PRO Core Update

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Purpose of the PRO Core

- The PRO Core was established to help researchers to identify opportunities for collection and assessment of patient reported outcomes (PRO) within Collaboratory projects.

- To give guidance to researchers on PRO data collection, with regards to the 4 major issues in PRO data collection:
  - Addressing IT infrastructure software/hardware issues
  - Choosing appropriate instruments for PRO data collection
  - Defining how to integrate their research and collection in the care process in a meaningful appropriate way.
  - Preparing for real-time reporting/analytic feed, as well as statistical analysis of PRO data
Review of Year 1

1. Documented PRO data collection capabilities of UH2
   • Used proposals and later communications to create a Use Case portfolio for all current UH-2 projects
     • Included: PROs measures being used, process of data collection and likely issues

2. Landscape summary of successful PRO implementation
   • Months reviewing recent literature and conducting formal and informal interviews regarding the use and implementation of PROs for clinical care.

3. On-site Investigations
   • “On the ground” review of how PRO data collection activities are being implemented in various settings.
   • Focused on healthcare systems/institutions that have successfully established processes for routine collection of PRO data.
Review of Year 1

4. PRO/PROMIS Workshop
   • Expressed need for Core to be a leader in identifying knowledge gaps PROs could fill.
   • Began planning 1 day meeting workshop (~30 participants)
   • The intention of the workshop was to address state of PRO use in clinic settings, with focus on PROMIS measures.
     • Includes:
       • Show impact of PRO data/implementation on clinical outcomes.
       • Address areas where PROMIS/ current PRO instruments work well/do not work at all/ effect can not be ascertained and explain why.
       • Highlight best methods for using PROs in clinical care/research.
       • Demonstrate superior data/analytics use of PROs/PROMIS.
Review of Year 1

5. Generalizable knowledge about PROs and useful resource links distributed via the HCS Collaboratory Living Textbook

Rethinking Clinical Trials
A Living Textbook of Pragmatic Clinical Trials

Patient-Reported Outcomes

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Progress in Year 2

1. **Two papers in progress***
   - Article on titled *“Practical Guide to Initiating and Implementing Patient Reported Outcomes Measures”* written for eGEMs special issue
     - Product of the past year of literature review, formal and informal interviews, and on-site visits.
     - Article documents real-world solutions for ePRO implementation from strategies for early end-user involvement to understanding and assessing data for completeness and consistency.
     - Submission planned for August 27th. Reviewed by the C3PC Committee. Final revisions in progress
   - White paper titled *“Strategies for Overcoming Barriers to the Implementation of Patient Reported Outcomes Measures”*
     - Product of the past year of literature review, formal and informal interviews, and on-site visits.
     - Article examines barriers to PRO use in the routine clinical setting from the clinician, administrator, and patient perspective (e.g. clogging workflow) and provides real-world solutions.

*Products of stated deliverables: “Current Solutions to PRO issues” and “Landscape summary of barriers and facilitators for PRO Implementation”*
Progress in Year 2

2. **PROMIS Workshop**
   - **Goal:** to identify current gaps in knowledge regarding the use of PROMIS and other PRO tools to provide PRO data relevant for clinical care as well as for comparative effectiveness research.
   - Meeting planned for early January.
   - Agenda proposed and several presenters identified
   - Scouting location

3. **Continued contributions to HCS Collaboratory Living Textbook**
   - Added new material on NIH Toolbox, NeuroQOL, and PROMIS.
     - E.g. PROMIS APIs and videos
   - Plans to add blog posts about barriers and facilitators to PRO implementation

**Products of stated deliverables:** Generalizable knowledge about PROs and useful resource links distributed via the HCS Collaboratory Living Textbook
Other Ongoing Activities

• **UH2 Projects**
  - Review PRO Data Collection Capabilities in Current UH2 Projects
  - Develop PRO Plans in collaboration with UH2 Projects

• **UH3 Projects**
  - Work together with UH3 projects to finalize plans for implementing PRO data collection in the studies
  - Development and initiation of plans for monitoring missing PRO data
  - Develop an overview of PRO-related issues recommendations

• *Core hosts monthly calls and monitors Issue Tracker biweekly*
Engagement with UH2 PIs and Expectations

- **Continues to offer expert advice and technical assistance**
  - Including: support with PRO implementation, measure selection and/or development, etc.
  - Help developing PRO plans and shoring up PRO data collection capabilities

- **PRO Core expectations from UH2/UH3 groups**
  - Foster open lines of communication between Core and project leaders
  - Participation of project representative on monthly calls
  - Contribute to data gathering and publications when appropriate (e.g. real-world experiences)