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Health Care Systems Research Collaboratory

Update on the Living Textbook

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Rethinking Clinical Trials

What is the Living Textbook?

- Authoritative, expertly curated, flexible compendium of knowledge on the design, conduct, and dissemination of pragmatic clinical trials

- Trusted web-based resource for a broad audience

- Content structured in chapter-like topics written by Collaboratory subject matter experts in close collaboration with writers/editors at Coordinating Center
  - Uses scholarly citations combined with links to other web resources
  - Includes increasing number of resources and products developed by Collaboratory and partners

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Previous Milestones (March 2014)

- Existing content ported to WordPress

- New site went live in March

- Two new topic chapters (Patient-Reported Outcomes and Regulatory Issues "stub" article) released

- "LT Blog" added to capture fast-moving developments

- Two new FTE writers/editors brought on board

Living Textbook Writing/Editorial Staff

- Managing Editor
  - Jonathan McCall, MS

- Contributing Editors
  - Karen Staman, MS
  - Gina Uhlenbrauck
  - Liz Wing, MA

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Rethinking Clinical Trials™

A Living Textbook of Pragmatic Clinical Trials

Welcome to the Living Textbook | Topic Chapters | Tools for Research | Blog | Site Map | Contact Us

Welcome to the Living Textbook

Welcome to the NIH Collaboratory's *Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials*! The *Living Textbook* is designed to provide a complete suite of information on how to understand, design, conduct, analyze & disseminate pragmatic clinical trials (PCTs). Although structured like a textbook, its web-based formatting allows us to deliver a flexible, continuously...content.

"Our goal in crea...

In the clinical setting, an item is a question posed to a patient along with a set of possible answers. A domain is the specific feeling, function, or perception being measured, i.e., pain, fatigue, emotional distress, physical functioning, and social role participation.

After the conceptual framework is hypothesized, it should be adjusted based on patient input. The instruments measuring the domains within the conceptual framework are then tested for reliability, validity, and ability to detect change. Only after this testing is complete are the instrument content, scoring, procedures, formats, and training materials finalized and ready for full use in the research environment. Because the development of an instrument is an iterative process, after data are collected, analyzed, and interpreted, the instrument may be further modified and the cycle repeated [1].
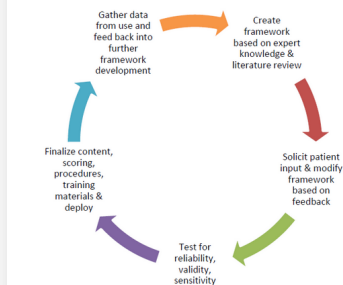
Development and improvement cycle for a PRO instrument.

Tags

AcademyHealth ANPRM CDER **Cluster randomized trials** Colon cancer Common Fund Common Rule **Comparative effectiveness** CTTI Data quality Data standards Demonstration Project **Electronic health records** FDA Federally Qualified Health Center **Grand Rounds** Group Health Research Institute Health systems **Informed consent** Kaiser Permanente Center for Health Research Learning health system

NIH Common Fund Video Competition Goes Live

April 30, 2014 Uncategorized Common Fund, NIH, NIH Collaboratory, Video competition Gina Uhlenbrauck

As part of its 10-year commemoration activities, the **NIH Common Fund** is holding a **video and song competition** to showcase Common Fund–supported activities in a fun and creative way. Grantees and program staff were encouraged to submit brief, original works that would be accessible and engaging to the public.

Informed Consent

Contributor

- Laura M. Beskow, MPH, PhD

Informed consent describes a process for enabling individuals to make voluntary decisions about participating in research with an understanding of the purpose, procedures, risks, and benefits of the investigation, as well as alternatives to participating. As described below, the basis for informed consent—including the requirement to obtain consent, situations in which that requirement might be modified or waived, and the content of the information provided—is grounded both in ethical principles and government regulations.

