



A Guided User Experience for Automated Mapping

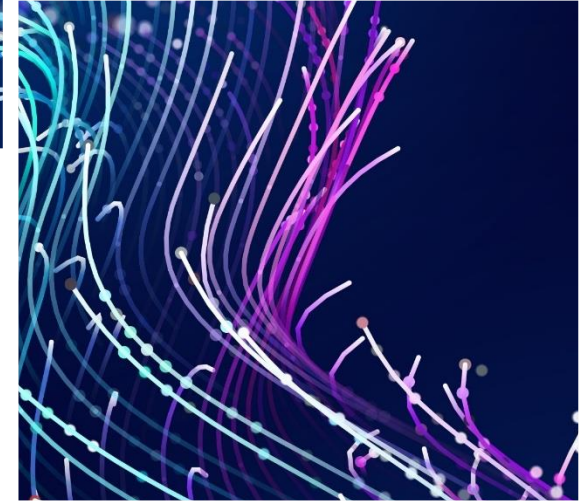
Achilleas Zaras

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eClinical Solutions

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PHUSE Connect EU 2024
10-13 November



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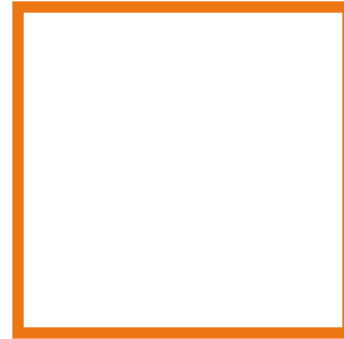
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Introduction: The Need for and Challenge of Automated Mapping

