



Integrating Privacy By Design to Enable Innovative Clinical Trials and Post-Trial Data Sharing

Principles & Strategies



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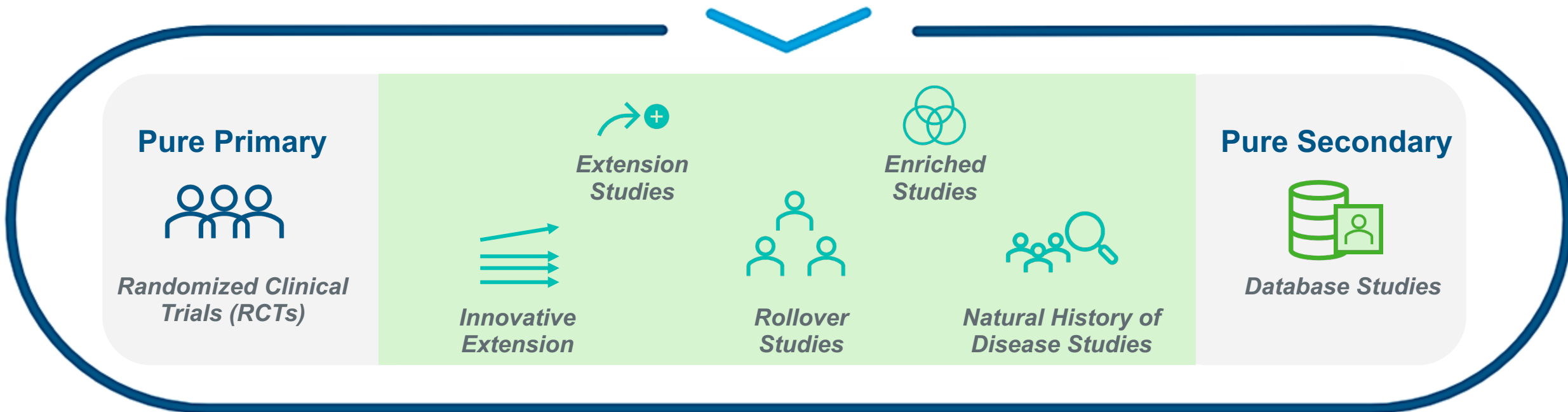
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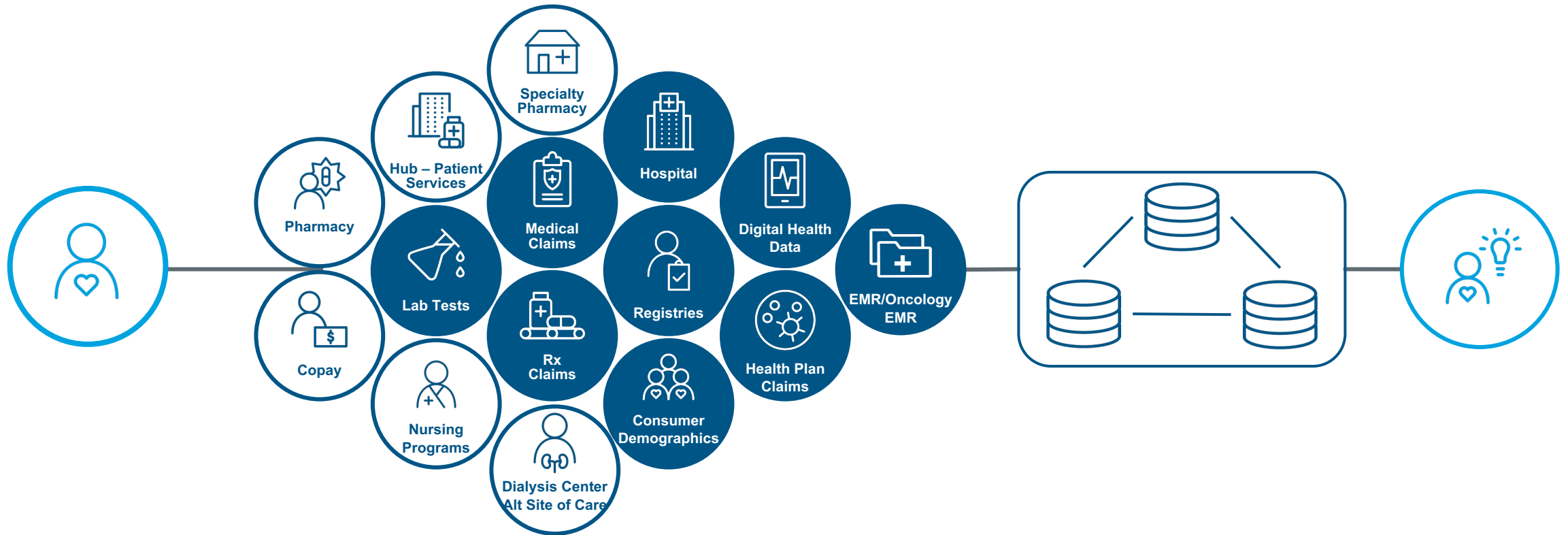
Innovative Clinical Studies to capture *untapped insights*