In this Topic:

- Ethical Foundations of Informed Consent
- Regulatory Foundations of Informed Consent
- Waiving Informed Consent Requirements
- Obtaining Informed Consent
- Special Situations and Settings
- Emerging Issues and Controversies
- Bibliography

Pages

Assessing Data Quality

Biostatistical Guidance Documents

Blog

Conflict of Interest

Contact Us

Electronic Health Records-Based Phenotyping

Table 1 Project

Informed Consent

Introduction

Learning Healthcare Systems*

Patient-Reported Outcomes

Regulatory Issues*

Site Map

Tools for Research

Tools for EHR-Based Phenotyping

Topic Chapters

Welcome to the Living Textbook

NIH Health Care Systems Research Collaboratory

The NIH Collaboratory is an NIH Common Fund–supported project devoted to building new national infrastructure for collaborative research and enabling the creation of a nationwide LHS. The Collaboratory's centerpiece is a series of demonstration projects that feature innovative approaches to clinical research utilizing EHRs as data sources across multiple institutions and health systems. Findings from these projects will be "fed back" to create datasets, tools, and best practices that will be organized and disseminated through the Collaboratory's Coordinating Center.

https://www.nihcollaboratory.org/Pages/default.aspx
http://sites.duke.edu/rethinkingclinicaltrials/

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Current Milestones

- Two new topic chapters added
  - Learning Healthcare Systems (stub)
  - EHR-Based Phenotyping

- "Tools for Research" tab added, with content served from Collaboratory Knowledge Repository
  - Three electronic phenotype definitions
  - Four biostatistical guidance documents
  - Data quality white paper

- Total of 30 blog posts

- RSS feed enabled; Living Textbook material available via PCORnet website

- Now on Twitter!
 - @Collaboratory1 #LivingTextbook #RethinkingClinicalTrials

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Our Growing Audience

As of June 4, 2014

- 257 viewing sessions
- 192 unique visitors

About 1/4 are returning visitors

Returning visitor   New visitor

25%

75%

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Source: Google Analytics session (6/4/2014).
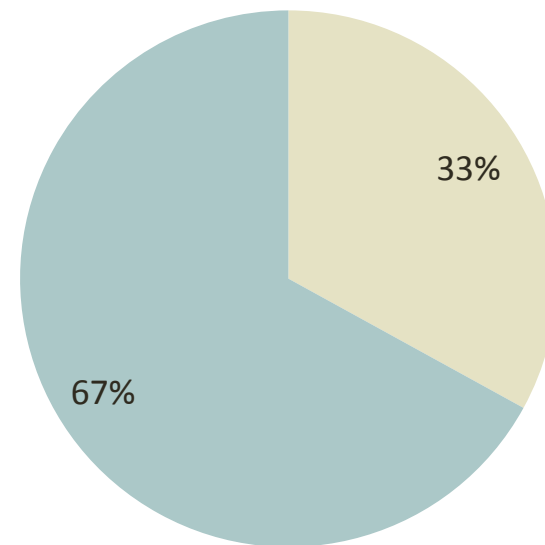
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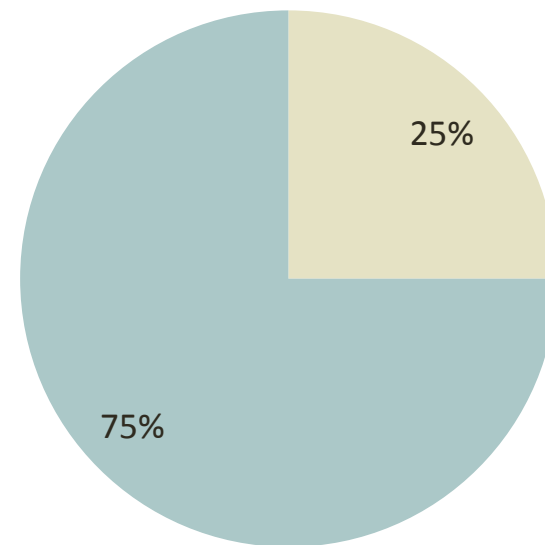
Our Growing Audience

As of July 23, 2014

- 804 viewing sessions
- 570 unique visitors
- 2,585 page views
- A busy day sees 45-50 visitors

About 1/3 are returning visitors

◻ Returning visitor   ◻ New visitor

33%

67%

Source: Google Analytics session (7/23/2014).

