

GenAI-Powered CSR Writing Automation with Quality Assurance

Company website: AlphaLifeSci.com

Pharma R&D Challenges

Higher Drug Costs

Average development \$2.3B in 2022, up by \$298M

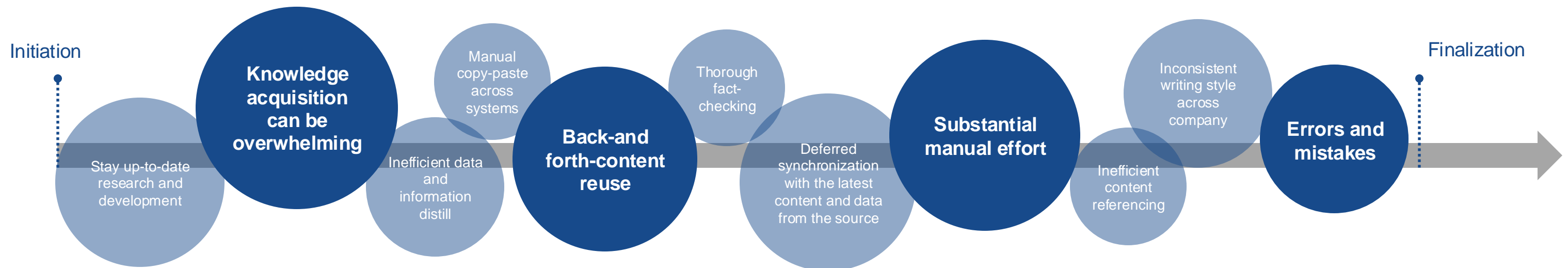
Narrow Value Window

Less time to recoup on new drugs—down 18 months to 9.8 years

ROI Decline

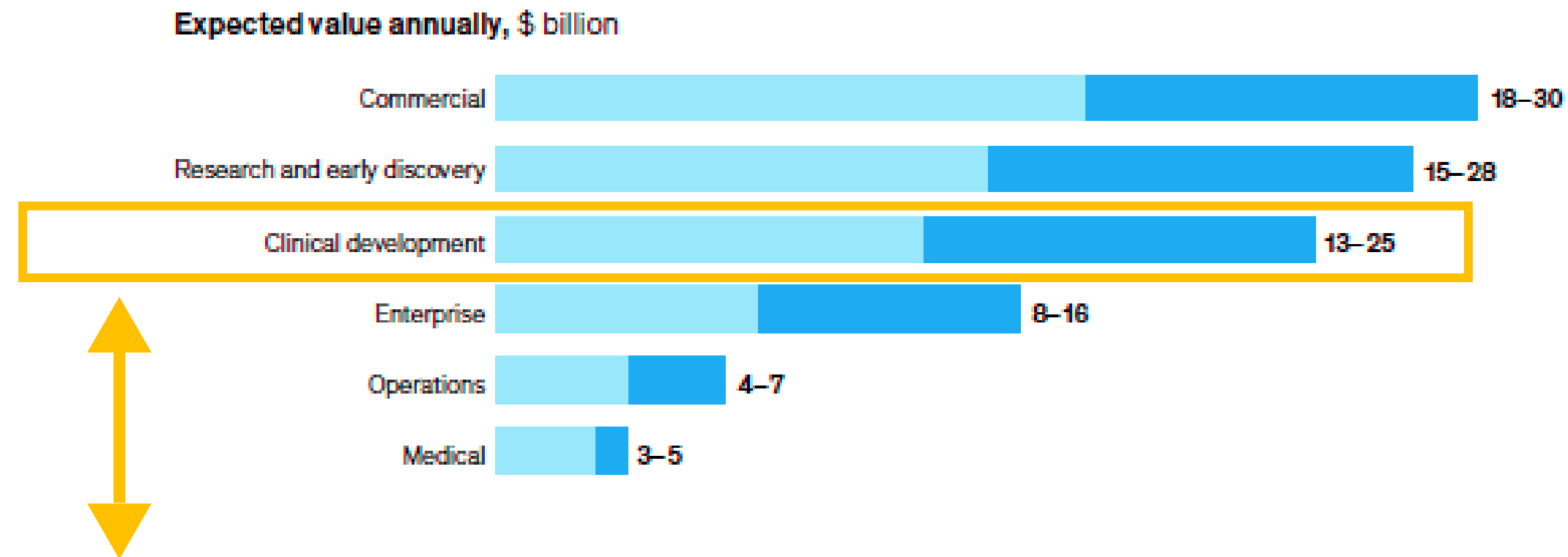
Average ROI at historic low of 1.2%

Medical writers face fragmented challenges in content creation



GenAI Expected to Generate \$13-\$25 Billion Annually in Clinical Development

McKinsey Analysis, Jan 2024



Opportunities

1

Submission Content Writing

- 40% faster regulatory submissions
- 50% improvement in cost efficiency
- Two times reduction in quality issues

