PCORI's Efforts to Implement a Data Sharing Policy: Lessons Learned (So Far)

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HRA Members' Meeting: Spring 2018

pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

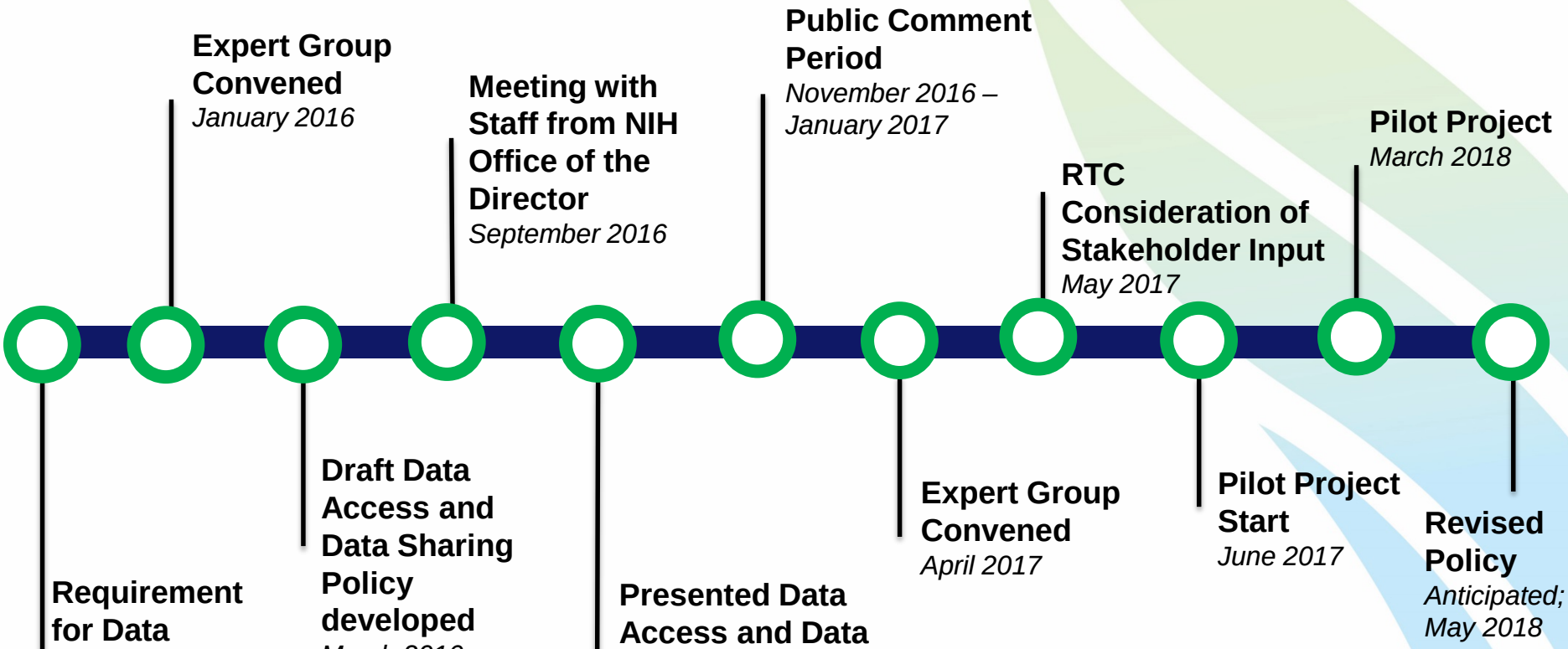
PCORI Funds Comparative Clinical Effectiveness Research

- Generates and synthesizes evidence comparing benefits and harms of at least two different methods to prevent, diagnose, treat, and monitor a clinical condition or improve care delivery
- Measures benefits in real-world populations
- Describes results in subgroups of people
- Helps consumers, clinicians, purchasers, and policy makers make informed decisions that will improve care for individuals and populations
- Informs a specific clinical or policy decision

Policy for Data Access & Data Sharing: Background

- PCORI is committed to open science and has implemented initiatives that enable public access to the findings from PCORI-funded studies.
- Intent of policy is to set forth expectations and guidelines for PCORI Research Awardees for management of their data in order to:
  - Promote data sharing to enable conduct of additional analyses using data from PCORI-funded studies, thereby augmenting the knowledge generated from the original study.
  - Facilitate reproduction of original analyses to increase the integrity of PCORI-funded research findings.
- Policy developed by PCORI staff, with input from expert advisory group and Research Transformation Committee (RTC)
  - PCORI staff also spoke with other funders/regulators of clinical research, including Gates Foundation, European Medicines Agency, and NIH.
- Policy is drafted in a manner that enables PCORI to incorporate additional operational details and procedures over time, based on learning from the public comment period and from a planned pilot project.

