



AI-Powered Authoring for Clinical & Regulatory Documents

Transforming Document Creation with NLP & Machine Learning

PhUSE US Connect 2026

February 2026

Agenda



The Current Landscape

Challenges in clinical documentation

5 min



AI-Assisted Authoring

NLP and Machine Learning in action

7 min



Technical Architecture

Templates, data integration, content libraries

5 min



10 Core Capabilities

Deep dive into features & outcomes

10 min



Conclusion & Discussion

Synergistic effects and Q&A

3 min

THE CURRENT LANDSCAPE

The Burden of Manual Processes

The Documentation Burden

**Weeks to
Months**

CSR authoring timeline

**Manual
Copy-Paste**

Primary workflow method

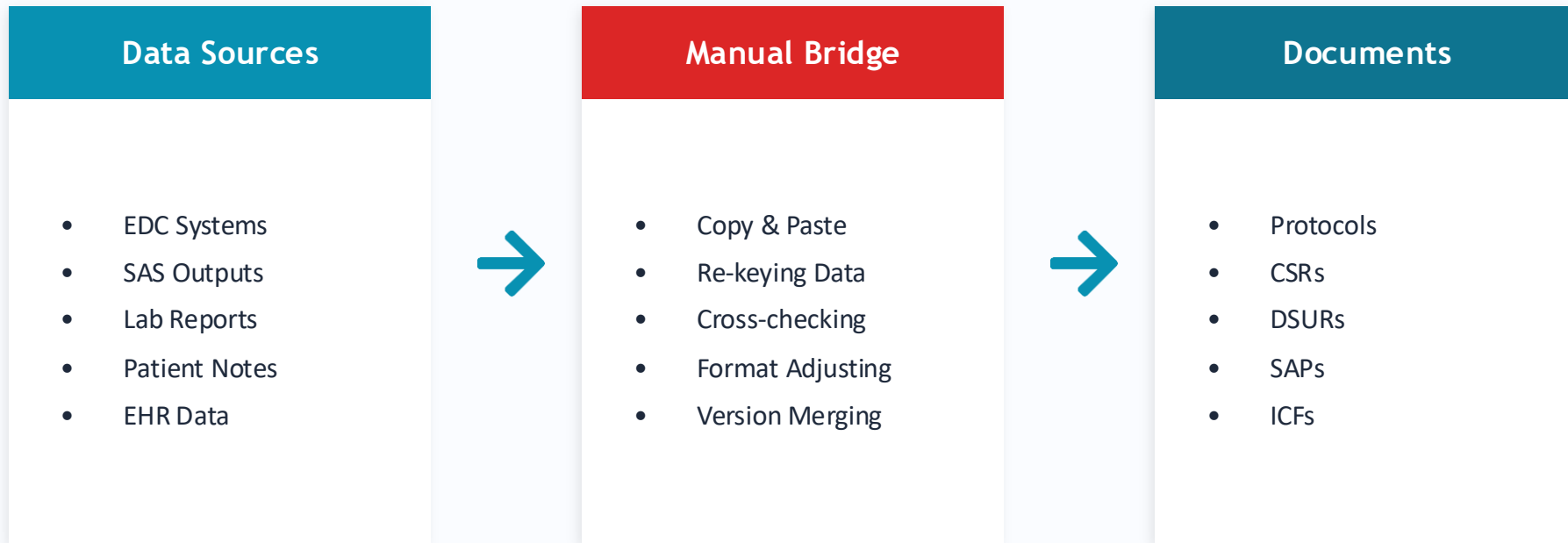
**High Error
Risk**

From manual transcription

Key Challenges

- Misplaced decimals or incorrect units trigger costly regulatory queries
- Disconnected data sources create a "digital gap" between systems
- Changes in one document must be manually propagated to related deliverables
- Line-by-line cross-checking drains highly skilled resources

The Digital Gap



A NEW PARADIGM

AI-Assisted Authoring with NLP & Machine Learning



NLP in Action

From unstructured data to accurate first drafts

How It Works

- 1 **Reads** unstructured text (notes, protocols, lab reports)
- 2 **Extracts** entities, data points, and narrative contexts
- 3 **Generates** accurate, comprehensive downstream content
- 4 **Enables** writers to refine rather than write from scratch



