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Single Day Events

Trivandrum (Kerala), India

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AI/ML-Driven Automation of SDRG & ADRG Generation
Using a Human-in-the-Loop Framework
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Will Discuss About

- **Background**
  - SDRG & ADRG in the Define Package
- **The Problem**
  - Manual, Template-Driven, Inconsistent
- **The Opportunity**
  - AL/ML pipeline + Human-in-the-loop
- **Intelli Define Tool**
  - Automated generation of SDRG / ADRG
- **Benefit and Business Impact**
- **Questions**

Background

SDRG & ADRG in the Define Package

Background

- **SDRG and ADRG are key regulatory documents & submitted with Define package (SDTM & ADaM)**
  - Below details are submitted in SDRG/ADRG:

SDRG
(Study Data Reviewer's Guide)

- Accompanies SDTM datasets
- Protocol & study design summary
- Standards & versions implemented
- Data conformance (Pinnacle 21) summary
- Explains 'Not Submitted' aCRF fields

ADRG
(Analysis Data Reviewer's Guide)

- Accompanies ADaM datasets
- Analysis considerations & conventions
- Key derivation & imputation logic
- Traceability SDTM → ADaM → TLF
- Conformance & known issues.

The Problem

Manual, template-driven, Inconsistent

The Problem

- **Manual authoring is slow and inconsistent**
  - Reviewer guides are mostly assembled from information that already exists — in the protocol, the annotated CRF, the metadata and the validation reports. The bottleneck is human transcription.

Time-Intensive
Days to weeks per study, repeated across every submission and amendment.

Inconsistent
Manually copying legacy study templates caused inconsistencies in wording, structure, and completeness.

SDRG/ADRG

Re-Work
Late data refreshes and re-runs of conformance reports force repeated manual edits.

Error-prone
Manually transcribed metadata and P21 Validation reports increase the risk of inconsistencies with Define-XML.

The Opportunity

AL/ML pipeline + Human-in-the-loop

The Opportunity

- **Why AI/ML?**

Document Understanding
Modern NLP / LLMs parse protocols and aCRFs to extract titles, design, objectives and field annotations

ML Analysis
Machine Learning and Rule based models analyze structured metadata for datasets summaries

AI/ML

Repeatable & Consistency
Automation engine maps extracted insights to standardized templates, which results in consistency across studies

Repeatable & Auditable
Templates encodes regulatory structure once, the model fills them consistently across all studies

The Opportunity

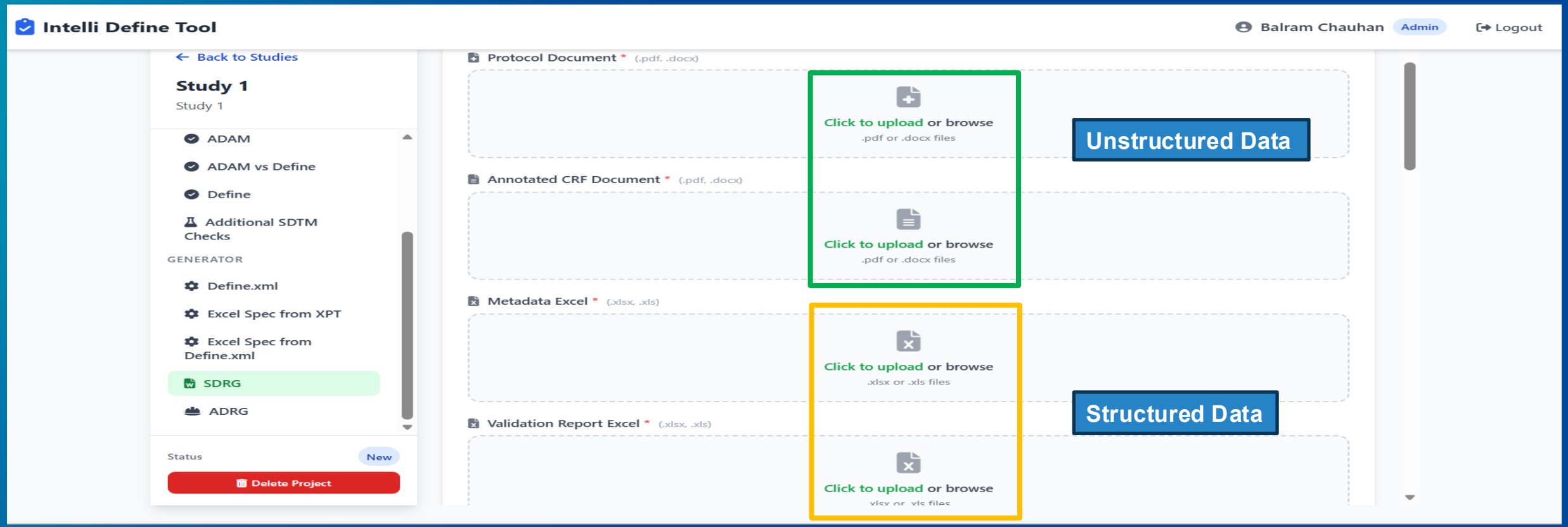
- **A human-in-the-loop generation framework**
  - Machines do the heavy lifting of extraction and drafting , subject matter experts reviews AI generated drafts to ensure accuracy and regulatory completeness.