Studies



Real-World Data (RWD) encompasses a diverse range of sources



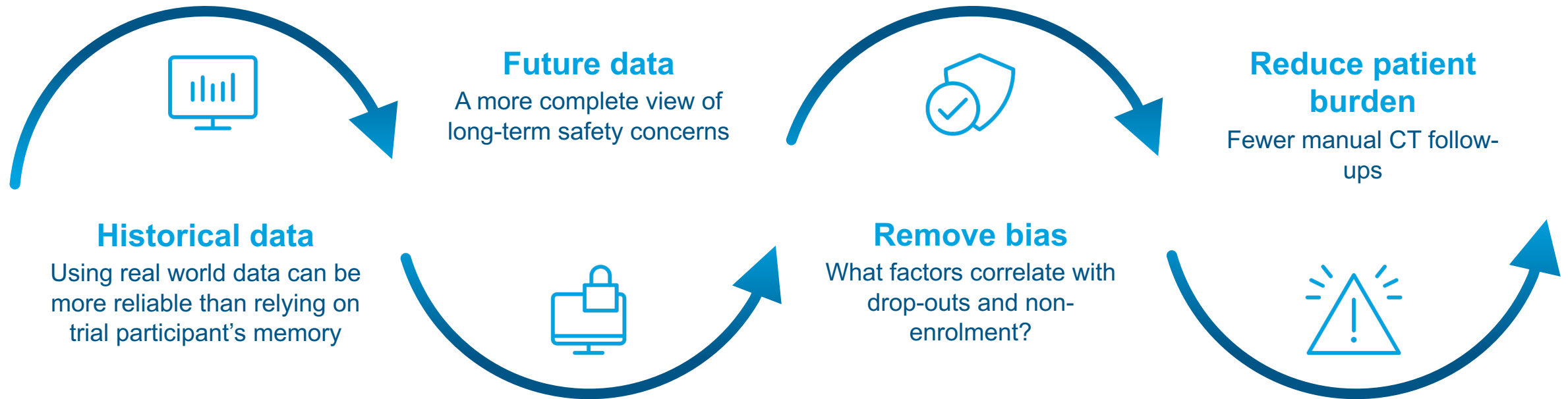
A single patient interacts across multiple points of care