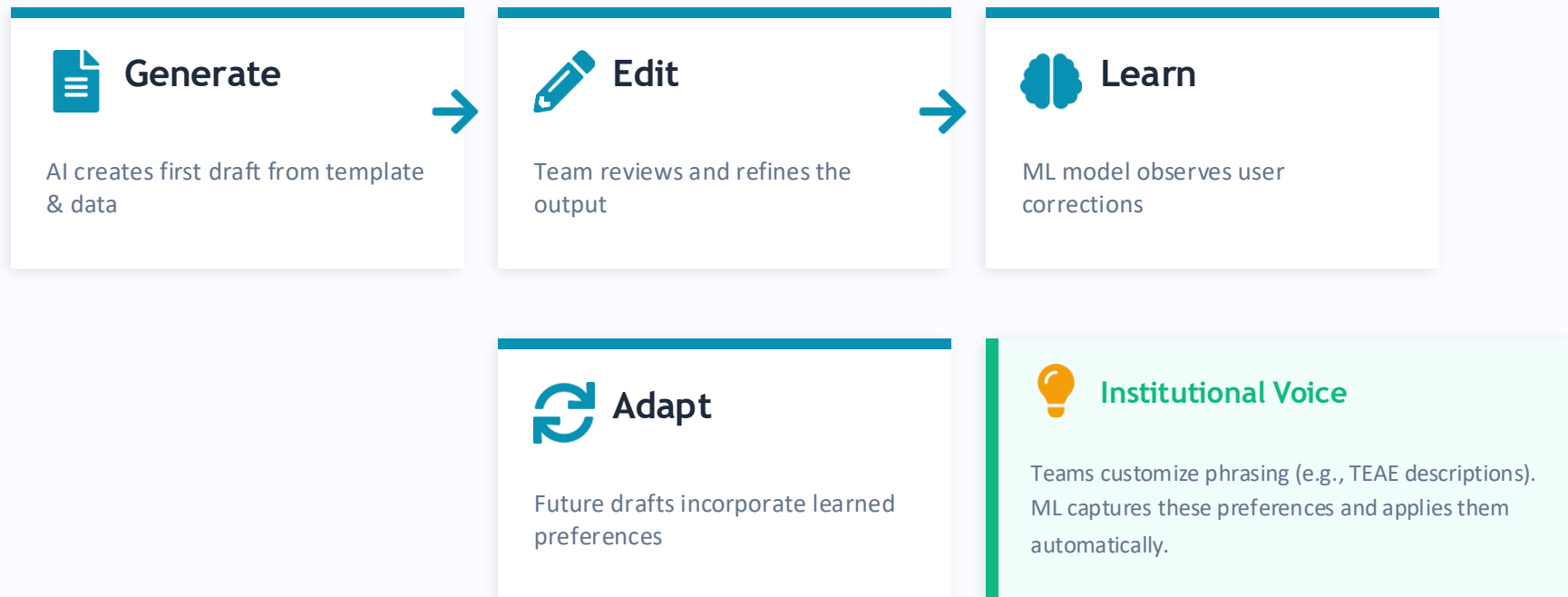
Example: Patient Narrative

Traditional: Writer manually reads listing outputs, patient profiles, and safety data to summarize a serious adverse event.

AI-Powered: System uses NLP to read unstructured notes and structured safety data, auto-drafting a chronological narrative with concomitant medications and outcomes.

The writer reviews and refines—not writes from scratch.

Machine Learning & Adaptability





TECHNICAL ARCHITECTURE

Templates, Data Integration & Content Libraries

Intelligent Templates & Conditional Logic



```
IF Region = 'EU'  
THEN Insert GDPR Clause  
  
ELSE IF Region = 'California'  
THEN Insert CCPA Clause  
  
IF Pediatric = TRUE  
THEN Insert Section 4.1
```

Benefits

- One master template serves multiple regions & study types
- Eliminates risk of missing region-specific clauses
- Auto-populates based on study parameters
- Reduces template maintenance overhead



Example: ICF for Berlin study site → GDPR clause auto-inserted. No risk of missing required privacy language.

Data Integration & Content Libraries



Structured Data Integration

Direct pipeline to source systems ensures numbers always match the source of truth.

- EHRs, patient registries, clinical databases
- Auto-refresh when safety database is locked
- Instant propagation of updated figures
- Eliminates days of manual updates



Content Libraries

Single Source Publishing: write once, reuse everywhere.