2

Smart Data Management

3

Trial Performance Co-pilot

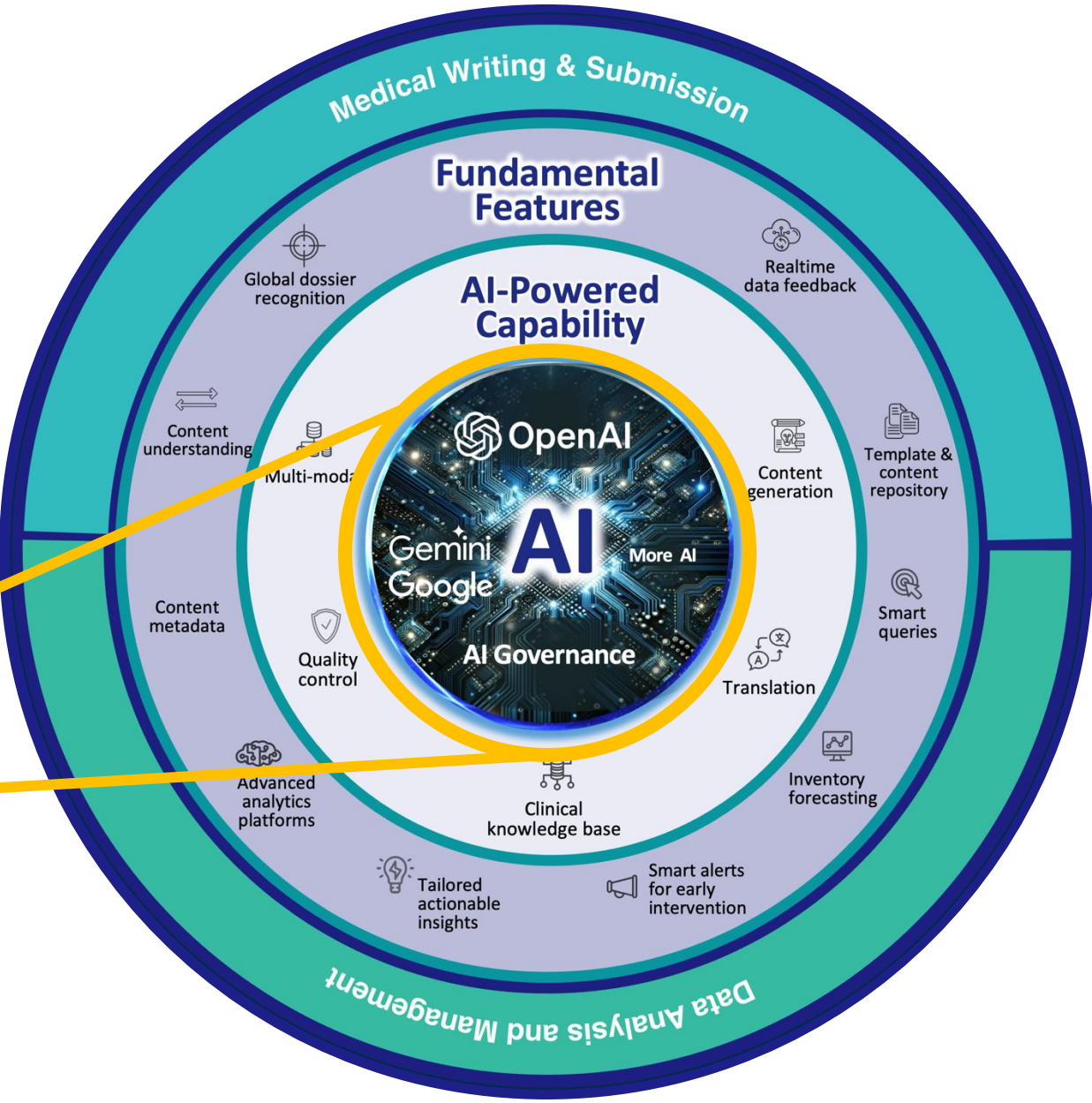
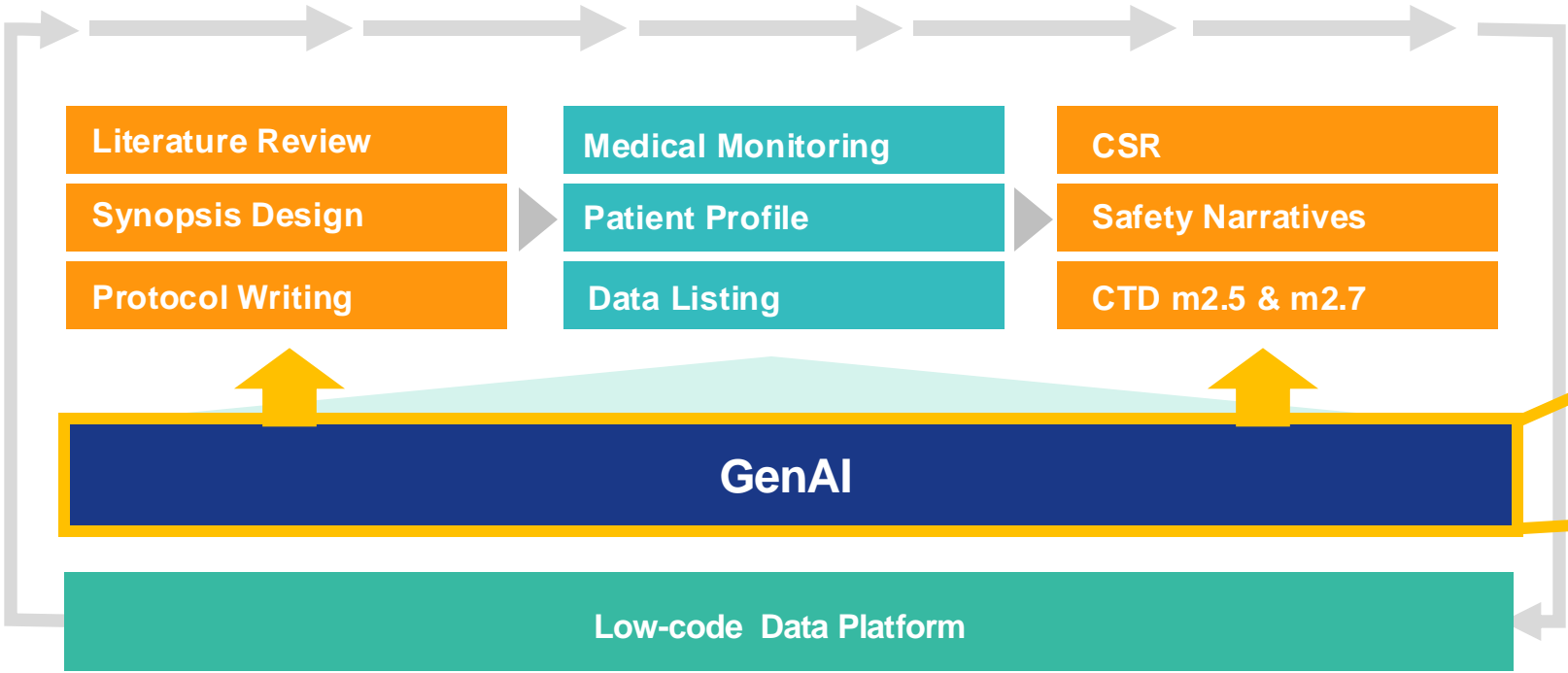
4

Regulatory Intelligence Engine

Accelerating Clinical Trials with GenAI-Powered Medical Writing Solutions



GenAI-Powered Clinical Trial Platform



Revolutionizing Clinical Trials with GenAI: Accelerating End-to-End Medical Writing

