

Sharing Clinical Trial Data: Challenges and a Way Forward

**Sean Coady, Division of Cardiovascular Sciences,
National Heart, Lung, and Blood Institute**

Infrastructure sustainability: a Platform perspective
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Commitment to wide sharing: NHLBI Data Sharing Timeline



Dr. Claude
Lenfant
1982-2003



Dr. Barbara
Alving
(acting)
2003-2005



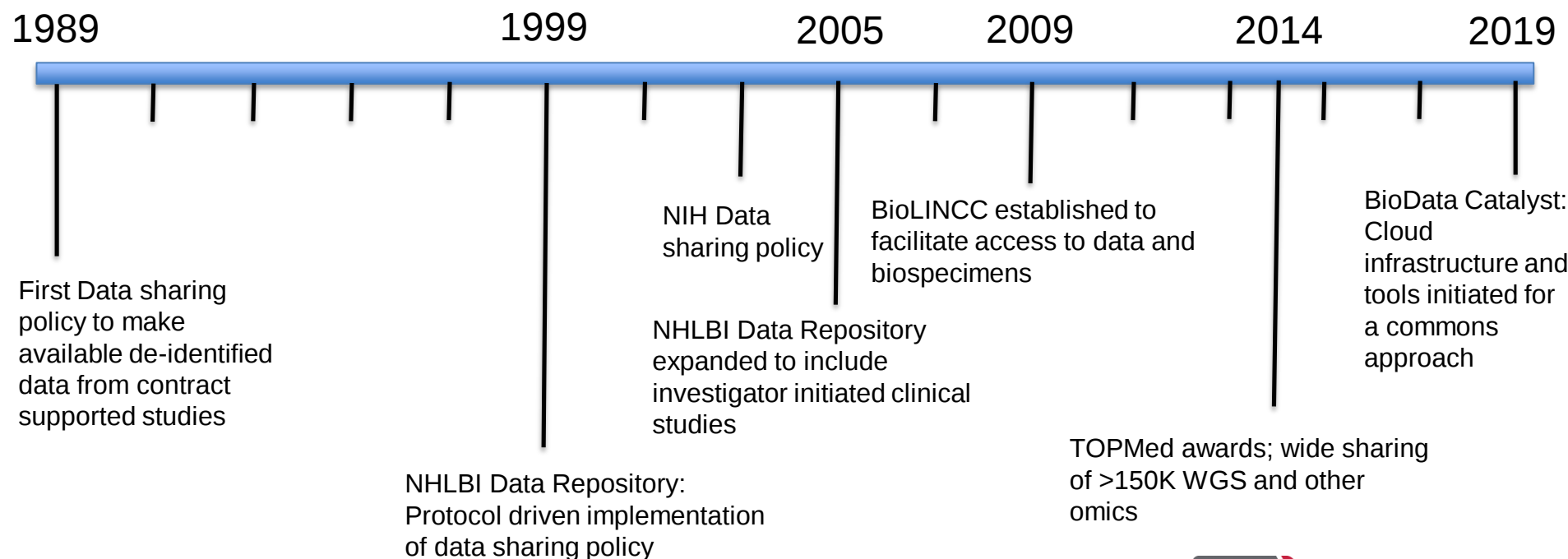
Dr. Elizabeth
Nabel
2005-2009



Dr. Susan
Shurin
2009-2012



Dr. Gary
Gibbons
2012-present



NHLBI Data/Materials Sharing

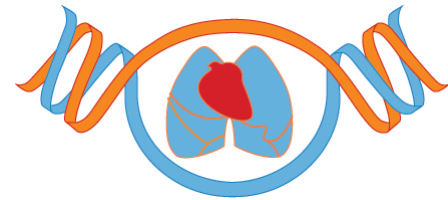


database of Genotypes and Phenotypes (dbGaP),
GWAS, microRNA, gene expression profiling

Storage, Toolspace, Access and
analytics for biG data Empowerment

BioData Catalyst

Trans-Omics for Precision Medicine (TOPMed); WGS, metabolic
profiles, protein and RNA expression, DNA methylation



