

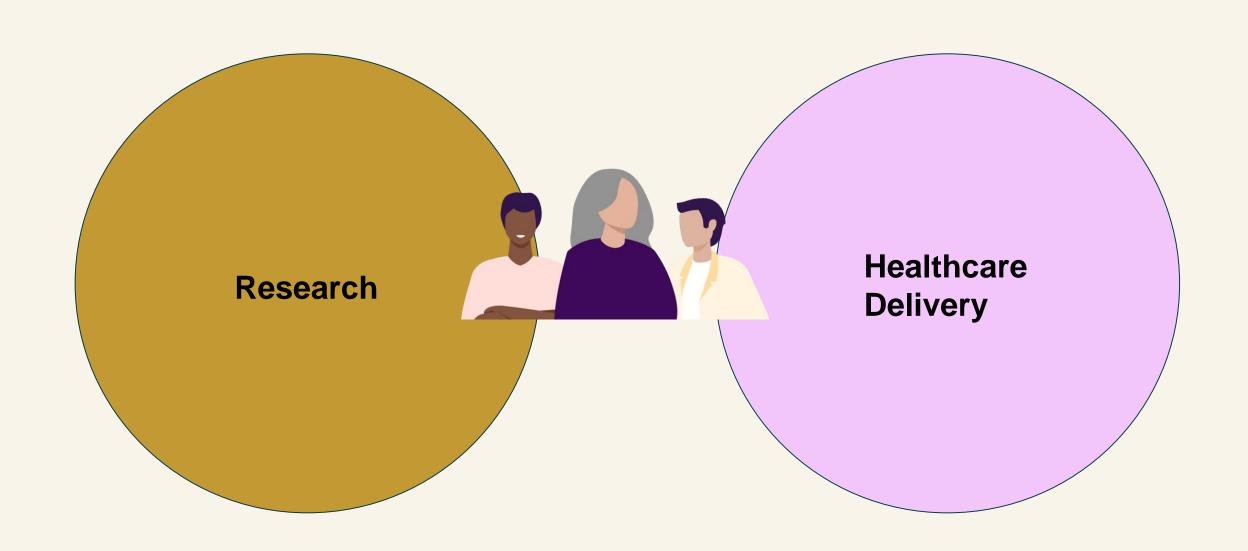
### **Disclosures**

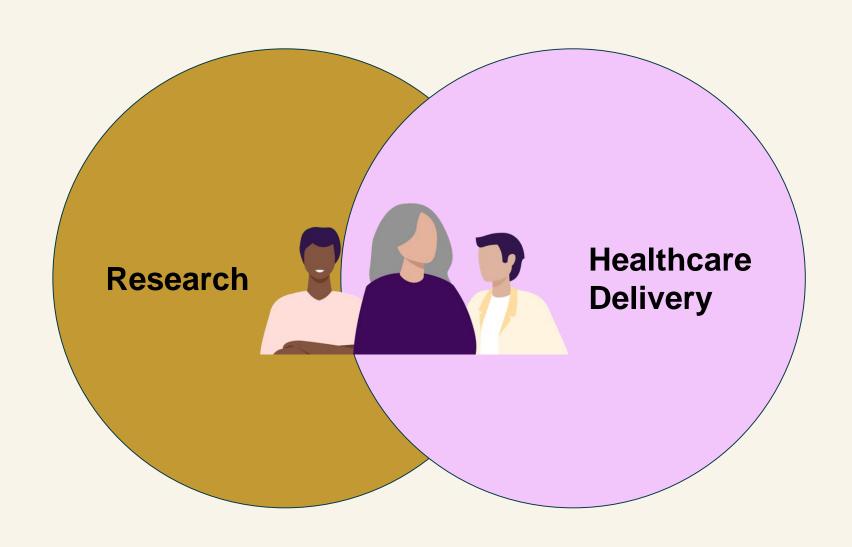
Highlander Health - Cofounder

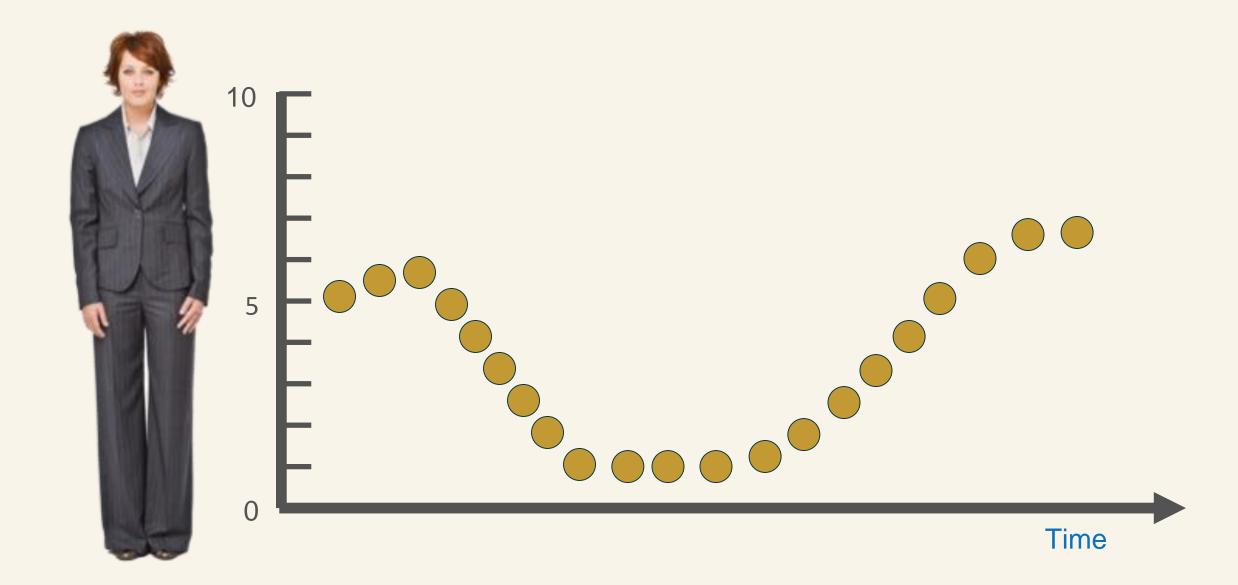
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Endeavor to create "research quality clinical data"

#### Improving Health Care Efficiency and Quality Using Tablet Personal Computers to Collect Research-Quality, Patient-Reported Data

Amy P. Abernetity, James E. Herndon II, Jane L. Wheeley, Mernal Patwardhan, Heather Shaw, H. Kim Lyerly, and Kevin Weinfurt

Objective. To determine whether o'Talkes balades tablet computes used it can marily smootings claims to collect series of symma substantian at point of usel an femilial, acceptable, and callel for collecting meants quality data in academic stocking. Data/Setting, Primary Duke Street Carcer Clink.

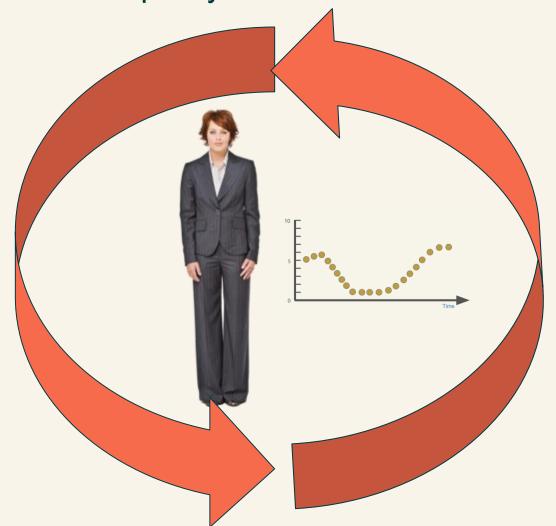
Design. Plot study smalling sample of 50 broast cancer patients.

