Authoring Clinical Documents with Public Disclosure in Mind

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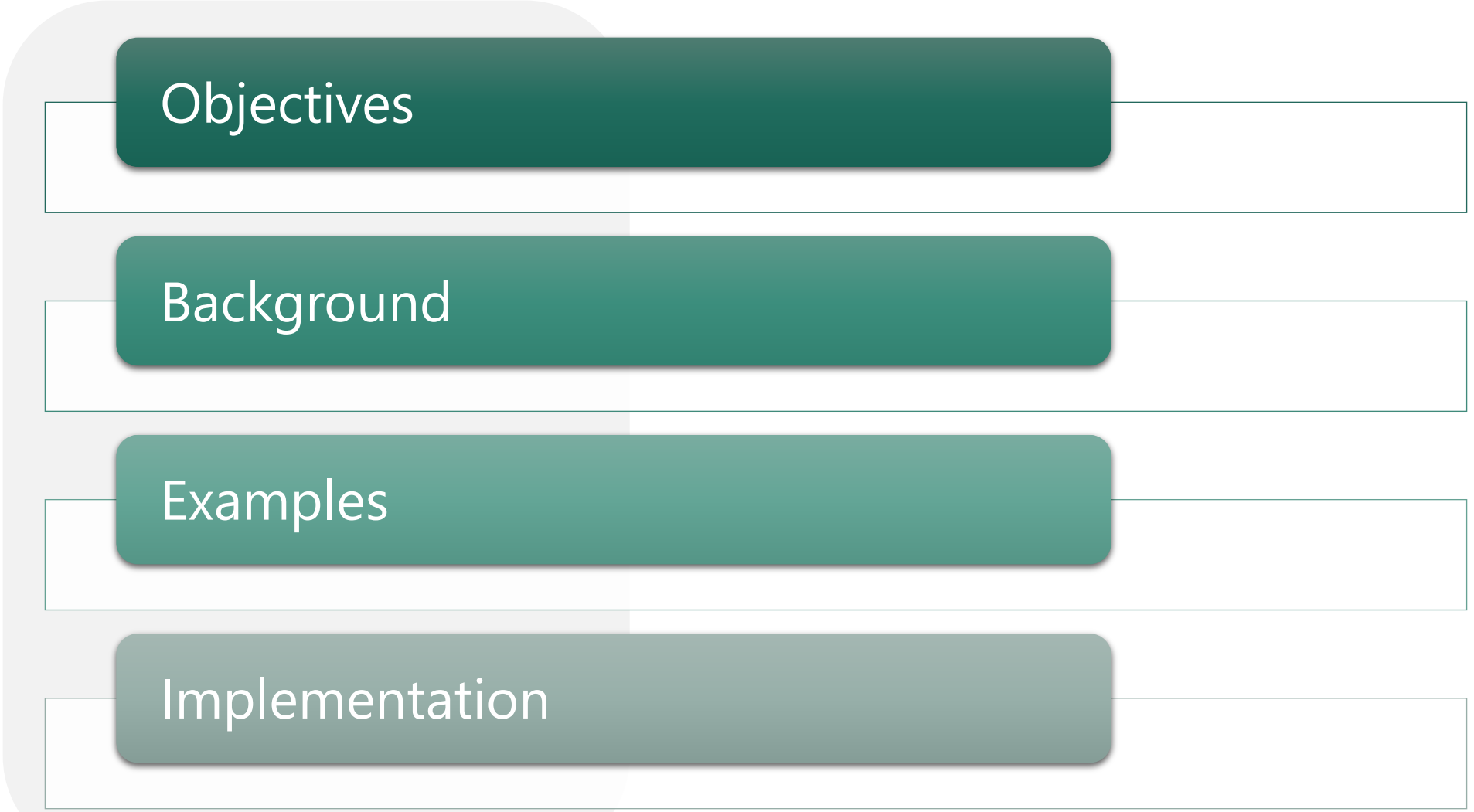
Senior Transparency Specialist