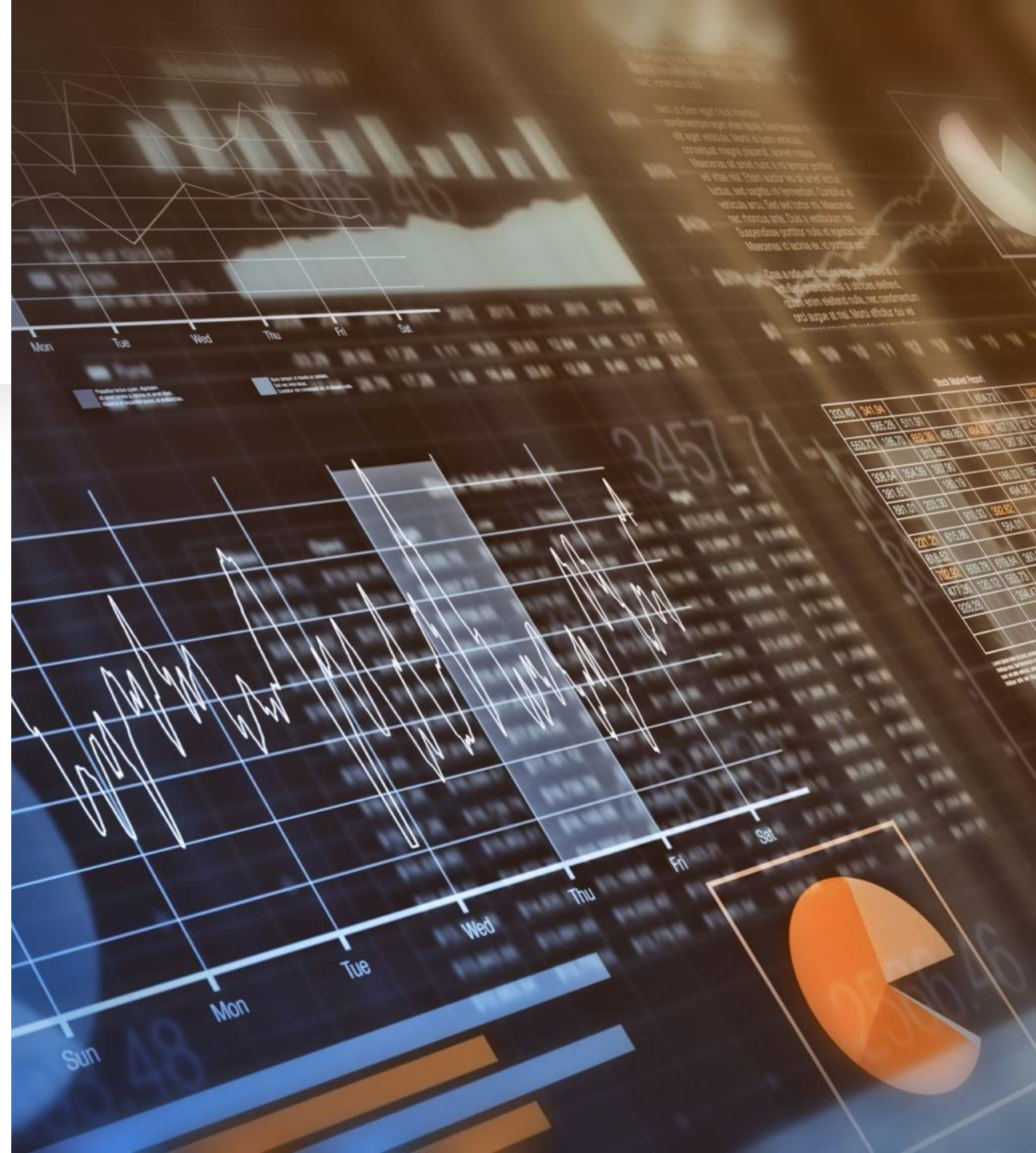


Journey Toward Automated SDTM Mapping

- Goal:
 - Fully automated SDTM mapping has been a longstanding aspiration for programmers and a major topic at PHUSE.
- Current Status:
 - Automation is increasingly seen as achievable, but key questions remain around how to make it documented, traceable, reproducible, and auditable.
- Current Process:
 - Relies heavily on standards experts and programmers to interpret SDTM guidelines and create specifications manually—a time-intensive and potentially inconsistent process.

The Drive for Automation

- **Why Automate?** AI and machine learning offer potential to automate repetitive, rule-based tasks.
- **Benefits:** Reduced cycle times, fewer manual interventions, and greater data consistency.
- **Impact:** Automation can accelerate clinical trials, shortening the path from data collection to analysis, submission, and patient benefit.



Challenges to Fully Automated SDTM Mapping



Complexity of Clinical Data

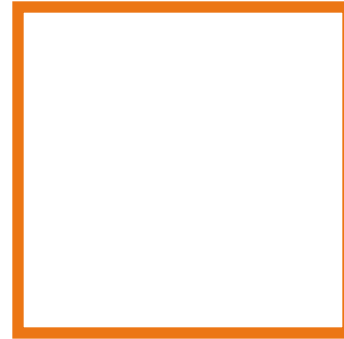
- **Variability:**
Clinical trial data often includes unique study-specific variables, non-standard data structures, and new digital health metrics.
- **Complexity:**
Interpreting diverse data accurately remains difficult, even for human experts, due to nuances in therapeutic and study areas.



