



NIH Collaboratory

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, PCORnet, and other partners

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, continuous content.

"Our goal in crea

In the clinical setting, we look at a patient group as a person who has a set of possible answers. It depends on the specific finding, function, or phenotype being measured, such as drug, response, treatment, duration, physical characteristics, and social data.

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 PCT Instrument

Tags

AcademyHealth 40761 2015 Cluster randomized trials Case series Common Fund Common Rule Comparative effectiveness CTN Data quality Data standards Demonstration Project Electronic health records Health equity Quality Health Center Grand Rounds Group health Research Institute Health systems Informed consent Patient Home

Informed Consent

Contributor

- Laura M. Binkow, 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

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/>

NIH Common Fund Video Competition Goes Live

April 30, 2014 Uncategorized Common Fund, NIH, NIH Collaboratory, Video competition Gisa Ulmerbauck

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.

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



Living Textbook writing/editorial staff

- Managing Editor
 - Jonathan McCall, MS
- Contributing Editors
 - Karen Staman, MS
 - Gina Uhlenbrauck
 - Liz Wing, MA

Previous milestones (August 2014)

- 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

Current milestones

- New in Tools for Research:
 - Biostatistical guidance document (frailty analysis) — Biostatistical/Study Design Core
 - Computer-Adaptive Testing for PROs— contributed by faculty at Feinberg School of Medicine
 - Two white papers on PRO definitions and implementation — joint Collaboratory PRO Core and PCORnet project
 - Introduction to Pragmatic Clinical Trials — contributed by Karin Johnson
 - Writing for Clinical Research — four-part webinar series developed for PCORnet
- Coming soon:
 - New Topic Chapter: Acquiring and Using EHR Data for Research (contributed by Meredith Zozus) – currently being edited, loaded, and formatted for later release
 - New Research Tool: Linking EHR Data with Geospatial SES Data (contributed by Monique Anderson)
 - New Topic Chapters, Research Tools, and other products from the “Ethics and Regulatory Challenges in Pragmatic Clinical Trials” project

Current milestones – site updates

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 information on how to understand, design, conduct, analyze & disseminate pragmatic clinical trials (PCTs).

Topic Chapters



Topic Chapters provide detailed, textbook-like information on various aspects of pragmatic clinical trials, complete with citations and links to resources.

Introduction • Conflict of Interest • Informed Consent • Patient-Reported Outcomes • Regulatory Issues • Learning Healthcare Systems • EHR Phenotyping

Tools for Research



Tools for Research encompasses practical guidance and "toolkits" for conducting different aspects of pragmatic clinical research.

Electronic Phenotyping • Biostatistical Guidances • Data Quality • Computer-Adaptive Testing • Patient-Reported Outcomes White Papers • Writing for Clinical Research • Intro to Pragmatic Clinical Trials

Blog

The **Living Textbook Blog** offers news and updates related to pragmatic clinical research, as well as bulletins about new content available on *Rethinking Clinical Trials* and the NIH

New on the Living Textbook

Researchers Find Poor Compliance with Clinical Trials Reporting Law March 11, 2015

FDA Issues Draft Guidance on Use of Electronic Informed Consent (eIC) March 10, 2015

Groundbreaking Suicide Prevention Trial has Enrolled Initial Patients March 5, 2015

PCORnet News

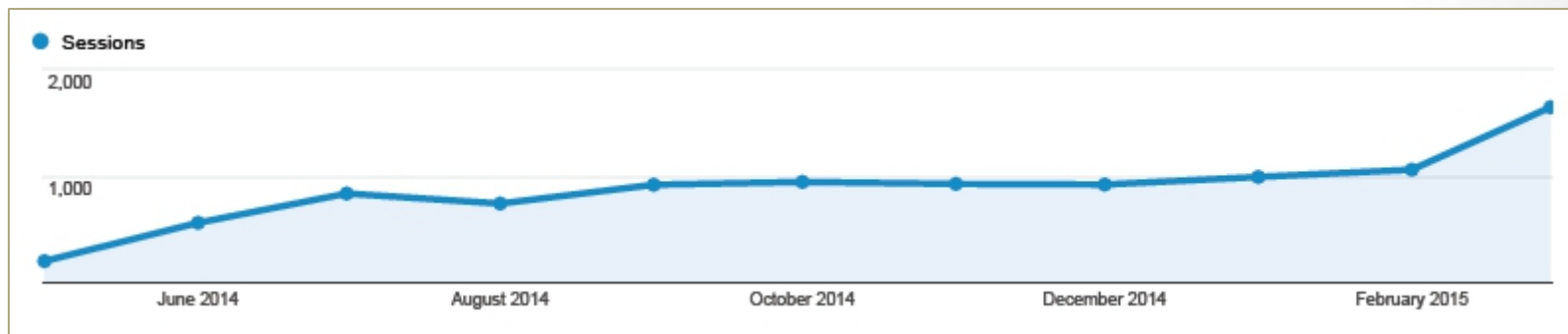
UPenn: Statistical Issues Arising in Pragmatic Clinical Trials - April 15