AUGUST 29TH, 2024

Agenda

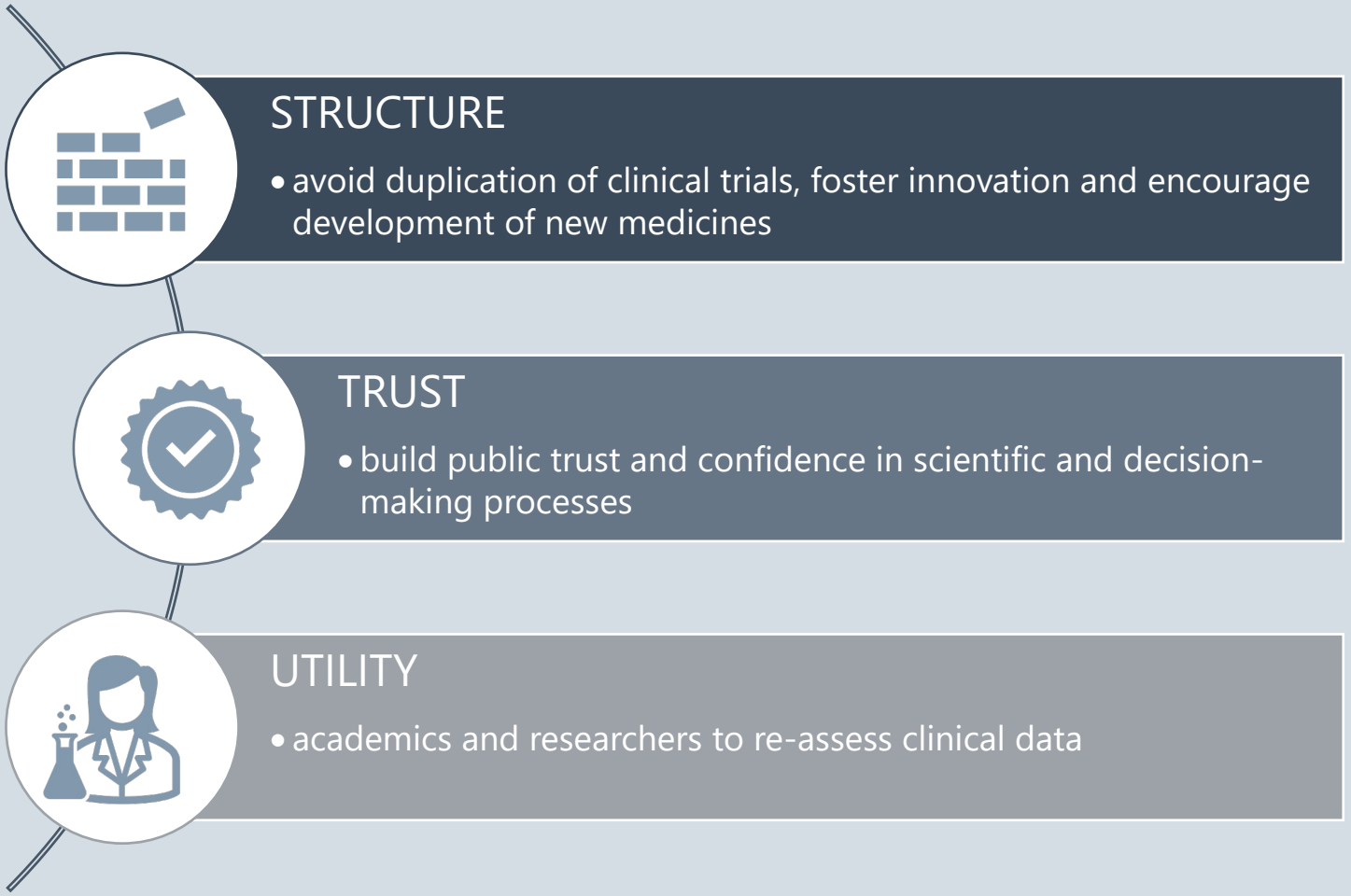


Objective

Proactive DISCLOSURE WITHOUT EXPOSURE

Clinical data to support pharmaceutical application for human medicines is submitted to regulatory publications for public disclosure.

- Personal data must be protected
- Submission must comply with regulations
- Emphasis should be on transparency



Streamlining Clinical Privacy

INDUSTRY CHALLENGE

Publishing of clinical data is bottle-necked at the data protection stage.

SOLUTION

- Move towards a data protection model that **proactive** and begins at the clinical authoring stage

OLD STRATEGY
•Reactive / Retroactive Model

NEW STRATEGY
•Proactive integration of data Protection

IMPACT

- A data protection model that is more:
  - *Accurate*
  - *Consistent*
  - *Efficient*

Protect your data against de-anonymization and re-identification.