These multiple touch points generate fragmented data streams

Linking these streams creates a singular complete view of the patient experience

Creating opportunities for richer patient analytics and insights

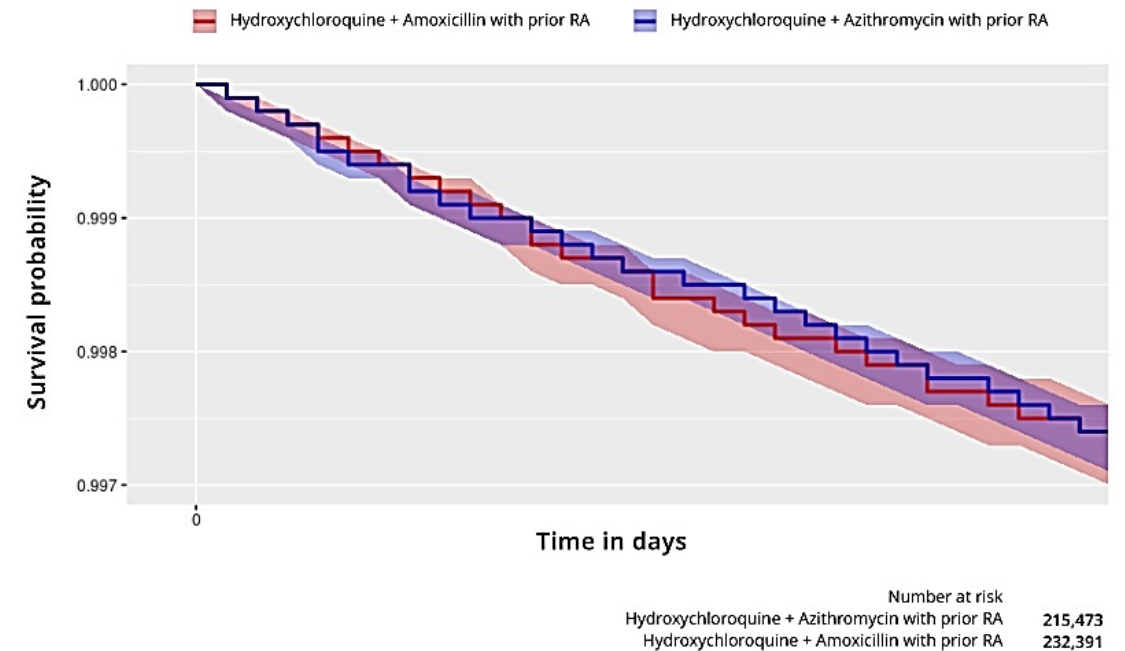
A few benefits of using RWD for evidence generation



RWD have immense potential to impact research and patient care

Example: IQVIA collaboratively conducts RWD observational study to reveals safety risks of therapy used to treat COVID-19

- In the early days of the COVID-19 pandemic, the safety risks of use of hydroxychloroquine (HCQ) alone and in combination with azithromycin (AZM) was unclear.
- IQVIA collaborated with a virtual community to conduct an observational study using three IQVIA databases and 10 other databases from data partners
- The study revealed that the combination of HCQ and AZM was associated with an increased risk of chest pain/angina, heart failure, and cardiovascular mortality (later confirmed through RCTs)