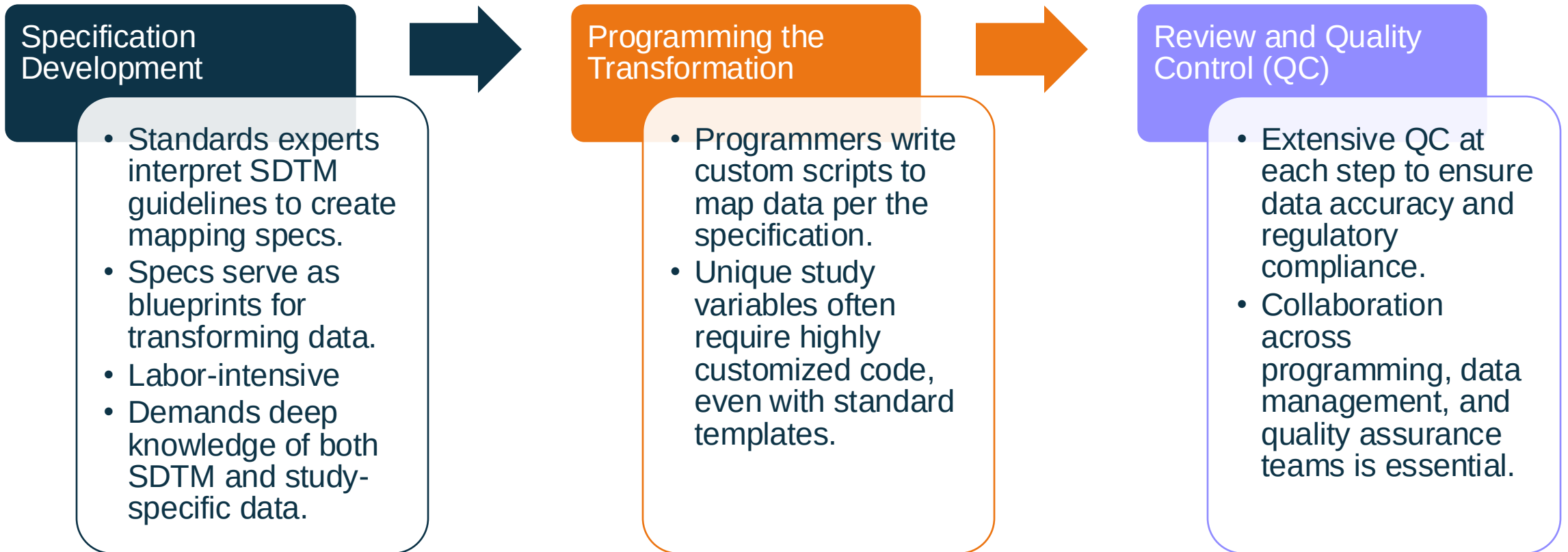
Trust in Automation

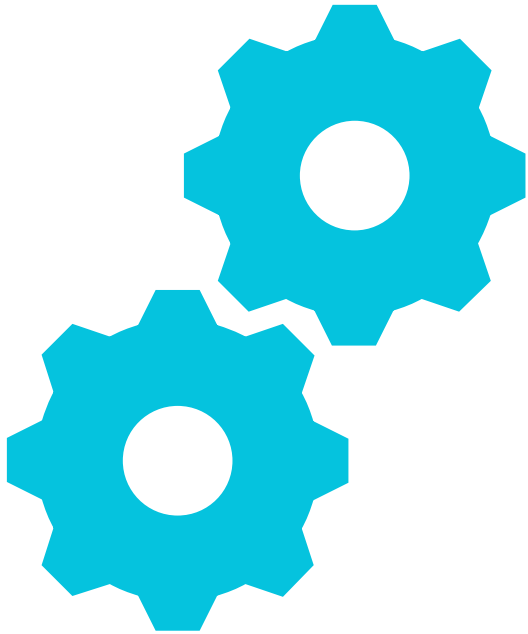
- **Transparency:**
AI models are often "black boxes," making it hard for users to understand decision-making.
- **Compliance:**
Without visibility, regulatory stakeholders hesitate to adopt automation, fearing errors or missed context.

Current State and Limitations of Automated Mapping



Traditional SDTM Mapping Process



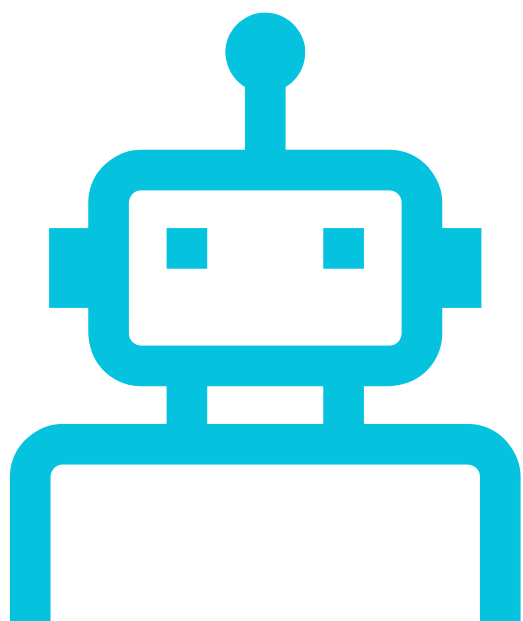


Limitations of Current Automated Approaches

- Partial Automation: Only Coding is Automated
 - Tools automate coding but still require manual, detailed specification creation.
 - Complex derivations often remain beyond the scope of automated coding tools.
- Increased Specification Complexity
 - Machine-readable specs need detailed technical logic, increasing time demands.
 - Risk of creating specifications that act as a "proxy programming language."
- Limited Flexibility
 - Systems struggle with unexpected data issues and require human adjustments.

Black Box Challenges

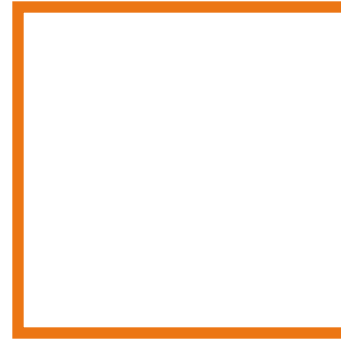
- Lack of Transparency
 - End-to-end automated solutions can become “black boxes,” hiding internal logic.
 - Limited visibility makes validation and traceability difficult.
- Traceability and Compliance Risks
 - Opaque systems hinder the creation of Define.XML and necessary audit trails.
 - Documentation of AI decisions is challenging, risking regulatory compliance.
- Erosion of Trust
 - Lack of decision-making clarity reduces user confidence, especially for complex mappings.



