



Strategic Authoring in Clinical Study Reports to Leverage AI for Data Privacy and Public Disclosure

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Anaya Rehman, MBBS, MSc
Senior Transparency Specialist



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The presenter does not have any conflict of interest.



Agenda



Clinical data
privacy and public
disclosure



AI clinical
data
protection



SMART
authoring

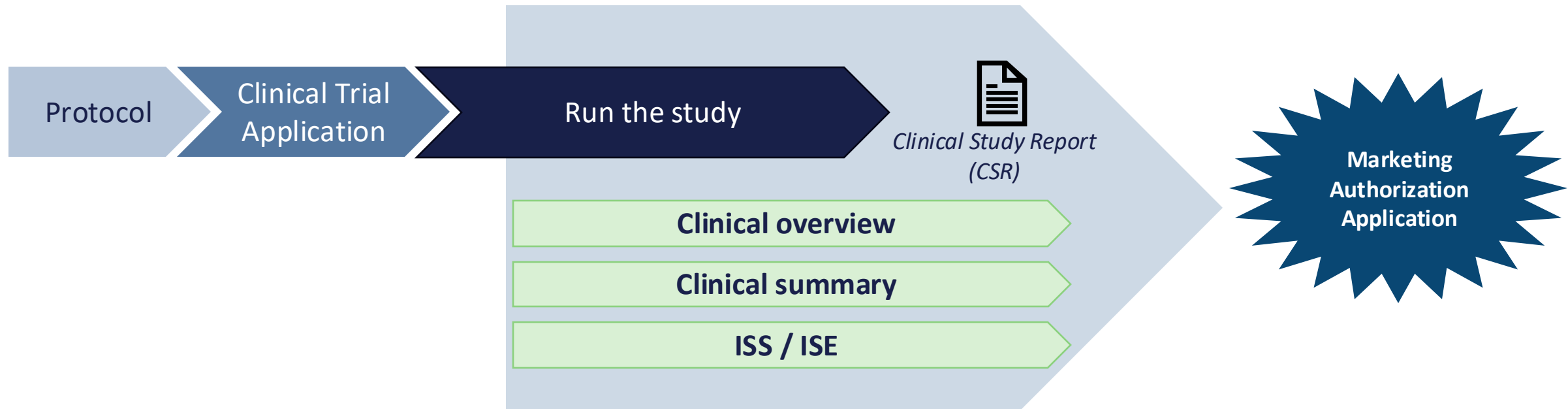


Real-world
examples

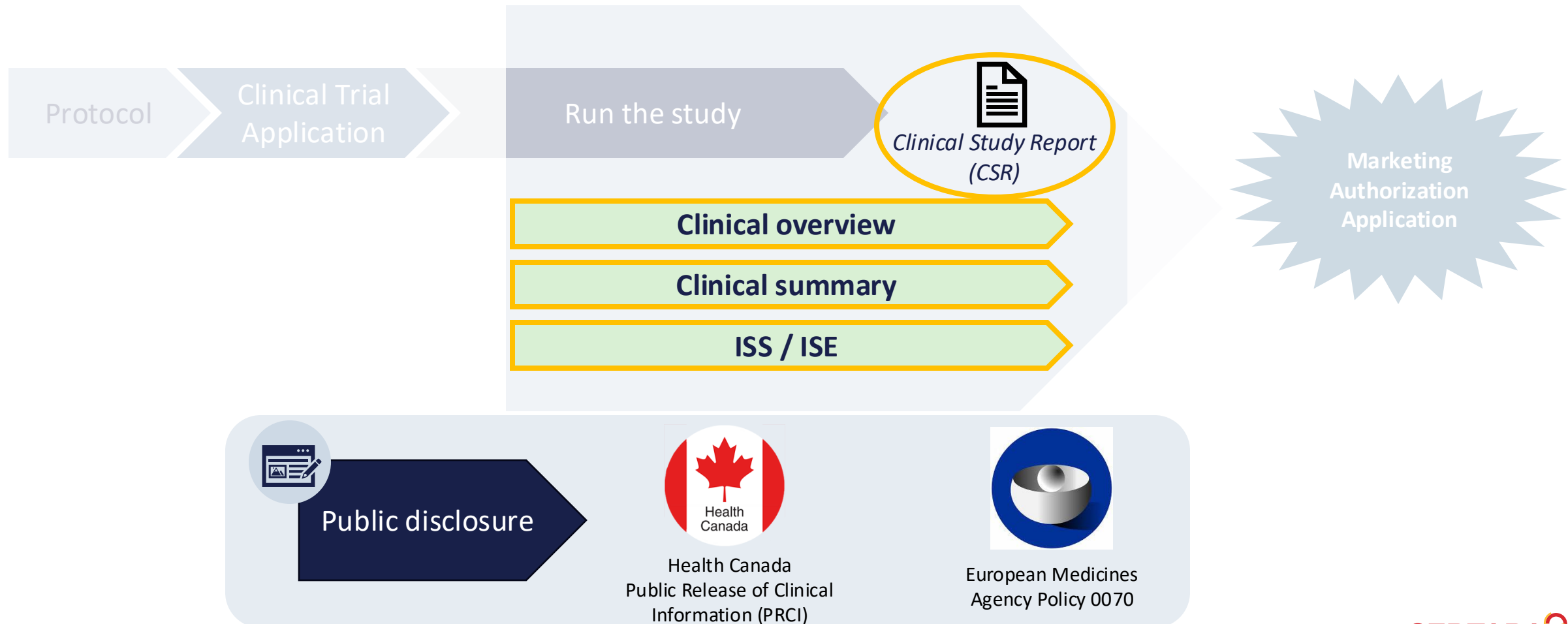
Drug development life cycle



Drug development life cycle



Drug development life cycle



Personal Information to be protected

Information about an identifiable individual that is recorded in any form

Direct identifiers	
	Name
	Subject ID
	Signature
	Social security number

Indirect identifiers	
	Gender
	Participant-related dates
	Race
	Geographical location

Study Number: CT123-003

Subject Number: 5076249

SAE: Type 1 Diabetes mellitus inadequate control

Reason for withdrawal from study drug: Adverse event

Subject 003-5076249 experienced an adverse event of Unstable Type II diabetes mellitus (Preferred Term: Type II Diabetes mellitus inadequate control) and withdrew from study CT123-003: An Open Label Phase 2 Trial to Evaluate the Safety of DTI234 Administered Intravenously in Patients with Congestive Heart Failure.

On 29 Nov 2017, subject 5076249, a 33 year-old Caucasian not Hispanic or Latino female was consented and on 12Dec2017 (Day 0) received study drug intravenously (100 mL) with a start time of 10:15 and stop time of 10:45, on 8-Mar-2018 (Week 12) received study drug intravenously (100 mL) with a start time of 11:20 and stop time of 11:50, on 23rdAug2018 (Week 36) received study drug intravenously (100 mL) with a start time of 10:24 and stop time of 10:54, and on 02May2018 (Week 72) received study drug intravenously (100 mL) with a start time of 08:40 and stop time of 09:10, before withdrawing from study drug administration due to an Adverse event of Type II Diabetes mellitus inadequate control.

The serious adverse event of Unstable type II diabetes mellitus was a worsening of a prior medical condition. The subject's medical history included: chronic migraines, depression, ankle fracture (2011), obesity, fatty liver, diabetes.

