MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

# Advancing Data Sharing: Data Collection as a key component

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- I have no personal conflicts of interests relevant to this presentation.

# The MRCT Center

The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.

## Vision

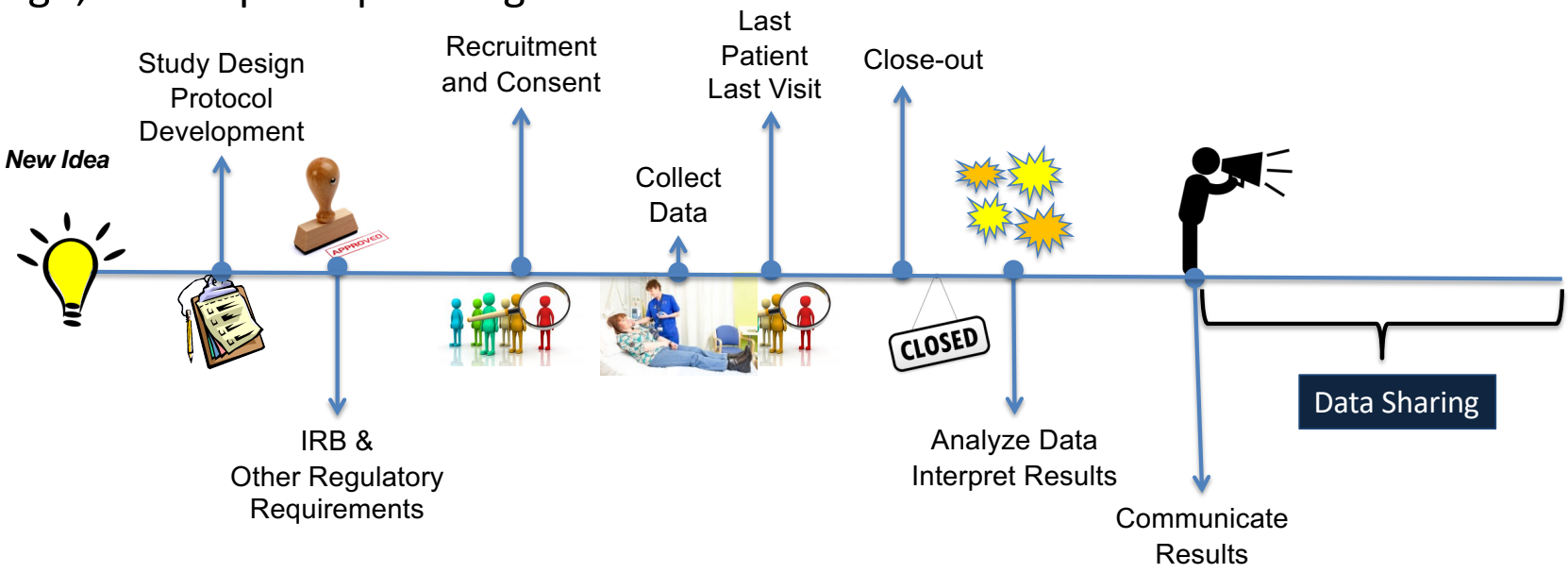
Improve the integrity, safety, and rigor of global clinical trials.

- Academic credibility
- Trusted collaborator
- Independent convener


Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

# Framework

- Decision to share data, and considerations for data collection, begin at study concept and design, and requires planning:




Privacy, Confidentiality, Security, Data Utility

# Framework: Data Sharing

- To whom
- Identifiability of data
- Data Source
- Data Origin
- Data Storage and Security
- Methods to Share
- Consent
- Data standards
- Metadata
- Harmonized DUAs, DCAs, Processes
- Infrastructure and Resources

More sharing or better sharing?