Using CSR as an Example

1

Accuracy Automation

GenAI-powered CSR writing with built-in quality control

2

Flexible Template Setup

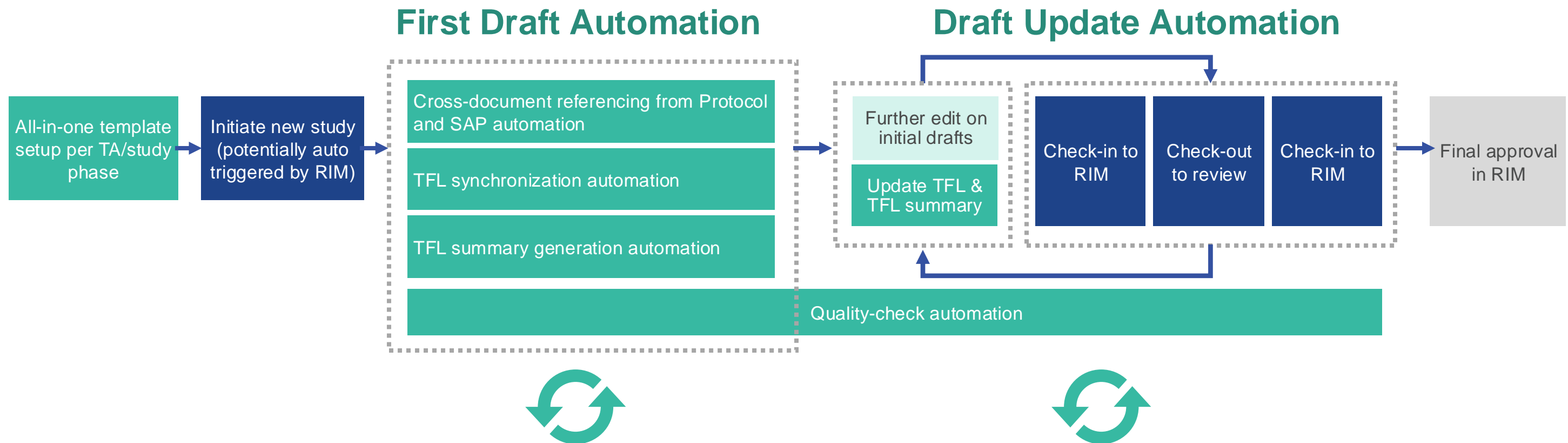
Easily configure templates for various documents and TAs, no coding needed.

3

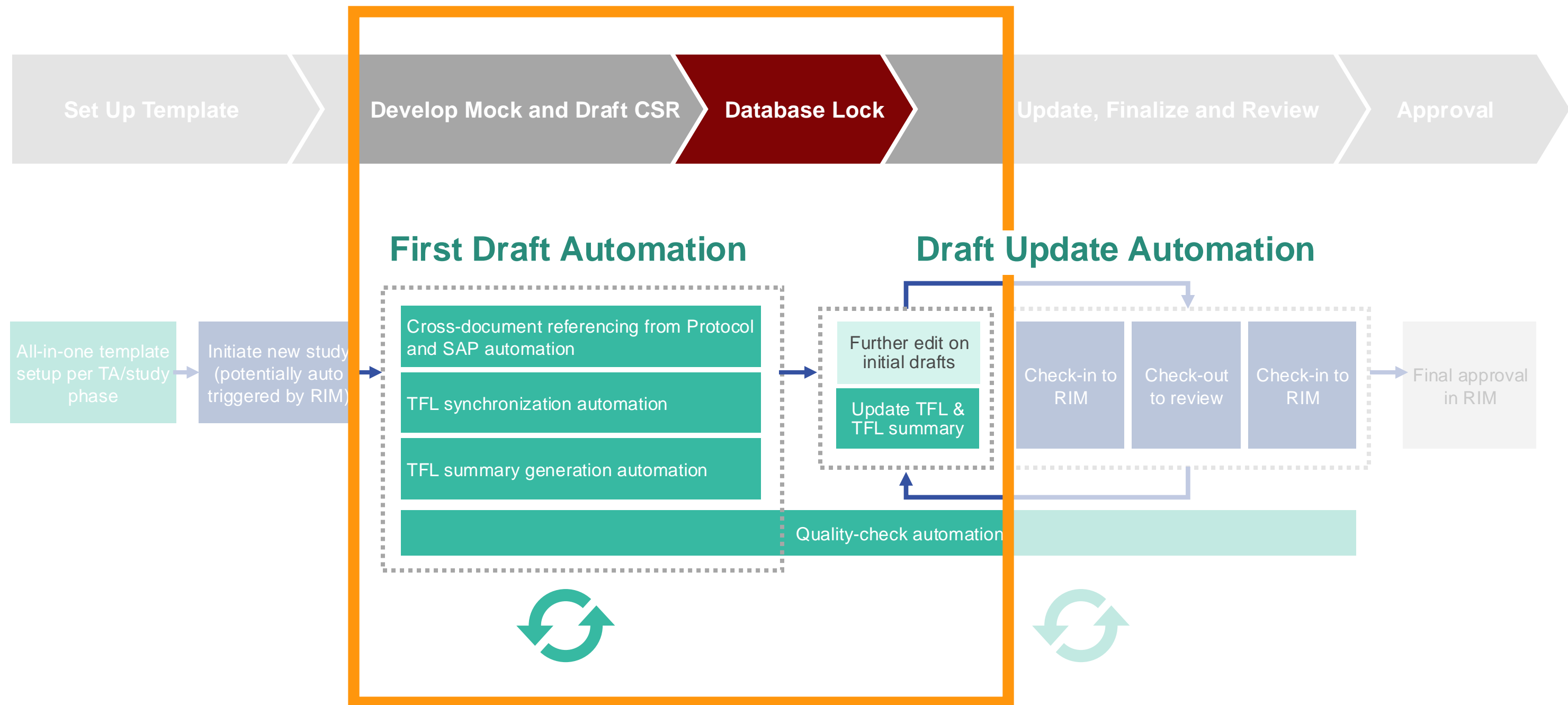
End-to-End Automation

Seamless integration to automate the entire CSR workflow.

