STAR CRN Engagement Guidance & Resources for Patient-Centered "Data-Only" Studies

The STAR CRN Stakeholder Engagement Team (SET) requires data-only studies that use or share patient-level data to be inclusive of people and patients represented in the data. All studies involving STAR CRN are patient-centered and require a rightsized stakeholder engagement plan indicated by the level of funding, resources available, and scope (e.g., pilot study versus a large-scale).

The STAR CRN defines *data-only studies* as: those studies that are observational, retrospective data abstractions that use electronic health record data from the sites participating in the STAR CRN. This can include electronic health record data from the STAR CRN Common Data Model (CDM), or from other electronic health record data sources that are being accessed as part of a STAR engaged project. This includes the extraction and analysis or data sharing of identifiable electronic health record data (with waiver of patient consent), or the use of limited data sets, or de-identified data. This policy does not apply to queries of the Common Data Model that return aggregate counts, such as for prep-to-research activities, "rapid queries" for PCORnet, or other very small data query projects.

Engagement Principles for Patient-Centered "Data-Only" Studies	
	1. Engagement strategies should consider opportunities to engage stakeholders across the continuum of a study including: 1) study design, 2) study implementation, 3) study analysis, 4) study results and dissemination. The PCORI Engagement Rubric and the Continuum of Community (Stakeholder) Engagement in Research can assist in building a framework for stakeholder engagement in health research and promote patient-centeredness. The STAR Stakeholder Engagement Team is available to assist in developing a plan that is feasible for the size of the study to be performed, and resources available.
	2. Engagement plans should strive to utilize the language and concepts of data democratization (making information accessible to people by removing the bottlenecks and putting information in the hands of communities) to allow study participants and other stakeholders access to study data that is informative and actionable. Who is using the data and where is it coming from? Strategies should include transparency and be comprehensive across stakeholder groups (i.e., proficiency levels and access to the necessary technologies).
	3. *Stakeholders* as defined by PCORI include patients, caregivers, advocates, clinicians, health systems, insurers, and researchers (non-research and research scientist). They can provide important insight into all aspects of a study lifecycle including variables of interest for study analysis, data security, confidentiality/privacy, ethics, cultural competence, and person-centered dissemination of study findings beyond academic deliverables (see Appendix 1).
	4. Stakeholders representing patients and/or communities can be engaged in the research as advisors, consultants, and active team members https://research-teams.pcori.org/.

	5. Patients from the populations of interest and/or community members should be approached to provide input on meaningful and beneficial treatments, analyses, shared governance, and research questions, as well as concerns related to treatment and research. 6. Person-centered goals and/or outcomes should be included to address the needs of patients and communities. 7. Early, informal discussions could become longer term. Establish relationships with stakeholders to provide input at different points of a study.
Compensation	1. Compensation should follow the guidance of the PCORI Stakeholder Compensation Framework o "PCORI expects that any research proposal submitted to PCORI will include a plan and related budget for fairly compensating patients, caregivers, and patient/caregiver organizations engaged as partners in the project. The linked document explains the rationale for such compensation."- PCORI 2. Additional guidance for budgeting for engagement activities is available here: PCORI Guide to Budgeting Engagement Activities. The STAR CRN team is also available to help with budgeting. 3. Researchers are encouraged to check with institutional funding sources for stakeholder compensation (*e.g., voucher applications*). 4. Allow time to complete any institution required documentation before engaging stakeholders.

Return of Research Results	1. Investigators are strongly recommended to develop a plan for returning results to study participants or the community. More information about the value of this approach is available here: Return of Value in Research
	
	2. Recommendations & Approaches to Person-Centered Return of Research Results (see Appendix 1)
	    • Take a systemic approach when developing a dissemination plan.
	    • Have dissemination as an agenda topic for every leadership and study team meeting.
	    • Explore ways to disseminate as appropriate to the patient population and community.
	    • Provide regular updates on how patient data is being used (e.g., newsletters, websites, webinars, Q&A).
	    • Plan recurring dissemination throughout the life of the study rather than just at the end.
	    • Collaborate with institution public relations / marketing teams.
	
	3. PCORI Dissemination & Implementation Framework & Toolkit

	The Framework illustrates PCORI's commitment to increasing the relevant knowledge available to people and organizations to support their health decisions. 4. Contact the PCORnet Engagement Team at your site and/or the PCORnet Engagement Coordinating Center to access support for this work and direct you to appropriate resources.

