

Meet the speaker

Michele Andrush brings more than 30 years of experience in the pharmaceutical industry, with deep expertise in data disclosure, project management, clinical data quality, and regulatory submissions. She specializes in delivering accurate, compliant, and timely clinical data and regulatory documentation while maintaining the highest ethical standards.

As an Associate Director and Project Manager, she has led complex, cross-functional initiatives, managed diverse stakeholder groups, and driven effective resolution of data and operational challenges. She thrives in dynamic environments, balancing strategic oversight with hands-on problem solving.

She is committed to continuous learning and professional growth and is passionate about advancing high-quality, transparent clinical research.



Meet the speaker

Anaya Rehman is a regulatory leader with more than a decade of experience spanning healthcare, academic research, and the pharmaceutical industry. As a medical doctor by training, she brings scientific depth and clinical insight to complex regulatory and transparency challenges.

At **Certara**, she provides strategic and technical leadership to the clinical trial transparency and disclosure team, advising global sponsors on compliance with evolving global clinical disclosure regulations. She is known for translating regulatory requirements into practical, risk-based strategies that enable both compliance, operational efficiency, and responsible integration of AI-enabled solutions.

Anaya is an avid speaker and thought leader in regulatory affairs, frequently presenting at industry conferences and professional forums on clinical trial transparency, disclosure strategy, and the evolving role of AI in regulatory innovation.





Harnessing AI to Streamline ClinicalTrials.gov PRS Submissions

PHUSE US Connect, 2026
Austin, Texas

Michele Andrush

Associate Director, Clinical Disclosure

Anaya Rehman, MBBS, MSc

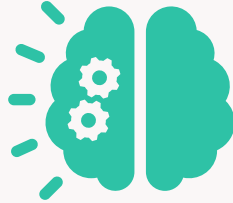
Senior Transparency Specialist

CERTARA 

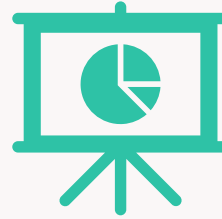
Agenda



Manual PRS
Process



AI-Driven Solution



The Wins and The
Challenges



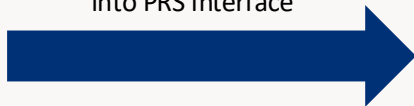
Future Outlook:
End-to-End
Transparency

Protocol Registration and Results System (PRS)



Study Protocol

Data manually extracted
from source documents
and manually entered
into PRS interface



ClinicalTrials.gov PRS Protocol Registration and Results System

* Organization's Unique Protocol ID: STUDY-12345

* Brief Title: New Updated E

[*] Acronym: (if any)

If specified, will

* § Official Title:

[*] Secondary IDs: (if any)

+ Add Secondary ID

Continue

Quit

* Require

* § Require

[*] Condition

* Brief Summary:

Detailed Description:

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

Arms:

* Arm Title:

Formerly Arm Label. Brief, descriptive label to be used as row or column heading in tables.

* Arm Type: --Select--

[*] Arm Description:

Describe the intervention(s) to be administered.
For drugs use generic name and include dosage form, dosage, frequency and duration.

Delete Arm

* Arm Title:

* Arm Type: --Select--

[*] Arm Description:

Delete Arm

* Record Verification Date: Month: September Year: 2025

* Overall Recruitment Status: --Select--

Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.

Tip: Day is not required for Anticipated dates.

* § Study Start Date: Month: --Select-- Day: Year: Type: --Select--

Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

* Primary Completion Date: Month: --Select-- Day: Year: Type: --Select--

Final data collection date for primary outcome measure.

* § Study Completion Date: Month: --Select-- Day: Year: Type: --Select--

Final data collection date for study.

