Clarity and Openness in Reporting: E3-based

Webinar by Obaraboye Olude, Privacy Analytics
“Statistical anonymization software for utility-preserving privacy protection in clinical documents for public disclosure”

Hosted by Alison McIntosh, for The CORE Reference Team
11 June 2025

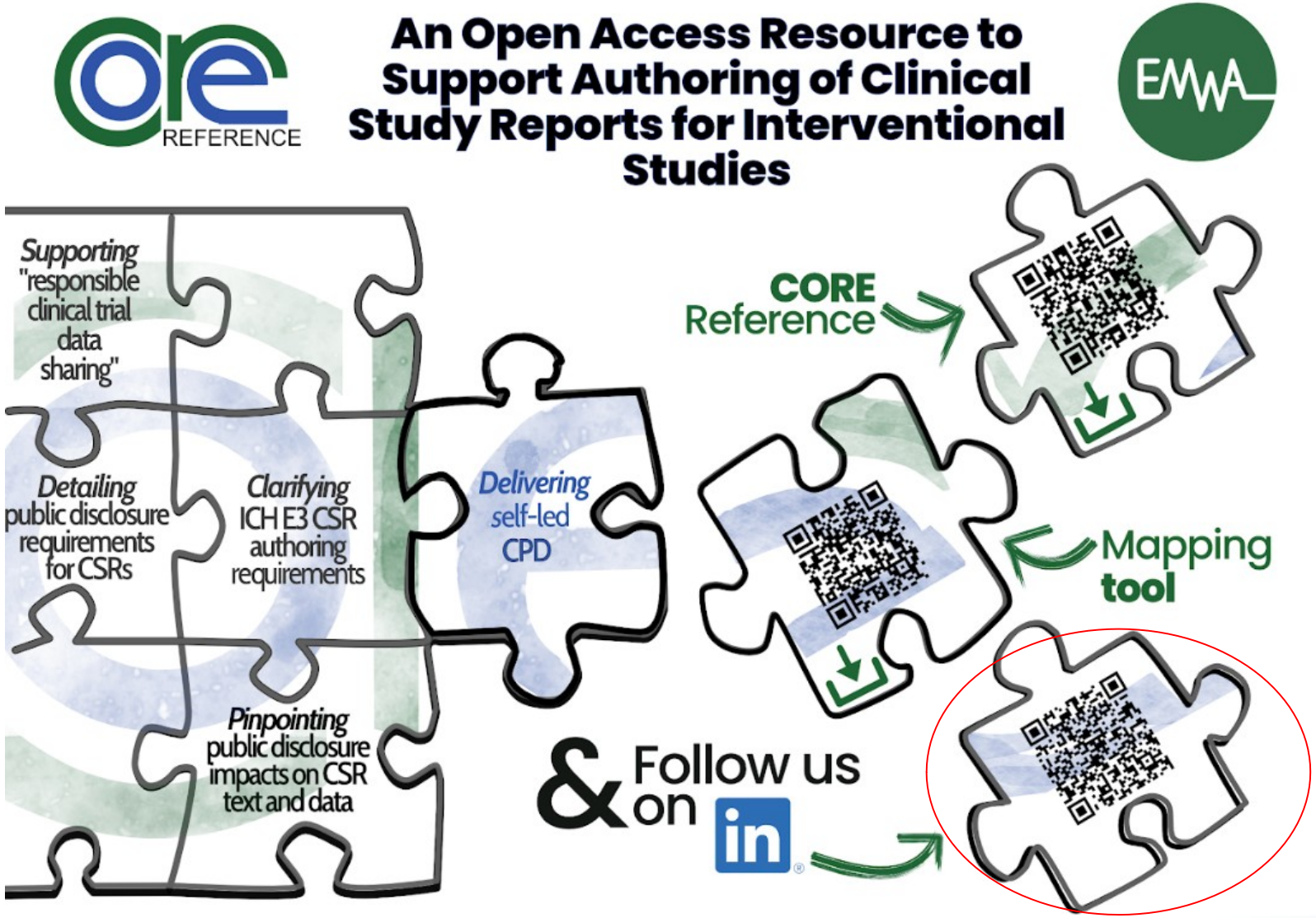
Agenda

- Recap: CORE Reference on LinkedIn
- Automated Anonymisation Processes
- External speaker: Obaraboye Olude, Privacy Analytics
- Questions from webinar attendees

