversight & Model Governance

SCOPE OF USE

Defined boundaries

MODEL RISK

Assessment

OPERATIONAL

Safeguards

MONITORING

Continuous



Discussion and Future Directions

The future of CSR

- 1 **AI-assisted CSR authoring** uses LLMs for regulatory writing, enabling faster, more consistent document generation.
- 2 **Modernized pipelines** allow deeper integration of metadata and narratives through standardized data formats.
- 3 **Reusable content libraries** improve consistency and reduce timelines across multiple studies.
- 4 The goal is to **maintain scientific integrity and regulatory trust** while improving efficiency.
- 5 This is achieved through **transparent, auditable, human-supervised systems** with rigorous controls.



KEY INSIGHT

The future of CSR development combines AI efficiency with human expertise for regulatory excellence.



| Conclusion

01

AI amplifies medical writers' impact

not replaces them. Human expertise remains central.

02

Rigorous controls, source-linked drafting

and human oversight reduce manual burden.

03

Improves narrative consistency

without compromising compliance through automated checks.

04

Early pilots on well-structured sections

prepare for wider adoption across portfolio.



KEY INSIGHT

From Tables to Text: Enabling faster, more consistent CSR development through human-AI collaboration



Conclusion

✗ WITHOUT AI ADOPTION

Prolonged Timelines

CSR drafting cycles remain lengthy, delaying submissions and market entry

Escalating Costs

Manual processes continue to consume significant resources per report

Inconsistency Risk

Manual data extraction prone to errors and narrative inconsistencies

Competitive Disadvantage

Peers adopting AI will outpace your submission velocity

vs

✓ WITH AI ADOPTION

Accelerated Drafting

Dramatically faster first drafts from TFLs to regulatory-ready narratives

Resource Optimization

Significant cost reduction per CSR through automated generation

Enhanced Accuracy

Source-linked drafting with automated consistency checks

Elevated Expertise

Medical writers focus on clinical interpretation, not data extraction



KEY INSIGHT

The question is not whether to adopt AI for CSR authoring — it's how quickly you can begin realizing value.

Questions?



SPA  MDR  CDR  SCE 

Thank You

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Appendices

Implementation Playbook

Getting started

01

ASSESS

Evaluate current CSR processes, identify pain points, and define success metrics

02

PILOT

Select low-risk CSR sections for initial AI-assisted drafting trials

03

VALIDATE

Implement QC processes, measure accuracy, gather medical writer feedback

04

SCALE

Expand to additional sections and studies, integrate into standard workflows

Key Implementation Activities

- Define governance structure and roles
- Establish data quality requirements
- Develop template libraries
- Train medical writing teams
- Configure validation checkpoints
- Integrate with existing systems
- Establish monitoring metrics
- Create feedback loops
- Document lessons learned



Implementation Playbook

Overview



ASSESS



PILOT



VALIDATE



SCALE

ASSESS MILESTONES

Process assessment complete.
Pain points documented.
Success metrics defined.
Stakeholder buy-in secured.

PILOT MILESTONES

Pilot sections selected.
Templates configured.
First AI-assisted drafts generated.
Writer feedback collected.

VALIDATE MILESTONES

QC processes validated.
Accuracy metrics met.
SOPs updated.
Training completed.

SCALE MILESTONES

Full section coverage.
Multi-study deployment.
Continuous improvement cycle.
ROI demonstrated.



Implementation Playbook

90 days (13 weeks) pilot

Task	WK 0	WK 2	WK 4	WK 6	WK 8	WK 10	WK12	W14
MOBILIZE	0 - 2 weeks							
CONFIGURE			3 - 6 weeks					
EXECUTE					7 - 10 weeks			
EVALUATE							11 - 13 weeks	

MOBILIZE

Select 1-2 completed studies with stable TLFs; define success metrics (e.g., time-to-first-draft).

CONFIGURE

Import templates, load data, and enable retrieval from protocol/SAP; tune prompts for 2-3 target sections.

EXECUTE

Generate drafts; run automated QC; conduct writer/statistician reviews.

EVALUATE

Compare to historical baselines; finalize SOP addenda; plan scale-out.



Implementation Playbook

Roles and RACI (Excerpt)

Activity	Medical Writing	Biostats	Data Mgmt	QA/CSV	Regulatory Ops
Section selection and scoping	R	C	C	C	I
Template configuration	R	C	C	C	I
Draft generation	R	C	I	I	I
QC and reconciliation	R	R	C	C	I
Final approval and publishing	A	C	I	A	A

R Responsible **A** Accountable **C** Consulted **I** Informed



Risk Register

Summary

RISK CATEGORY	DESCRIPTION	LIKELIHOOD	IMPACT	RISK LEVEL
Data Quality	Incomplete or inconsistent TLF data leads to inaccurate narratives	Medium	High	HIGH
Hallucination	LLM generates unsupported claims or fabricated statistics	Medium	High	HIGH
Regulatory Acceptance	Uncertainty around agency acceptance of AI-assisted documents	Medium	Medium	MEDIUM
Change Management	Writer resistance or skill gaps in adopting new workflows	Medium	Medium	MEDIUM
Model Drift	LLM updates may change output quality or consistency over time	Low	Medium	LOW
IP/Confidentiality	Sensitive trial data exposure through external LLM services	Low	High	LOW



Risk Register

Risk Mitigations

DATA QUALITY

Implement pre-flight data validation checks. Require complete TLF packages before generation. Automated concordance verification.

HALLUCINATION

Strict source-linking requirement. Block unsupported claims. Deterministic prompting with grounded context. Human review gates.

REGULATORY ACCEPTANCE

Maintain full audit trails. Document AI-human collaboration model. Engage early with regulators. Follow FDA/EMA AI guidance.

CHANGE MANAGEMENT

Phased rollout with champions. Comprehensive training program. Emphasize AI as augmentation not replacement. Feedback loops.

MODEL DRIFT

Version-lock LLM deployments. Regression testing suite. Output quality monitoring. Controlled update cycles with validation.

IP/CONFIDENTIALITY

Private cloud or on-premise deployment. Data anonymization where possible. Enterprise agreements with data protection. No training on customer data.



KEY PRINCIPLE

Proactive risk management with layered controls ensures AI-assisted CSR development meets GxP quality and regulatory expectations

Implementation Playbook

Metrics to Track



TIMELINE EFFICIENCY



Time-to-first-draft and time-to-approval by section.



DATA ACCURACY



Concordance rate to TLFs; number of escalations from QC.



QUALITY IMPACT



Defect density (pre- and post-AI) and top error classes.



CONTENT REUSABILITY



Reuse rate of boilerplate across studies/indications.

