### Human Data Review Committee: Purpose, Structure, and Function & CuriMeta: Overview and Data Collaboration

### **Philip Payne**

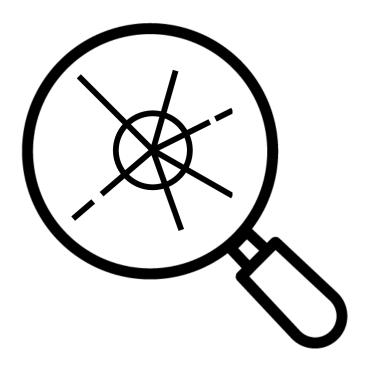
Director, Institute for Informatics

Associate Dean and Chief Data Scientist, Washington University School of Medicine



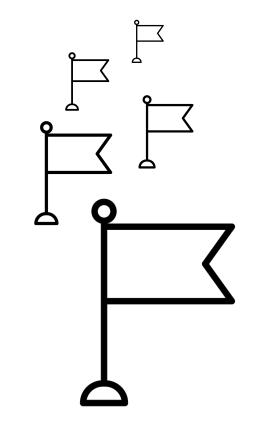
### **Current state of human data review activities**

- Broad variety of agreements being developed and executed involving sharing human data with third parties for research and/or technology development
- Coordination is complex and highly variable:
  - Approval process
  - Financial terms
  - Scope of use
  - ➢ Reporting
- In many cases, this leads to:
  - Frustration by those proposing disclosure
  - Challenges tracking and understanding agreements
  - Diminished impact



## **Goals of this committee**

- 1) Accelerate biomedical research and advance science in support of the missions of WashU and BJC, particularly when such efforts involve collaboration with third parties
- 2) Ensure we are acting as good stewards for data derived from patients and research participants
- 3) Align decision-making with sound scientific and ethical principles
- 4) Comply with all applicable laws, regulations and policies
- 5) Simplify and clarify decision-making processes



#### Background:

- Data are assets owned by the institutions (WashU and BJC)
- Data are not owned by individual investigators
- Use or disclosure of data are governed by applicable laws and institutional policies

#### What *is* governed by policy:

 Data that are disclosed to for-profit entities for the purposes of product development

### What *is not* governed by policy:

 Data that are disclosed for the purposes of patient care or for research directly involving, managed by, or oversee by personnel of WU

**Data** means all individual-level patient/participant data collected using the resources and/or under the auspices of the Institutions, whether in the course of clinical care or as part of a research study.

**Research** means a systematic investigation – including research, development, testing, and evaluation – designed to develop or contribute to generalizable knowledge. Characteristics of Research may include IRB oversight, consent of participants, and scientific leadership by a Principal Investigator affiliated with the Institutions.



### Four critical principles



Should be overseen and monitored in a systematic and comprehensive manner. Benefits generated should accrue to the Institutions to enable improvements in health care delivery, research, and education.

3

Should be decided in a manner that seeks the potential for direct and indirect benefits to the patients and populations from which such data are collected/generated (new diagnostics, therapies, interventions).

2

Should be transparent to promote scientific advancement within confines of ethical and legal commitments to patients and research participants. We have ethical responsibility to ensure disclosures in accordance with human subjects and privacy approvals and protections.

Should aim to recover appropriate value, defraying historical acquisition costs, capturing maintenance costs, recovering preparation and transfer costs, and securing market value. The benefit/risk assessment and approval of the valuation will be determined in accordance with this policy.



## Human Data Review Committee (HDRC)

The voting members of the Human Data Review Committee (HDRC) decide whether to approve (or decline) a proposed data disclosure.

- HDRC will balance numerous considerations to determine:
  - i. If the proposed disclosure achieves important Institutional missions.
  - ii. If the risks and challenges attendant to such proposed disclosure are substantially more significant than the perceived benefits of the disclosure.
- Should the HDRC decline, the members will facilitate working with the appropriate administrative units to determine whether proposer has alternative options within guidelines of this policy and in accordance with appropriate human subject and privacy protections to proceed.
- The proposer may resubmit the revision for consideration. If a declined after such further review and consideration, the matter may be referred and appealed to the chairs of the HDRC for still further review and consideration.