Best Practices Session - Supporting Precision Medicine - March 30

Categories

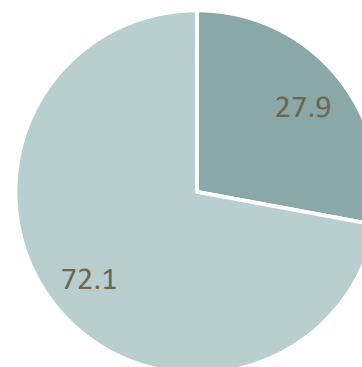
Biostatistics **Clinical trials**
Cluster Randomized Trials
Comparative
Effectiveness Research
Data privacy Data quality Data sharing Data standards Electronic health records
Guidance document Health analytics
Health outcomes **Informed Consent**
Institutional review boards Learning health systems Mobile Health (mHealth)
Patient-Centered
Outcomes Research
Patient-Reported Outcomes Patient

Ten months of the Living Textbook: May 2014–March 2015



New vs Returning Visitors, %

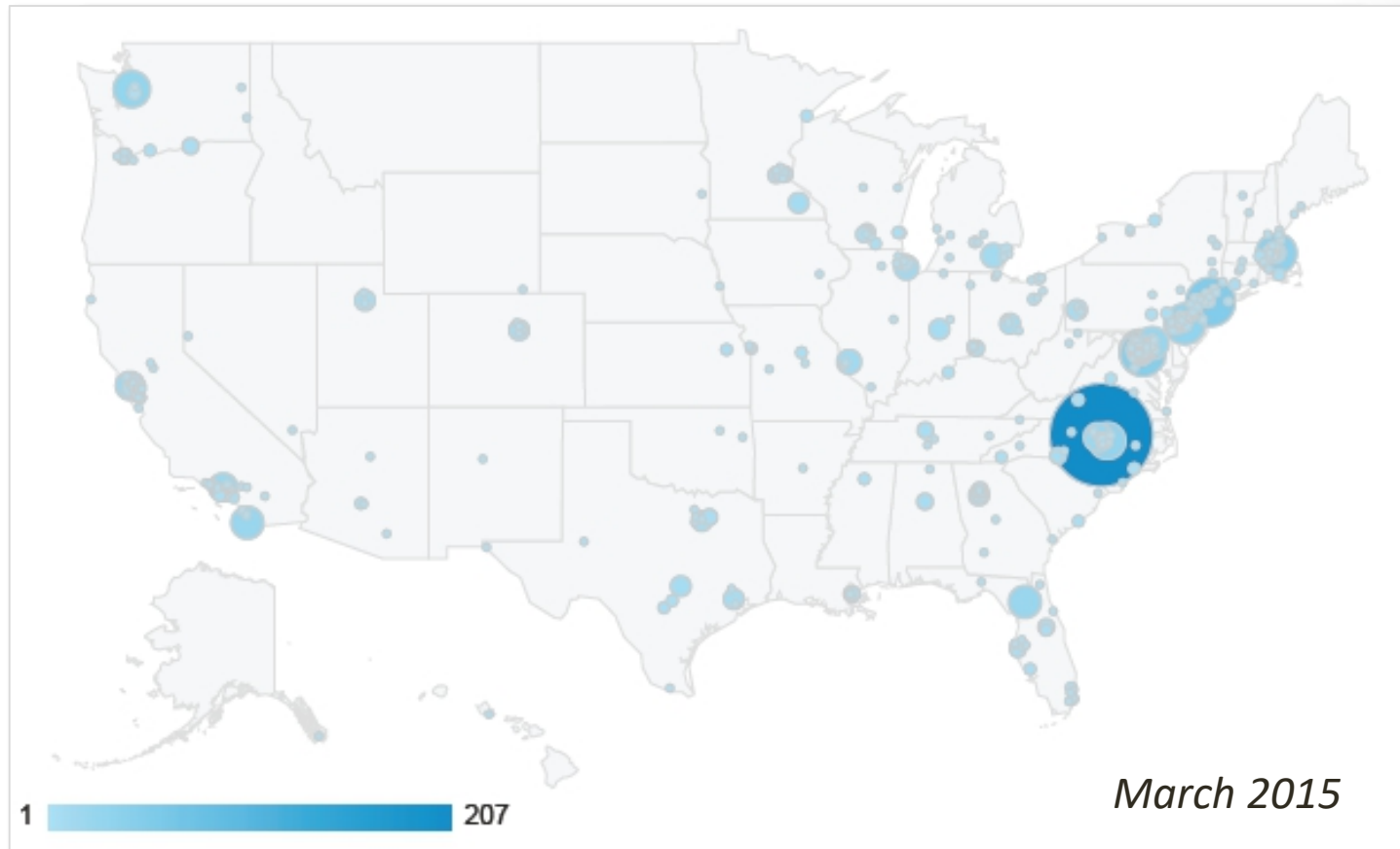
- 9,374 total sessions
- 7,018 users
- 19,692 total pageviews
- Bounce rate: 71%
- Average session: 2 minutes