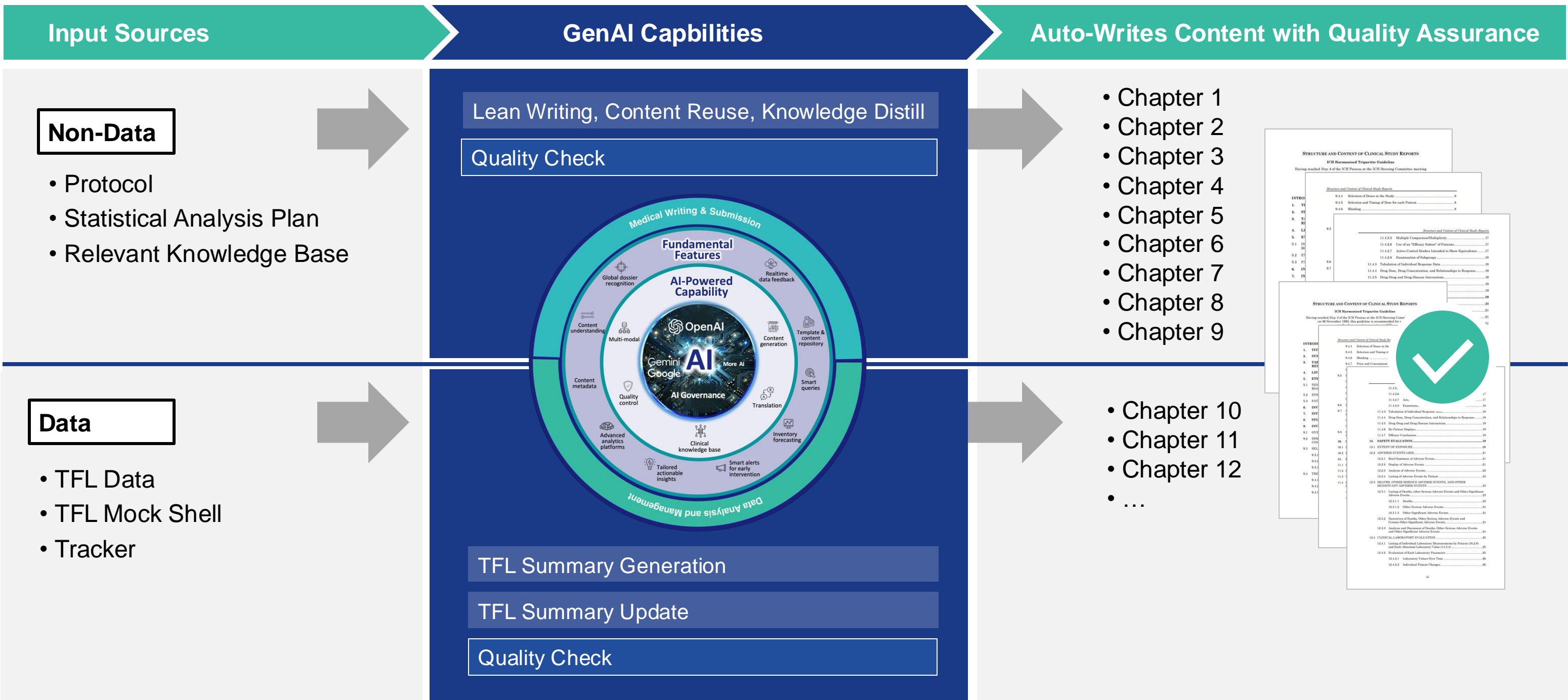
Fully Automating End-to-End CSR Writing Process with Quality Assurance



CSR: Automatically Generates First Draft by Integrating Upstream Data and Documents



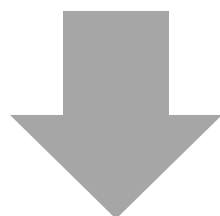
Using GenAI to Auto-Generate Data and Non-Data CSR Sections



Using GenAI to Batch Auto-Generate Data and Non-Data CSR Sections

Organization-level CSR template

1. Sections, format/style, writing guidance, variables
2. Content reuse from Protocol and SAP configuration
3. Content generation examples for GenAI



Study-level document

1. Protocol and SAP file upload
2. TFL placeholder mapping and data sync
3. TFL summary generation automation

The screenshot displays the Adobe Acrobat interface for a document titled "Summary of Clinical Safety" for a "Drug for the Treatment of Patients with Metastatic Castration-sensitive Prostate Cancer". The document content includes a "Confidentiality Statement" at the bottom. The right sidebar, titled "Aurora", contains a "Welcome to AuroraPrime Create!" message and a form to initialize settings for the document. The form includes dropdown menus for "Organization" (set to "xxx"), "Study" (set to "001"), "Document type" (set to "Summary of Clinical Safety"), and "Document language" (set to "English"). A checkbox for "Generate Initial Draft" is checked. A "Confirm" button is located at the bottom of the form. The status bar at the bottom of the Acrobat window shows "Page 1 of 5", "854 words", and "English (United State)".

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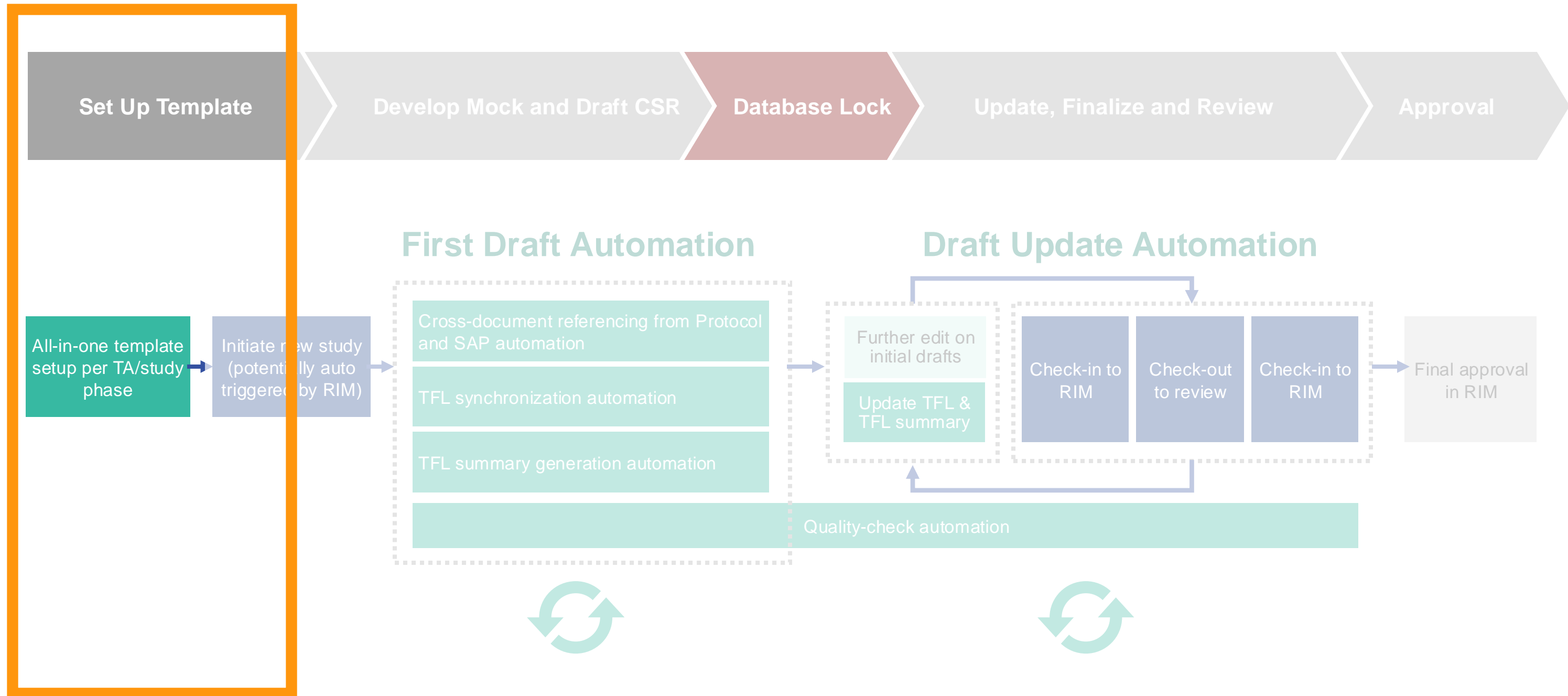
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End-to-End Automation

Seamless integration to automate the entire CSR workflow.