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6 WashU representatives

Washington University in St. Louis

SCHOOL OF MEDICINE

+ 6 BJC representatives

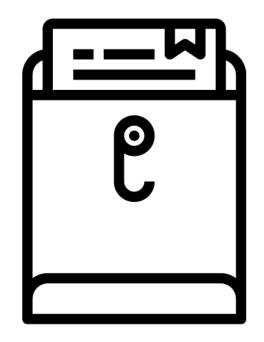
12 Total members

Two (2) are voting members from WashU Two (2) are voting members from BJC



# The following are required when proposing a disclosure:

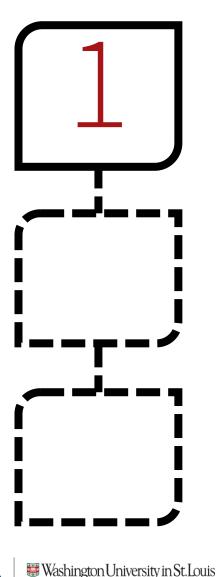
- 1) Project overview
- Details of the Data to be Disclosed (i.e., discrete data elements, as well as the Data sources – both at the institutional level, systems/database level)
- 3) How the Disclosure supports the missions of the Institutions
- 4) PL or WashU faculty/staff intellectual contribution to the project aims
- 5) Summary of any sponsoring entity terms and conditions under which the Data were collected if the Data are retrospective, including any applicable data sharing plan
- 6) Draft budget and other financial terms
- 7) Draft agreement or term sheet (unless WashU drafting)





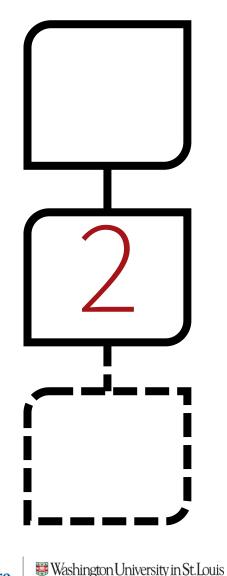
# **Considerations for approving disclosures**

- Requests closely aligned with WashU/BJC missions and including (material) intellectual contribution by WashU and/or BJC in project aims will more likely be approved.
- HDRC will evaluate each request to determine data's level of identifiability, including whether aggregate, summary-level data could achieve the purpose of the disclosure.
- HDRC will evaluate the data recipient, including where the recipient is located, to determine if there are reasonable data protection measures and laws in place to protect the data. *In addition, and to the extent applicable, the HDRC will assess whether the recipient abides by other ethical and/or business principles that are important to the Institutions.*
- HDRC will engage appropriate information security personnel to provide oversight ensuring methodology used adheres to appropriate safeguards and security.
- HDRC, or proposer at HDRC's request, will confirm with Human Research Protection Office (HRPO) that any consent documents used to collect the data, if applicable, are consistent with the proposed disclosure.
- HDRC will assess potential conflicts of interest. *The HDRC will also consider potential conflicts impacting WashU/BJC business interests.*



# **Considerations for approving disclosures**

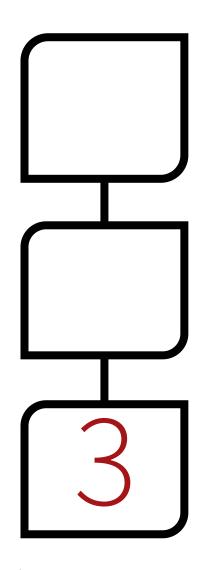
- Inclusion of preferred terms in the agreement with the data recipient is recommended.
- Approval of the data Disclosure by the HDRC may be contingent on negotiations with the data recipient to ensure such preferred terms are accepted.
- Preferred agreement terms should include:
  - 1) Data ownership remains with the Institutions, if at all possible
  - 2) Data is de-identified
  - 3) Recipient cannot attempt re-identification of, or attempt to contact, data subjects
  - 4) Data use is limited to research or technology development
  - 5) Secondary use of data for purposes not disclosed to HDRC is prohibited without HDRC's prior approval
  - 6) Recipient cannot publish, redistribute, disclose or sell the data or any portion thereof in any manner, without HDRC's prior approval