Amount of Clinical Data

From a single COVID-19 vaccine development

- 25 identifiers per individual
- At least 1,000,000 data points per study
- Over 30,000,000 data points across studies

Studies published:

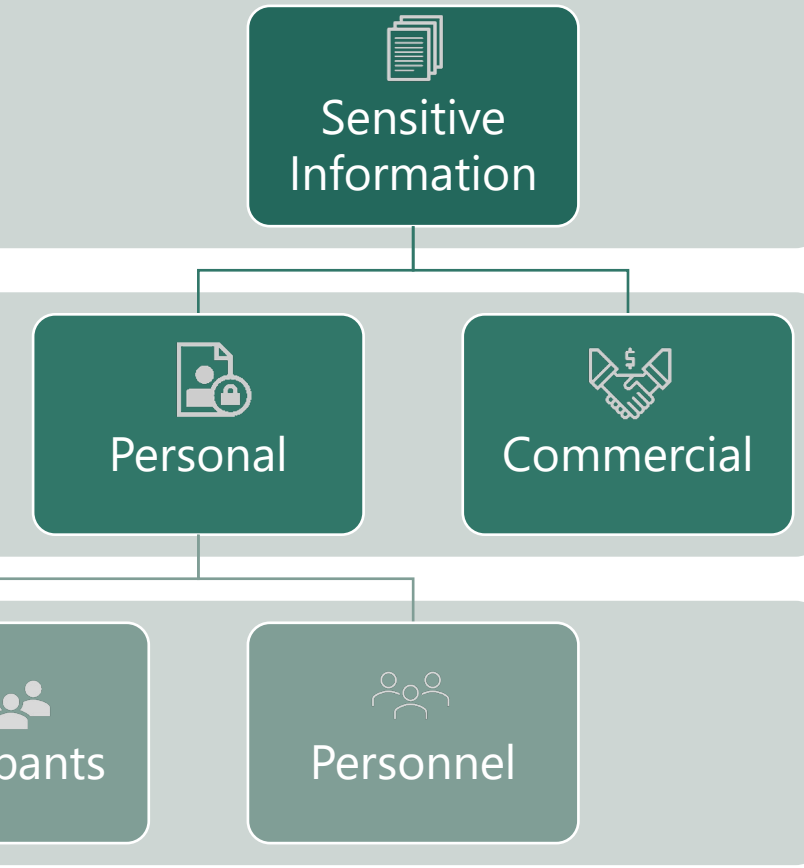
- Over 2 years
- 31 studies published

Participants

- ~40,000 participants
- ~26 documents

Data

- Demographics, names & addresses, contact info, medical history, adverse events, dates