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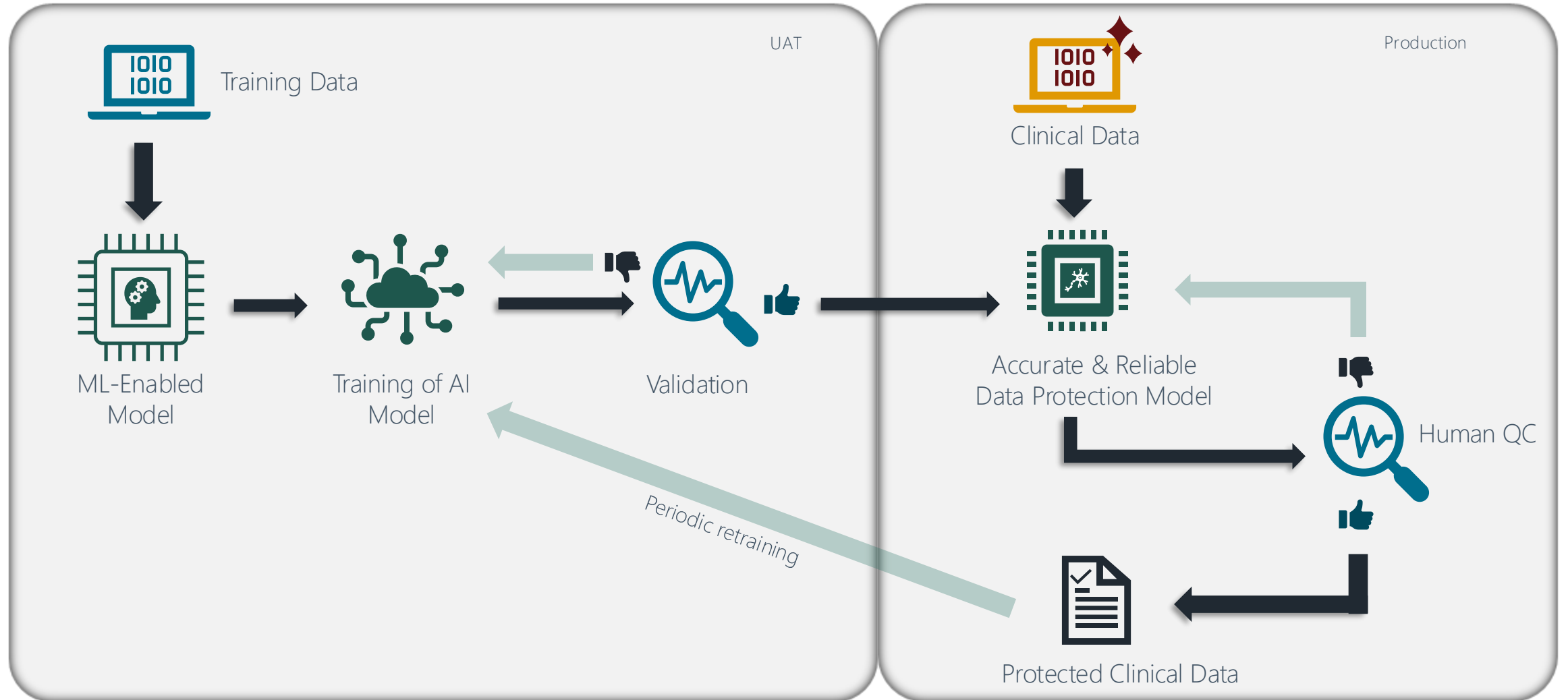
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