CORE Reference Team

- Sam Hamilton – Chair
- Vivien Fagan
- Alison McIntosh
- Zuo Yen Lee
- Raquel Billiones
- Jen Bell

LinkedIn


An Open Access Resource to Support Authoring of Clinical Study Reports for Interventional Studies
REFERENCE
EMWA
Supporting "responsible clinical trial data sharing"
Detailing public disclosure requirements for CSRs
Clarifying ICH E3 CSR authoring requirements
Delivering self-led CPD
Pinpointing public disclosure impacts on CSR text and data
CORE Reference
Mapping tool
& Follow us on in

LinkedIn

https://www.linkedin.com/company/the-core-reference-project

Please share with your networks - forward, like, comment

Automated Anonymisation Processes

Commercial Tools & Services

XOGENE

Real Life Sciences

GENINVO

Shadow – Data Anonymization Tool.

PRIVACY ANALYTICS
an IQVIA company

- **Tools are operated by Sponsor/CRO under license or the vendor offers anonymisation as a service**
- **Sponsor/CRO should investigate and complete own cost analysis**

Webinar

External speaker: **Obaraboye Olude**, Privacy Analytics

“Statistical anonymization software for utility-preserving privacy protection in clinical documents for public disclosure”

Statistical anonymization software for utility-preserving privacy protection in clinical documents for public disclosure

June 11, 2025

Obaraboye Olude MBBS,MPH
Sr Advisor and Technical Manager, Clinical Trial Transparency

© 2025. All rights reserved. IQVIA® is a registered trademark of IQVIA Inc. in the United States, the European Union, and various other countries.

Disclaimer

As with any attempt to estimate future events, the forecasts, projections, conclusions, and other information included herein are subject to certain risks and uncertainties and are not to be considered guarantees of any particular outcome.

All reproduction rights, quotations, broadcasting, publications reserved. No part of this presentation may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopy, recording, or any information storage and retrieval system, without the express written consent of IQVIA.

IQVIA's Privacy Analytics

Privacy Solutions

Solutions combining proven technology and expertise

We deliver solutions (software and services) that empower our clients to use sensitive data safely and responsibly for innovation that benefits everyone.

Pioneer & Leader

Pioneer in data and document anonymization/redaction

We have informed 20+ regulatory guidelines and standards, anonymized thousands of datasets and millions of pages.

An IQVIA Company

A wholly-owned subsidiary of IQVIA

As an IQVIA company, we benefit from the global scale of 86,000+ employees in over 100 countries globally and offer an award-winning workplace.

PA Platform for anonymization and redaction of clinical documents

PA Platform Mirage module

Fine-tuned, domain-specific, large language model (LLM)
Powers high-speed and high-accuracy detection of personal information

Statistical anonymization
High-utility, industry best practice for maximum transparency

Redaction
Fast and cost-effective way to handle unforeseen or time-sensitive requests

As-a-Service or License
Benefit from the experience of our 100-strong team of experts **or** deploy Mirage on-premise

PA Platform for anonymization of clinical trial datasets

PA Platform
Eclipse module

Statistical Anonymization
Flagship product for structured data anonymization with defensible proof of privacy protection