NHLBI Data Repository

Stores and distributes
data sets from
NHLBI clinical studies

Est. 2000

NHLBI BioRepository

Stores and distributes
biospecimens from
NHLBI clinical studies

Est. 1975

BioLogic specimen & data
repositories INformation
Coordinating Center (BioLINCC);
biospecimens & phenotypic data

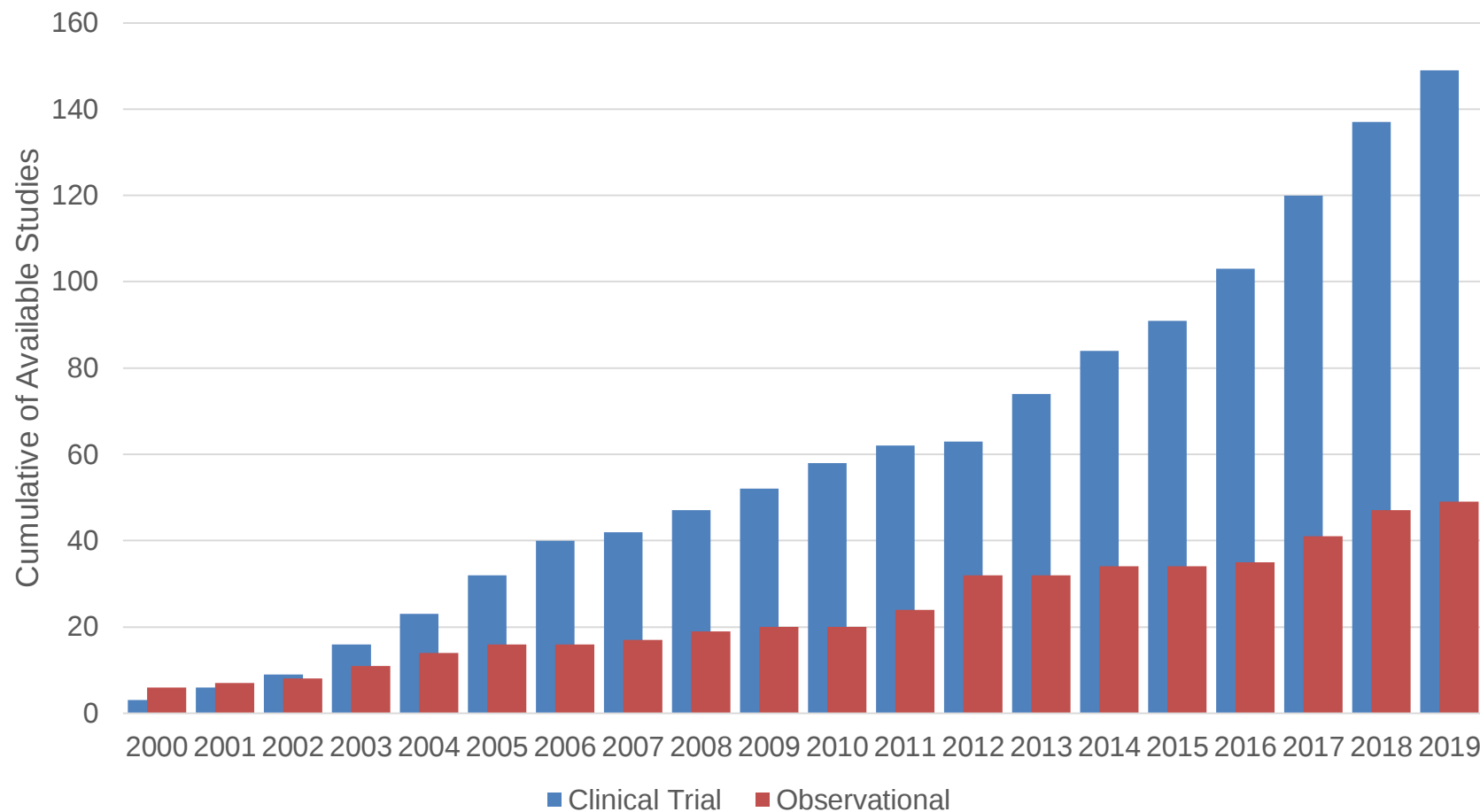