Intelli Define Tool

Automated solution generation of SDRG/ADRG

Input

- Structured Sources : P21 Conformance Reports, Metadata
- Unstructured Sources: Study Protocol, Annotated CRF



Methods

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Sections are auto-populated:

Guide Section	Primary Source	Methods
Protocol title & study design	Study protocol	AI/ML Parsing
Standards & versions implemented	User Configuration Input	Positional placement
Data conformance summary	Conformance reports	Classification & Placement
Derivation descriptions (ADRG)	Specs / SAP notes	AI/ML Parsing & Summarization
'Not Submitted' CRF fields	Annotated CRF	Annotation rules with AI/ML Parsing
Dataset categorization & summarization	SDTM metadata + IG	Summarization

Document Editor

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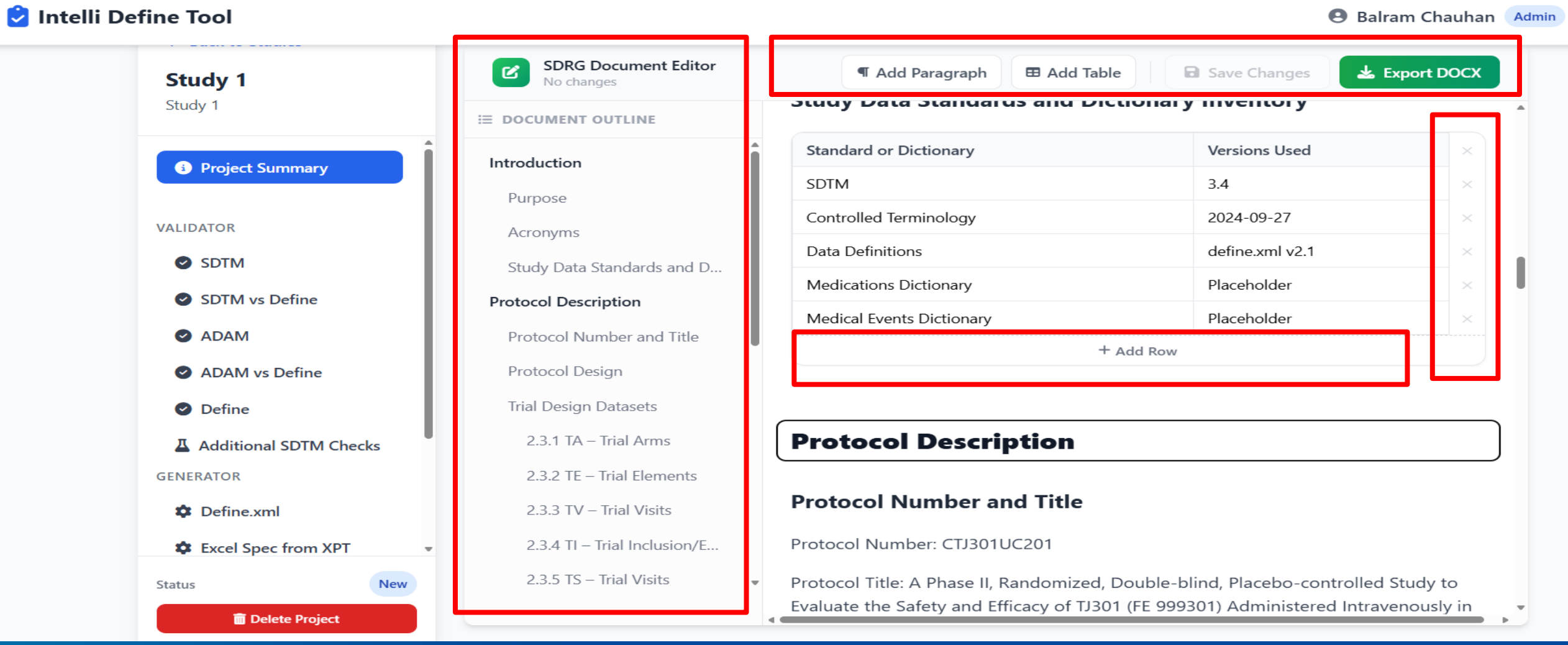

Benefits and Business Impact

Benefits

Increasing Organizational compliance over time

Efficiency Gains

AI/ML automation reduces time upto 70%

Enhanced Quality

Better Define.xml alignment lower regulatory risk, shorten review time, and improves inspection readiness

Benefits

Consistency

Standardized generation logic ensure consistent output across studies, minimizing variability from different authors

Audit Trails & Version Control

Every Validation reports and document generated link back to its results and Historical Navigation

Business Impact

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Faster, more Consistent Reviewer Guides

up to

70-85%

reduction in preparation time

for the SDRG / ADRG authoring cycle

Relative authoring effort (illustrative)

Consistency

Uniform structure and wording across studies.

Repeatability

Re-runs after data refresh in minutes, not days.

Traceability

Source-linked content speeds reviewer Q&A.

Questions & Discussion

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