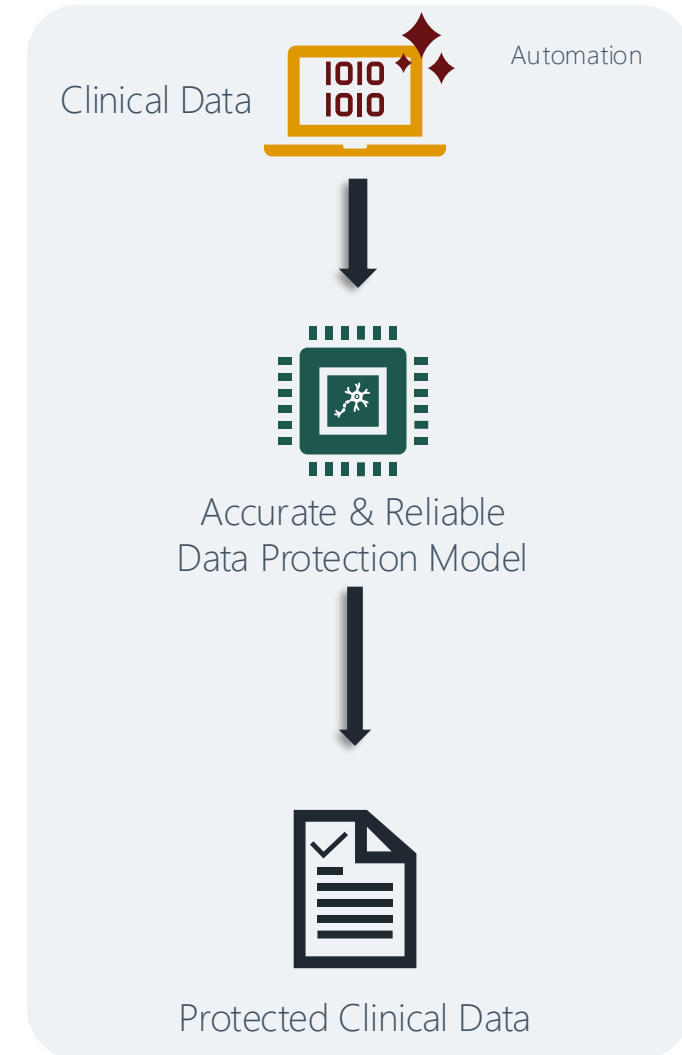
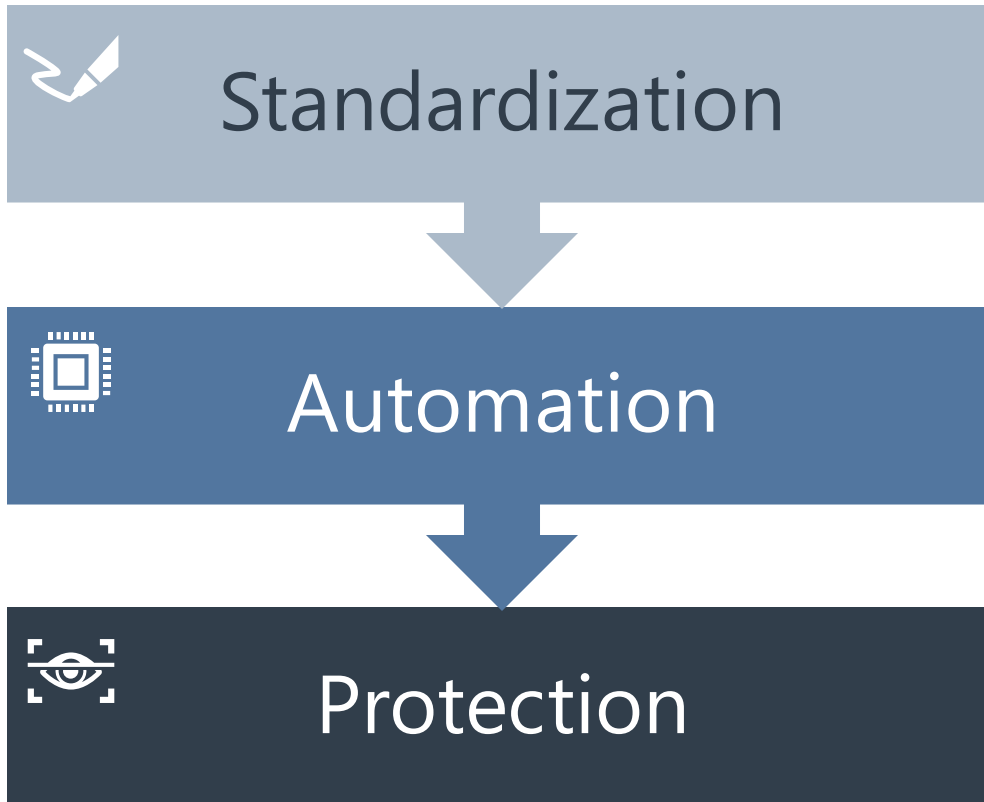
AI Data Protection