Need for a Balanced Approach

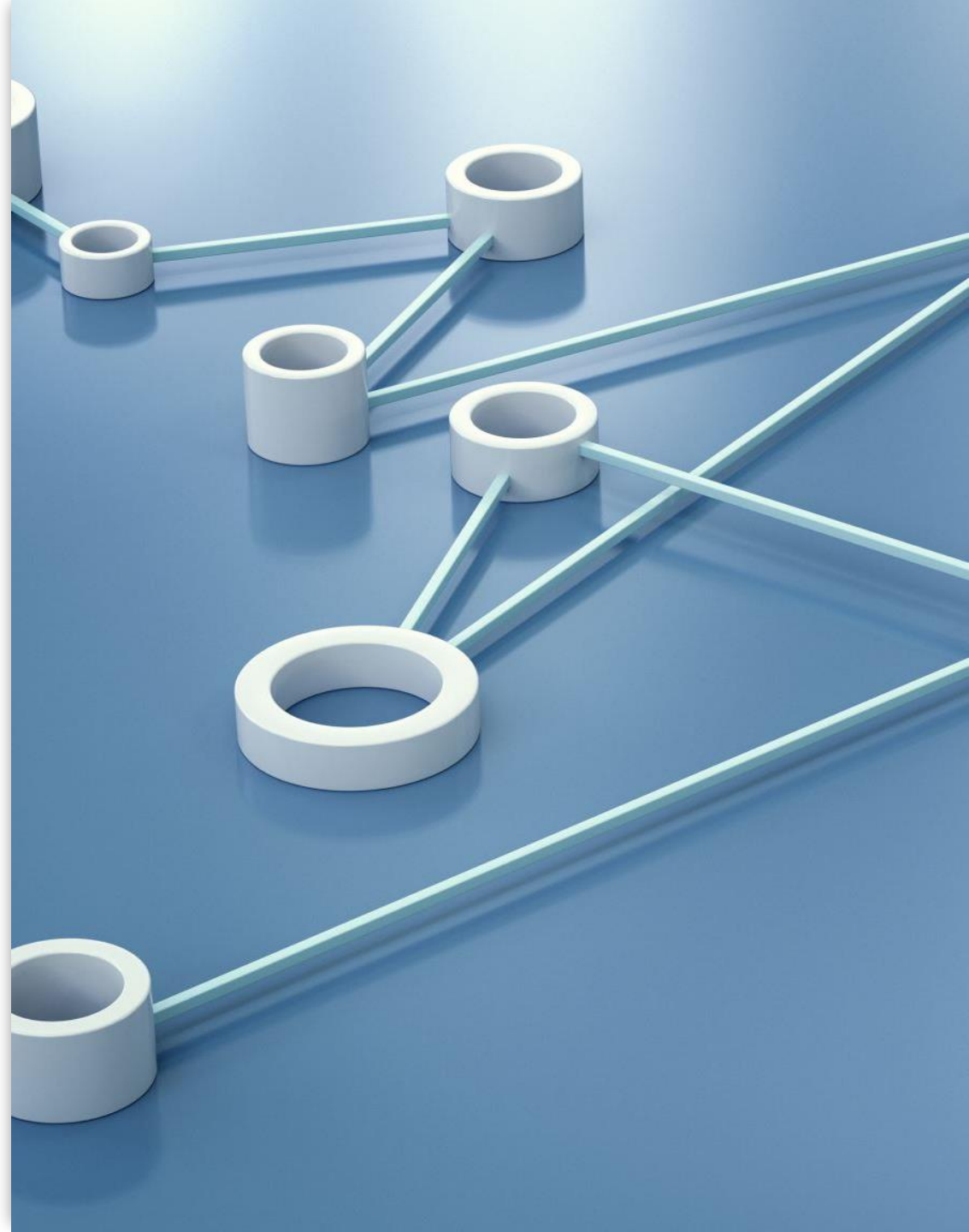
- Limitations in Current Automation
 - Partial automation only addresses programming, not specification burden.
 - Black box systems lack the transparency needed for compliance and trust.
- Human-Guided Automation Solution
 - Combining AI-driven efficiency with human oversight for transparent, adaptable mapping.

