

Johnson & Johnson

**MEDICAL
DEVICES
COMPANIES**

The Future of Global Evidence Generation – Advancing the Role of Big Data in Innovation

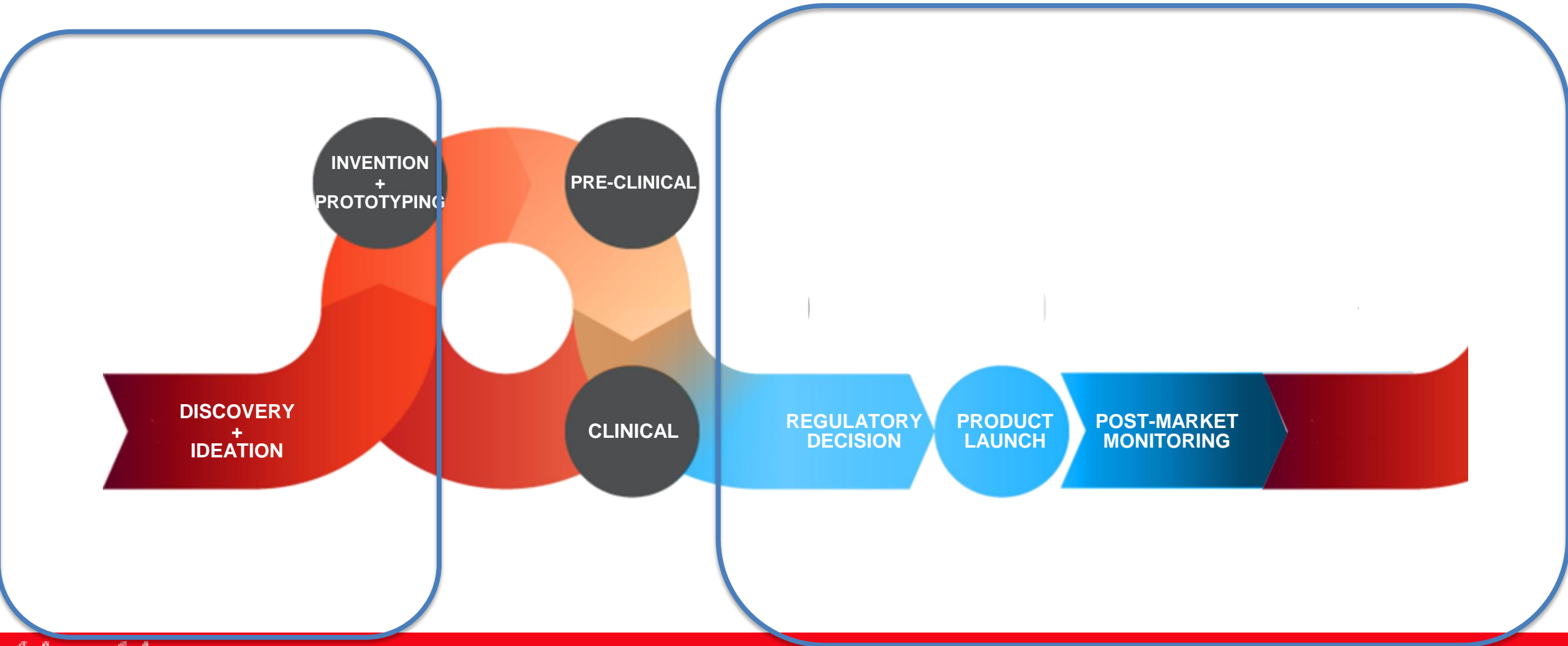
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Medical Devices Companies of Johnson & Johnson