Incentives and barriers to data sharing

# Framework: Data Sharing

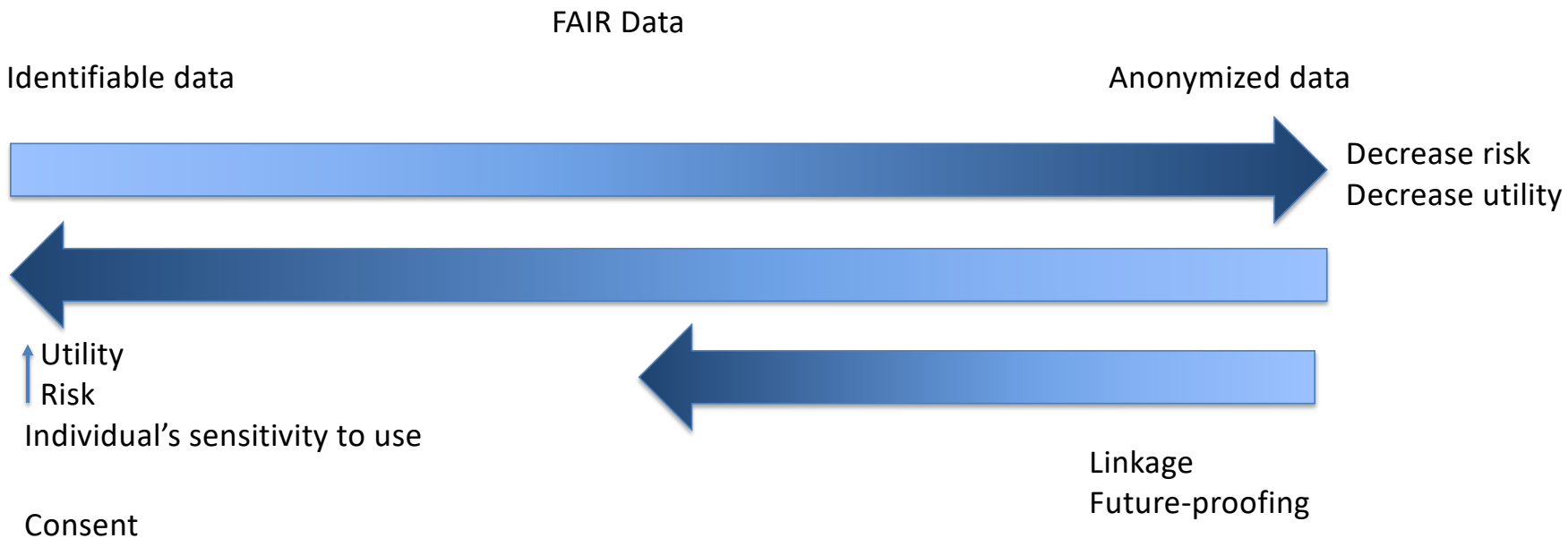
- To whom
  - To participant → individual, aggregate study results
  - To participant and public → aggregate study results
  - To collaborators and business associates → pre-identified, identifiable data, BAA, DUA, Contract
  - To third parties
    - Scientists and Researchers → who, what, when, where, for what, identifiable or not, etc.
    - Other → public, commercial purposes, litiginous purposes, etc.

- Identifiability of data
  - Identifiable → sensitivity, source, consent
  - Coded/Deidentified/Pseudonymized → nevertheless identifiable
  - Anonymized → if no linkage to other data sources, compromise utility
  - Linkage or not → modifies identifiability
  - Other (differential privacy, etc.)

# Framework: Data Sharing

- Data Source
  - Clinical trials (structured) data
  - Observational data (and source)
  - EHR
  - Imaging
  - Genetic
  - Mobile technology
  - Other
- Data Origin
  - National (US)
  - EU (GDPR)
  - Other (China, Japan, Australia, etc.)
- Data Storage and Security
- Methods to share
  - Downloadable and freely accessible
  - Secure compute platform
  - Permission for specific use
  - Other

# In General


FAIR Data
Identifiable data
Anonymized data
Decrease risk
Decrease utility
Utility
Risk
Individual's sensitivity to use
Consent
Linkage
Future-proofing

# Consent for data sharing (US)

- To advance science, medicine, and public health, we might share information about you from this research study with other researchers, but only after personal information that may identify you has been removed. Your information may be combined with other people's data and/or placed in a repository for future research. Some repositories are freely available to anyone. Other repositories may only be accessed by scientists who have permission. We protect your privacy by removing any identifiers, but despite our best efforts, there is still a very small chance that you could be re-identified. In the unlikely event that we learn of a breach of confidentiality, someone from the research team will contact you with additional information. If, at any point during or after this study, you think that you may have been re-identified, please contact us and let us know.

Reviewed by IRBs, institutional officials, patients and patient advocates

# Framework: Data Sharing

- Data Collection and Data Standards
  - Universality of standards
  - Adoption
  - Pain of adoption

- Metadata
- Harmonized DUAs, DCAs, Processes
- Infrastructure (platforms, access)

# More data or better data

- Better data before more data (and then more data)
  - Demonstration of utility important
  - Resource intensive

- Data scientists are generally not the clinical trialists
- Data scientists: all data all the time all freely accessible forever
- Clinical trialists: challenging
  - Incentives for sharing data
  - Academic credit for data sharing
  - Funder expectations, appreciation, and ability to track portfolio
- Reuse important to understand value, risk (?), benefit (!)

Thank you!!