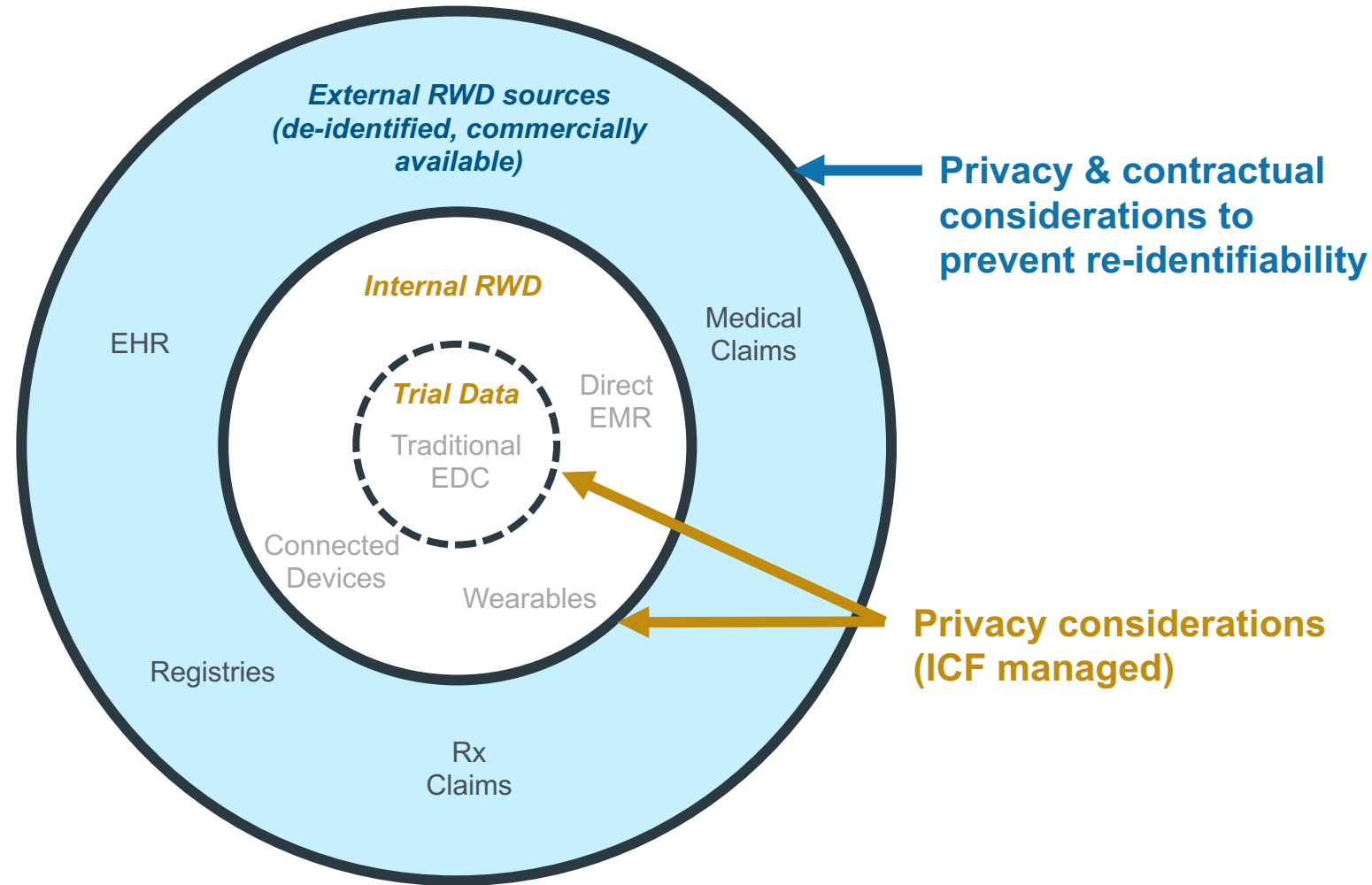
Source: <https://data.ohdsi.org/Covid19EstimationHydroxychloroquine/>



Privacy considerations are often underestimated and multi-faceted for innovative clinical studies

Many RWD sources have been de-identified and study design must ensure contractual and privacy obligations are upheld