REACH MORE
PATIENTS

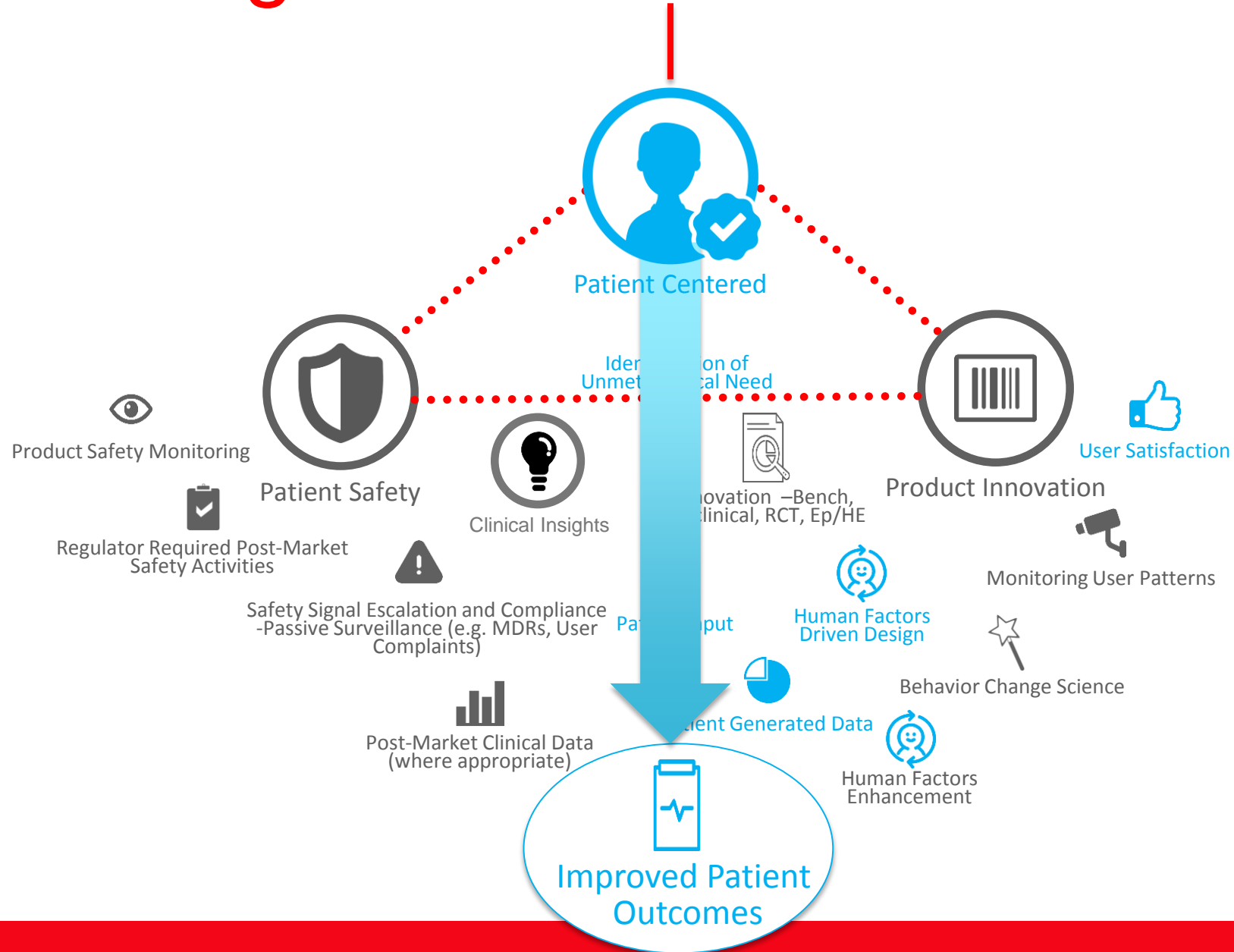
RESTORE MORE
LIVES



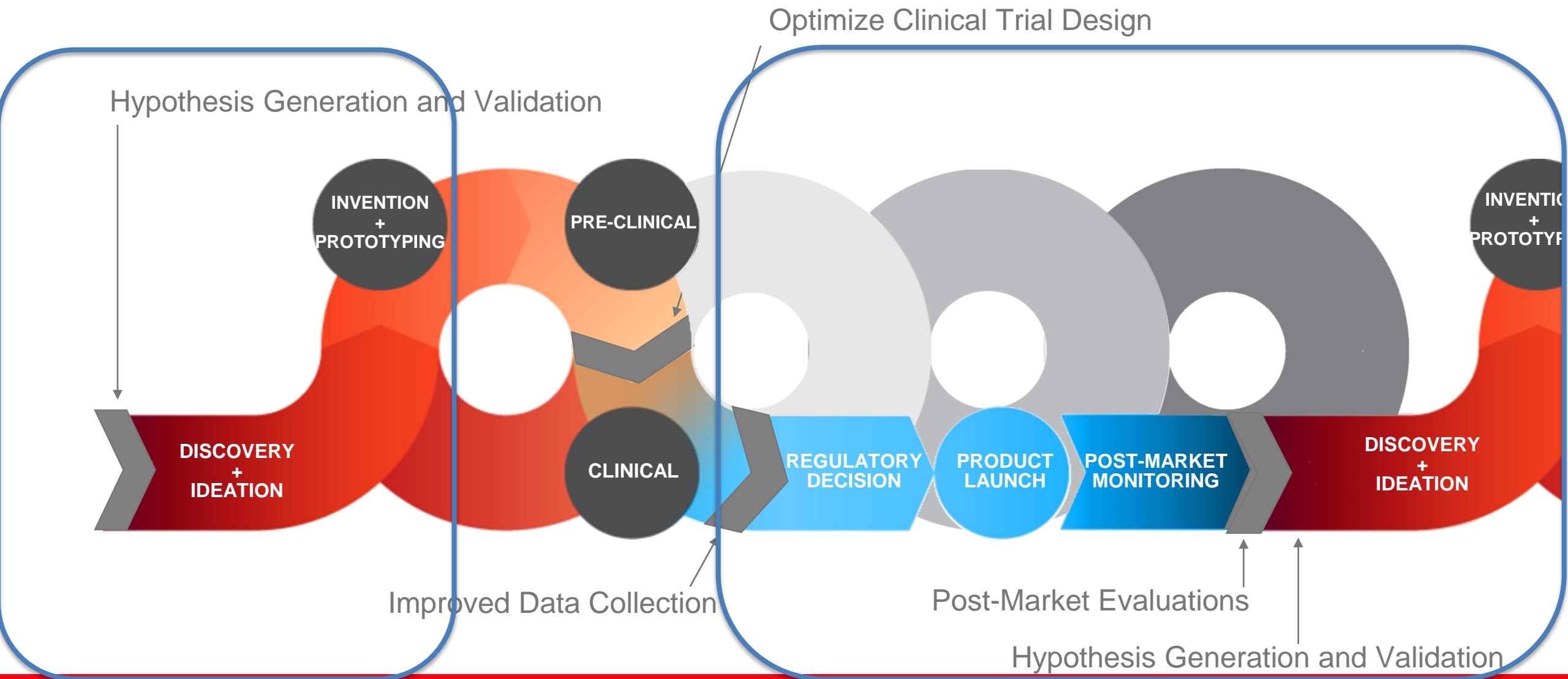
Integration of RWE into Total Product Life Cycle



Advancing the Role of Data in Innovation



Integration of RWE into the Total Product Life Cycle



Considerations and Challenges

- Access to Data
 - Technical Considerations/Barriers
 - Ownership
 - Health systems
 - Payors
 - Patient-generated health data
 - Infrastructure/Governance
 - Patient privacy
- Validation and Analytic Methods
- Security of data
- Global considerations

Striving for a Harmonization Approach

Benefits

- Leverage regional and global data to promote innovation
- Quicker dissemination of effective new therapies across regions
- Dramatically advance the ability to identify potential safety problems and respond more act to protect

Challenges

- Variation in regulatory requirements limiting the use of novel data and methods
- Legal restrictions
- Balancing the need to protect patient privacy and ensuring appropriate access to data
- Lack of consensus on shared and accepted analytical methods that are both nimble and reliable