Variability of Clinical Data

August 1st, 2023

Variability of Clinical Data

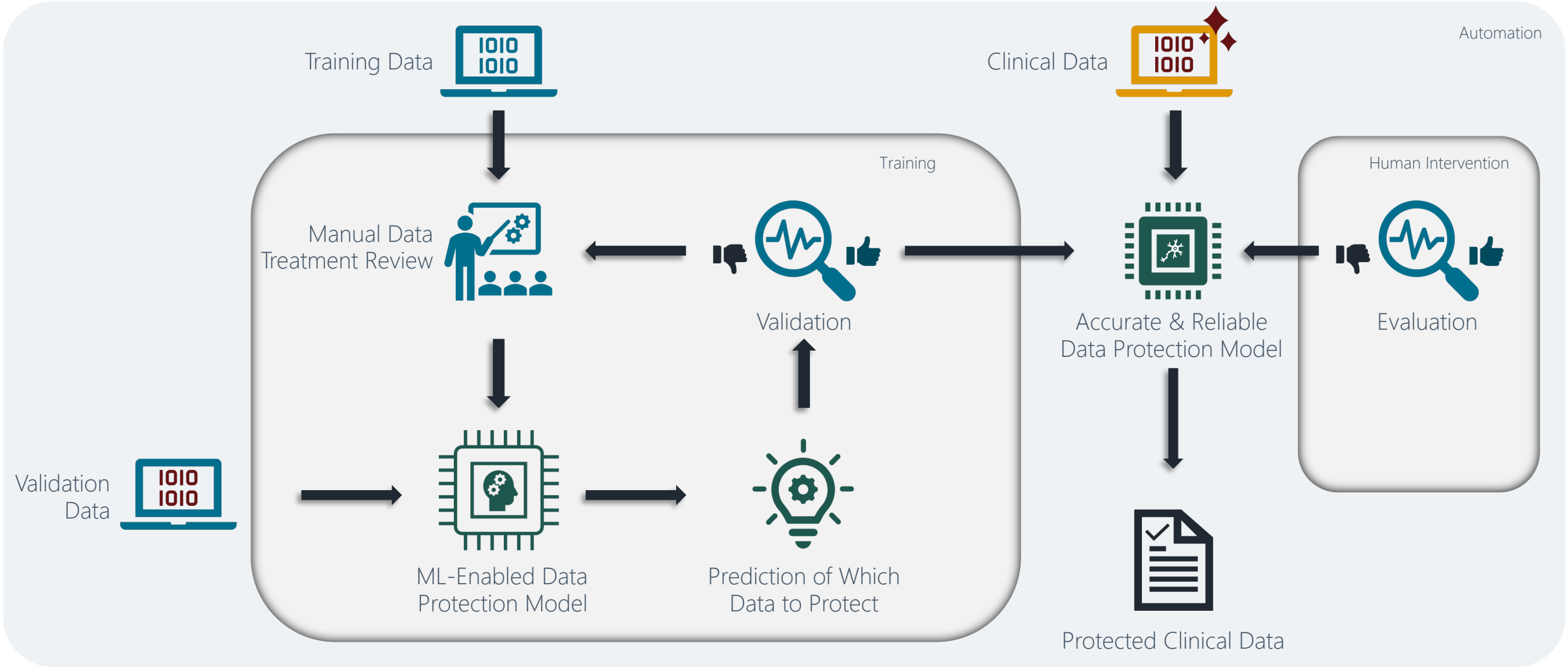
August 1st, 2023

Date	Day (01 to 1)	Month (08 to 8)	Month (Aug to August)	Year (2023 to 23)
•ddMMMyyyy (01AUG2023) •dd-mmm-yyyy (01-aug-2023) •dd-mm-yyyy (01-08-2023) •dd/MM/yyyy (01/08/2023) •MM-dd-yyyy (08-01-2023) •MM/dd/yyyy (08/01/2023) •1st of Aug •First of the month (ie dosing or sample dates) •"New years eve"	•dMMMyyyy (1AUG2023) •d-mmm-yyyy (1-aug-2023) •d-mm-yyyy (1-08-2023) •d/MM/yyyy (1/08/2023) •MM-d-yyyy (08-1-2023) •MM/d/yyyy (08/1/2023)	•d-M-yyyy (1-8-2023) •d/M/yyyy (1/8/2023) •M-d-yyyy (8-1-2023) •M/d/yyyy (8/1/2023) •dd-MM-yyyy (01-8-2023) •dd/M/yyyy (01/8/2023) •M-dd-yyyy (8-01-2023) •M/dd/yyyy (8/01/2023)	•ddMMMyyyy (01AUGUST2023) •dMMMyyyy (1AUGUST2023) •1st of August •August 1st	•20+ more variations

False Negative	False Positive	Error
•Missed data •New format, untrained software etc.	•Incorrectly identified data •Overtraining & noise •**Jan-24-0123** (hypothetical Janssen study from 2024) could be identified as a date.	•Mismanaged data •08-01-23 •*dd-mm-yy* or *mm-dd-yy* or *yy-mm-dd* ?