The Guided User Experience Approach



Human-in-the-Loop Design

- Balanced Control and Flexibility
- Contextual Interpretation and Real-Time Adjustments
- Adaptive Specifications





AI-Guided Experience

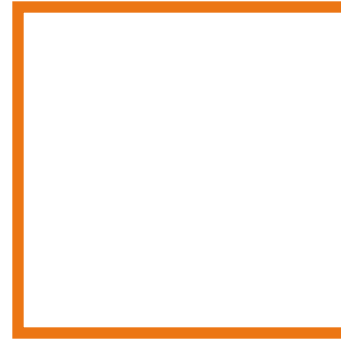
- Transparency and Decision Support
- Decision Support with Interactive Feedback
- Clear Validation Cues and Confidence Indicators
- Automated Traceability for Compliance

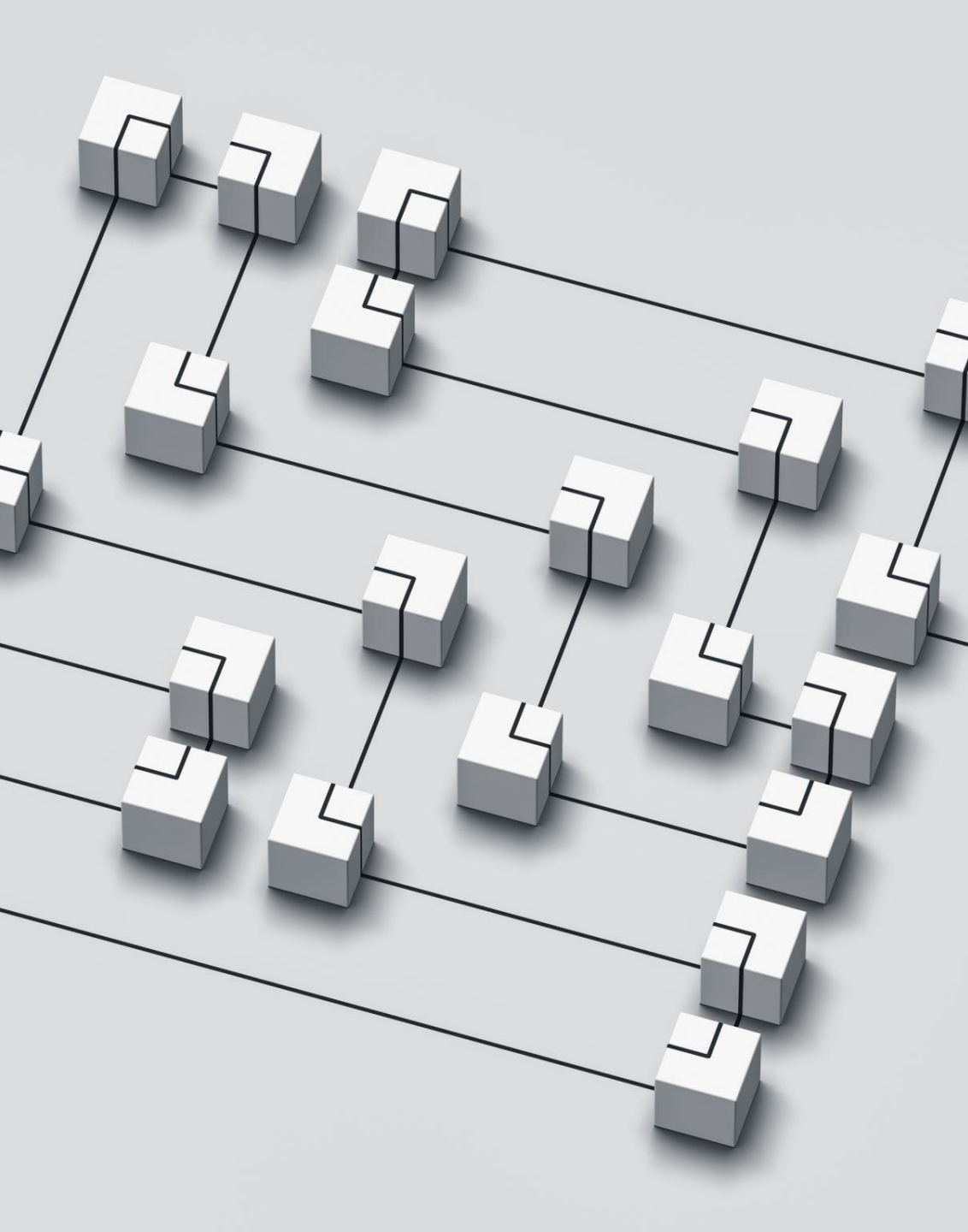


Balancing Automation with User Control

- Address Complexity and Build Trust
- Enhanced Transparency for Trust and Adoption
- User-centric Design to Increase Adoption
- Learning from Expert Input

Creating a Roadmap to Full Automation with Human-at-the-Helm AI





Incremental Steps Toward Automation

- Progressive Learning with Human Expertise
 - Guided user experience as a framework for incremental automation.
 - AI learns from user adjustments, building a stronger, more accurate model over time.
- Dynamic Feedback Loops
 - Real-time user feedback helps AI identify patterns and automate more edge cases.
 - Reduces human interventions progressively, moving closer to autonomous mapping.