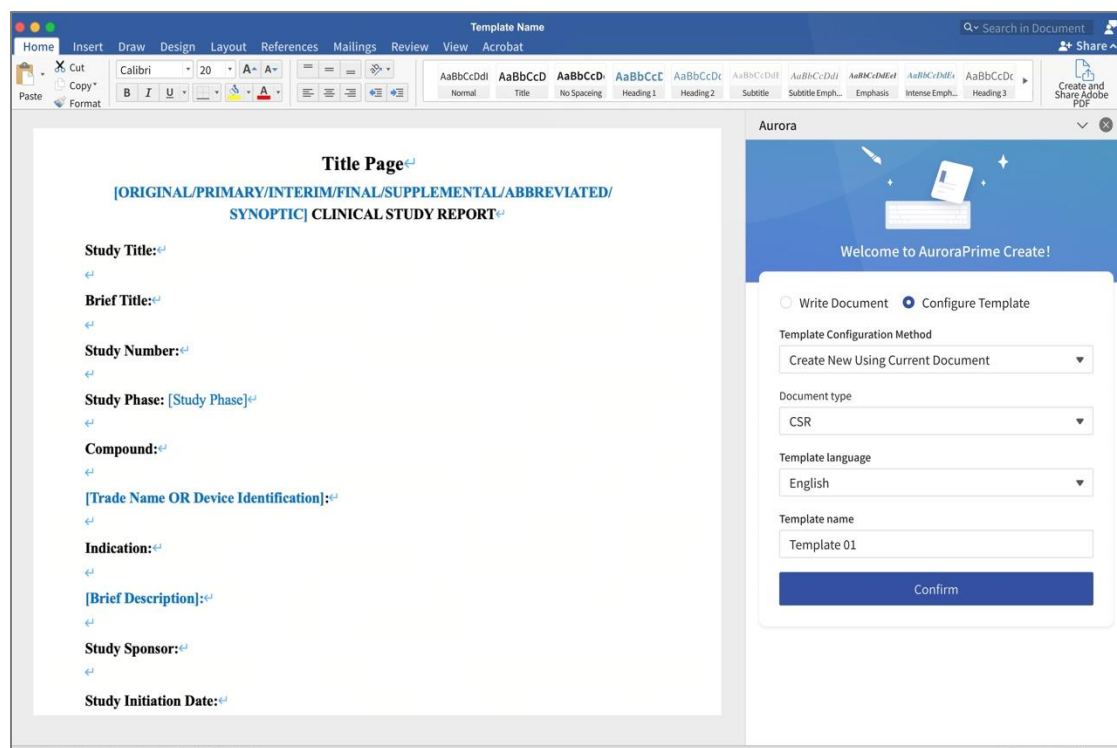
Flexible Template Setup to Accelerate CSR Writing with No Coding Required



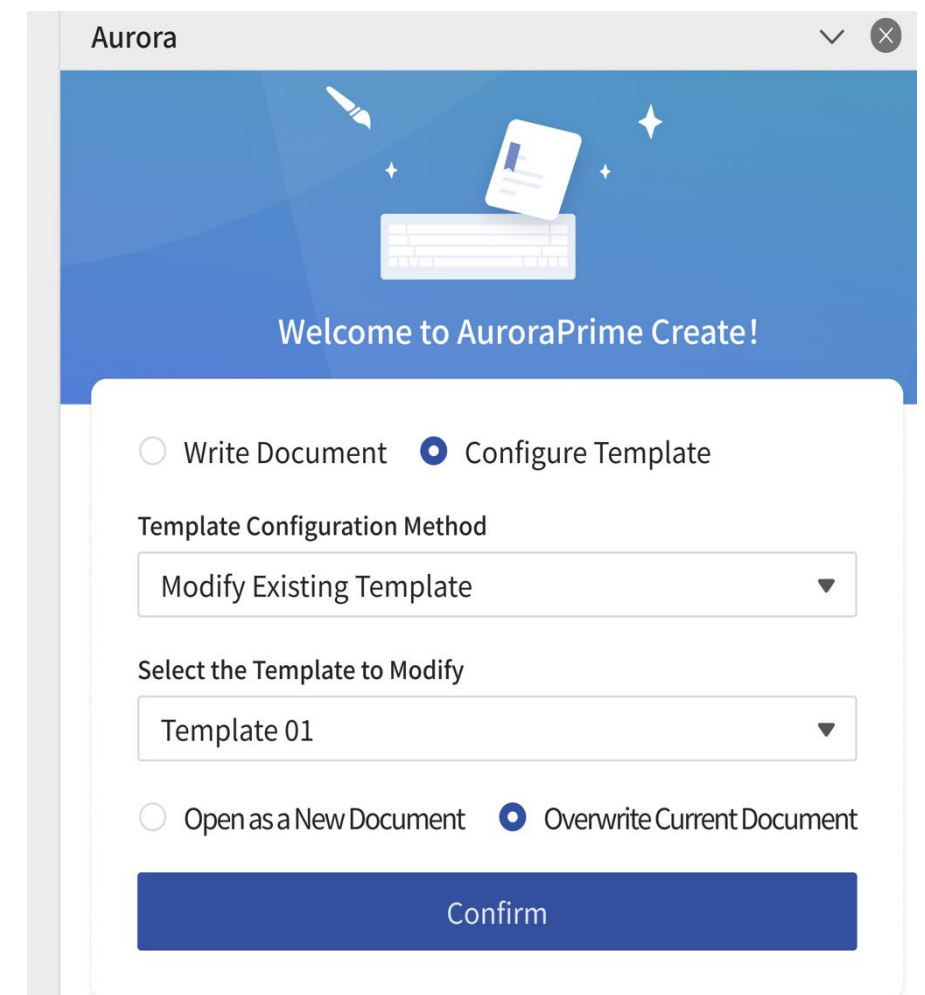
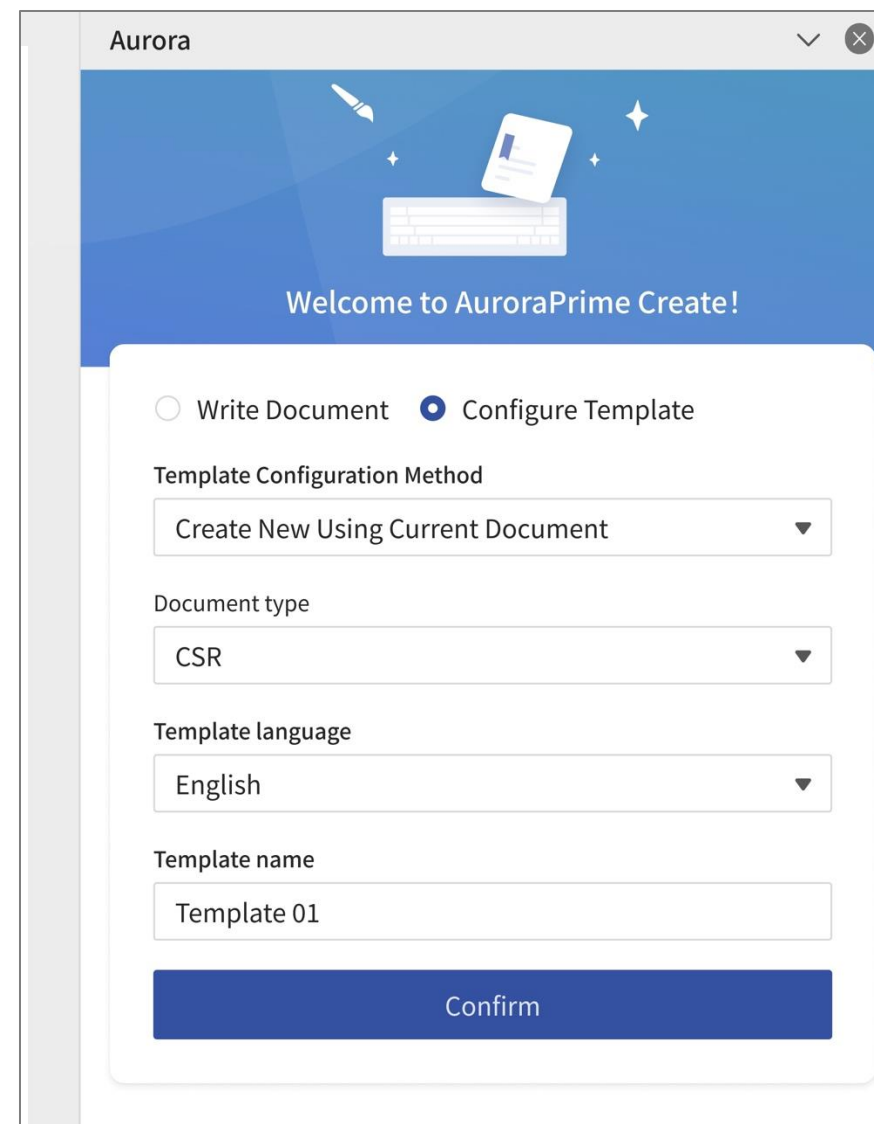
Any New Template Can Be Self-configured in 2 Days Without Coding