Methods. Data was collected using paper and a Tables hand servey. Functional

Assessment of Canar Therapy General, Functional Assessment of Canar Therapy Broad, MD Anderson Symptom Investory, Functional Assessment of Chronic Bloom Therapy S'ACTY, Sell-Efficacy, and two-questionnaires fourfolds, satisfactors. Through Findings. Patients supported o'Takint as say to read 34 percent, may to request to 184 percent, combractin weight 37 percent, Generally, dictivitie impanion validly effected responses provided by manded paper dan collection on

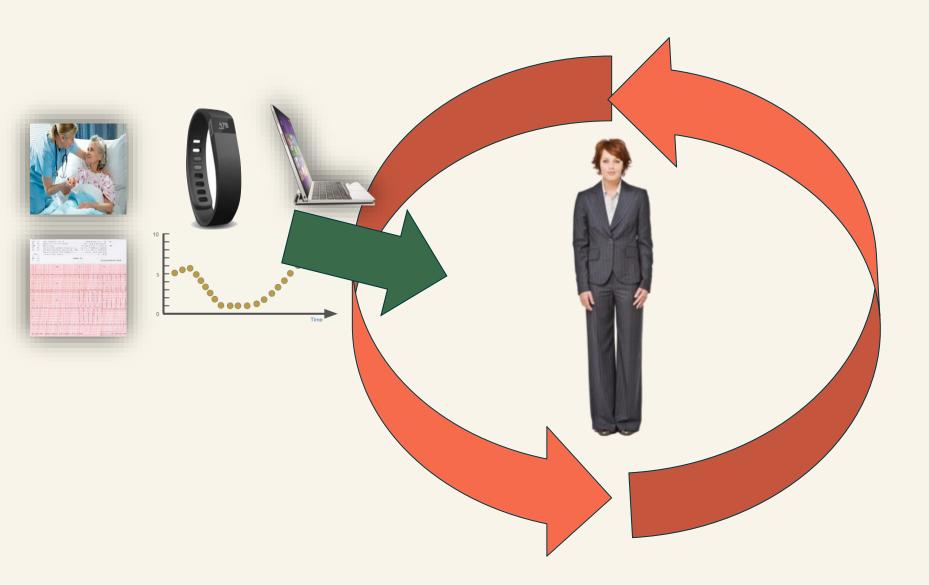
Conclusions, o'Tableo eller a valid, bushle, acceptable method for collecting to much quality, patient reported naturates data to outpetient academic meeting Key Words. Patient reported successor, data collection, quality of life, ne-planes

Patient exported outcomes (PEOs) have increasingly gained acceptance as importest and valid measures of symposes, experiences, and builth-related quality of Mr 508CCCL, and thus no critical narries for evaluating the value of health case services to patients (Gaze 1894, Cellust al. 1807, Coase, Present, and Oroba 1997; Duscoy et al. 1997; Major policy making emittes which and Advant offer, Linkey et al. (201), steps passy margin quate seals, have emphasized the importance of economising PEOs into concernment, and pulsy farmation (Aprentio, Coste), and Suyde 2007, include the National Cancer Institute (2006, American Cancer Society 2005, U.S. Food

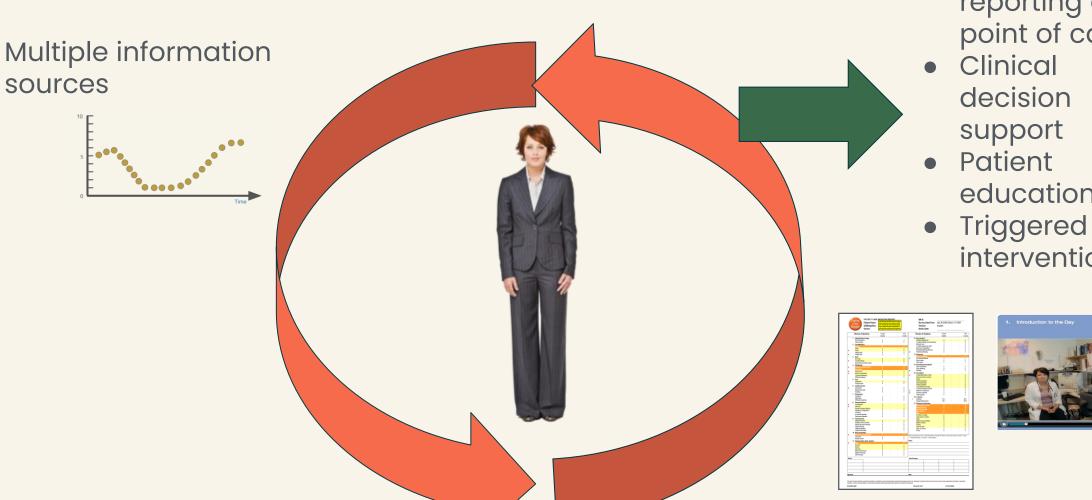


Reliable data is parsed out for clinical trials, clinical care, healthcare quality monitoring, and healthcare improvement simultaneously