Developing Transparent AI Capabilities

- Context-Aware Decision Making
 - AI develops contextual understanding, recognizing when additional human input is needed.
 - Expands AI's capability to handle a broader range of cases autonomously.
- Audit Trails and Documentation
 - AI generates audit trails based on user inputs and adjustments.
 - Ensures transparency and compliance for regulatory confidence.

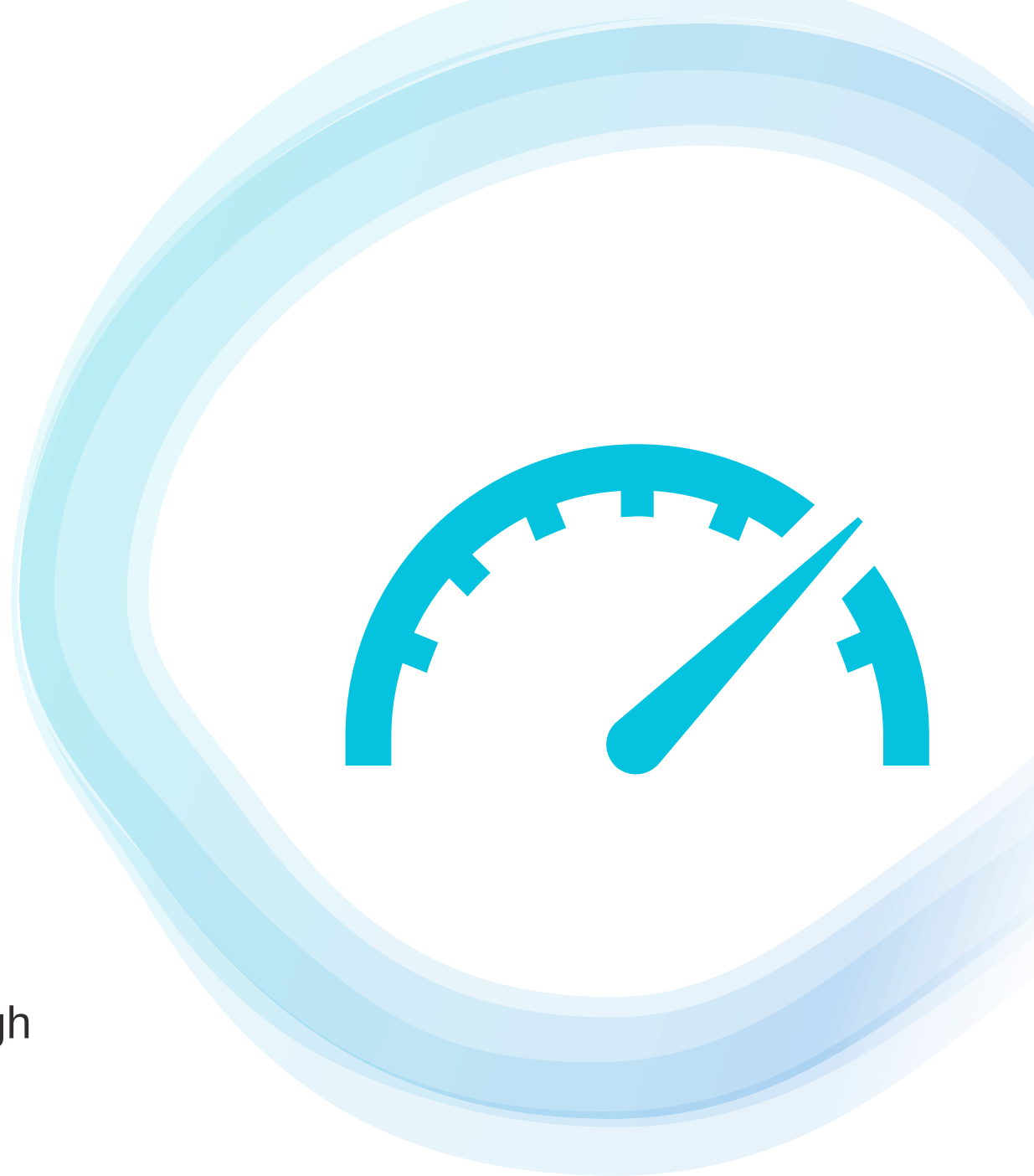
Targeted Automation for High-Impact Areas

- Prioritizing High-Frequency Mappings
 - Focuses on automating repetitive, high-burden mappings to maximize efficiency.
 - Frees experts to focus on novel or complex data elements.
- Expanding to New Data Types
 - Initial human oversight enables the system to adapt to new therapeutic areas.
 - Lays the foundation for future automation of emerging data standards.