AI Data Protection

ML in the context of Clinical Data Protection



CERTARA

Typical Clinical Document

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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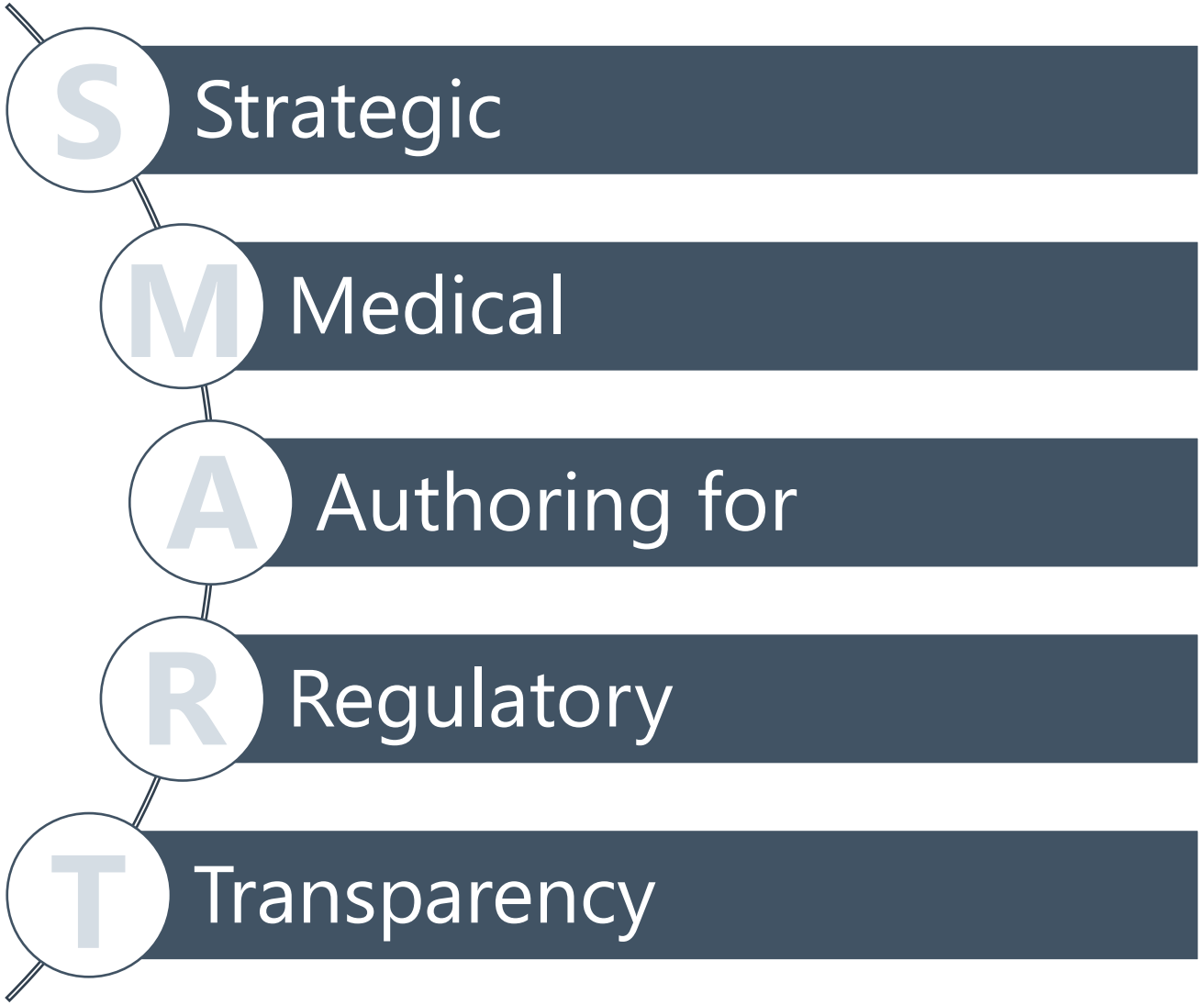
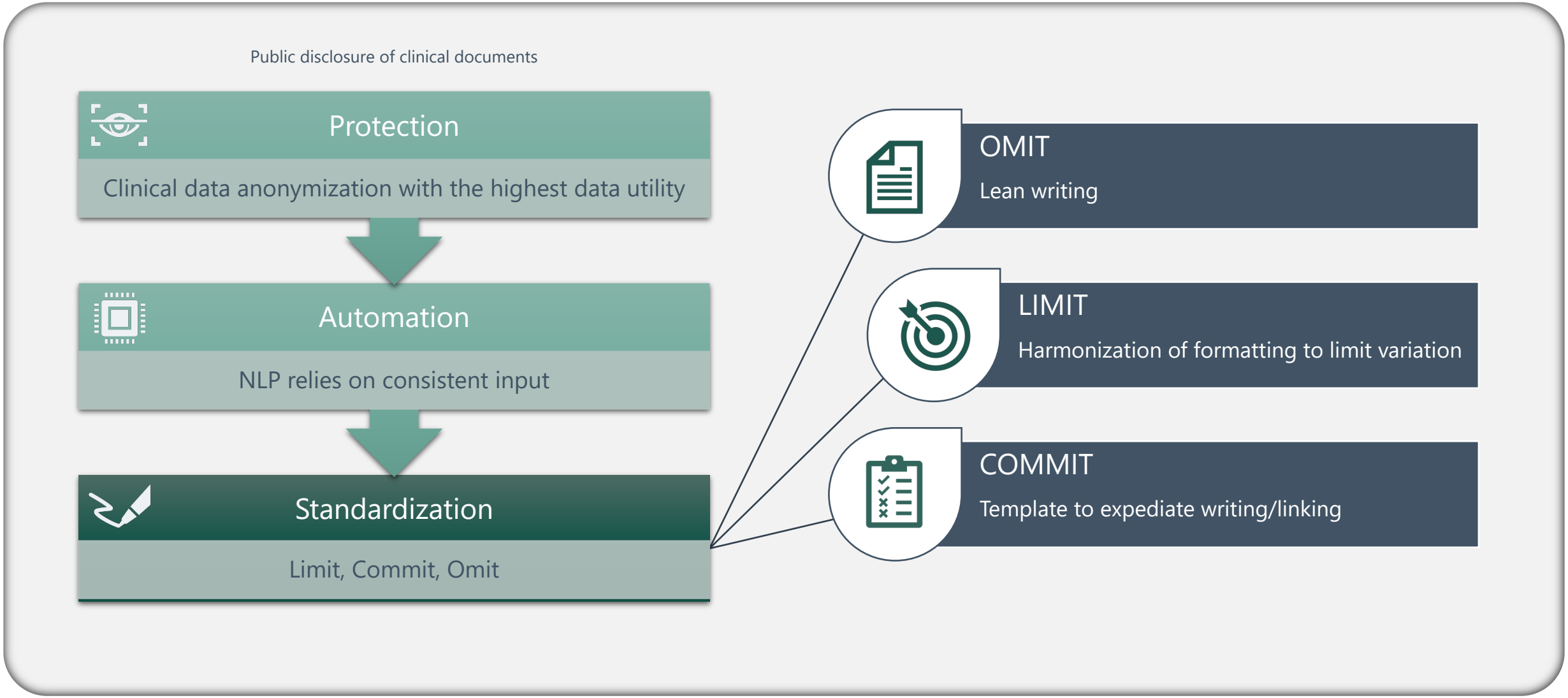
SMART Approach

