



# PRO Core Update

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The Collaboratory



# 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



# Demonstration Projects

- We currently have 3 of 6 projects collecting PRO data
- Instruments being used include:
  - Brief Pain Inventory (BPI)
  - Patient Health Questionnaire-9 (PHQ-9)
  - Short Form-36 (SF-36)
- Range of PRO data collection methods and processes being utilized
  - Paper-pencil
  - Electronic via Patient Portal
  - Telephone using Interactive Voice Recognition System (IVRS)
- Potential issues for investigators collecting PRO data
  - Compliance
  - Missing data
  - Data standardization



# Addressing the Issues

## 1. Landscape Summary of successful PRO implementation

- Months reviewing recent literature regarding the use and implementation of PROs for clinical care. Recently added PRO intervention literature to this list

## 2. On-site Investigations

- This is an “on the ground” review of how PRO data collection activities are being implemented in various settings with the purpose of bring this information back to the Collaboratory
- Focused on healthcare systems/institutions that have successfully established processes for routine collection of PRO data.
- Currently developing interview questions and strategy
- First on-site visit scheduled for mid-March



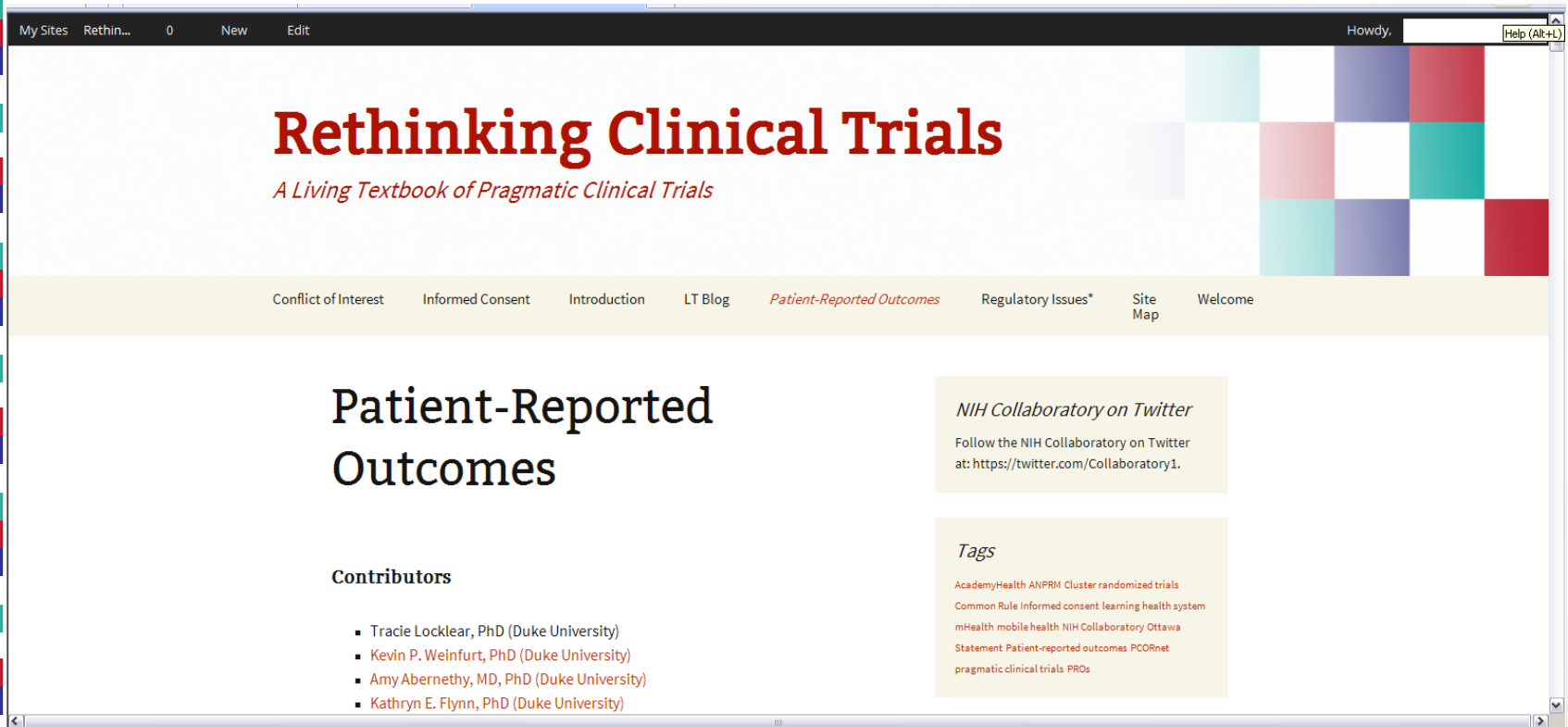
# Addressing the Issues

## 3. PRO/PROMIS Workshop

- Planning 1.5 day meeting workshop (~30 participants)
- The intention of the workshop is to address issues of PRO use in clinic settings. Focus will be on PROMIS.
- We are inviting PROMIS investigators to present cases studies that do the following:
  - 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.

# Addressing the Issues

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



The screenshot shows a web browser window displaying the 'Rethinking Clinical Trials' website. The browser's address bar shows 'My Sites Rethin...' and the page title is 'Rethinking Clinical Trials'. The main heading is 'Rethinking Clinical Trials' in a large, bold, red font, with the subtitle 'A Living Textbook of Pragmatic Clinical Trials' in a smaller, italicized red font. Below the heading is a navigation menu with links: 'Conflict of Interest', 'Informed Consent', 'Introduction', 'LT Blog', 'Patient-Reported Outcomes' (highlighted in red), 'Regulatory Issues\*', 'Site Map', and 'Welcome'. The main content area features a large heading 'Patient-Reported Outcomes' and a 'Contributors' section with a list of names and affiliations. To the right, there are two sidebars: 'NIH Collaboratory on Twitter' with a link to the Twitter page, and 'Tags' with a list of keywords.

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## Rethinking Clinical Trials

*A Living Textbook of Pragmatic Clinical Trials*

Conflict of Interest Informed Consent Introduction LT Blog *Patient-Reported Outcomes* Regulatory Issues\* Site Map Welcome

### Patient-Reported Outcomes

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