# **Considerations for approving disclosures**

#### • Data are valuable Institutional assets.

- Expenditures of resources are necessary to generate, manage, secure and curate data.
- Agreements to disclose data to a third party may consider many things, including:
  - Recovery of Costs: Revenue received to cover the total cost of any work performed to prepare, curate, store and transfer the data should be allocated to the Department(s) and/or Institution performing the work in accordance with standard processes for budgeting research and service agreements, including any applicable indirect cost rates.
  - In-Kind Contribution: Includes data, information, license rights, future product or service discounts, or derivatives, returned to the Institutions that may be recognized in lieu of monetary considerations, either in part or in full, depending on circumstances.
  - Fair Market Value: WashU/BJC seeks to obtain fair market value for its data.
- If a project that involves a data license results in or from WashU personnel developing intellectual property that falls within the scope of the Intellectual Property Policy, and if such WashU IP is licensed, the licensing revenues received by WashU will be distributed pursuant to WashU's then-current Intellectual Property Policy.
  - ➢ For any particular intellectual property asset or significant intellectual contribution created by an individual, which is made available to a third party, the individual may only collect a personal share of revenue under this policy or the WU IP policy, if applicable, but not both.





# Introducing: CuriMeta

Advanced Real World Data (RWD) and Research Platform Providing Next Generation Evidence and Insights to Life Sciences Manufacturers





#### **Research solutions**

Clinical studies (exclusive of prospective interventional trials)

• Retrospective or prospective

#### Trial enablement

- Synthetic control arms
- Protocol feasibility/trial design
- Patient recruitment



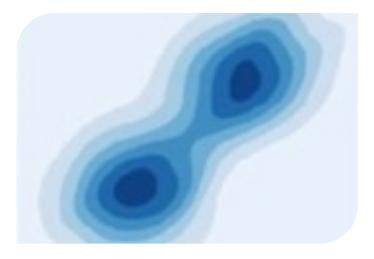
#### **Data solutions**

#### Data

• Real-world de-identified data extracts

#### Analytic solutions

• Derived insights



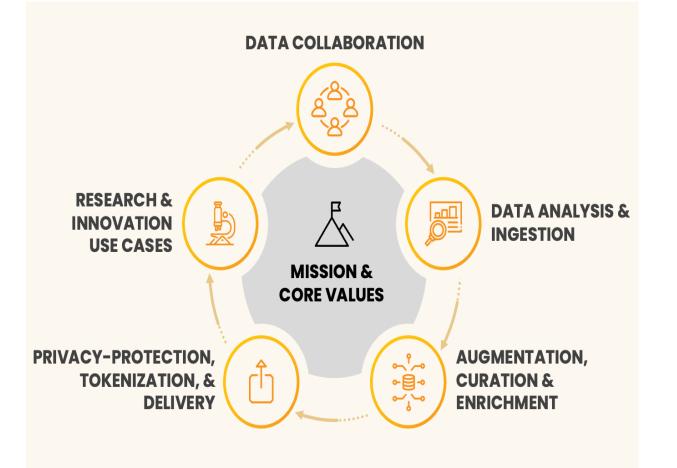
#### **Synthetic solutions**

#### Synthetic data

- Synthetic health data extracts
- Derived insights

### **CuriMeta:**

- 1) Data and technology platform partner
- 2) DLA and BAA in place with WashU/BJC
- 3) Aim is to accelerate research and health sciences to find new cures and diagnostics faster
- 4) Team comprised of experts from clinical informatics, data science
- 5) Full spectrum of real-world health data management, curation and deidentification processes