Clinical Trials

Observational Studies

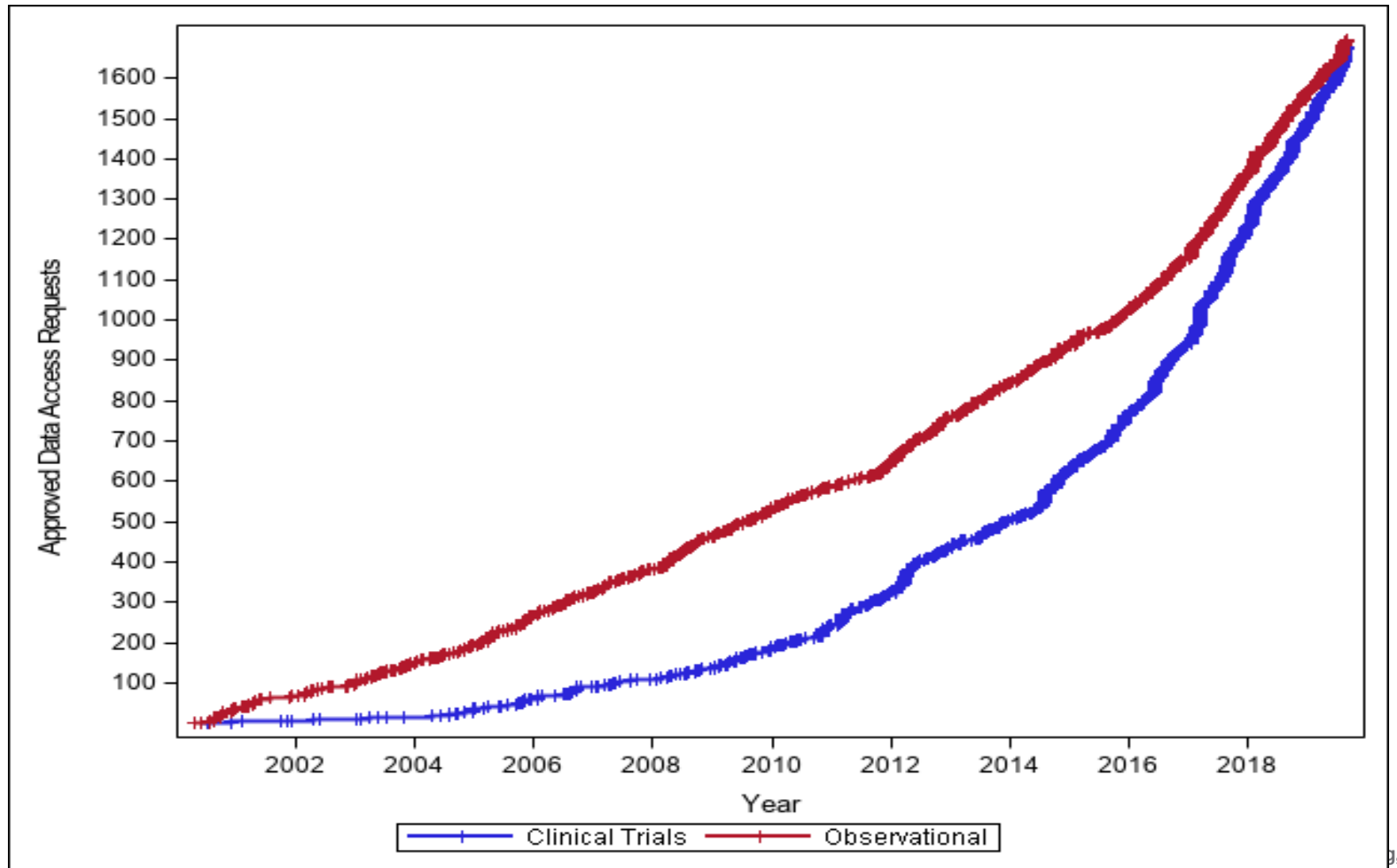
Challenges: Usability and Resource constraints

- “Come as you are” repository. No real standard for metadata impacts data discovery as repository grows
- Stewardship burden: detailed review prior to release
- Implicit support of investigators accessing data