## Multiple information sources linked via coordinated databases



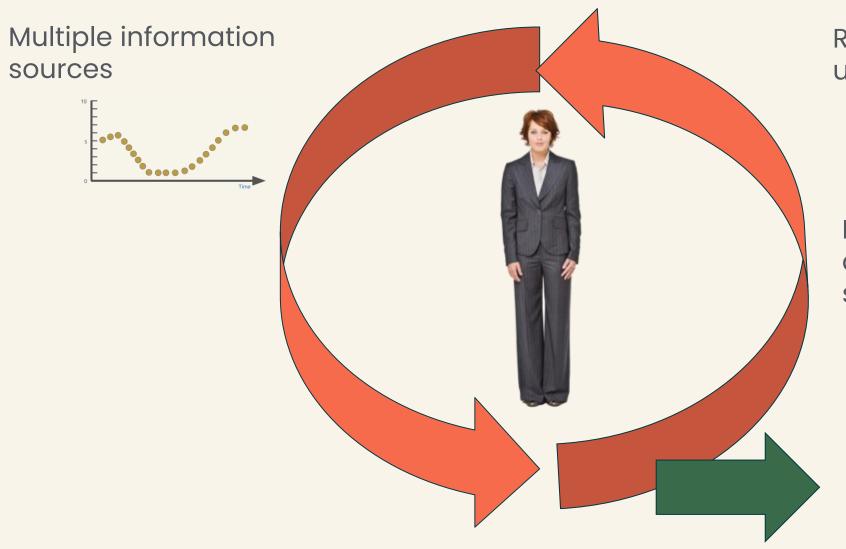
## Real-time clinical use improved data quality