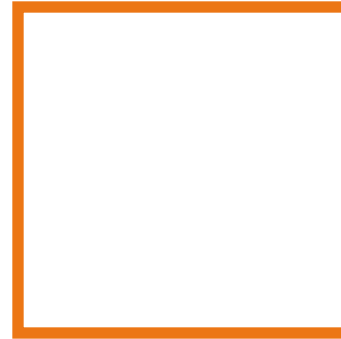


Long-Term Vision – Balanced Automation

- Higher Automation with Human Confidence
 - Automation of routine tasks while humans remain engaged in complex cases.
 - Balanced ecosystem for speed, accuracy, and adaptability.
- Users as System Supervisors
 - Human experts shift to supervisory roles, overseeing quality with minimal intervention.
 - Reduces cycle times while maintaining high data quality and compliance.



Case Study: Early Wireframes of a Guided User Experience



Domains

-  AE
-  CM
-  DD
-  DM
-  DS
-  MH
-  LB
-  QS
-  TA
-  TE
-  TI
-  TS
-  TV
-  VS

VS – Vital Signs

 Auto Map

	TARGET	TARGET LABEL	SOURCE	
1	STUDYID	Study Identifier		
2	DOMAIN	Domain Abbreviation		
3	USUBJID	Unique Subject Identifier		
4	VSSEQ	Sequence Number		
5	VSGRPID	Group ID		
6	VSSPID	Sponsor-Defined Identifier		
7	VSTESTCD	Vital Signs Test Short Name		
8	VSTEST	Vital Signs Test Name		
9	VSCAT	Category for Vital Signs		
10	VSSCAT	Subcategory for Vital Signs		
11	VSPOS	Vital Signs Position of Subject		
12	VSORRES	Result or Finding in Original Units		
13	VSORRESU	Original Units		
14	VSSTRESC	Character Result/Finding in Std Format		
15	VSSTRESN	Numeric Result/Finding in Standard Units		
16	VSSTRESU	Standard Units		
17	VSSTAT	Completion Status		
18	VSREASND	Reason Not Performed		
19	VSLOC	Location of Vital Signs Measurement		

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3	USUBJID	Unique Subject Identifier	RAW.VS1.STUDY RAW.VS1.SUBJECT	 100%
4	VSSEQ	Sequence Number	Derived	 100%
5	VSGRPID	Group ID	Not Mapped	 94%
6	VSSPID	Sponsor-Defined Identifier	RAW.VS1.RECORDID RAW.VS1.RECORDPOSITION	 92%
7	VSTESTCD	Vital Signs Test Short Name	RAW.VS1.VSSYSBP RAW.VS1.VSDIABP RAW.VS1.VSTEMP RAW.VS1.HEIGHT RAW.VS1.WEIGHT RAW.VS1.VSHR RAW.VS1.VSRR	 89%
8	VSTEST	Vital Signs Test Name	VSTESTCD	 98%
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12	VSORRES	Result or Finding in Original Units	RAW.VS1.VSSYSBP RAW.VS1.VSDIABP RAW.VS1.VSTEMP RAW.VS1.HEIGHT RAW.VS1.WEIGHT RAW.VS1.VSHR RAW.VS1.VSRR	 89%
13	VSORRESU	Original Units	mmHg' 'mmHg' RAW.VS1.VSTEMP_UN RAW.VS1.HEIGHT_UN RAW.VS1.WEIGHT_UN 'bpm' 'bpm'	 85%

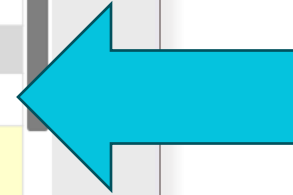
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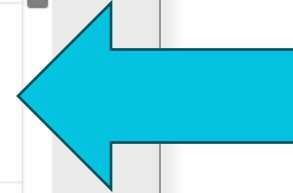
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Search

