Rare Disease Cures Accelerator-Data and Analytics Platform Virtual Workshop 2020
Up Next: Data ingestion and data governance

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C-Path
RDCA-DAP: Data ingestion and data governance

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Why share data?

**Patients/Patient Groups**
- Faster drug development
- Understand disease course/variance
- Visibility to industry
- Drive collaboration

**Industry**
- Design more effective trials
- Understand disease course/variance
- Understand / develop biomarkers/endpoints

**Academics**
- Improves their research
- Understand disease course/variance
- Understand / develop biomarkers/endpoints
- Visibility of data and research, collaboration
- Publish more/better papers
Patients are willing to share data – with conditions

- Meta-analysis of 27 surveys concluded patients support data sharing if specific conditions are met.
- Rare disease patients are particularly willing to share data.
- Conditions included: value, privacy, risk minimization, data security, transparency, control, information, trust, responsibility and accountability.
Optimizing data ingestion and usability:

Permissions and conditions for sharing data

Permissions and conditions for using data
Permissions and conditions for sharing data

Data Flow in RDCA-DAP

INPUT
Clinical Trial Data
Natural History Data
Patient Registry
Clinical Data
Other Data

C-PATH PROCESS
RDCA-DAP contact with custodian, negotiate data sharing agreement
Data transfer
Data exploration and mapping

Permissions and conditions for using data

C-PATH OUTPUT
Tools and analysis developed with data made available
Data available per custodian’s direction
The Data Sharing Agreement

Legal document between RDCA-DAP and the custodian that dictates how RDCA-DAP can use a dataset.

- Tells us that the data was collected ethically, the patient consent allows sharing of the data, and that the custodian is able to share the data, and that it will be de-identified

- Tells us what we are allowed to do with the data – share with anyone, share after approval, or only share metadata or summary data

- Assures the data custodian of data protection/data privacy

- Details any other feedback agreed to by both parties (e.g. publication notifications, credit to the custodian)

- Provides details of the dataset and associated documents to help us interpret the data
Interactions with the custodian

INPUT
- Clinical Trial Data
- Natural History Data
- Patient Registry
- Clinical Data
- Other Data

C-PATH PROCESS
- RDCA-DAP contact with custodian, negotiate data sharing agreement
- Data transfer
- Data exploration and mapping

C-PATH OUTPUT
- Feedback to custodians on data gaps, gaps in standardization, other enhancements to collection
- Standardized data returned to custodians
- Analysis and tools available
- Larger dataset available

Tools and analysis developed with data made available
Data available per custodian’s direction
Accessing Data Through RDCA-DAP

Summary-Level Data

In RDCA-DAP Platform

search interface

Conditions of use
Accessing Data Through RDCA-DAP

In RDCA-DAP Platform

Search interface

Conditions of use

Approval Process as agreed in DCA:
- Automatic approval
- Approval reviewed by RDCA-DAP data use committee
- Approval reviewed by RDCA-DAP data use committee and data custodian
- Internal use only

Summary-Level Data

Patient-Level Data

Conditions of use

Approval Process as agreed in DCA:
- Automatic approval
- Approval reviewed by RDCA-DAP data use committee
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- Internal use only

RDCA-DAP
Accessing Data Through RDCA-DAP

RDCA-DAP

Summary-Level Data
- search interface
- Conditions of use

Patient-Level Data
- advanced analytics interface
- data download
- Conditions of use

Approval Process as agreed in DCA
Terms and Conditions of Use of Data

Legal document between RDCA-DAP and the data users that dictates what the user can do with the data

- Ensures secure data storage, data privacy (limitations of use to approved researchers and subcontractors)
- Ensures that use is limited to the approved research
- Requires acknowledgement of data source in public disclosures
- Ensures ethical use of data
- Ensures data is not sold or shared on to other users, data cannot be patented etc.
- Encouragement of public disclosure of results, sharing results with data custodian
Who should share data?

By working together and sharing data together we can accelerate therapy development for Rare Diseases.

Patients/Patient Groups

Industry

Academia
RDCA-DAP in the Ecosystem of Rare Disease Data

**Individual Studies**
- Clinical Trial Data
- Registry Data
- Natural History Data
- Genomic Data
- Imaging Data
- Surveillance Data
- Preclinical Data
- Other Novel Data

**Groups that share Individual Datasets**

**Registry Systems**

**EHR systems**

**RDCA-DAP DATA COLLABORATION CENTER**
- Data Vault
- Curation
- Metadata Annotation
- Standardization
- Data Lake
- Data Warehouse
- User Friendly, Secure Cloud Interface

**ACTIONABLE RARE DISEASE DRUG DEVELOPMENT SOLUTIONS**
- C-Path Quantitative Medicine Program
- Other Researchers

**More Efficient Development of New Therapies**

- Improved standardization, ontologies, use of instruments, standardized data
- Access to more data for analyses
- Shared tools and analyses to improve future studies
THANK YOU!

Don't forget to answer survey questions.

For more information, email rdcadap@c-path.org