- Store pre-approved clauses, paragraphs, and sections
- Pull approved blocks into any document
- Update once in library → propagates everywhere
- Ensures absolute consistency across submissions



10 CORE CAPABILITIES

Detailed Feature Analysis

Core Capabilities 1-3

01



Natural Language Processing

Challenge: Clinical data in unstructured formats—notes, protocols, lab reports

Solution: NLP algorithms extract entities, data points, narrative contexts

Outcome: Faster drafting, higher accuracy, writers refine not retype

02



Collaborative Workflows

Challenge: Global teams, version control issues, emailing docs back and forth

Solution: Real-time co-editing, centralized hub for comments & review

Outcome: Shorter review cycles, no version confusion, faster finalization

03



Conditional Logic Templates

Challenge: Requirements vary by region, phase, and therapeutic area

Solution: If/Then statements auto-insert/hide text based on criteria

Outcome: One master template serves all variations, zero omissions

Core Capabilities 4-6

04



Machine Learning & CI

Challenge: Static templates never improve; same errors repeated

Solution: ML observes user edits and adapts generation logic

Outcome: Self-optimizing system captures team voice automatically

05



Content Libraries

Challenge: Writers rewrite identical descriptions across multiple docs

Solution: Pre-approved content blocks stored and reused across documents

Outcome: Single Source Publishing—update once, propagate everywhere

06



Auto-Formatting

Challenge: Hours spent on margins, fonts, table borders for ICH/eCTD

Solution: Auto-applies industry-standard styles during generation

Outcome: Submission-ready structure instantly; hours redirected to analysis

Core Capabilities 7-8

0
7



Validation & Verification

Challenge

Manual QC misses undefined abbreviations, broken cross-refs, data mismatches

Solution

Built-in scanner checks compliance, data integrity, and flags issues automatically

Outcome

Higher baseline quality, fewer regulatory queries, compressed QC timeline

0
8



Customizable Templates

Challenge

Rigid software fails to accommodate unique branding and internal standards

Solution

Fully configurable templates with user-defined business rules, branding, and layouts

Outcome

Tool adapts to the organization—not the other way around

Core Capabilities 9-10

09



Electronic Signatures

Challenge

Collecting signatures is a bottleneck—wet ink or disconnected tools

Solution

Integrated e-signature within the same authoring environment

Outcome

Streamlined approvals with full audit trail, no version export

10



Multi-Language Support

Challenge

Global trials need patient-facing materials in multiple languages

Solution

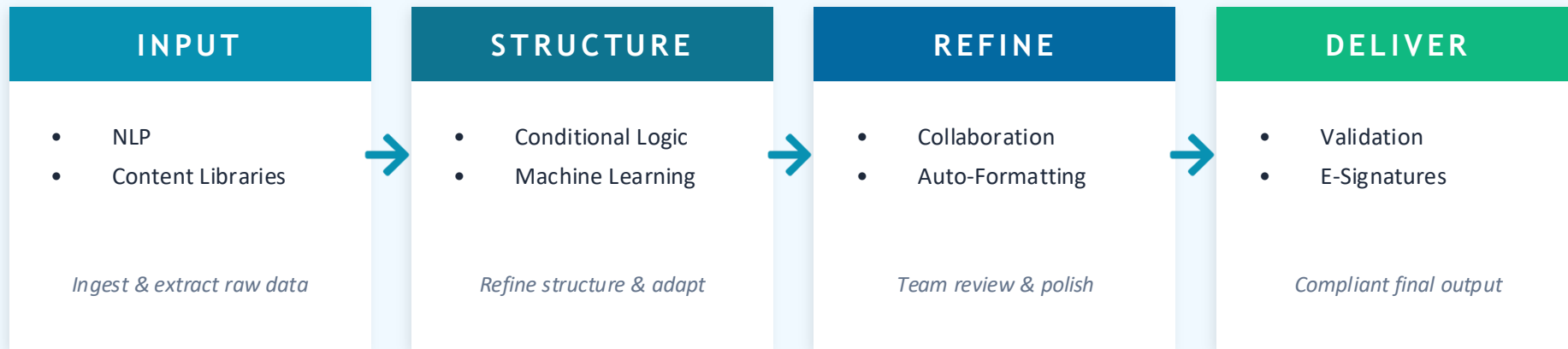
Multi-language template management and document generation

Outcome

Local sites receive quality docs in their native language faster

The Synergistic Effect

How the 10 capabilities work together as a unified pipeline



**Minimize
Repetitive Effort**



**Promote
Consistency**



**Accelerate
Delivery**



**Experts Stay
in Control**

Key Takeaways



Accelerated Timelines

AI-generated first drafts reduce authoring from weeks to days, freeing writers for strategic work.



Higher Quality Baseline

Built-in validation catches errors that manual QC misses, reducing regulatory queries.



Self-Improving System

Machine learning captures institutional voice and preferences automatically over time.



Compliance by Design

Conditional logic and content libraries ensure consistent, region-appropriate outputs.



Experts in Control

AI assists the author—it does not replace them. SMEs remain the final authority on content.

Thank You

Questions & Discussion

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