Organization-level document template

1. Sections, format/style, writing guidance, variables
2. Content reuse section configuration (Protocol and SAP)
3. Content generation examples for GenAI



Configure Templates From Existing Documents or Existing Templates



Demo: Effortlessly Create Templates by Extracting from CSR Samples

1. Historical CSRs are the best examples – Golden Data Sets
2. “Good” CSRs can be loaded to the Word and structured into TFL Summaries paired with TFLs
3. Easily extracted into Good Example database (library) with the corresponding meta data

The screenshot displays the Microsoft Word interface with the AuroraPrime Create add-in. The main document is a Clinical Study Report (CSR) template with the following fields:

Study Title:		
Brief Title:		
Study Number:		
Study Phase:		
Compound:	Number or Name	
[Trade Name OR Device Identification]:		
Indication:		
Brief Description:	Enter brief description	
Study Sponsor:	legal address	
Study Initiation Date:	[DD Month YYYY]	
Early Study Termination Date:	[DD Month YYYY] () The analyses presented in this report are based on a database lock date of [DD Month YYYY].	
Primary Completion Date:	[DD Month YYYY] () The analyses presented in this report are based on a database lock date of [DD Month YYYY].	
[Study Completion OR Interim Data Report Date]:	[DD Month YYYY] () The analyses presented in this report are based on a database lock date of [DD Month YYYY].	
Regulatory Agency Identifier Number:		
[Pediatric Investigational Plan Number]:		
Report Date:	Document Version	Date

The AuroraPrime Create configuration dialog is open, showing the following settings:

- Document Writing (selected), Template Design, Sampling
- Associated Study: CSR-Demo-0313
- Document Type: CSR
- Document Language: English
- Import from Template?: No
- Confirm button

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Easily configure templates for various documents and TAs, no coding needed.

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End-to-End Automation

Seamless integration to automate the entire CSR workflow.



Word Add-in Solution

The screenshot displays the Microsoft Word interface with the AuroraPrime Create Sandbox add-in. The main document content includes a TFL Summary section with three paragraphs of text and a table titled "Table 1 Baseline Characteristics of Participants (All Participants Randomized)".

TFL Summary

The clinical study involved a total of XX participants, with XX in the placebo group, XX in the YC-1234-01 group, and XX in the YC-5678-01 group. The gender distribution across all groups was slightly skewed towards females, with XX% of the total participants being female and XX% being male. However, the YC-1234-01 group had a higher proportion of males (XX%) compared to the other two groups.[†]

The mean age of participants was similar across all groups, with an overall mean of XX years. The placebo group had the highest mean age of XX years, followed by the YC-5678-01 group with XX years, and the YC-1234-01 group with XX years. The median age was also comparable across all groups, with a total median of XX years.[†]

In terms of race, the majority of participants across all groups were White (XX%), followed by Black or African American (XX%). The YC-5678-01 group had the highest proportion of White participants (XX%), while the YC-1234-01 group had the highest proportion of Black or African American participants (XX%). Only one participant, in the YC-1234-01 group, was identified as American Indian or Alaska Native.[†]

Table 1 Baseline Characteristics of Participants (All Participants Randomized)