Challenges: Usability



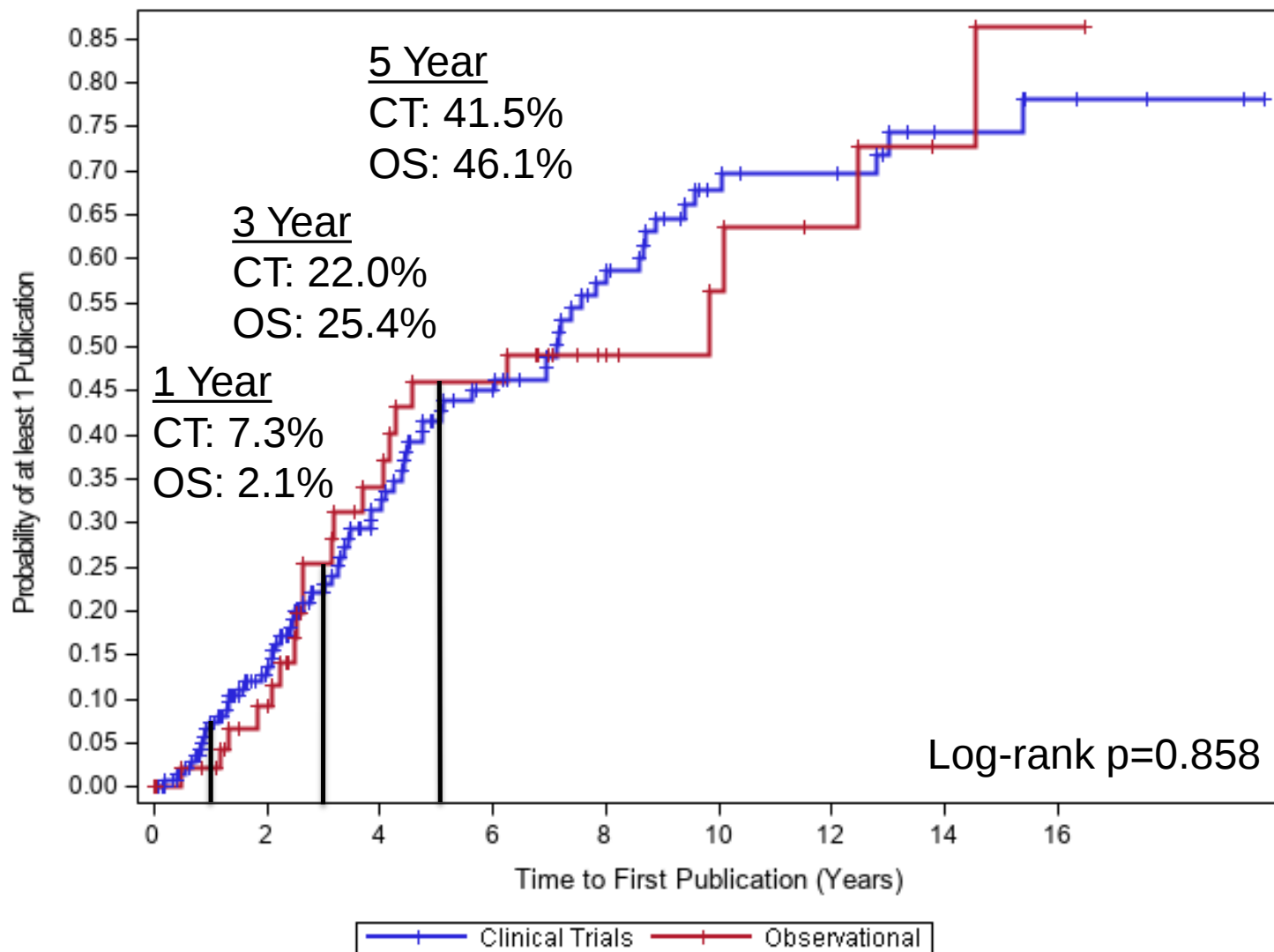
Challenges: Accommodate a growing user base



Challenges: Outcome Metrics

- Evaluating the investment
 - # Website visits, # data access requests fulfilled
 - Publications
 - Workforce training
 - Follow-up grant applications

Time to “Incident” publication by type of study (through August 2019)



1130 publications
570 Included data
from 1 or more
trials

68 Trials 1+
publications

482 investigators
have published at
least once. Mean
number of
pubs/inv=3.0