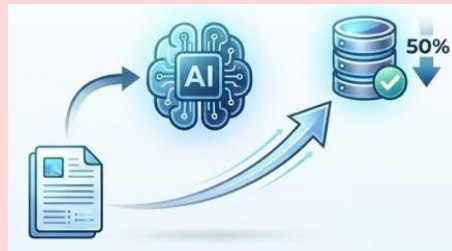
Objectives for automation

The Problem: Resource-Intensive



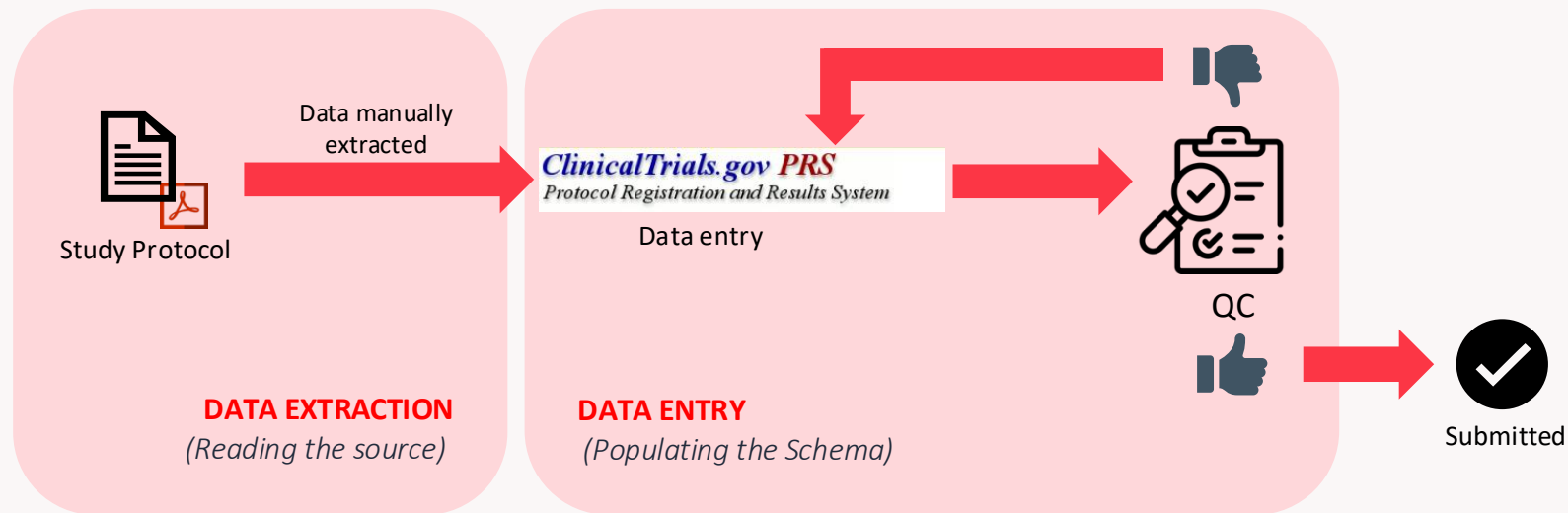
- High administrative burden leads to submission delays
- Risk of inconsistencies between the protocol and the registry

The Objective: AI-Driven Efficiency



- Leverage AI to automate the mechanical aspects of registration
- Target: Reduce manual effort while increasing data accuracy

The Solution: Splitting the Workflow



Intelligent Data Extraction



AI ingests
Clinical Study
Protocol and
statistical
Analysis Plan



User submits
unique, targeted
prompts for
specific data
extraction



AI parses the
document and
extracts specific
data points without
'hallucinating' new
content

Structured Data Entry



AI maps extracted text
to ClinicalTrials.gov
fields (e.g. Study
Design, Outcome
Measures)