	Placebo [†] (N=86) [†]	YC-1234-01 [†] (N=84) [†]	YC-5678-01 [†] (N=84) [†]	Total [†] (N=254) [†]
SEX [†]				
... Female [†]	53 (61.6%) [†]	40 (47.6%) [†]	50 (59.5%) [†]	143 (56.3%) [†]
... Male [†]	33 (38.4%) [†]	44 (52.4%) [†]	34 (40.5%) [†]	111 (43.7%) [†]
Age [†]				
... Mean (SD) [†]	75.2 (8.59) [†]	74.4 (7.89) [†]	75.7 (8.29) [†]	75.1 (8.25) [†]
... Median [Min, Max] [†]	76.0 [52.0, 89.0] [†]	76.0 [56.0, 88.0] [†]	77.5 [51.0, 88.0] [†]	77.0 [51.0, 89.0] [†]
RACE [†]				
... Black or African American [†]	8 (9.3%) [†]	9 (10.7%) [†]	6 (7.1%) [†]	23 (9.1%) [†]
... White [†]	78 (90.7%) [†]	74 (88.1%) [†]	78 (92.9%) [†]	230 (90.6%) [†]
... American Indian or Alaska Native [†]	0 (0%) [†]	1 (1.2%) [†]	0 (0%) [†]	1 (0.4%) [†]

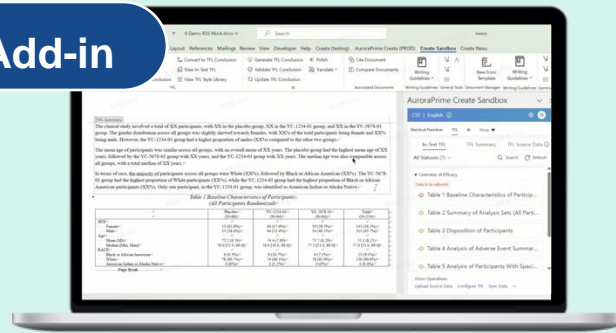
The add-in sidebar on the right shows the "AuroraPrime Create Sandbox" interface with tabs for "In-Text TFL", "TFL Summary", and "TFL Source Data". It includes a search bar, a list of tables to be adjusted, and various operation buttons like "Upload Source Data", "Configure TFL", and "Sync Data".

Seamless Integration of Document Systems to Streamline End-to-End CSR Creation



Document **Authoring**

Word Add-in



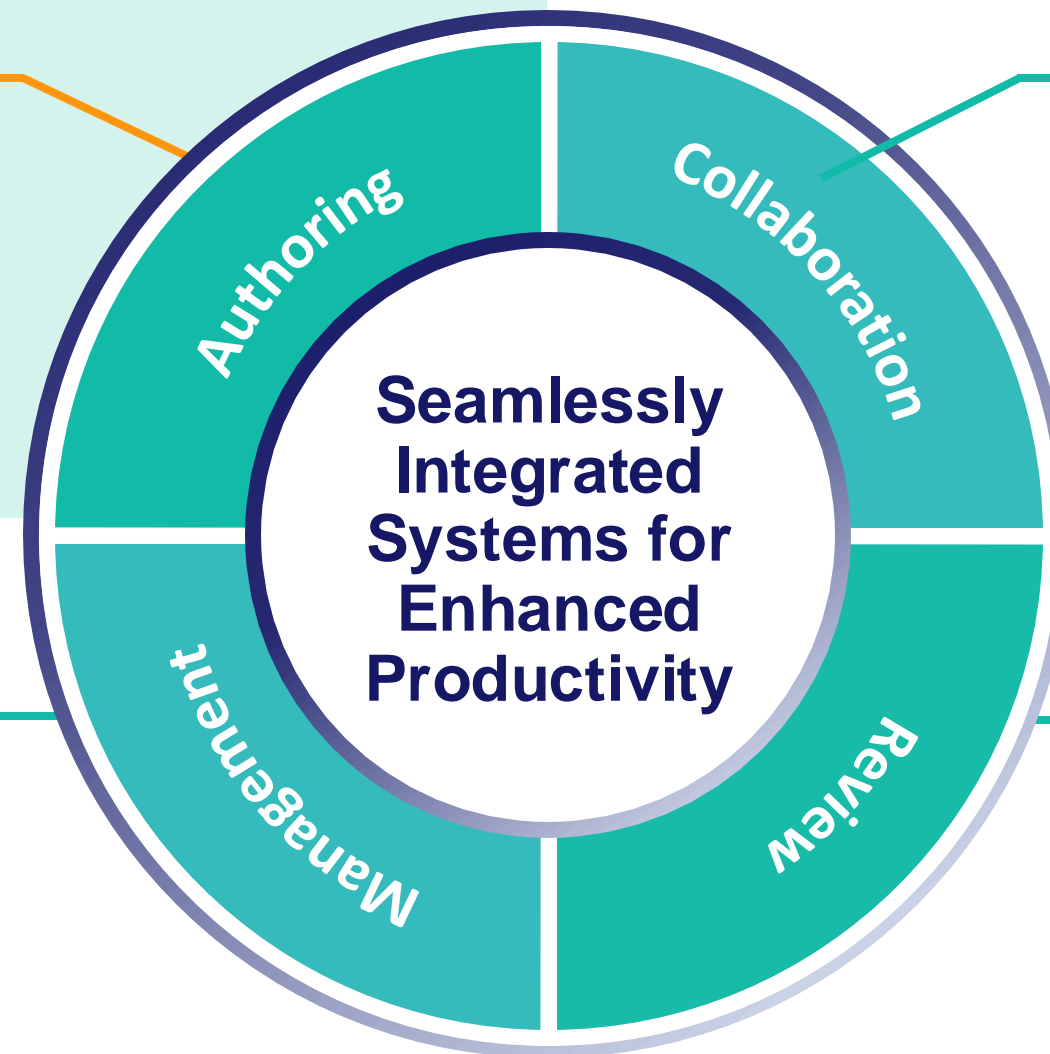
Document **Collaboration**

Document editing environment:

