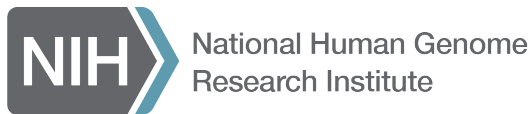


CSER: NHGRI perspective

Lucia A. Hindorff, PhD, MPH
Program Director, Division of Genomic Medicine

*Integrating Genomic Sequencing into Clinical Care:
CSER and Beyond*

September 28, 2015



RFA HG 10-017, HG 12-009

Clinical Sequencing Exploratory Research “U-Awards”

- Research the challenges to applying comprehensive genomic sequence data to the care of patients:
 - Generation and application of genomic sequence data in the clinical workflow and timeline
 - Interpretation of the data for the physician
 - Communication to the patient and family
- Examine the ethical, legal and psychosocial implications of bringing broad genomic data into the clinic.

CSER U-Award Project Structure



1. Clinical
Genomic Study



2. Sequencing,
Analysis, and
Interpretation of
Sequencing Data



3. Ethical, Legal
and Psychosocial
Implications
Research



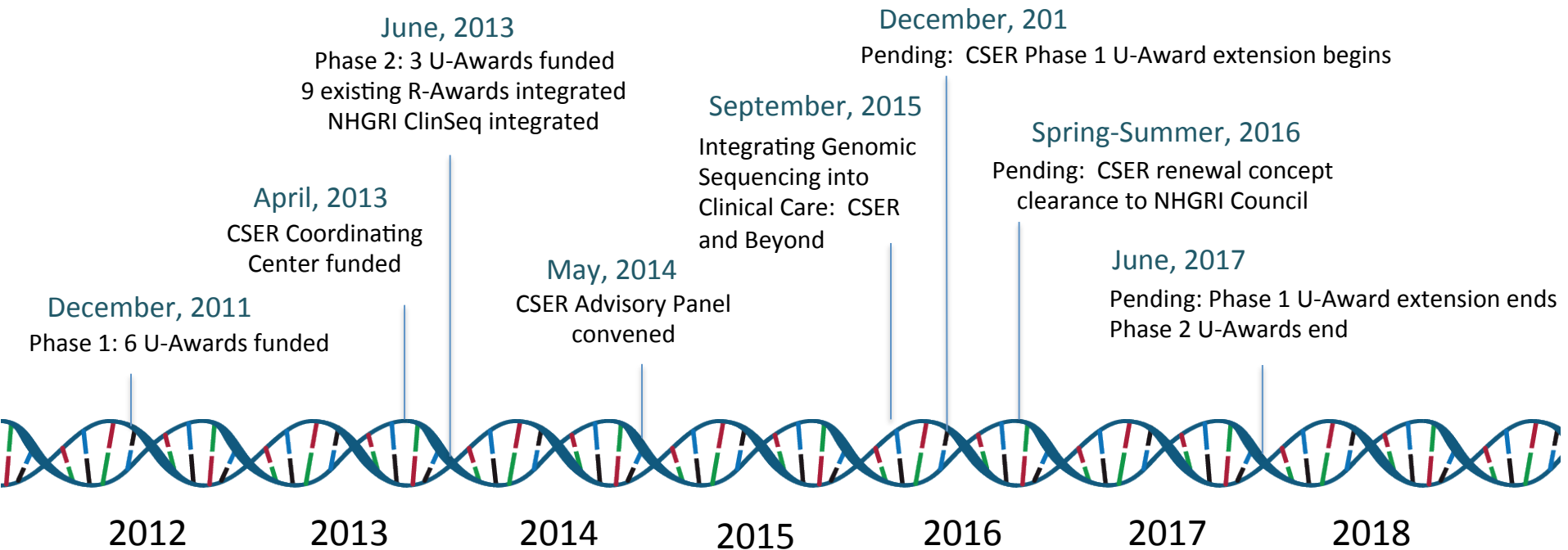
RFA HG 11-003, HG 11-004

Returning Research Results to Genomic Research Participants, “R-Awards”