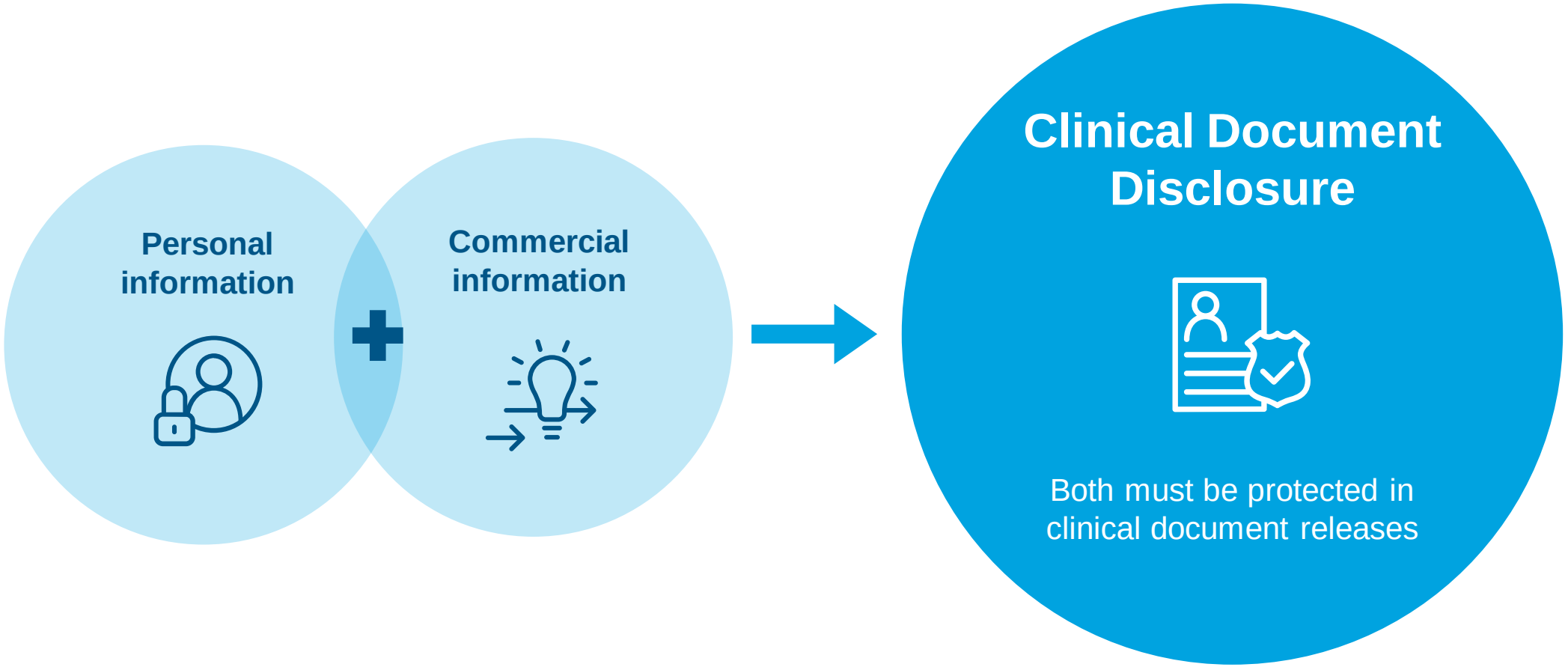
Tailor-Made for Trials Data
Auto-classification for CDISC-compliant datasets, PHUSE-shifting

Flexible Transformation Strategies
Optimizes utility to achieve sub-threshold re-identification risk for a given release context

As-a-Service or License
Benefit from the experience of our 100-strong team of experts **or** deploy Eclipse on-premise

IQVIA

Sponsors must protect personal and commercial information when disclosing documents publicly under EMA Policy 0700, Health Canada Public Release of Clinical Information