ML in the context of Clinical Data Protection



AI Data Protection

Focus on efficient protection of personal information



Clinical Data Protection

CHALLENGE

Variability in personal identifiers complicates protection efforts, increasing risks of data compromise and regulatory non-compliance.

Ensuring robust data security is critical, as a single breach can expose millions of patients.

CERTARA SOLUTION

Disclosure friendly authoring – SMART approach



IMPACT

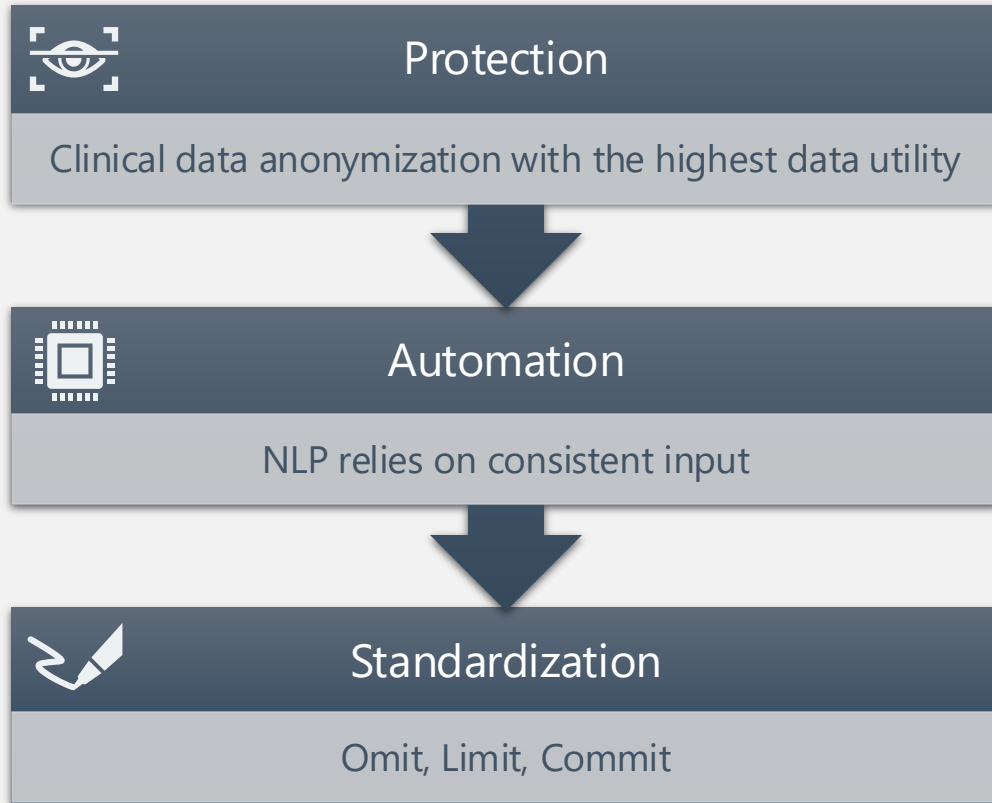
- Robust protection of data privacy
- Consistent process
- Increased regulatory compliance