- Generate empirical evidence (quantitative and qualitative)
- Analyze normative considerations
- Analyze legal and regulatory issues
- Goal: to ensure that any recommendations made regarding clinical sequencing are evidence-based and ethically and legally sound



Clinical Sequencing Exploratory Research Program Timeline





U-Award project 1/2/3 structure
Emphasis on WG's
Collection of standardized metrics

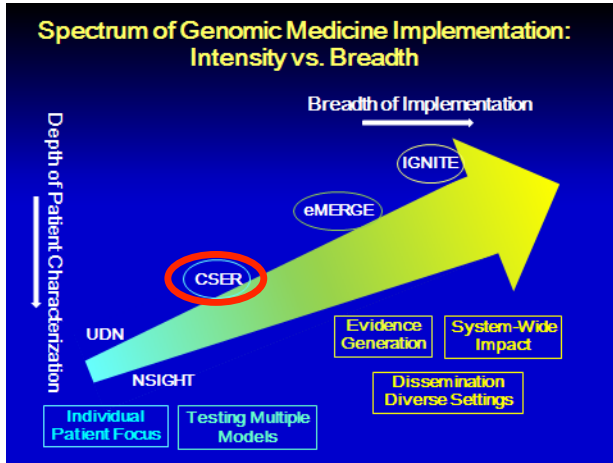
Clinical settings
Research methods and approaches
Site-specific innovation





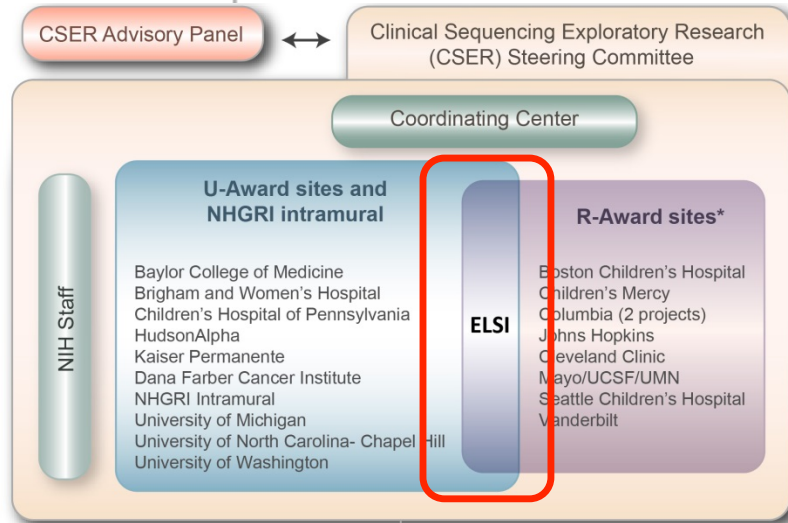
National Human Genome
Research Institute

National Cancer Institute



National Human Genome Research Institute

DIVISION OF GENOME SCIENCES

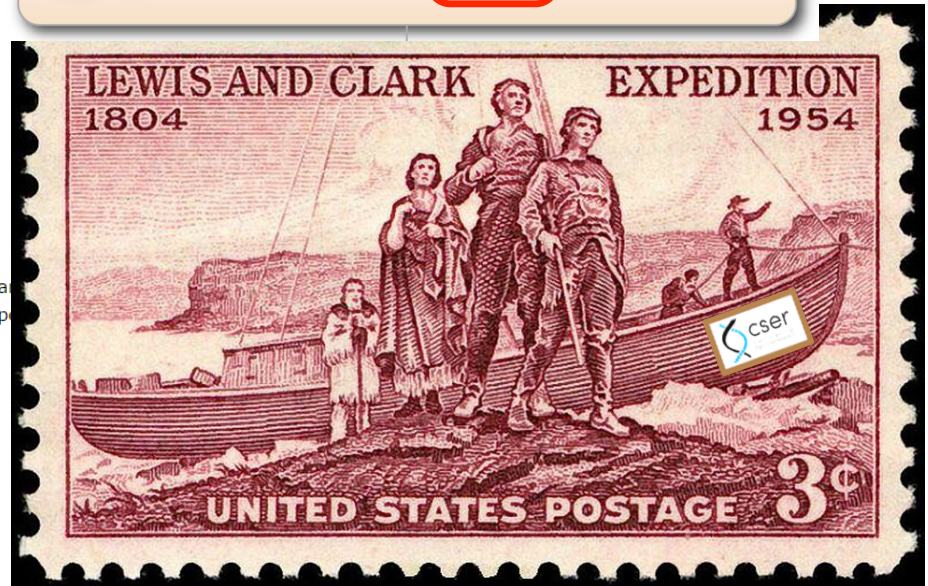
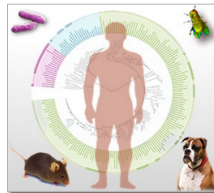