### **Data Stages**

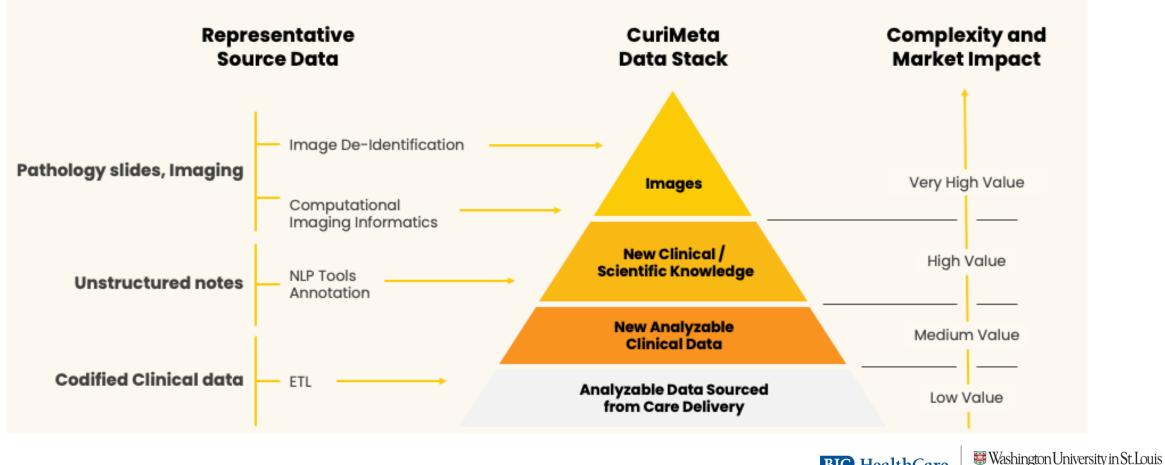


- NLP/Data Mining
- Enhanced data available

**BJC** HealthCare

Washington University in St. Louis

### The Potential of Advanced Real-World Data (RWD)



**BJC** HealthCare

### Advanced RWD includes powerful and difficult-tosource data types

Pathology
Genetic variants
Imaging

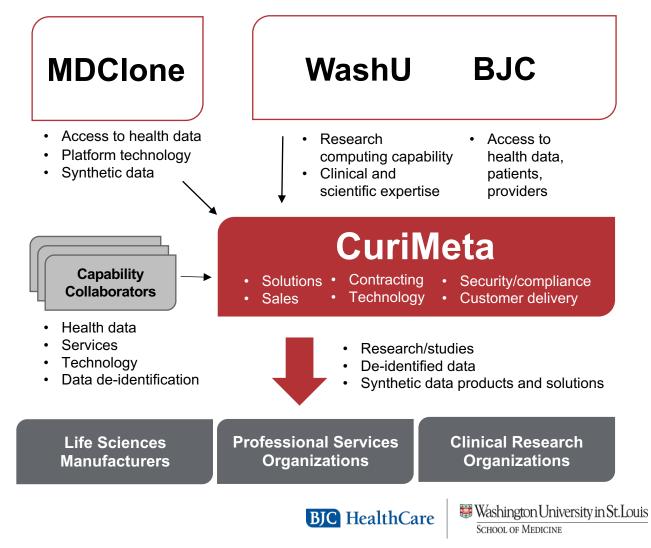




### **Business model highlights**

- (Final) draft agreements with BJC and WashU enable compliant access to data and research capabilities
- Economic structure designed to benefit all parties as the business grows; no per-patient cap to provider economic upside
- High partnership/visibility/control by BJC and WashU into accepted projects
- Highly professional and focused sales, contracting, technology security, compliance, and delivery capabilities
- High pedigree/top-level team/capability partners to bring data, services, and technology assets and know-how

Best-in-class solution management, selling, contracting, information technology, and customer delivery – all surrounded by superlative privacy/compliance practices



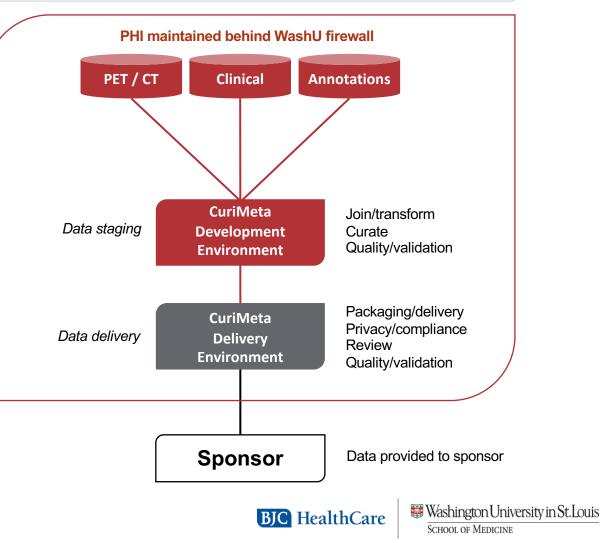
### **Operational flow**

#### Create cross-functional research project teams

- CuriMeta
  - Technical project management
  - Data science
  - Research informatics
  - BioStatistics/methods support
- Institute for Informatics (I<sup>2</sup>)
  - Data broker (funded)
  - Security/compliance
  - Secure computing environment
- BJC/WashU Joint Governance
  - > Oversight and approvals
- WashU Department Heads
  - PI support (funded)
  - Clinical expertise (funded)
  - Clinical research coordination (funded)
  - Research informatics support (funded)

#### IRB Governance Review

Identify WashU Principal Investigator



### **Questions?**

<u>https://sites.wustl.edu/ohids/governance/healthdata/</u>

• <u>Data-sharing@wustl.edu</u>



### **BJC** HealthCare

Washington University in St.Louis