SMART approach emphasizes on data protection from the inception of the drug development process, significantly improving the accuracy, consistency, and the speed at which clinical trial documents are anonymized.



SMART Approach

Focus on efficient protection of personal & commercial information



CERTARA

Subject ID

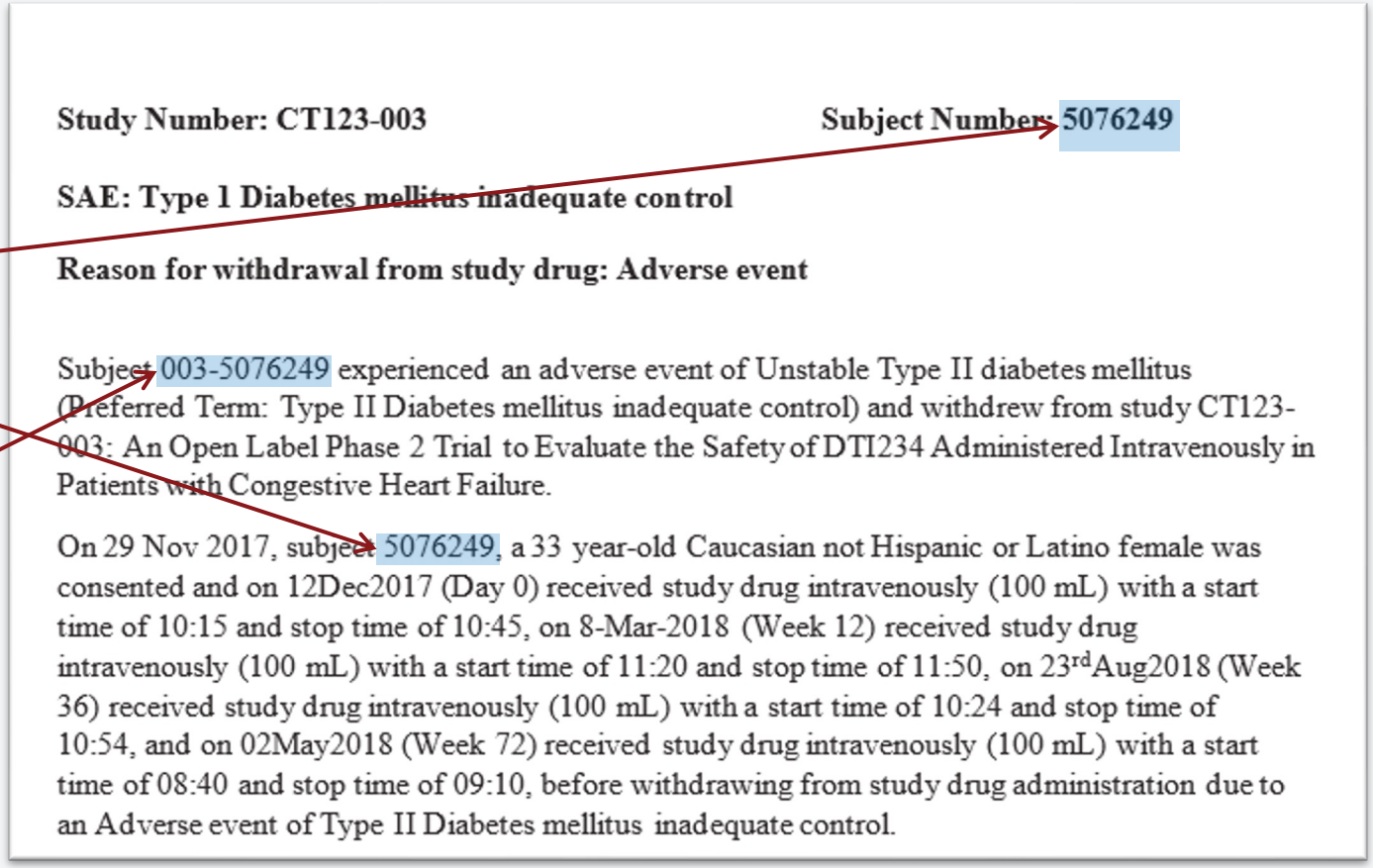
Used to identify individuals within the study

