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Secondary Use of Research Data and Samples:

Challenges and Opportunities

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Research data and samples can hold tremendous value to companies and researchers, requiring time, effort, money, and often consent to collect, store, and test. But once a study is complete, does that mean everything must be discarded or can't be further used? Often there are questions, during and after studies, about whether the data and samples can be used for additional analyses, other testing, and future research. This panel will discuss what types of laws and agreements govern the secondary use of data and samples, and possible pathways for secondary uses. The panel also will discuss some of the practical realities of managing secondary uses internally and how to mitigate the typical challenges and legal risks.

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Agenda

- The challenge of secondary uses
- What is secondary research?
- U.S. laws and considerations
- Consent considerations in the U.S.
- Challenges and considerations in the EU
- Practical reality of managing secondary uses
- Ways to mitigate risk and future-proof

The challenge

- What is the challenge of secondary research uses and how does it arise?

What is Secondary Research?

Primary Research

- Part of the main study
- End points for the study
- Exploratory research described in the protocol
- Validation/confirmatory testing

Secondary Research

- Not described in the protocol or ICF
- Not part of the main study
- Not in furtherance of study end points
- Third party research
- Different disease state
- Creation of new product
- Variation of study product/drug

Sometimes ICFs use the term “future research” which can be confusing as to whether such research can occur during the main study

What Laws Apply in the U.S.?

- HIPAA
  - ❑ Initial disclosure of PHI to the Sponsor
  - ❑ Authorization addressing secondary uses
  - ❑ Typically does not apply to pharma and device manufacturers
  - ❑ HIPAA-regulated entities may still be subject to HIPAA for secondary use
- Common Rule/FDA Regulations
  - ❑ Broad consent for secondary use of identifiable private information with IRB review
  - ❑ Broad consent for secondary use of identifiable biospecimens with IRB review
- State Privacy, Consumer Health Data, and Sensitive Condition Laws
- State Genetic Testing Laws
  - ❑ Genetic testing of samples and use/disclosure of genetic information
- FTC
  - ❑ False/deceptive/misleading statements or representations
  - ❑ Consent for use of sensitive data

Additional Considerations that Impact Secondary Use

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- Content of ICF/HIPAA Authorizations and variations
- Clinical trial agreements
- IRB approvals
- Protocol
- Any promises/representations made in initial collection of data/samples
- Global studies, varying laws/agreements/approvals apply and may have country specific addenda

Are the Data and Samples De-Identified?

- HIPAA Safe Harbor versus Statistician Method
  - Dates of service, dates of care, DOB/DOD
  - “Coded data” and linking codes
  - Geographic indicators smaller than state
  - Accession code for samples
  - Any other unique identifying number, characteristic or code except for certain reidentification codes
  - Actual knowledge
- State law standards
- Genetic data
  - WES/WGS
  - Ambiguity of state genetic laws applicability
  - Property rights in genetic data/samples in certain states

Some Key Challenges of Secondary Use in EU

- Legal Implications
  - EU CTR (Clinical Trial Reg), MDR (Med Device Reg)
  - GDPR and Member State Variations
  - Public Health Sector and Research laws/regulations
- Whether consent obtained/relied on for processing of data for main study
- Notice/transparency requirements for secondary uses
- Variations among member states in terms of research exemption or consent required

Panel Discussion

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- Consent considerations in the U.S. and ways to address
  - Optional versus required
  - Alternatives to consent
- Consent challenges in the EU and ways to address
- De-identification/anonymization
- Challenges of managing secondary uses in an organization
- Additional considerations for genetic testing of samples
- Risk mitigation/future-proof

Questions & Contacts

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Appendix

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Consent for Secondary Research in the U.S.

- Inform participant in the ICF/authorization about the intended secondary uses of data/samples, where anticipated
- This is true even of coded data and samples as likely not considered truly “de-identified”
- For the secondary use of identifiable data or biospecimens, the Common Rule requires that the description be sufficient that a reasonable subject would expect their data/specimens to be used for the secondary study. HIPAA requires the same for the use of identifiable data/PHI.
  - “Future unspecified research” versus broad research buckets with some descriptions
- Genetic testing requires consent (some states PRA and property rights)

Practical Considerations for Inclusion of Secondary Uses in ICF in U.S.

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Main ICF

- Simpler tracking operationally
- Broader participation in secondary use
- May result in refusal to participate in main study
- Variations in language approved by sites

Separate Opt-in Consent

- More challenging to track who opted-in to secondary use
- Complicates withdrawal
- Less participation
- Variation in language approved by sites
- Refusal to sign prevents IRB waiver

Alternatives to Consent in U.S.

- IRB review of secondary research study/use
- IRB waiver of ICF and HIPAA Authorization
- Notification with opt-out (higher risk except in very limited circumstances)
- Use of truly de-identified samples and data
- Could reconsent if necessary/able

Some Key Challenges of Secondary Use in EU

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- Risk based approach
  - Consent for some countries, not for others
  - Notice
    - Sponsors typically don't have information for reconsenting/notice
  - New purpose compatible with original
    - Open door in original ICF/notice but without additional detail
    - Provide notice of secondary research once identified, through PI/site
- Legacy data not obtained for research initially
  - Inform patient with opt out
  - Rely on research legal basis where possible
  - Reconsent
  - Anonymization
    - Very high standard
    - Debate; guidance pending on more flexible interpretation

Some Realities of Managing Secondary Uses Internally

- Process for review/approval of ICF language and structure
- Process for review of secondary uses
  - ICFs/HIPAA Authorizations/Information Notices—multiple versions
  - CTAs
  - Applicable Laws
  - IRB/EC Approvals
  - Protocols
- Data governance
- Negotiations with sites
- Pressure from sites, CROs, collaborators and third parties and internal teams
- Laws that apply (US and OUS) and representations/promises made in initial collection

Ways to Mitigate Risk and Future-Proof

- Implement processes to address secondary uses before study starts
  - Alignment of internal teams
  - Negotiation/review of ICFs/CTAs
  - Decide on approach of inclusion in main ICF versus opt-in consent
  - Language that is broad but compliant
  - Appropriate legal basis in EU depending on member state
  - Open door to secondary compatible use in EU
- Process for review of secondary use requests after study in progress/complete
- Tracking of ICF/IRB/EC/CTA permissions and withdrawals all along
- Legal considerations related to country of origin of data/samples
- De-identification/anonymization process
- Safeguards to protect against reidentification