Safeguard patient data to avoid penalties, legal action, and reputational damage!

Strategic Medical Authoring for Regulatory Transparency (SMART)

Focus on efficient protection of personal information

Public disclosure of clinical documents



Subject IDs

Used to identify individuals within the study

Approach:

OMIT

LIMIT

COMMIT

Standardized format:

[study ID]-[site ID]-[subject ID]

Study Number: CT123-003

Subject Numbers **5076249**

SAE: Type I Diabetes mellitus inadequate control

Reason for withdrawal from study drug: Adverse event

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Dates

Subject related dates within the study

Approach:

OMIT

LIMIT

COMMIT

Standardized format:
ddMMMyyyy

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Demographics

Subject related dates within the study

Approach:

OMIT

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Standardized format:

33yo vs 33-year-old vs age of 33

Study Number: CT123-003

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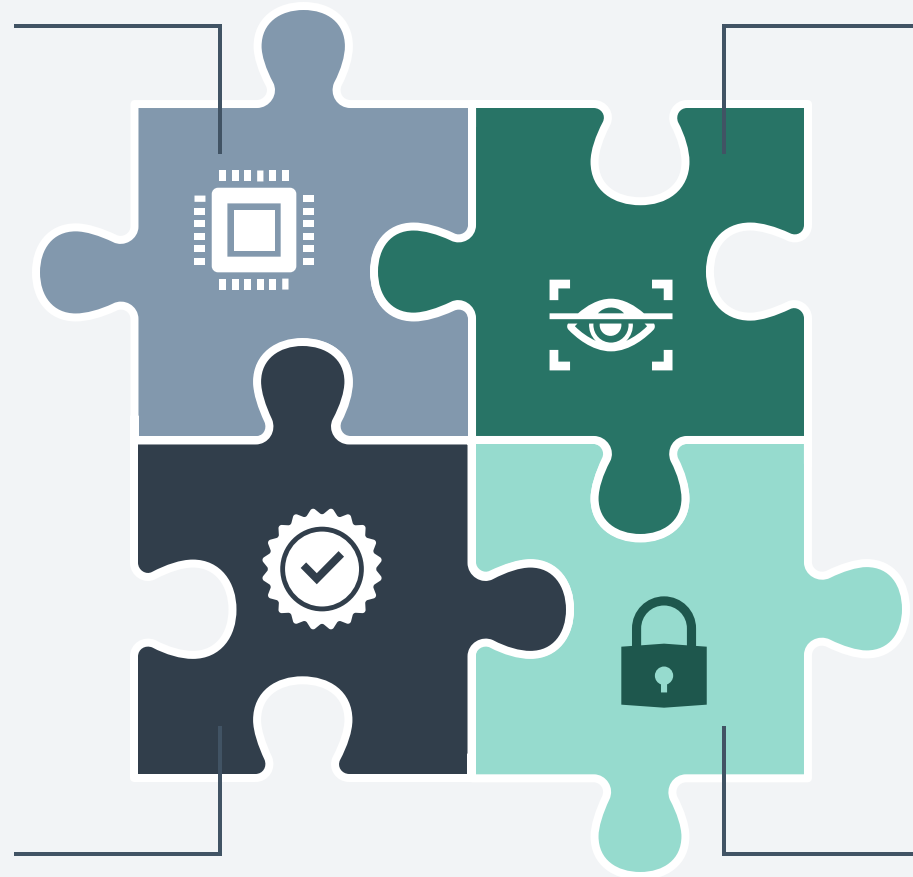
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SMART ensures transparency while protecting patient privacy!

Strategic medical
authoring allows us to
leverage AI tools

Efficient, consistent
anonymization



Regulatory compliance
and faster approvals

Robust data
protection with
enhanced data utility



Thank you

Anaya Rehman, MBBS, MSc
Senior Transparency Specialist

anaya.rehman@certara.com