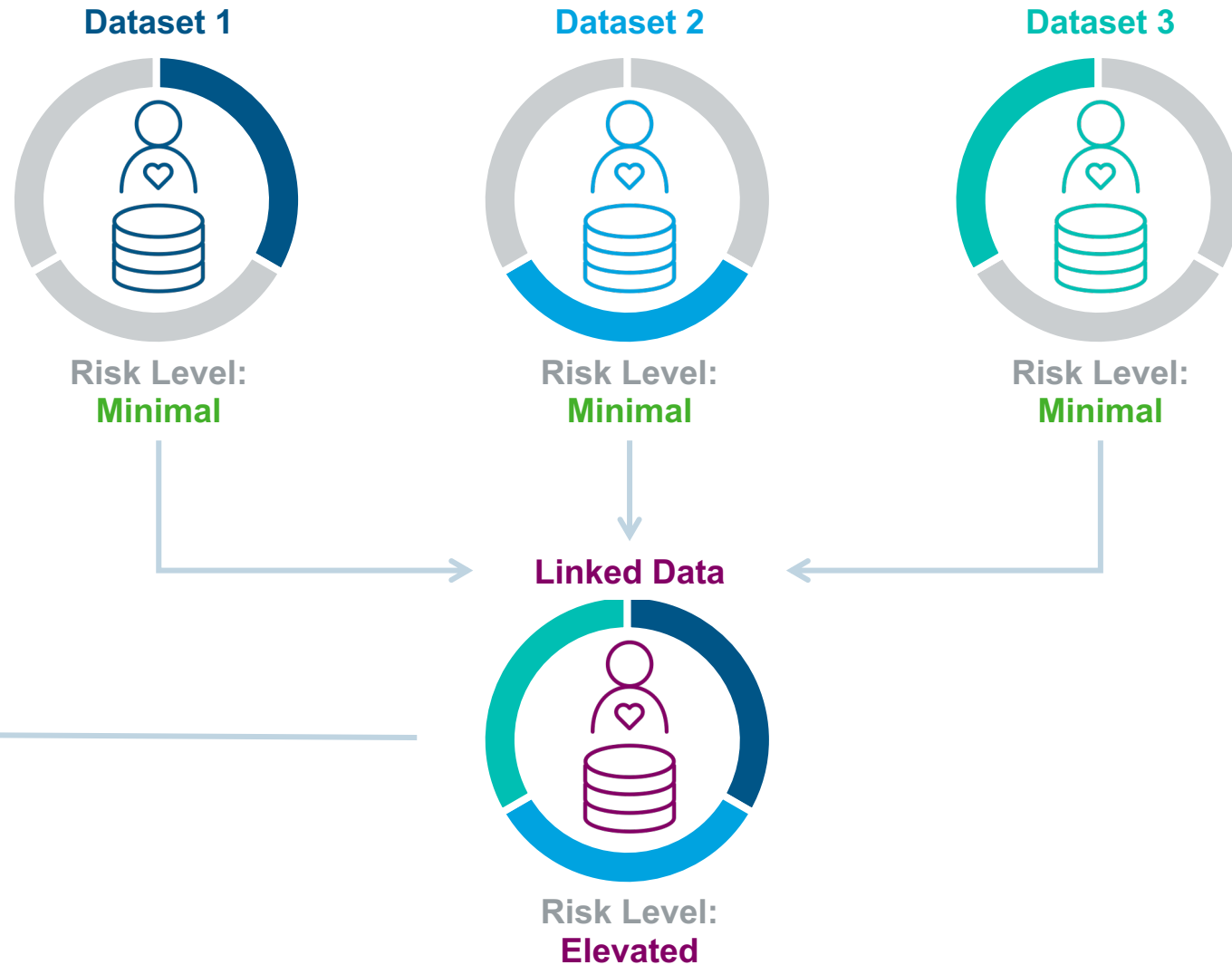
- When not mandated or permitted, use and disclosure of health data for secondary purposes requires either consent (authorization) or anonymization in accordance with regulations (e.g., HIPAA, GDPR).
- Patients in a trial might be heavily incentivized to give broad coverage consent, including linking their trial data to all and any RWD that might be available about them.
 - › Caveat: RWD may not have collected or anonymized the data under this broad consent framework
 - › Re-consenting is not always an option



Privacy considerations of linking disparate RWD sources

Datasets are often evaluated as stand-alone assets and determined to have minimal risk for re-identification

Integrating multiple datasets from multiple sources via common identifiers, generates incremental information about any given participant, creating an elevated degree of identifiability through data linking





How can we proactively identify & address privacy considerations for innovative clinical trials?

Privacy-by-Design for Innovative Clinical Studies

Empower the team

Proactively identify
privacy considerations

Use robust, utility-
preserving approaches

Increase transparency

*Focus on a **proactive, preventative approach** instead of implementing reactive measures*

Privacy-by-design encompasses *people*, processes, and technology

Empower the team

Proactively identify
privacy considerations

Use robust, utility-
preserving approaches

Increase transparency

Unlike traditional RCTs (pure primary), innovative clinical studies often incorporate RWD sources → skills, knowledge and training for handling anonymized data assets.