- education
- interventions



## Health system use of data reinforces importance and improves data quality



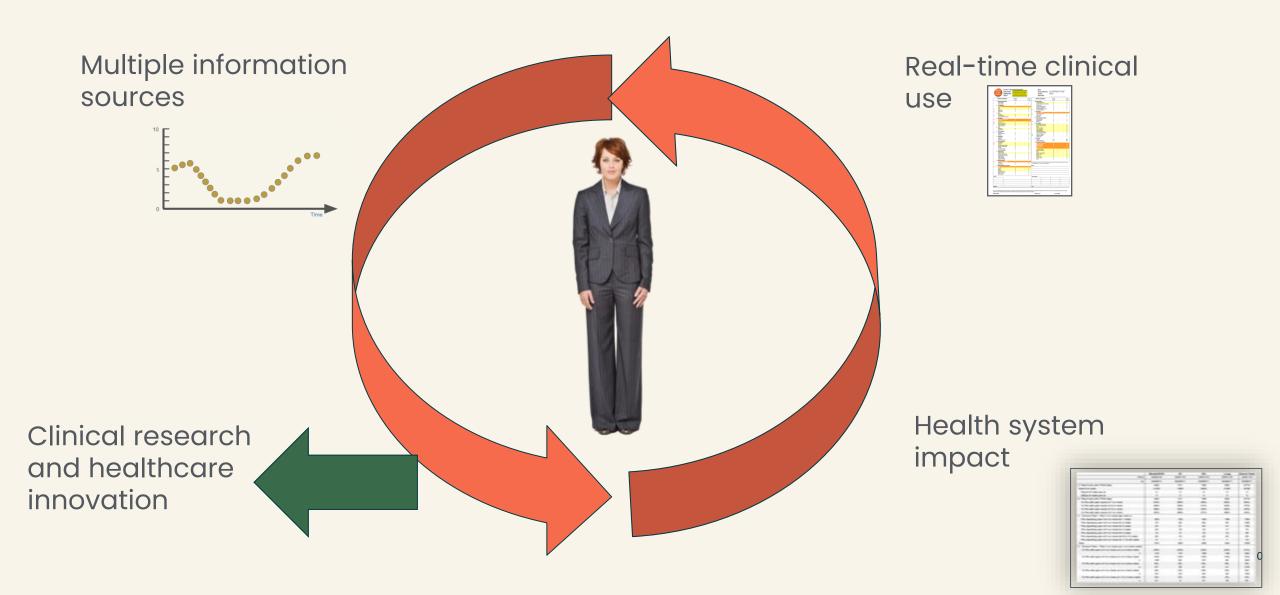
Real-time clinical use

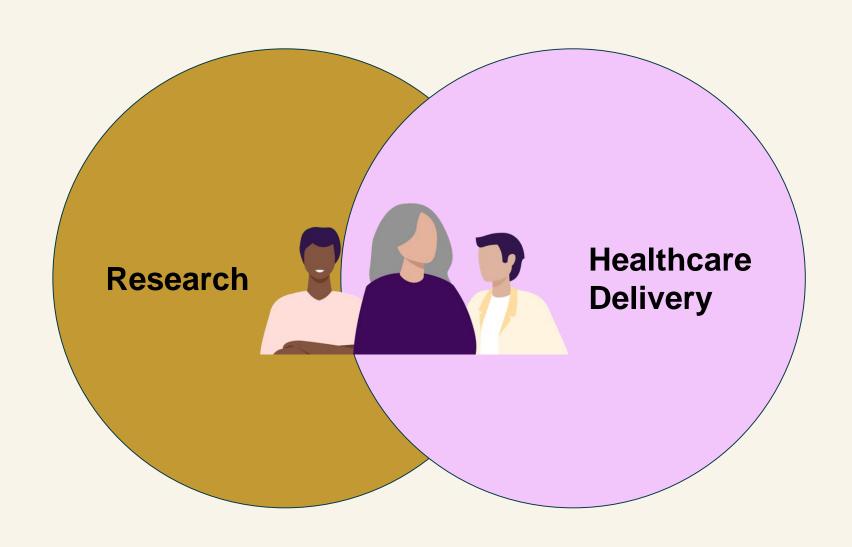
Meaningful use of data in local health system

- Quality monitoring
- Improving operations

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## Health system use of data reinforces importance and improves data quality





Clinical Review & Education

#### JAMA | Special Communication | INTEGRATING CLINICAL TRIALS AND PRACTICE

### Modernizing the Data Infrastructure for Clinical Research to Meet Evolving Demands for Evidence

Joseph B. Franklin, JD, PhD; Caroline Marra, PhD; Kaleab Z. Abebe, PhD; Atul J. Butte, MD, PhD; Deborah J. Cook, MD; Laura Esserman, MD, MBA; Lee A. Fleisher, MD; Cynthia I. Grossman, PhD; Nancy E. Kass, ScD; Harlan M. Krumholtz, MD, SM; Kathy Rowan, PhD; Amy P. Abernethy, MD, PhD; for the JAMA Summit on Clinical Trials Participants

**IMPORTANCE** The ways in which we access, acquire, and use data in clinical trials have evolved very little over time, resulting in a fragmented and inefficient system that limits the amount and quality of evidence that can be generated.

OBSERVATIONS Clinical trial design has advanced steadily over several decades. Yet the infrastructure for clinical trial data collection remains expensive and labor intensive and limits the amount of evidence that can be collected to inform whether and how interventions work for different patient populations. Meanwhile, there is increasing demand for evidence from randomized clinical trials to inform regulatory decisions, payment decisions, and clinical care. Although substantial public and industry investment in advancing electronic health record interoperability, data standardization, and the technology systems used for data capture have resulted in significant progress on various aspects of data generation, there is now a need to combine the results of these efforts and apply them more directly to the clinical trial data infrastructure.

**CONCLUSIONS AND RELEVANCE** We describe a vision for a modernized infrastructure that is centered around 2 related concepts. First, allowing the collection and rigorous evaluation of multiple data sources and types and, second, enabling the possibility to reuse health data for multiple purposes. We address the need for multidisciplinary collaboration and suggest ways to measure progress toward this goal.