Timeline of Data Sharing Initiative



Implementing data sharing policy: where PCORI stands viz. other health funders

- Recent *NEJM* piece re: data sharing by staff from Wellcome Trust, Medical Research Council, Gates Foundation, Cancer Research UK
- RWJF-commissioned report re: funder data sharing policies
- Check-ins with NIH staff leading data sharing initiatives/activities

- (Non-self-serving) key take-away: PCORI is still well-positioned to be a leader among health funders re: data sharing
  - Committed to provide funding to support data preparation/ deposit/ maintenance
  - Committed to grappling with complex technical and governance challenges prior to implementation
  - Committed to understanding business model/operations of data repositories
  - Spade work (public comment; expert group; pilot) we've done will lead to smoother implementation of policy

Key Implementation Issues: Public Comment

- **Issue 1**: Restrictions on Data Use
- **Issue 2**: Requestor qualifications and Required documentation
- **Issue 3**: Informed consent
- **Issue 4**: Applicability to studies using EHR and other health systems data

Issue 1: Restrictions on Data Use

Discussion Points

- Potential types of data uses (e.g., Research, quality improvement, commercial purposes)
- Challenge of being overly prescriptive regarding permitted uses in the Policy

RTC Recommendations

- Explicitly prohibit re-identification of data in the Policy
- Adhering to principle of transparency is paramount regardless of purpose for which data is used
- Require third parties to report all findings to PCORI including negative findings

Issue 2a: Requestor Qualifications

Discussion Points

- Whether Policy should specify certain education level or scientific expertise requirements
- Challenges of imposing team qualifications rather than specific individual credentials

RTC Recommendations

- Include general qualifications for teams
- Indicate technical assistance will not be provided by PCORI or primary study investigators

Issue 2b: Required Documentation

Discussion Points

Consider minimum documentation requirements for data requestors including:

- Scientific purpose
- Data requested will be used to enhance scientific knowledge
- Assurance that proposed research can be addressed using requested data

RTC Recommendations

Concur with minimum requirements gathered from stakeholder input.

Additionally,

- Assurance data will not be re-distributed
- All findings and associated data will be shared with PCORI

Issue 3: Informed Consent

Draft Policy requires:
"Appropriate documentation of patient consent that permits data collected as part of the study to be de-identified, used for future research purposes and shared broadly with researchers not affiliated with the institution conducting the study." (Section IV.B.1.d)

Discussion Points

- Challenge of data sharing if primary study:
  - Had insufficiently broad informed consent; or
  - Was conducted based on waiver of informed consent

RTC Recommendations

- Specify the data subject to the Policy are data that have been de-identified in accordance with HIPAA
- Case-by-base reviews for data that do not satisfy general requirement

Issue 4: Applicability to studies using EHR and other health systems data

Discussion Points

- Strict prohibitions on data sharing due to contractual and legal obligations that may attach to health system data (e.g., EHR and claims data)
- Potential value of sharing the research queries used to generate study datasets

RTC Recommendations

- Case-by-case review for studies that involve health system data
- Require query codes and parameters to be made available when underlying data cannot be shared
- Consider availability of data for secondary uses when evaluating applications at funding stage

Data Sharing Pilot Project

Objectives:

- To assess operational challenges of implementing a data sharing requirement and generate learnings to further inform refinement and finalization of the Policy
  - Which features and capabilities of repositories (e.g., data models, governance structure, security, staffing, experience with health data/IPD) are most critical for depositing and sharing of clinical data
  - What time/effort is needed for awardees to prepare data package for sharing
  - What are the challenges/concerns for PCORI awardees and their institutions and how they can be addressed in a manner consistent with PCORI's commitment to open science
  - What PCORI resources (staff and funding) are required to support data sharing

PCORI Awardees:

- Five awardees are participating: Three completed studies from the Broad PFAs and two ongoing PCS studies.
- Awardees were selected to represent a diversity of therapeutic areas, study designs (both observational and RCTs) and data sources (EHR, claims data, imaging data).

Data Repositories:

- Multi-Regional Clinical Trials (MRCT) Center, Brigham and Women's Hospital
- ICPSR at the University of Michigan

Data Sharing Pilot Project (2)

MRCT:

- Focused on governance issues and documents – Data Use Agreement (DUA), Data Contributor Agreement (DCA), Informed Consent Forms (ICF)

ICPSR:

- Worked with 4 awardees to archive data of varying types with ICPSR
- Documented the experience of working with various research projects in hopes of enabling PCORI to plan for broader data sharing activities amongst its awardees
- Created a demonstration repository for PCORI, initially for internal review and use

Data Sharing Pilot Project: Lessons Learned

- Top Learnings for Data Governance
  - Variability in understanding of data package and data sharing terms
  - DCA, DUA and ICF are valuable documents for setting expectations
  - PCORI awardees desire recognition when data used in secondary research

- Top Learnings for Data Submission
  - Preparing data for submission can take time
  - Curation and review of submitted data is key part of process
  - Need to determine upfront the date for releasing data (embargo)

Crossing the Goal Line

- Revisions to policy (v1.0 doesn't have to be perfect!)
- Buy-in from leadership about key details, esp. best repository model and enforcement mechanisms
- Board of Governors approval