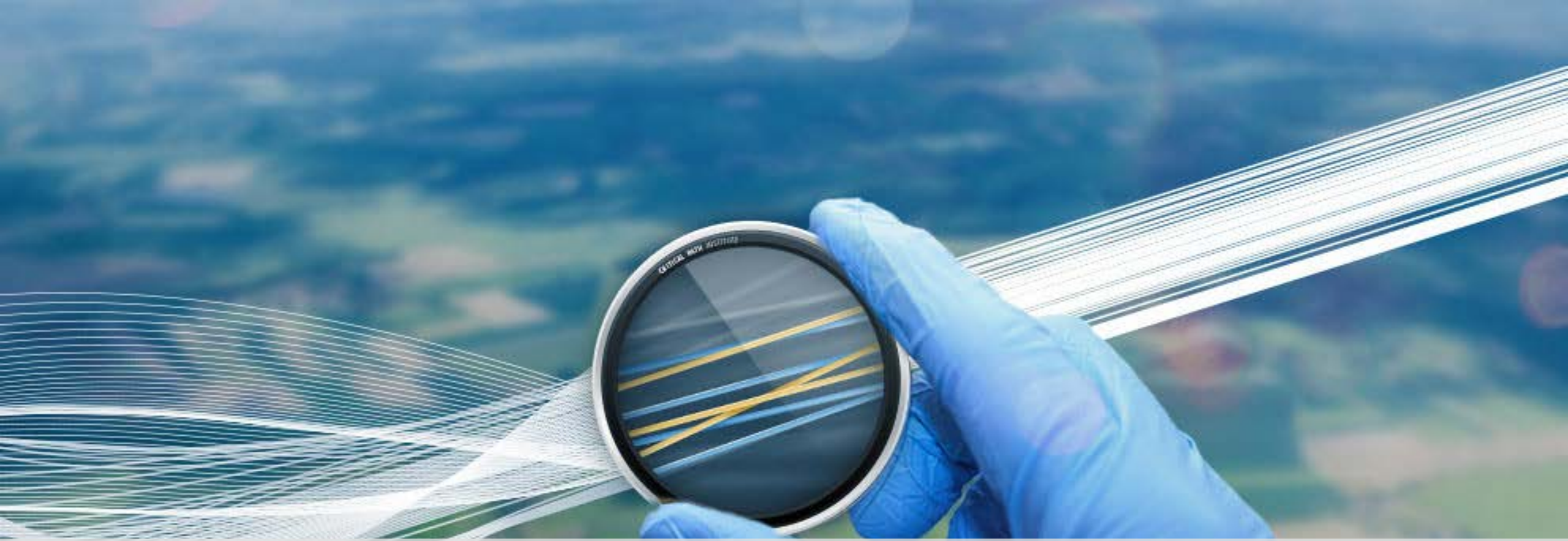

Notes on data sharing and acquisition

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Addressing Drug Development Gaps through Data Sharing: Converting Data into Knowledge

C-Path Biomarker Program Workshop

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Case Study #1

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Barrier: Concerns about Protected Health Information and/or Sponsor Identification

How to prevent users from identifying:

- ✓ The individual's past, present, or future physical or mental health or condition,
- ✓ The provision of health care to the individual, or
- ✓ The past, present, or future provision of health care that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.
- ✓ The study Sponsor's name, or
- ✓ The study's identifiers, or
- ✓ The active drugs evaluated in the study

Case Study #1: data anonymization

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Solution: Development and application of best practices for data anonymization

Data anonymization for Protected Health Information:

- ✓ Provide the prospective data contributors with:
  - ✓ Clear description of applicable regulations (country and region-level)
  - ✓ Comprehensive guides on how to anonymize variables to reduce "distinguishability" to compliant levels with international/cross-border transfer considerations (for example, eliminate SSN and convert dates to timeframes)

Examples:

- ❑ C-Path: Duchenne Regulatory Science Consortium (D-RSC) Database
- ❑ Others: World Wide Antimalarial Resistance Network (WWARN)

Case Study #1: data anonymization

Solution: Development and application of best practices for data anonymization

For Sponsor Identification:

- ✓ Establish rules for anonymization of Sponsor's name, study's identifiers and drugs evaluated in active arms, through
- ✓ A process governed by comprehensive Data Contribution Agreements (discussed further in the next case study)

Examples:

- ❑ C-Path: Critical Path for Alzheimer's Disease Database
- ❑ Others: European Medical Information Framework (EMIF)

Case Study #2: Data Accessibility

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Barrier: Concerns about accessibility, transportability and redistribution

How to ensure:

- ✓ Which parties will have access to:
  - ✓ Full data (active and control arms, extension periods, etc.)
  - ✓ Portions of the data (only control arms, only specific periods, etc.)
- ✓ Adequately answering these questions if data are to be made “publicly available”:
  - ✓ Which users can access the data?
  - ✓ Can users transport the data or only execute remote views?
  - ✓ Can the data be redistributed by “qualified researchers”?

Case Study #2: Data Accessibility

Solution (Part 1): Implementation of "Data Contribution Agreements" (DCAs) as legal documents to govern the data-sharing process

Definition of level of sharing:

- ✓ DCA provides full flexibility to contributor to define:
  - ✓ Which parties get to see which portions or the totality of data (active and control arms, versus control arms only), varying from:
    - ✓ All potential users
    - ✓ Only certain parties/organizations
    - ✓ Only single party/organization
  - ✓ Moratoria on level of sharing, varying from:
    - ✓ Only after a specific regulatory decision that is tied to the specific data is reached (drug approval, for example)
    - ✓ Only the primary analysis are concluded or published
    - ✓ Only after a fixed date

Case Study #2: Data Accessibility

Solution (Part 1): Implementation of “Data Contribution Agreements” (DCAs) as legal documents to govern the data-sharing process

Examples:

- C-Path:
  - TB Platform for Aggregated Clinical Trials (TB-PACTS)
  - Critical Path for Parkinson’s (CPP) Database
- Others:
  - European Prevention of Alzheimer’s Disease Consortium
  - Biomarker Enterprise to Attack Diabetic Kidney Disease

Case Study #2: Data Accessibility

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Solution (Part 2): Definition of Terms and Conditions, and Implementation of "Data Use Agreements" (DUAs)

The access request, governance and DUA execution help define:

- ✓ Which users can access the data?
  - ✓ Adequately define the criteria for determining who can be a "qualified researcher"
  - ✓ Establish and communicate a clear access request and review process
- ✓ Can users transport the data or only execute remote views?
  - ✓ Perform a comprehensive analysis of advantages of each approach, in light of objective of the data sharing effort (further research versus tangible regulatory purposes).
- ✓ Can the data be redistributed by "qualified researchers"?
  - ✓ Redistribution should generally be avoided, and provisions should be defined through specific DUA language, as well as through the acknowledgment, agreement and adherence to the terms and conditions.

Case Study #2: Data Accessibility

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Solution (Part 2): Definition of Terms and Conditions, and Implementation of "Data Use Agreements" (DUAs)

Examples:

- C-Path:
  - Relational Sequencing TB Data Platform (ReSeqTB)
  - Multiple Sclerosis Outcome Assessments Consortium (MSOAC) Placebo Database
- Others:
  - The Global Alzheimer's Association Interactive Network (GAAIN)
  - Parkinson's Progression Markers Initiative (PPMI)

Thank you

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