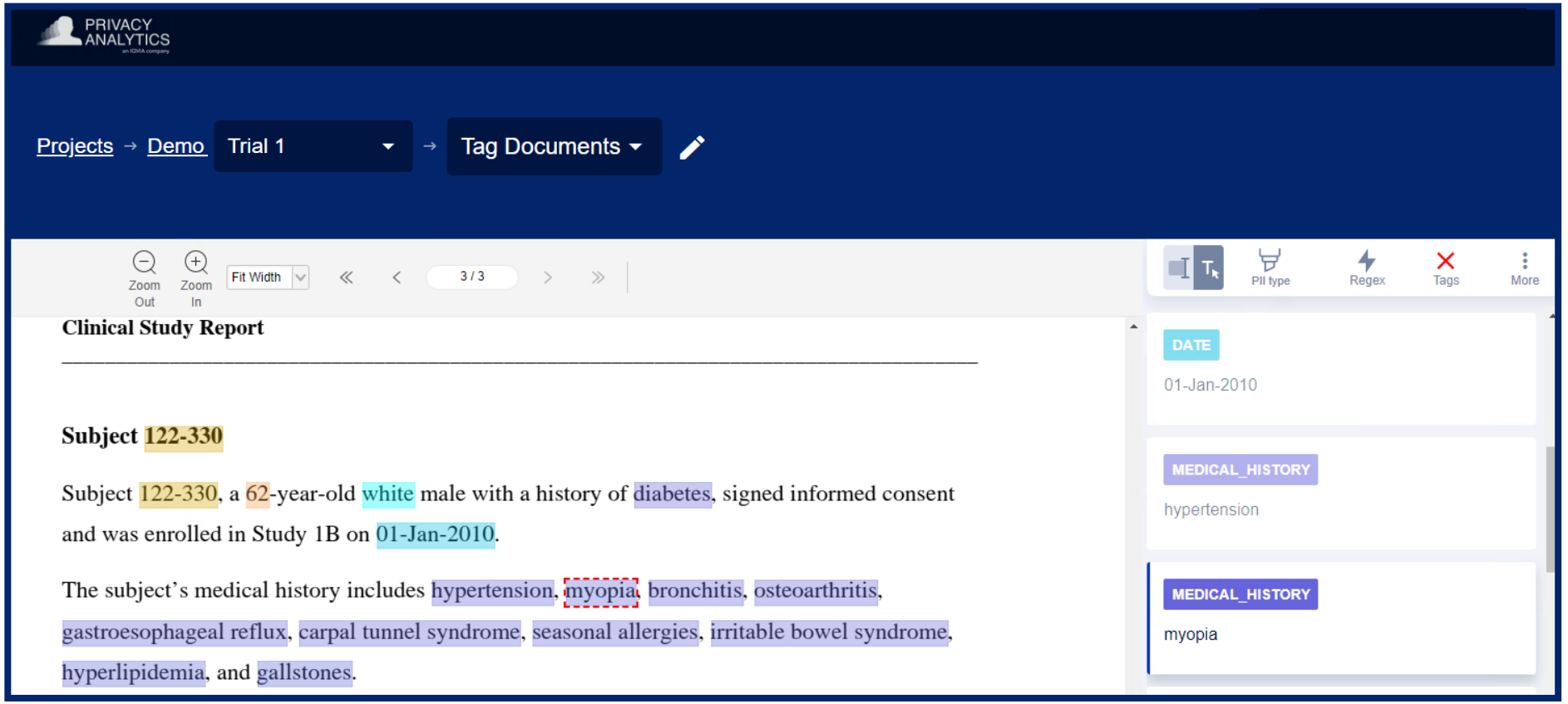
Workflow for anonymization of clinical trial documents

