

An abstract graphic on the left side of the slide, featuring a dark blue background with glowing light blue lines and rectangular nodes, resembling a digital network or data flow diagram.

Trends in Health Data Sharing in Industry

What do we all need to know?

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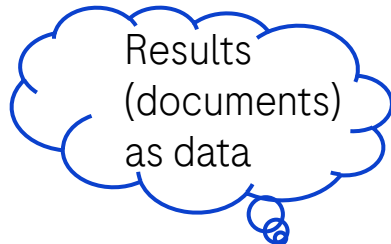
1. What do we mean by Healthcare data?
2. Key Messages
3. Data = Documents
4. Data = Participant Level Data
5. Outside pressures

What do we mean by “healthcare data”

The different flavours of data

A blue-outlined thought bubble with a small tail at the bottom. Inside, the text reads: Trial participant level data.

Trial
participant
level data

A blue-outlined thought bubble with a small tail at the bottom. Inside, the text reads: Results (documents) as data.

Results
(documents)
as data

A light blue-outlined thought bubble with a small tail at the bottom. Inside, the text reads: Real world data.

Real world
data

Health Data Sharing

Key Messages

Collect data with reuse in mind

- FAIR data strategies from the start (Findable, Accessible, Interoperable and Reusable) including FAIR ICFs
- As statisticians, you play a key role in ensuring the data you help generate has life beyond the CSR and filing

Evolving environment and challenging mismatches between key stakeholders

- Country variations in ICF text within a trial
- Expectations of some Ethics Committees
- Expectations of some Data Protection Authorities
- Government strategies (e.g. EU Raw Data Pilot, European Health Data Space)

Evolving technical solutions

- Privacy Enhancing Technologies (PETs) continue to develop
- Focus on technology to support a clear purpose/need, rather than the other way around!

Documents as “data”

Evolving space: Regulators requiring public versions of key filing documents

- **EMA** (Policy 70) and **Health Canada** (Public Release of Clinical Information (PRCI) process). Documents released publicly after the review process has completed

- Requirement that anonymized copies of the Clinical Study Report(s) are included in the submission
 - Reports include the patient narratives
 - Participant level listings (in appendices) not included
 - Expectation to maintain as much clinical utility in the information as possible

- Quantitative risk methodologies to be used (lots of software solutions and organisations available)
 - Not sufficient to obscure (black out) specific information
 - Expectation to replace or group identifying information in the text
 - Risk report generated and part of the submission requirements

- Valuable source of [competitor] information for statisticians working on trials in the same disease area

Trial Participant Level Data (PLD) Sharing

Responsible participant level data reuse and sharing is a balancing act (the WHY)

Ensure compliance with privacy/legal/ethical obligations associated with data and their reuse

IP Protection and Ethical Considerations

Patient's Rights & Consent

Data Privacy and Data Protection Laws

Enable rapid generation of scientific insights from reuse of internal data or via collaborations

Increase scientific knowledge

Accelerate new discoveries

Avoid duplicative trials. More efficient trial designs



Responsible PLD Sharing is not a one time thing

Constant balancing act (the HOW)

Compliance/Obligations

Country level variations in ethics committee requirements (e.g. re consent)

GDPR subject to a variety of interpretations (e.g. legal basis)

Expectations to inform patients when data reused

New laws and their application to old data

Speed & Efficiency

Responsible FAIR data sources

Expectations of data scientist (data at their fingertips)

AI / ML relies on “trustworthy” data

Robust Data Governance as an enabler to new insights

New requirements within the EU

This will impact how we share data going forward

EMA Raw Data Pilot

- Inclusion of the SDTM and AdAM (“raw data”) datasets within the submission =>
 - Faster review process
 - Reduce the number of questions back to the company
 - Implications for “freedom of information” requests via EMA Policy 40
 - Access to PLD by competitors?
 - Implications for data reuse (privacy, ethical obligations) unclear

European Health Data Space (EHDS)

- At an individual level: Exchange of data for the delivery of healthcare across the EU
- Provide a consistent, trustworthy, and efficient system for **reusing health data** for research, innovation, policy-making, and regulatory activities
 - Implications for Pharma sponsored trials?
 - Opting out for reuse?

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Doing now what patients need next