Use Cases	Use cases illustrate key factors to right size stakeholder engagement in alignment with the scope of a study:
	
	1. Target Patient Population and Population Size
	2. Type of Patient Level Data (De-identified, Limited, or Identified)
	3. Sensitivity of the Data (rare disease patients, data on psychiatric illness, HIV, substance use)
	4. Level of Funding
	    a. Duration of the Study
	    b. Size of the Study (#of sites involved nationally)

Additional Engagement Resources	1. PCORI Engagement Resources:
	    • Building Effective Multi-Stakeholder Research Teams
	    • Engagement Rubric
	    • Engagement Tool & Resource Repository
	    • Engagement in Health Research Literature Explorer
	
	2. PCORnet Engagement Resources:
	    • SET Webinar on STAR Engagement & PCoR Scale
	
	3. STAR CRN Engagement Resources:
	    • Person Centeredness of Research (PCoR) Scale
	    The intent of this rating scale is to assess whether research reflects the needs and viewpoints of people the research intends to help. The scale can be used to rate research products such as abstracts, manuscripts, proposals, and protocols. This scale could 1) help patients, communities, reviewers, researchers, and funding agencies assess the person--centeredness of research, 2) help evaluators assess the extent to which research meets person--centered criteria, and 3) assist researchers in strengthening the person-centeredness of their work.
	    • Stakeholder Advisory Council (SAC) reviews and consultations from the patient stakeholder perspective SAC Review FAQ's
	    • Stakeholder Engagement Team (SET) reviews and consultations (community and academic expertise).

Appendix 1.

Bullet point one in the *Return of Research Results* section of this document states, "take a systematic approach when developing a dissemination plan." Additionally, the *PCORI Dissemination and Implementation Framework* defines "dissemination as the intentional, active process of identifying target audiences and tailoring communication strategies to increase awareness and understanding of evidence, and to motivate its use in policy, practice, and individual choices."

The purpose of this rubric is to provide specific actions that may be taken by the stakeholders of data-only research to accomplish these dissemination goals. The rubric provides several specific action items that the leadership team should consider. It also provides a matrix of target audiences with examples of communication strategies that can be used for those audiences. Some of these strategies are traditional while others may be novel to the research team. Investigators are expected to work with all stakeholders (especially patient stakeholders), to determine which Stakeholder channels and which content modalities best fit with the research, data, and audience. It is expected that data-only research projects will use some of these approaches to ensure best-practice, but each project will have unique dissemination outcomes. Contact the PCORnet Engagement Team at your site and/or the PCORnet Engagement Coordinating Center to access support for this work and direct you to appropriate resources.

Person-Centered Return of Research Results					
	Written/Hard Copy	**Written/ Electronic**	**Verbal/Presentation**	**Curricular**	**Other Innovations**
Stakeholder Channels					
Participants	Public abstracts as a model; lay/audience-appropriate briefs	PowerPoint, video, whiteboard, or educational animation (i.e., Canva)	In-person or remote (i.e., Zoom, or Zoom recorded sessions)		
Support Groups					
Patient	Collaborate with Patient led organizations to develop and disseminate written information. -	Summary of results and disseminate plan			
Community	If community organizations assisted with recruitment or provided data			Community colleges in geographic area	
Traditional Channels					

Academic Papers	Academic journals		Presentations and posters at professional conferences	Journals with different audiences (i.e., professional education journals)	
Professional Groups	i.e., American Heart Association	Newsletters, patient, and stakeholder social media groups.			
Public Distribution					
Non-Traditional Channels	Departments of Health in target communities.	Record Plan-Do-Study-Act (PDSA) style reviews of the research for radio, especially rural and minority broadcasters	Other gatherings of interest. i.e., TED Talks	School nurses, health faculty in schools; parent teacher organizations	
Targeted Communities					
Organizational & Geographic	Faith organizations; NORD's organizational database; local schools; Federally Qualified Health Centers (FQHC)	Social media (text and video); organization public relations departments	Presentation, booth/table, and posters at community events, fairs, festivals, etc.	Public health workers (i.e., FQHC), school nurses, health departments, high schools, and community colleges	

Dissemination Action Items	1. Professional vs Public Abstract and Content
	2. Patient and other stakeholders are recruited to the research team for many reasons - recruitment, expertise, and their relationships with Principal Investigators. Stakeholder knowledge of unique dissemination channels and their ability to assist with dissemination must be a consideration for inclusion of patients and other stakeholders.
	3. Dissemination plan and activities (action plan) for dissemination are standing items on the Leadership Team Agenda.
	4. A budget for dissemination is specified in detail.
	5. Detailed planning for dissemination and material development must start by project mid-point
	    a. Written detailed plan
	    b. Written and electronic/video materials being created.
	6. Responsibility for ongoing dissemination efforts after the research is concluded (and the Team has gone on to other activities) are detailed as dissemination activities in award schedule (should be included in the Gantt Chart beyond regular grant activities.)
	7. Dissemination responsibilities and specific dissemination activities are assigned by name.				

	8. Dissemination plan is assigned a separate evaluation score. It is considered part of evaluation for both the proposal stage and final review of the research activity.
Source: Robert Stevens, PhD, 2022 (STAR CRN, Health Sciences South Carolina)	