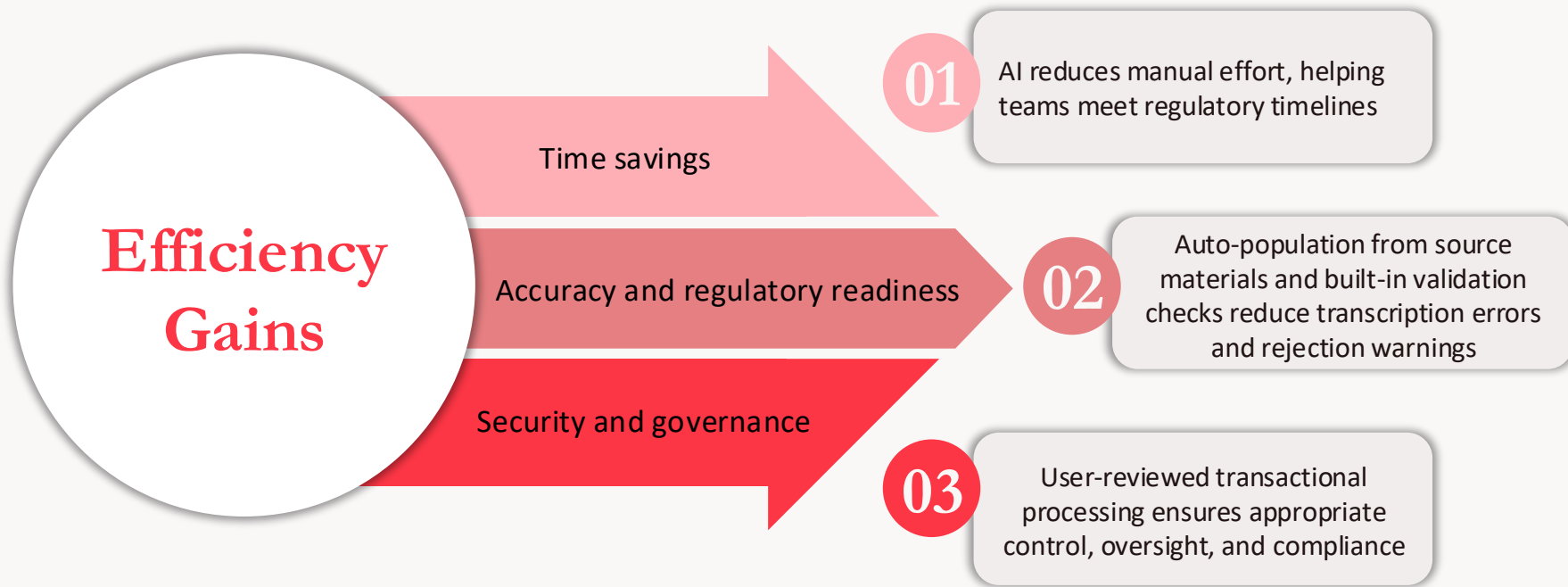


Schema
Compliance:
Ensures data fits
the formatting
rules of PRS



Validation

The Wins: Efficiency Gains



The Challenges: Lessons Learnt



CONSISTENCY

Minor inconsistencies in
AI outputs required
prompt refinement



HUMAN-IN-THE-LOOP

Automation is not
Autopilot! Expert review
still required as a
validation layer



COMPLEX DESIGNS

AI may struggle with
highly complex trial
designs

Our Vision: End-to-End Transparency



SPLIT PROCESS

Process split into data extraction and structured data entry



AI-AUGMENTED WORKFLOW

Successfully shifted from a manual to an AI-augmented workflow



MEASURABLE GAINS

Efficiency gains in cost, quality, and delivery rate measurable



NEXT STEPS: BROADER IMPLEMENTATION

- Expand AI from protocol registration to results postings
- Connect registration and results workflows for speed, quality, and reuse across registries

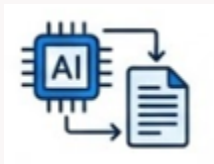
Key Takeaways

Future-proofing your PRS workflow



Audit your data silos

Digitize protocol data stored in non-searchable PDFs



Structure AI for PRS

Map protocol data directly to required PRS data points



Human-in-the-Loop Validation

AI to draft, but teams for accuracy before submission



Start small

Pilot AI-augmented workflow on one study

Thank you

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Let's continue the conversation...

Michele Andrush

Associate Director, Clinical Disclosure
michele.andrush@certara.com

Anaya Rehman, MBBS, MSc

Senior Transparency Specialist
anaya.rehman@certara.com