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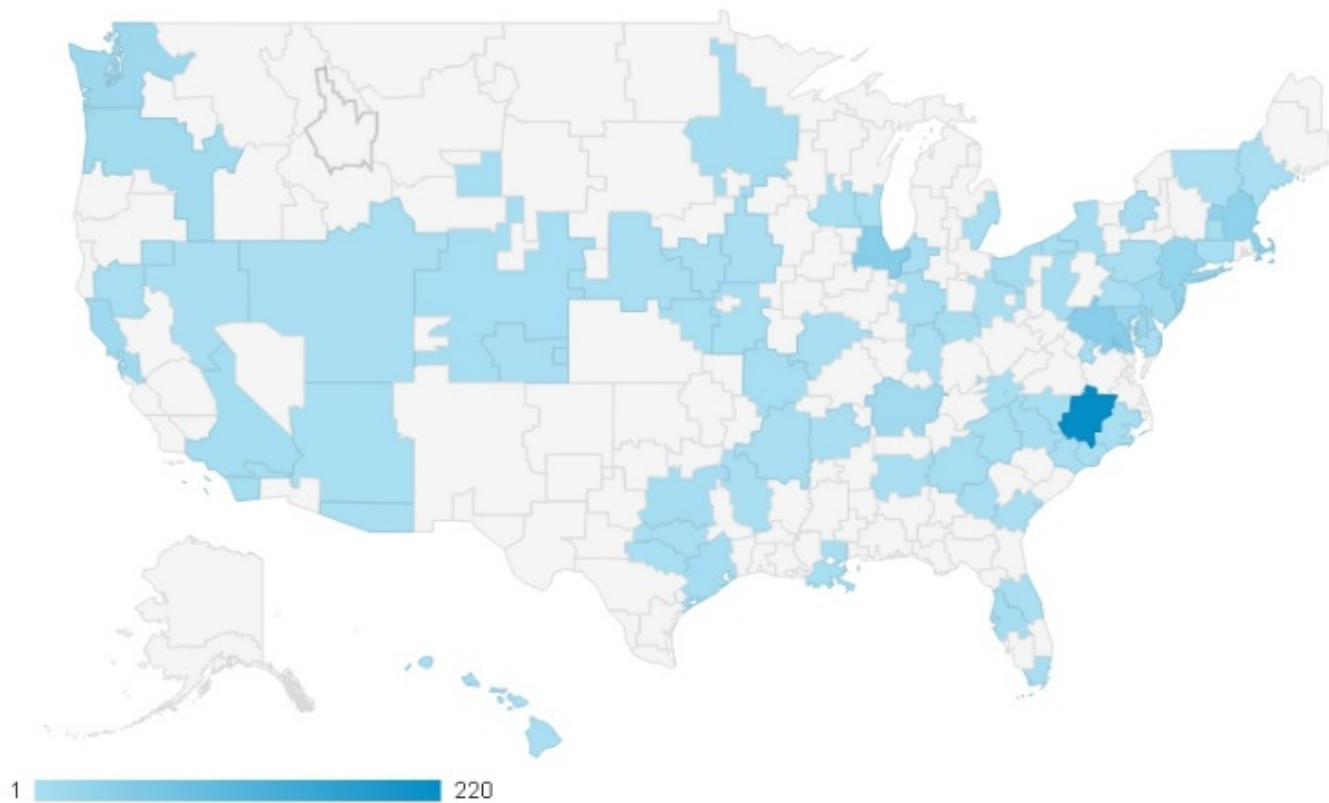
Our Growing Audience