Leadership



Someone to be accountable for the process with the right skills and knowledge

Training



- Basic training on data handling
- Advanced training on disclosure control, data security, data protection law etc.

Staff Agreements



Sign non-disclosure agreements for confidentiality responsibilities

Identify privacy considerations during study planning and design

- Empower the team
- Proactively identify privacy considerations
- Use robust, utility-preserving approaches
- Increase transparency

Identify



Data Sources

What and where is the data,
How will it be used

Assess



Contractual Agreements

Allowable options and necessary controls for linkage

Validate



Regulations & Guidelines

Applicable privacy legislation,
IRB ethics and review guidelines

Strategize data linkage method(s) based on what is feasible in terms of data collection technology and data privacy laws

Empower the team

Proactively identify privacy considerations

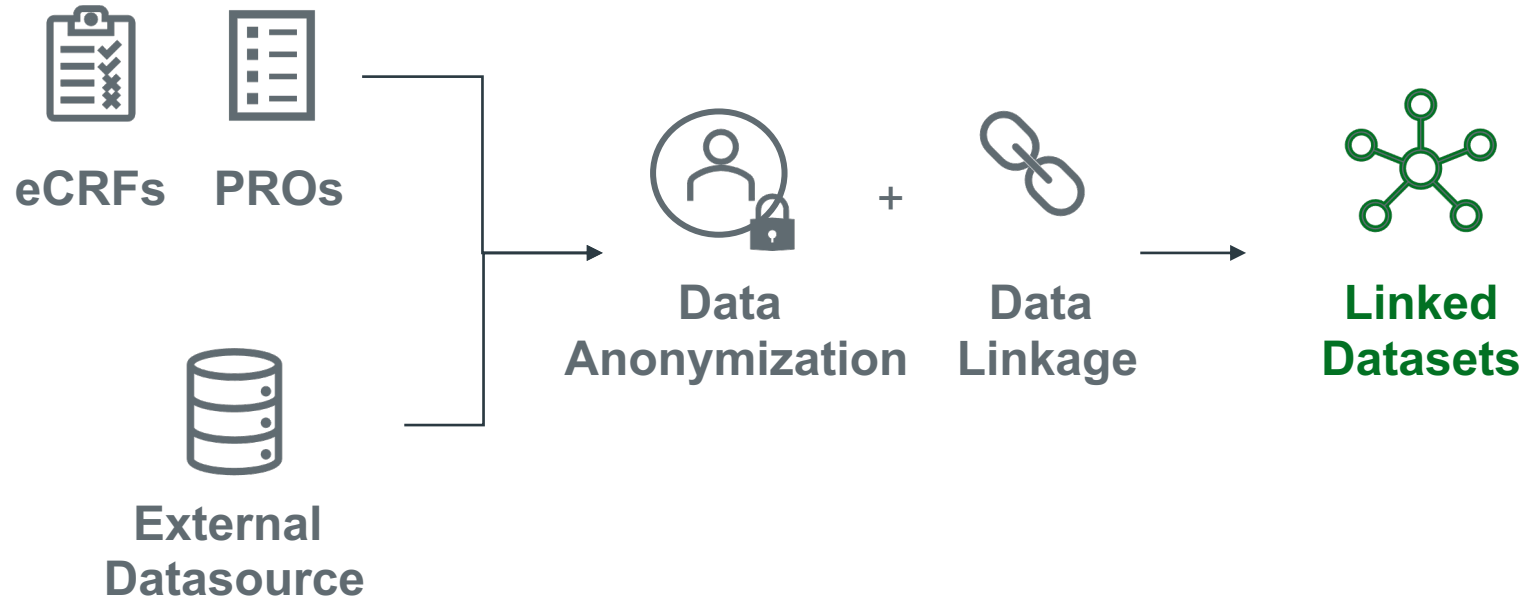
Use robust, utility-preserving approaches

Increase transparency

Case: Data linkage via a Trusted Third Party (TTP)

Study Sites/External Source

Trusted Third Party (TTP)



Risk-based approaches for increased quality, utility and agility

Empower the team

Proactively identify
privacy considerations

Use robust, utility-
preserving approaches

Increase transparency

Factors

Regulations & Guidelines

Evolving privacy laws and regulations
New de-identification guidelines by regulators, standards groups, etc.