Approach:

OMIT

LIMIT

COMMIT



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Standardized format:
[study ID]-[site ID]-[subject ID]

Subject ID

Used to identify individuals within the study

Standardization

- Harmonization of formatting to limit variation
- Template to expediate writing/linking

Automation

- AI relies on consistent input
- Focus on future of technology and modernization of clinical research

Protection

- Focus on maintaining high standard of patient privacy
- Most common direct identifier

OMIT

unnecessary details

- Do not include patient name/ID/initials
- Only use "*subject*" and not "*participant*" or "*patient*"

LIMIT

appearance within the text

- Do not include in sections other than narratives
- Only include once

COMMIT

to harmonization of text

- Use standardized format: [study ID]-[site ID]-[subject ID]

CERTARA

Dates

Subject related dates within the study

Approach:

OMIT

LIMIT

COMMIT

Standardized format:
ddMMMyyyy

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Dates

Subject related dates

Standardization

- Harmonization of formatting to limit variation
- Template to expediate writing/linking

Automation

- AI relies on high quality input
- Focus on future of technology and optimization of current processes

Protection

- Focus on maintaining high standard of patient privacy
- Dates can be knowable

OMIT

atypical formats

- Do not include references to known dates of significance e.g. public holidays, Christmas etc.
- Do not include times unless necessary

LIMIT

appearance within the text

- Do not include in sections other than narratives
- Alternatively, use Study Day 1, 2, 3 and so on.