Document Anonymization Workflow

Upload documents to PA platform

Automated PI detection

Manual Optimization



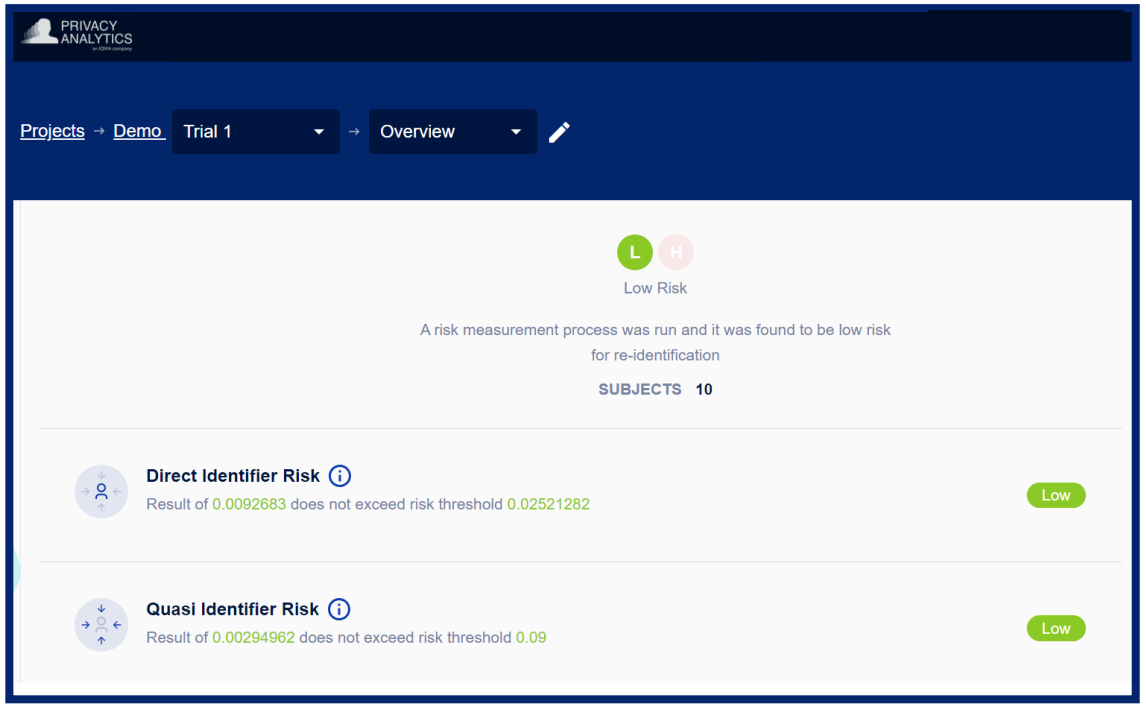
Document Anonymization Workflow

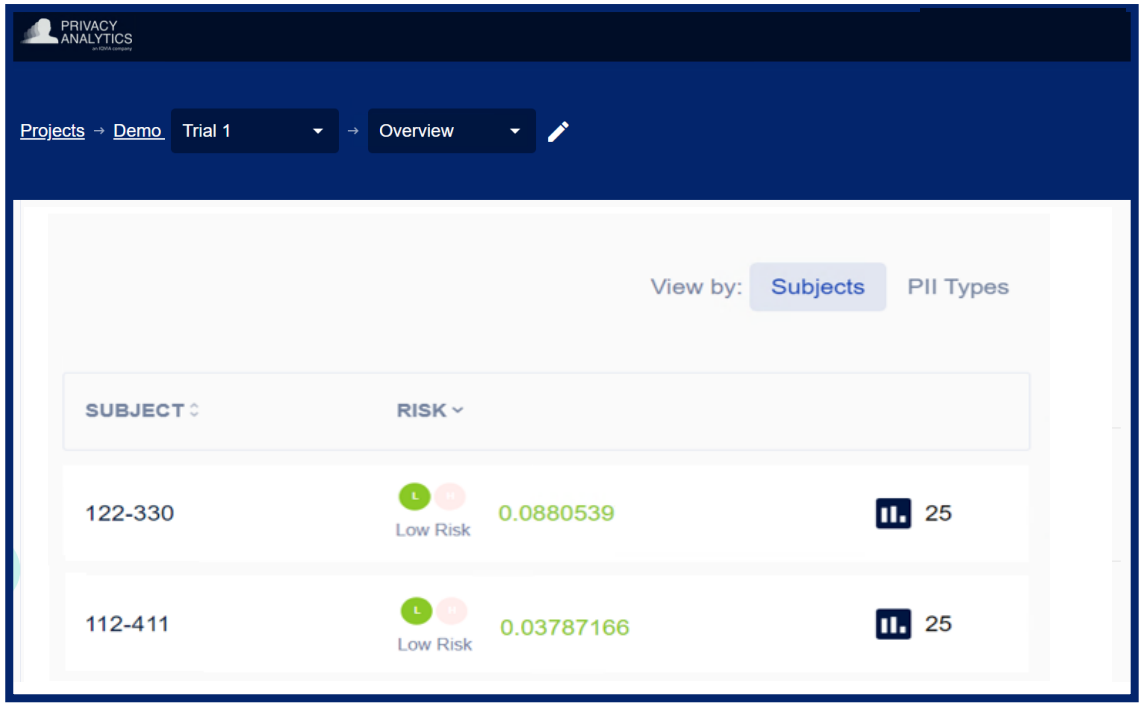
PRIVACY ANALYTICS

Projects → Demo Trial 1 → Subject Profiles

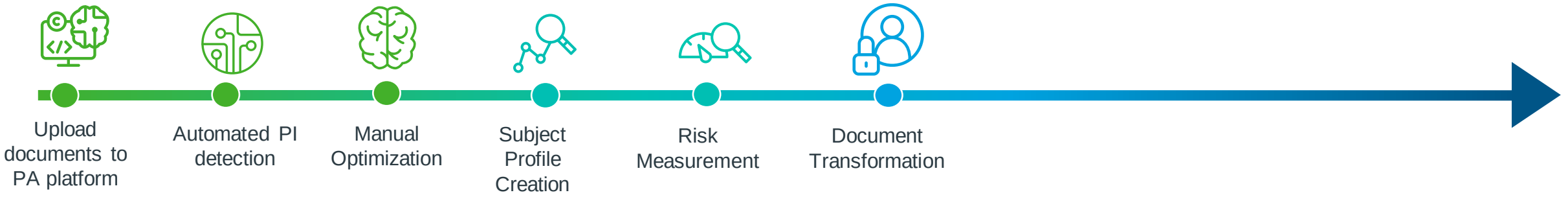
Subject	PII Type	Value	Document	Page
122-330	DATE	23-Sep-2011	Trial 1_Clinical_Study_Report.p	2
122-330	MEDICAL_HISTORY	bronchitis	Trial 1_Clinical_Study_Report.p	2
122-330	MEDICAL_HISTORY	carpal tunnel syndrome	Trial 1_Clinical_Study_Report.p	2
122-330	MEDICAL_HISTORY	diabetes	Trial 1_Clinical_Study_Report.p	2

Document Anonymization Workflow





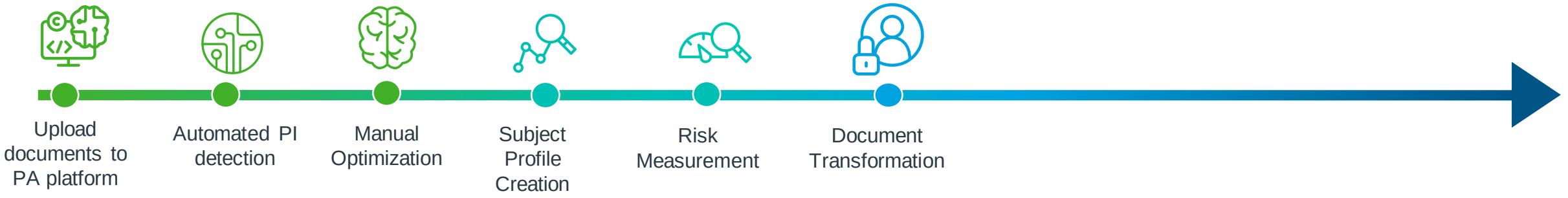
Document Anonymization Workflow



Subject 123-425 was a 32-year-old with a medical history of coeliac disease.

