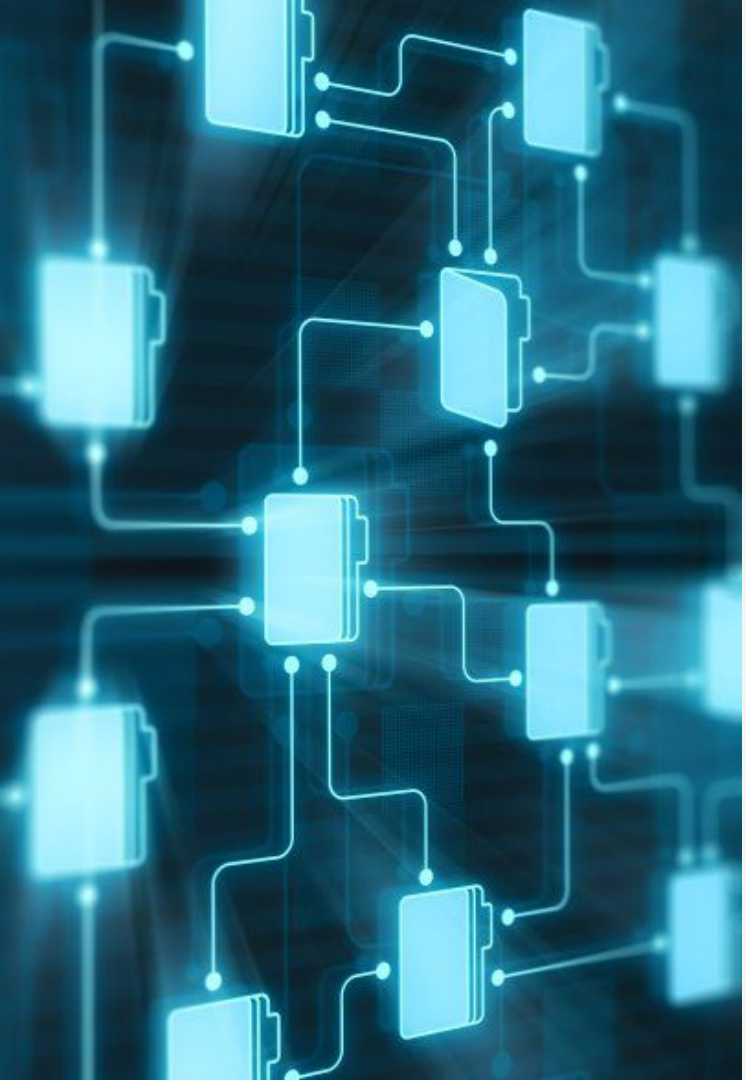

Trends in Health Data Sharing in Industry

What do we all need to know?

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16 May 2024 | Basel BBS

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The different flavours of data

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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

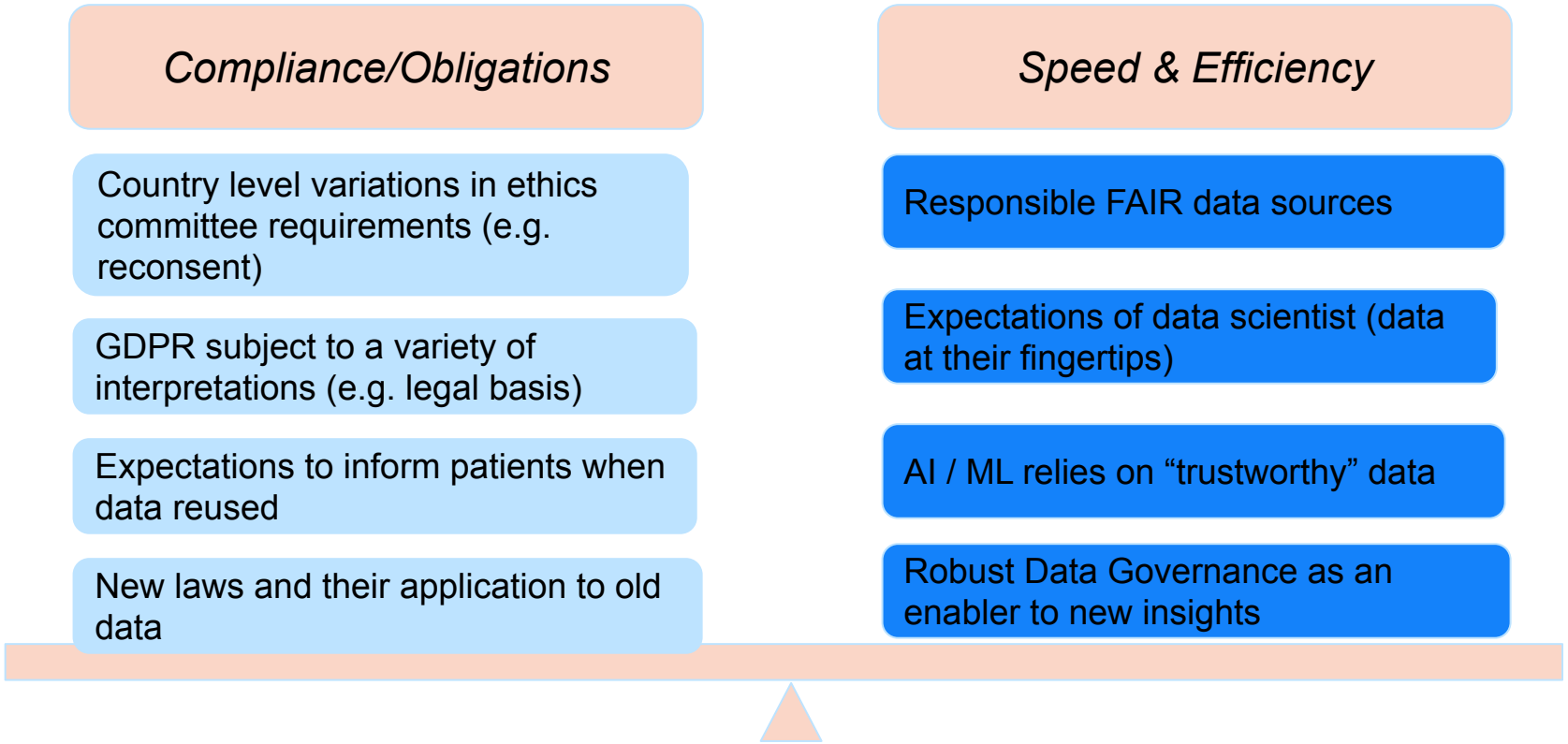
- IP Protection and Ethical Considerations
- Patient's Rights & Consent
- Data Privacy and Data Protection Laws

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)



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