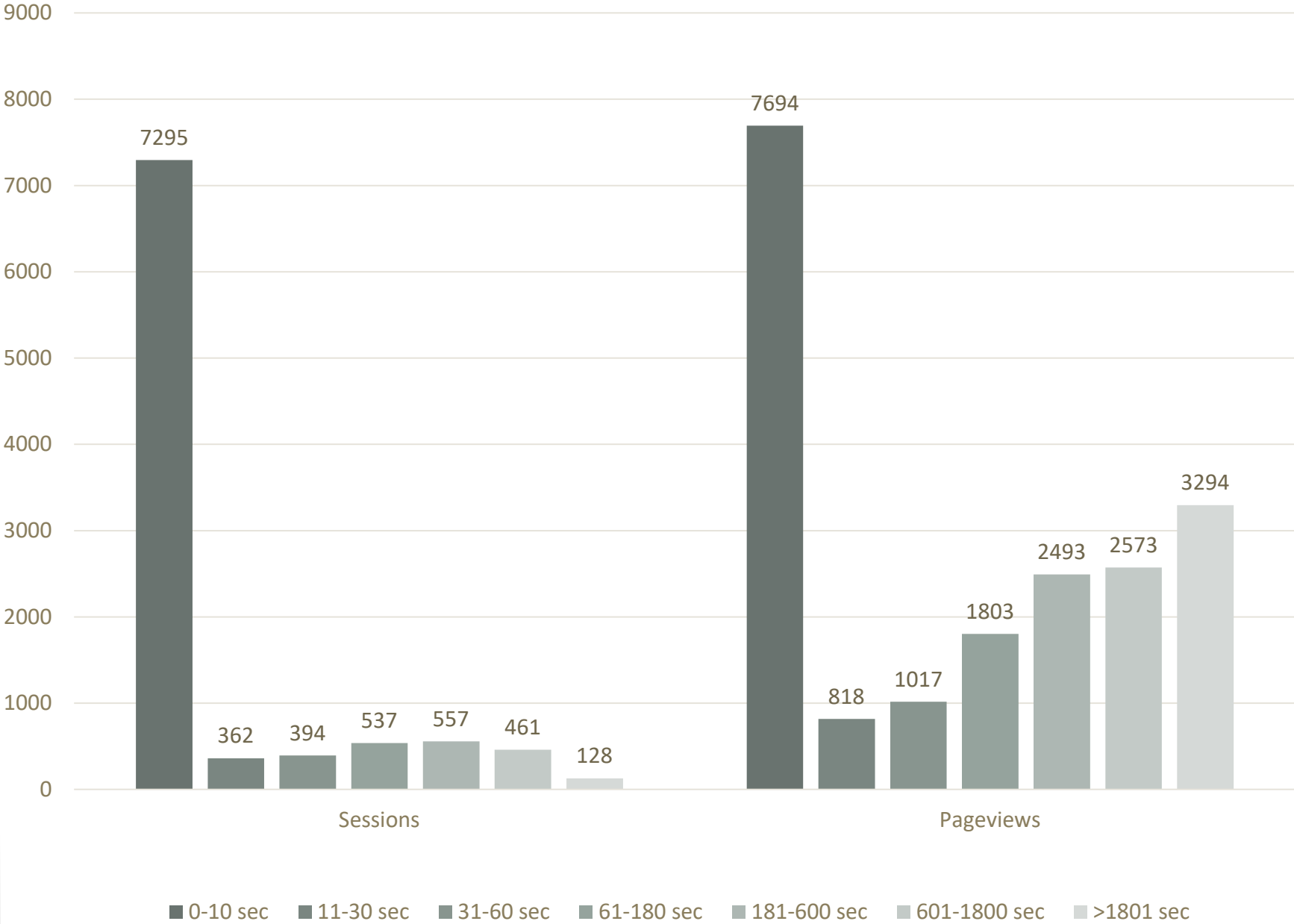
■ New Visitor ■ Returning Visitor

March 2015

Who's reading the Living Textbook?