COMMIT

to harmonization of text

- Use standardized format: ddMMMyyyy
- Consistent across all studies & documents

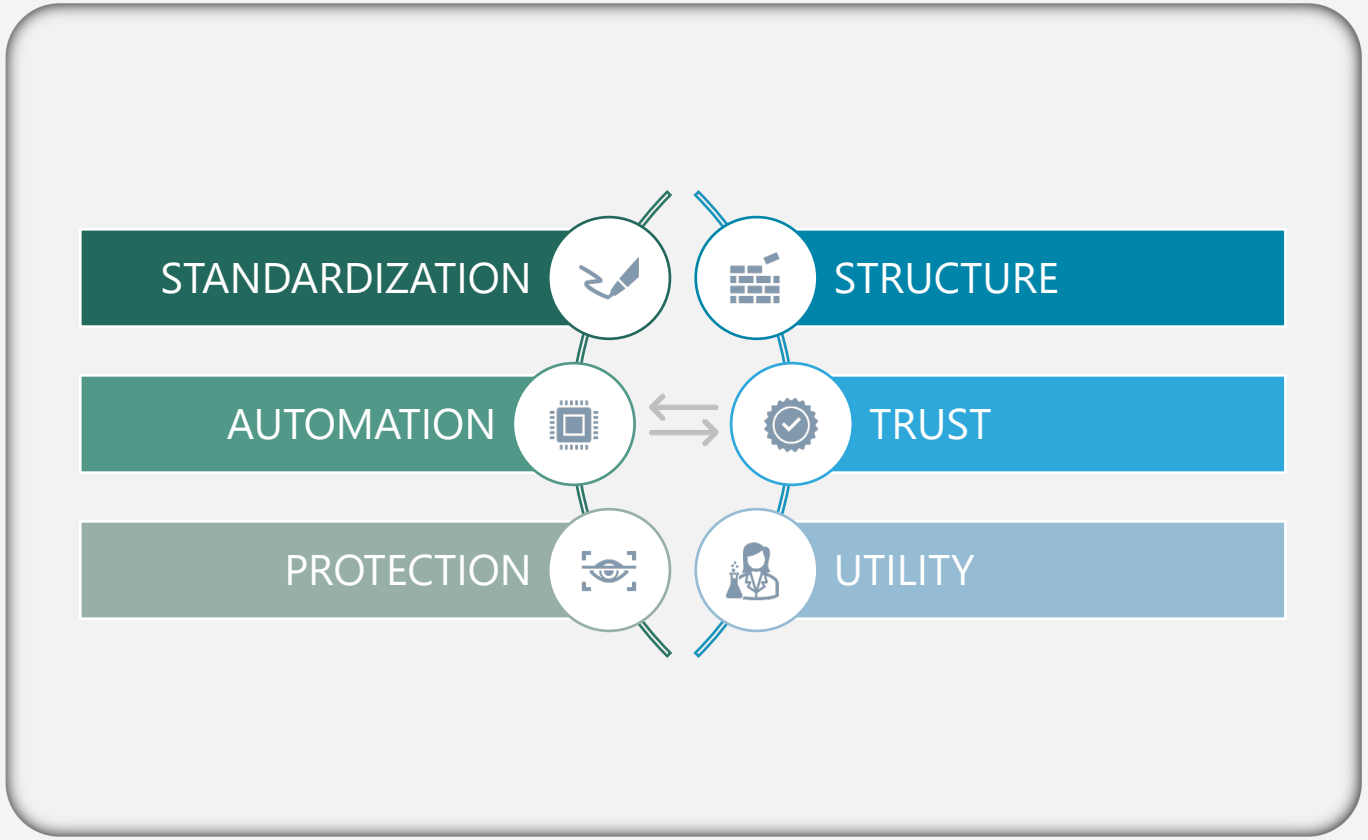
CERTARA

SMART approach ensures efficient & transparent data sharing!

Proactive disclosure without exposure

- Strategic medical authoring for regulatory transparency can help us leverage available tools & technology
- AI-enabled software can help us write, protect and disclose information for regulator submission

Protect your clinical data!



Thank you

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The Value of Clinical Data

Ongoing Trial

Fines & Losses

- Costs related to the data breach estimated between $2.3B-2.45B


PAYERS

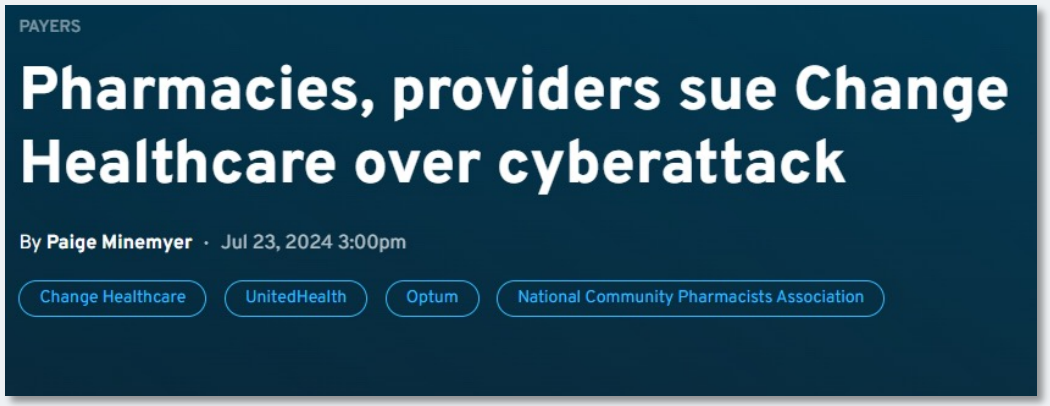
UnitedHealth expects cyberattack-related impacts to top $2.3B

By **Paige Minemyer** · Jul 16, 2024 2:30pm

UnitedHealth | Earnings | Optum | Andrew Witty

Class Action Lawsuit

- 49 lawsuits against UnitedHealth Groups Change Healthcare payment processing unit


PAYERS

Pharmacies, providers sue Change Healthcare over cyberattack

By **Paige Minemyer** · Jul 23, 2024 3:00pm

Change Healthcare | UnitedHealth | Optum | National Community Pharmacists Association

CBI/CCI

Confidential Business Information/Commercially Confidential Information

Standardization

- Include/excluding consistently
- Harmonization across authors/ documents/ studies

Automation

- AI relies on consistent input
- Search standardized terms

Protection

- Limit release of sensitive information

OMIT

Eliminate CBI/CCI-type information from publishable documents

- Establish CCI library
- Reference library to verify presence of CBI/CCI

LIMIT

Only include CBI/CCI-type information when necessary, and in minimal documents

- Ex. Formulation in protocol or IMPD
- Include only once

COMMIT

Use direct text found in the CBI/CCI library for accuarte capture

- Easy to search

CERTARA

Demographics

Subject related dates within the study

Approach:

OMIT

LIMIT

COMMIT

Standardized format:
33-year-old

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Demographics

Age, Race, Ethnicity, Height, Weight, BMI

Standardization

- Harmonization of formatting to limit variation
- Template to expediate writing

Automation

- AI relies on high quality input
- Focus on future of technology and optimization of current processes

Protection

- Focus on maintaining high standard of patient privacy

OMIT

atypical formats

- Values in words (e.g. age)
- Non-standard units (e.g. height, weight)

LIMIT

appearance within the text

- Do not include in sections other than narratives
- Alternatively, present in a table at the beginning of a narrative for accurate capture and efficient anonymization

COMMIT

to harmonization of text

- Use standardized format
- Consistent across all studies & documents

CERTARA