The NHGRI Genome Sequencing Program (GSP)

Overview

The Genome Sequencing Program of the National Human Genome Research Institute is an over-arching program - programs in their own right - that have been established to address current scientific opportunities of the [Strategic Plan for Genomics](#):

- [Large-Scale Genome Sequencing and Analysis Centers \(LSAC\)](#)
- [Centers for Mendelian Genomics \(CMG\)](#)
- [Clinical Sequencing Exploratory Research \(CSER\)](#)
- [Genome Sequencing Informatics Tools \(GS-IT\)](#)



*What have we learned from our explorations?
Where should we go next?*



For Today



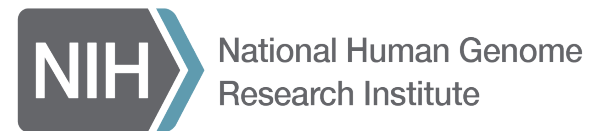
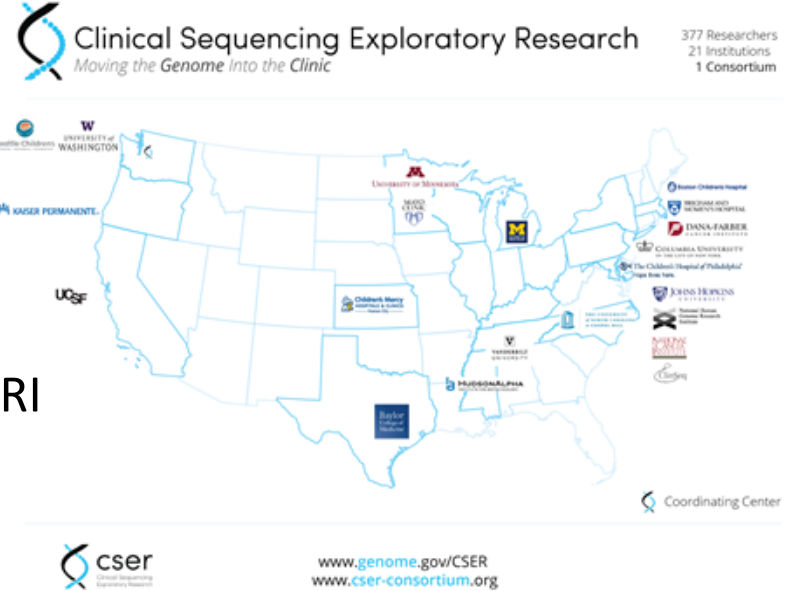
Everyone has a role to play



Meeting structure

Acknowledgments

- CSER and Beyond planning committee
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 - Council
 - Genomic Medicine Working Group
 - Genomics and Society Working Group
 - CSER Advisory Panel
 - Sequencing Network Advisory Panel
- CSER Staff Team
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 - NCI: Charlisse Caga-Anan, Kelly Filipski



Eric Green, Teri Manolio, Larry Brody, Jeff Schloss

Team Sequence: Adam Felsenfeld, Heidi Sofia, Lu Wang (+Brad Ozenberger)