Standards

Controlled Terminology

Projects

Specifications

> Workflows

> Templates

> Rules

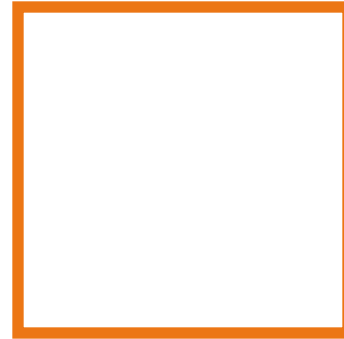
Workflows

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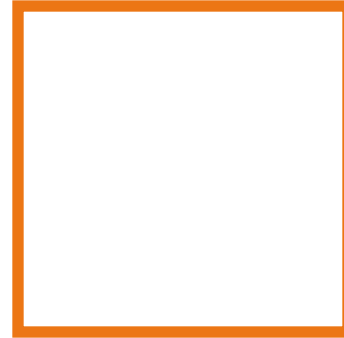
AE	Data Output 1		Method 1		Method 2					
STUDYID	DOMAIN	USUBJID	AESEQ	AESPD	AETERM	AELLT	AELLTCD	AEDECOD	AEPTCD	AEHLT
eCS-DS-003	AE	eCS-DS-003-10-101-002	1	AE1-7430-1	URINARY TRACT INFECTION ASY...	Urinary tract infection	10046571	Urinary tract infection	10046571	Urinary tract infections
eCS-DS-003	AE	eCS-DS-003-10-101-010	1	AE1-84276-1	ECTOPIC PREGNANCY	Ectopic pregnancy	10014166	Ectopic pregnancy	10014166	Maternal complications of pregn...
eCS-DS-003	AE	eCS-DS-003-10-101-024	1	AE1-156924-2	BACTERIURIA	Bacteriuria	10004056	Bacteriuria	10004056	Bacterial infections NEC
eCS-DS-003	AE	eCS-DS-003-10-101-024	2	AE1-84400-1	WORSENING OF ELEVATED LIVE...	Elevated liver enzymes	10014481	Hepatic enzyme increased	10060795	Liver function analyses
eCS-DS-003	AE	eCS-DS-003-10-101-024	3	AE1-156926-3	FATTY LIVER INFILTRATION	Fatty liver infiltration	10016263	Hepatic steatosis	10019708	Hepatocellular damage and hepa...
eCS-DS-003	AE	eCS-DS-003-10-101-029	1	AE1-85347-1	LEUKOCYTURIA	Leukocyturia	10050791	Leukocyturia	10050791	Urinary abnormalities
eCS-DS-003	AE	eCS-DS-003-10-101-033	1	AE1-169103-1	LEUKOCYTURIA	Leukocyturia	10050791	Leukocyturia	10050791	Urinary abnormalities
eCS-DS-003	AE	eCS-DS-003-10-101-036	1	AE1-256301-1	ELEVATED LIPASE	Lipase increased	10024574	Lipase increased	10024574	Digestive enzymes
eCS-DS-003	AE	eCS-DS-003-10-101-062	1	AE1-460843-1	URINARY TRACT INFECTION	Urinary tract infection	10046571	Urinary tract infection	10046571	Urinary tract infections
eCS-DS-003	AE	eCS-DS-003-10-104-003	1	AE1-83929-3	HEADACHE	Headache	10019211	Headache	10019211	Headaches NEC
eCS-DS-003	AE	eCS-DS-003-10-104-003	2	AE1-46441-1	ASYMPTOMATIC UTI	UTI	10046848	Urinary tract infection	10046571	Urinary tract infections
eCS-DS-003	AE	eCS-DS-003-10-104-009	1	AE1-156077-1	HEADACHE	Headache	10019211	Headache	10019211	Headaches NEC
eCS-DS-003	AE	eCS-DS-003-10-104-009	2	AE1-256121-4	WORSENING DIARRHEA-IBS REL...	Diarrhea predominant irritable bo...	10060845	Irritable bowel syndrome	10023003	Gastrointestinal spastic and hyp...
eCS-DS-003	AE	eCS-DS-003-10-104-009	3	AE1-157000-2	WORSENING DIARRHEA-IBS RE...	Diarrhea predominant irritable bo...	10060845	Irritable bowel syndrome	10023003	Gastrointestinal spastic and hyp...
eCS-DS-003	AE	eCS-DS-003-10-104-009	4	AE1-232254-3	WORSENING DIARRHEA-IBS REL...	Diarrhea predominant irritable bo...	10060845	Irritable bowel syndrome	10023003	Gastrointestinal spastic and hyp...
eCS-DS-003	AE	eCS-DS-003-10-104-015	1	AE1-284051-1	WORSENING DIARRHEA-IBS REL...	Diarrhea predominant irritable bo...	10060845	Irritable bowel syndrome	10023003	Gastrointestinal spastic and hyp...

**Conclusion:
Towards a Fully Automated,
User-Centric Future**

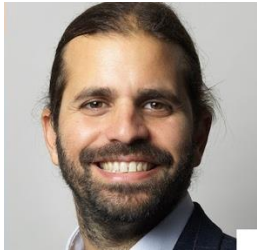




Q&A



Thank you



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