User Characteristics

- Viewing an average of ~3.2 pages per visit

- ~92% using desktops to access Living Textbook

- ~8% using phone/tablets

- Desktop users spending average of 4.5 min/visit; tablet users ~30 s; phone visitors ~13 s
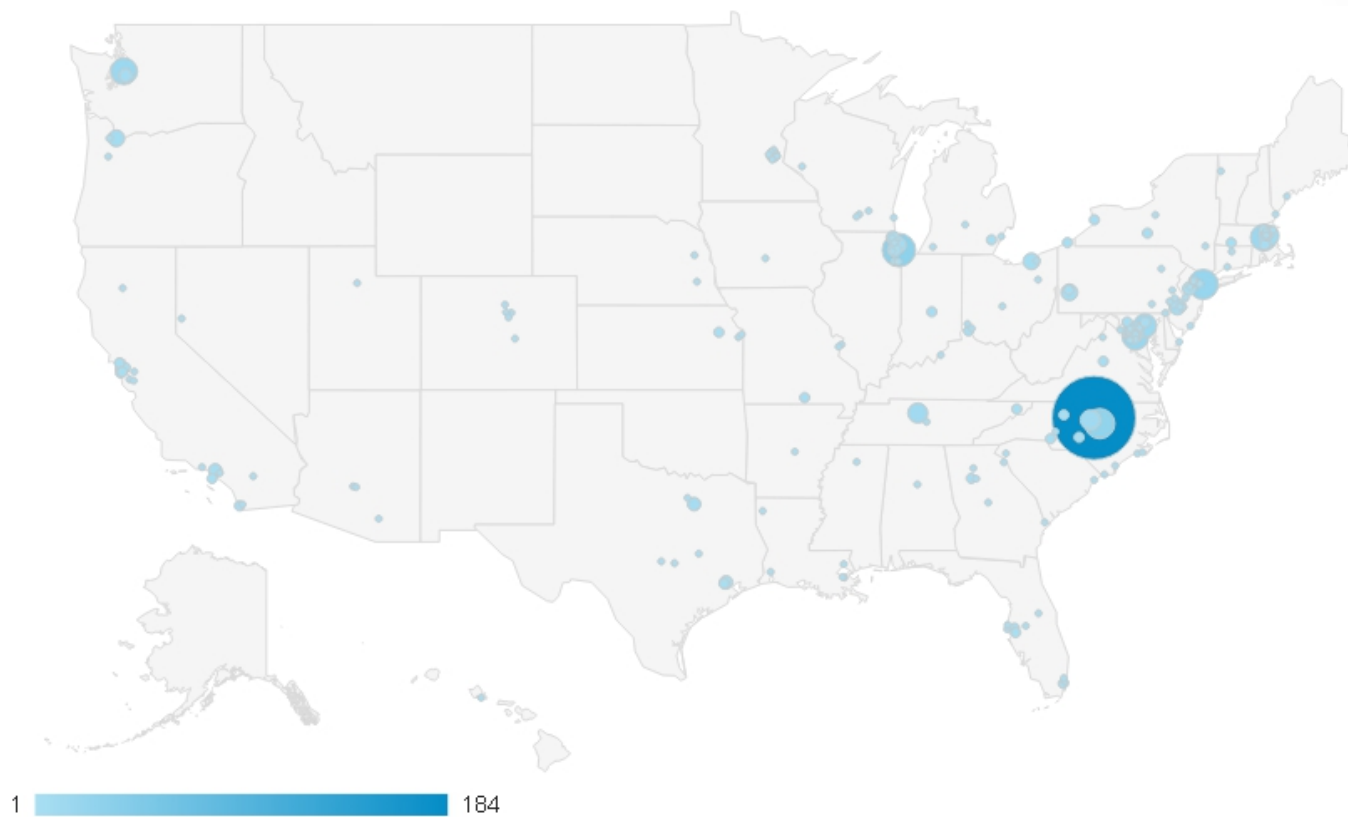
Usage Patterns

- Currently most popular pages (not including landing/intro) are EHR-Based Phenotyping, Learning Health Systems, Blog, PROs, and Informed Consent

- Visitors appear to be using multiple navigation options on pages, with exception of tag cloud

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Source: Google Analytics session (7/23/2014).

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Usage by Metro Area

1 ▬▬▬▬▬▬▬▬ 220

Source: Google Analytics session (7/23/2014).
Usage density by session.

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Usage by City

| 1 | ... | 184 |

Source: Google Analytics session (7/23/2014).
Usage density by session.

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Room for Improvement

- Despite growth in visitors/sessions, bounce rate remains high at ~62%
  - "Bounce" indicates visitors who enter page and leave without interacting with any internal/external links

- Uptake on mobile devices negligible

- Need to continue to spread the word about the Living Textbook and research tools available there
  - Twitter
  - Blog posts
  - RSS feeds
  - Conference presentations (where appropriate)

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Currently Under Construction

- Topic Chapters
  - Provider-Health Systems Interactions
  - Data Sharing and Interoperability
  - Clinical Trials Process (in conjunction with PCORnet Clinical Trials Task Force)
  - Basics of Clinical Research
  - Additional PRO research tools

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What's Next?

- Work with us!
  - Whether you've got a little time or a lot, we're eager to work with Collaboratory leadership and partners in developing content. This includes:
    - Updates to existing chapters
    - Chapters currently in development
    - Proposing new or additional chapters
    - Additional research tools or extensions to existing tools
- Feed us!
  - Even if you don't have bandwidth for writing, we are grateful for any pointers to new developments, articles, news, etc.
- Help spread the word!

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Thank You!

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