Data Complexity

Linked data
Data collection in multiple jurisdictions

Expanding Threats

More sophisticated adversaries
More public data available for re-identification attacks

Approach

Masking
Approaches

**Risk-based
Approaches**

↓ *Data Utility*
Data Privacy

↑ *Data Utility*
Data Privacy

Case Study: Innovative study design to conduct a comparative study between a new treatment and existing alternatives.

Situation

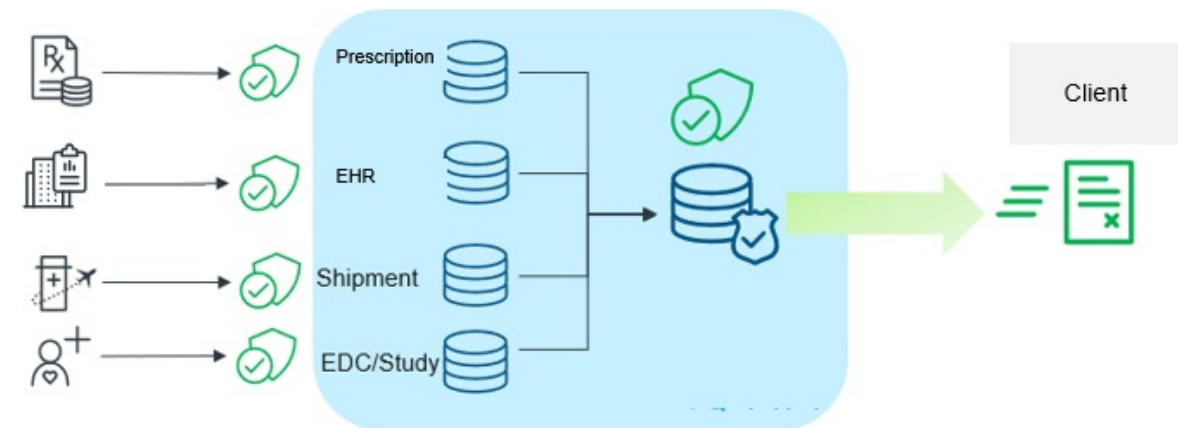
- A global pharma company received FDA approval for a novel drug; and wanted to publish a comparative observational study between the new drug and existing alternatives.
- The sponsor wanted to optimize the study by using de-identified RWD. However, linking identifiable EDC study data with de-identified RWS introduced complex privacy and contractual risks

Solution

- Privacy Analytics collaborated with the sponsor to develop a custom process and data flow enabling a compliant and privacy-preserving linkage.
- Privacy Analytics conducted a holistic assessment to determine the context-specific likelihood of patient identification across the various data sources.

Results

- The sponsor was able to leverage innovative approaches to sourcing and linking data more easily and cost-effectively.
- Using a single, consolidated privacy evaluation, the sponsor was enabled to realize their innovative study, costing 35% less than the cost of traditional study design techniques, saving the sponsor nearly \$10 million.



Informed consent is a useful tool for transparency

Empower the team

Proactively identify
privacy considerations

Use robust, utility-
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Increase transparency

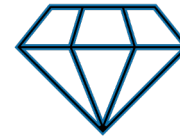
A simple statement can be introduced in the informed consent form to outline risks and benefits.

Risks



How will participant data be protected, used, and shared (including for secondary purposes)

Benefits



What are the benefits of using/reusing health data that are associated with the study

Post-trial data sharing for secondary uses is now considered *part of study lifecycle* and requires *anonymization*



Accelerated drug discovery

New insights, new signals

Transparency and accountability

Build Trust

Outcomes of Privacy-by-Design:

- *Safe Data Enablement*
- *Ensure Compliance*
- *Build Trust*
- *Enhance Reputation*
- *Patient-centered Care*



Any Questions?



Thank You!



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