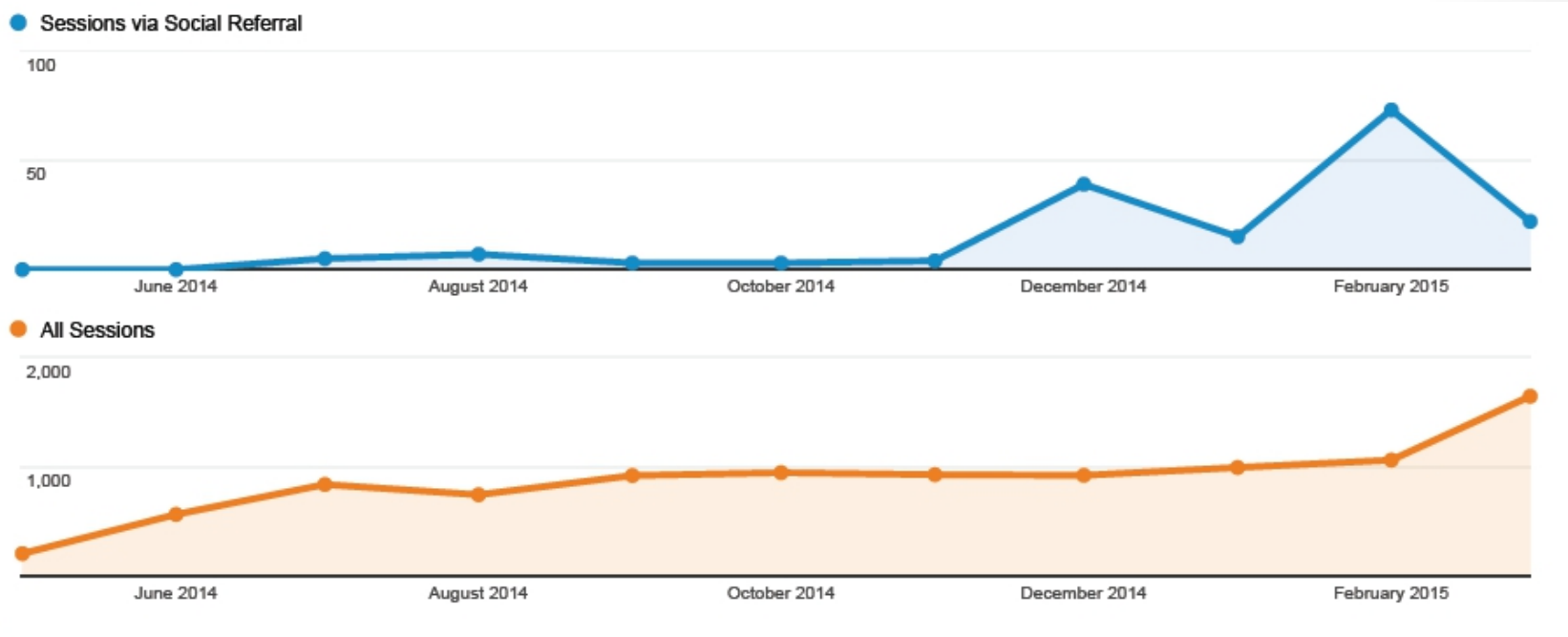


Session Duration, by Session and by Pageviews



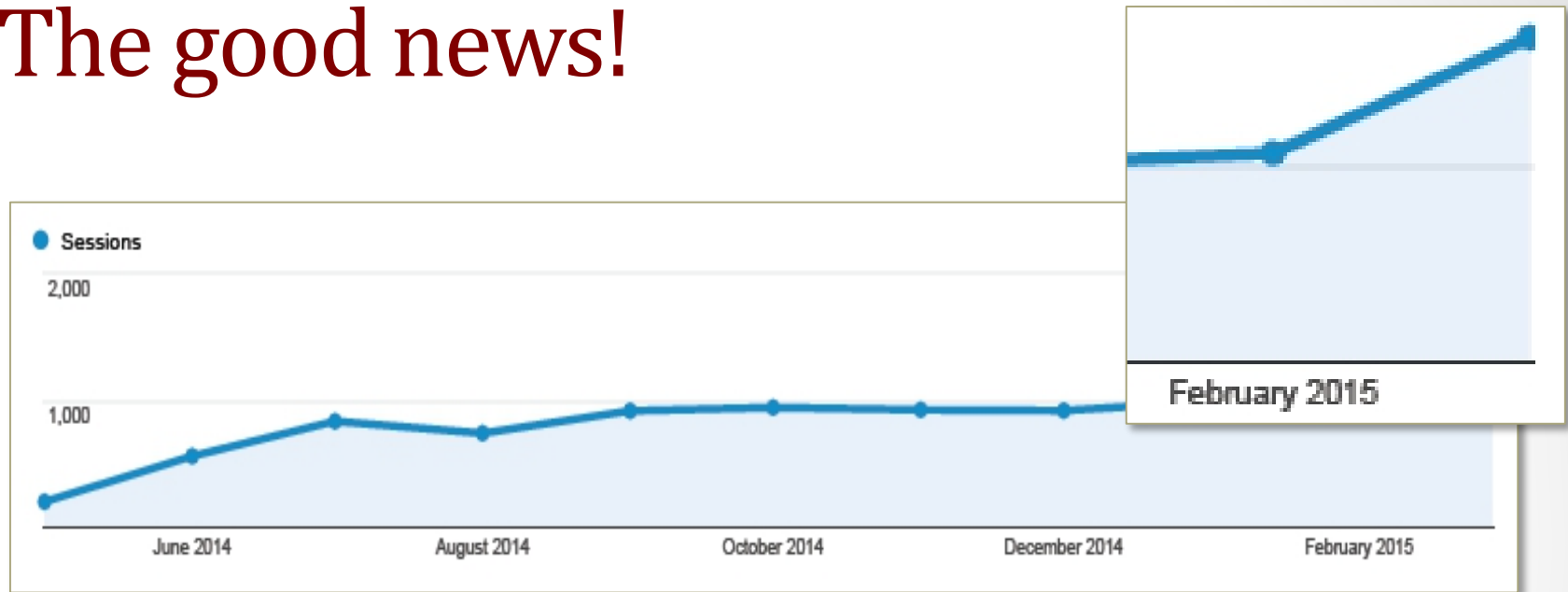
Our growing audience

- Aside from the front page, the pages most often visited were:



- Social referral also emerging, but currently accounts for ~2% of session origins

The good news!



Room for improvement

- Bounce rate remains quite high, at ~72%, and average session time is low.
 - Current site design changes are intended to foster site exploration and provide better content overview at a glance.
- Referral and sharing via social media is an obvious target for improvement.
 - We are working on a more comprehensive and coordinated social media/sharing strategy for Living Textbook content.
- We are working on immediate and longer-term improvements to the site to improve the function and feel of the Living Textbook.

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.
- 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!



Eastine Cowner, building the S.S. George Washington Carver, 1943. Photo credit: E. F. Joseph for the US Office of War Information (Public domain image via Wikimedia Commons)



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Thank You!