The subject was enrolled on 01-Jan-2010 and experienced an adverse event on 04-Jan-2010.

Document Anonymization Workflow



Subject 123-425 was a 32-year-old with a medical history of coeliac disease.

The subject was enrolled on 01-Jan-2010 and experienced an adverse event on 04-Jan-2010.

Pseudonymization with FPE

Generalization

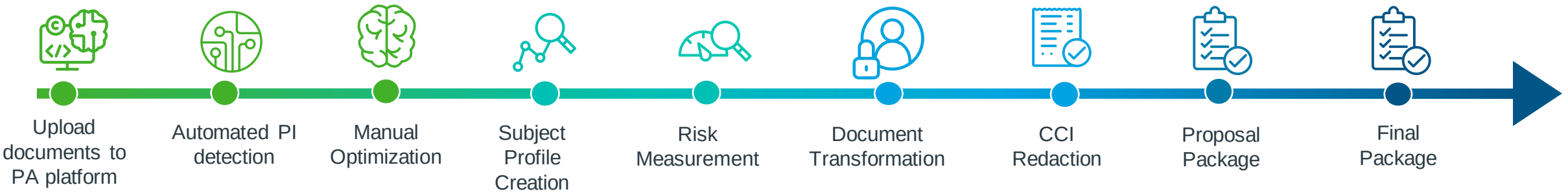
Subject 627-889 was a 30-35-year-old with a medical history of autoimmune disorders.

Generalization (SOC)

The subject was enrolled on 03-Mar-2009 and experienced an adverse event on 06-Mar-2009.

Date offset

Document Anonymization Workflow



Demo - Statistical anonymization with sample file

Questions?

Thank you! For more information:

Obaraboye Olude MBBS, MPH
Sr. Advisor, Clinical Trial Transparency
oolude@privacy-analytics.com