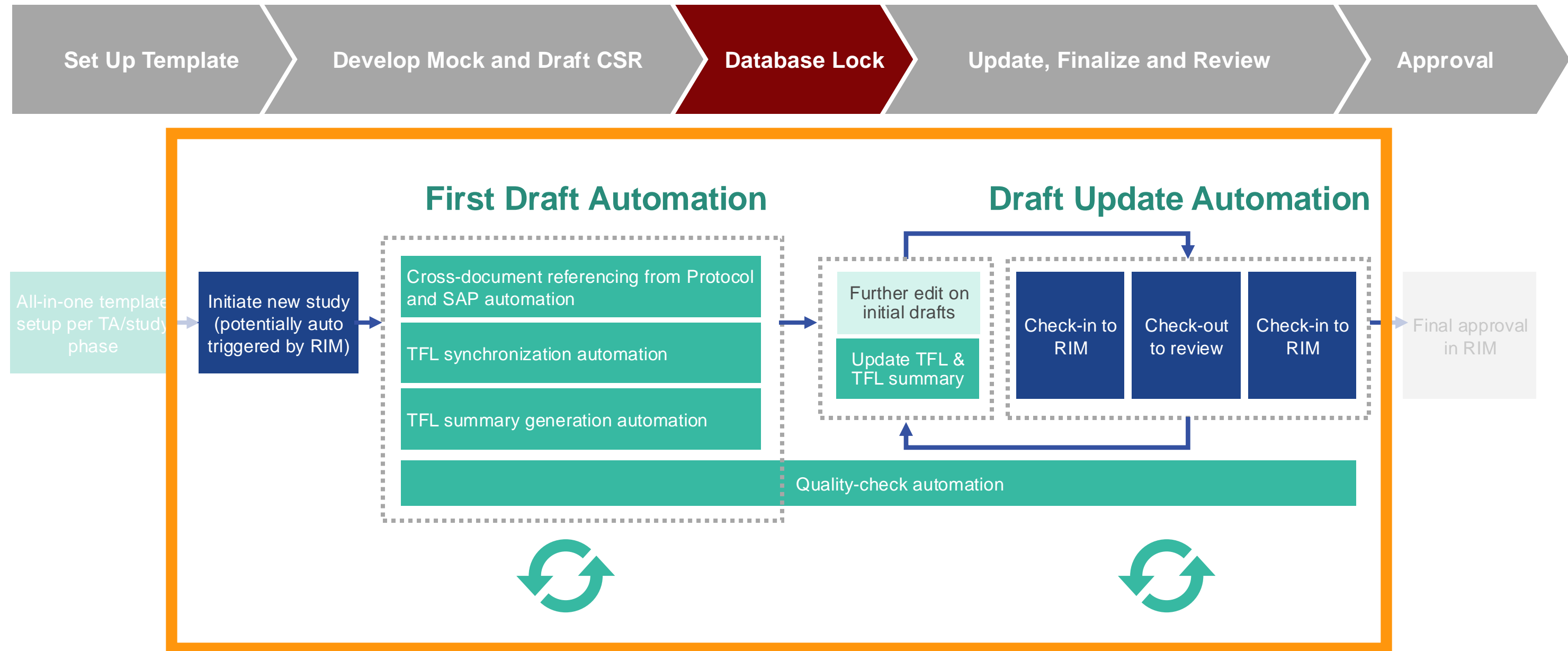


Document **Management**

Document **Review**



Automatically Pre-Processes and Generates CSR Content When Data Updates



Pilot Plan



Objectives

1. Efficiency increase and quality acceptance with confidence

- Product user flow and function verification
- Gain confidence in AI-generated content quality with client specific translation memory configured

2. Solution tailoring for production prediction and future working model's anticipation

- Plan and address identified requirements in agile approach
- Align on improvements in post-pilot and pre-production stage

Highlights

1 Fast add-in installation

Medical Writer, IT Specialist

- IT Specialist helps to install add-in from Microsoft App Source following installation guide
- Confirm the email invitation from user-end to set up user access and roles

2 Minimum data required

NA

- Mock data is prepared from public source information to experience standard version of pilot
- Minimum input required for AI example and content template set-up. Most client's own data are pre-existing (for example RTF files for CSR)

3 Security and compliance

IT Specialist


- Standard information required from large pharma via questionnaires (refer to GCP Security and Compliance session for supporting info.)
- Rapid response and fully compliant to client's security standards

Customization Plan: Tailored Data Set and Template


Project Timeline			Week 1					Week 2					Week 3					Week 4					
			D1	D2	D3	D4	D5	D1	D2	D3	D4	D5	D1	D2	D3	D4	D5	D1	D2	D3	D4	D5	
SETUP	1. User accounts	Confirm client users for AuroraPrime																					
		1.1 Client provides user emails	█																				
		1.2 Alphalife enables user access	█																				
	2. Configurations	Configure environment in AuroraPrime based on input materials																					
		2.1 Client sends materials and provide specifications or requirements	█	█	█																		
		2.2 Alphalife pre-configures template and data-set		█	█	█																	
3. Training	Deliver Aurora Prime system training																						
	3.1 Alphalife provides training with hands-on practice											█											
UAT	4. UAT	Conduct AuroraPrime UAT for POC																					
		4.1 Client conducts user acceptance testing							█	█	█	█	█	█	█	█	█	█	█	█	█	█	
		4.2 AlphaLife conducts interactions on selected features																					
	5. Communication	Communication plan during conducting Pilot																					
		5.1 AlphaLife provides Q&A and trouble shoot through Teams or emails																					
		5.2 Weekly meetings for project governance and steering																					
	5.3 AlphaLife provides pilot exit report and post-pilot plan																				█	█	

Pilot support team

 **Product Specialist**
Provides training services, guides function testing during UAT.

 **Project Manager**
Oversees planning, execution, and delivery, ensuring the system meets client requirements, timeline, and budget constraints.

 **Tech Support**
Deployment, releases, and IT support

 **Tech Lead**
Understand and clarify business requirements; manages technical aspects of project planning and execution; AI and Infra.

Customization Plan: Tailored Data Set and Template

Data/Meeting Requests	Format	Description
CSR template	Word	Must have
Finalized statistical TFL outputs	rtf	Must have
Protocol and SAP	Word	Must have
In-text/post-text TFL presentation mapping file	excel/word	If applicable
Historical full CSRs to tune TFL summary prompts (1-2), better to have historical TFL outputs paired	Word	Must have


1. Template is configured per client requirement: selected TA/study phase, or harmonized template
2. TFL, Protocol, SAP are aligning with the target CSR that to be tested

Standard Plan: Default Data Set and Template


Project Timeline			Week 1					Week 2				
			D1	D2	D3	D4	D5	D1	D2	D3	D4	D5
SETUP	1. User accounts	Confirm client users for AuroraPrime										
		1.1 Client provides user emails	Orange									
	1.2 Alphalife enables user access	Teal										
	2. Configurations	Prepares pilot environment in AuroraPrime										
		2.1 Alphalife prepares pilot environment		Teal								
	3. Training	Deliver Aurora Prime system training										
3.1 Alphalife provides training with hands-on practice				Teal								
UAT	4. UAT	Conduct AuroraPrime UAT for POC										
		4.1 Client conducts user acceptance testing				Orange	Orange	Orange	Orange	Orange	Orange	Orange
	5. Communication	Communication plan during conducting Pilot										
		5.1 AlphaLife provides Q&A and trouble shoot through Teams or emails				Light Green	Light Green	Light Green	Light Green	Light Green	Light Green	Light Green
		5.2 Weekly meetings for project governance and steering							Teal			Teal
		5.3 AlphaLife provides pilot exit report and post-pilot plan									Teal	Teal

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Thank You

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