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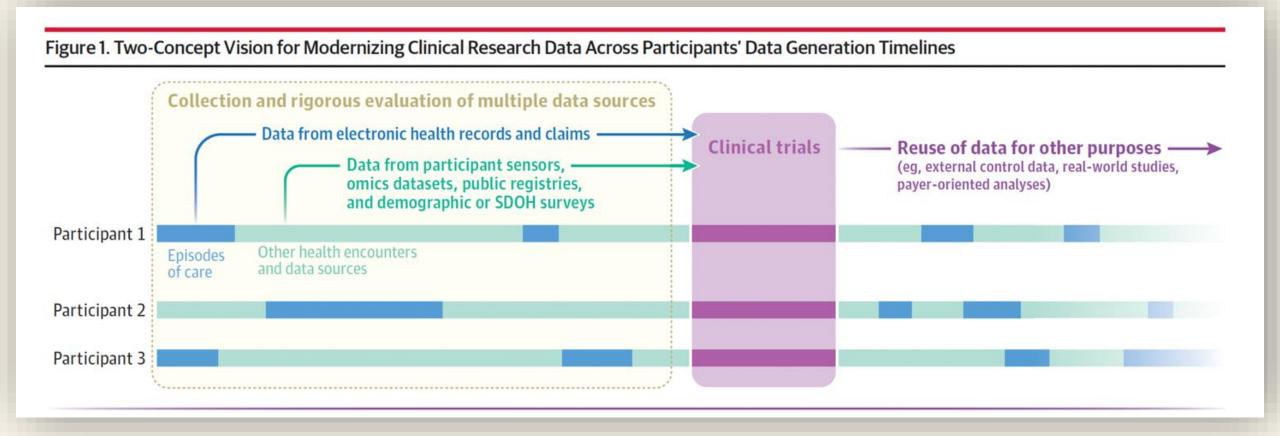
Supplemental content

CME at jamacmelookup.com

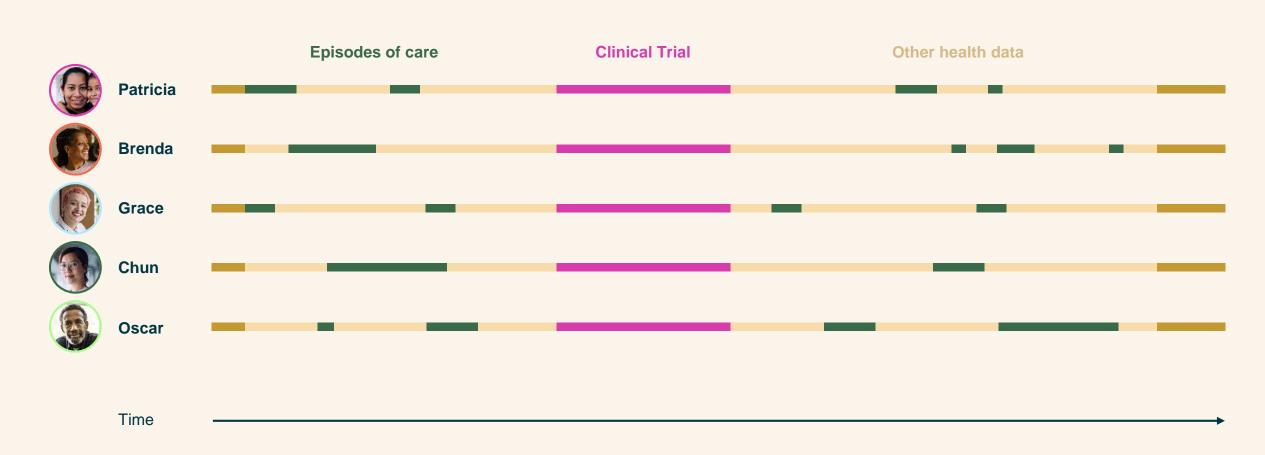
**Author Affiliations:** Author affiliations are listed at the end of this article.

**Group Information:** The full list of the Participants of the JAMA Summit on Clinical Trials appears in the Supplement.

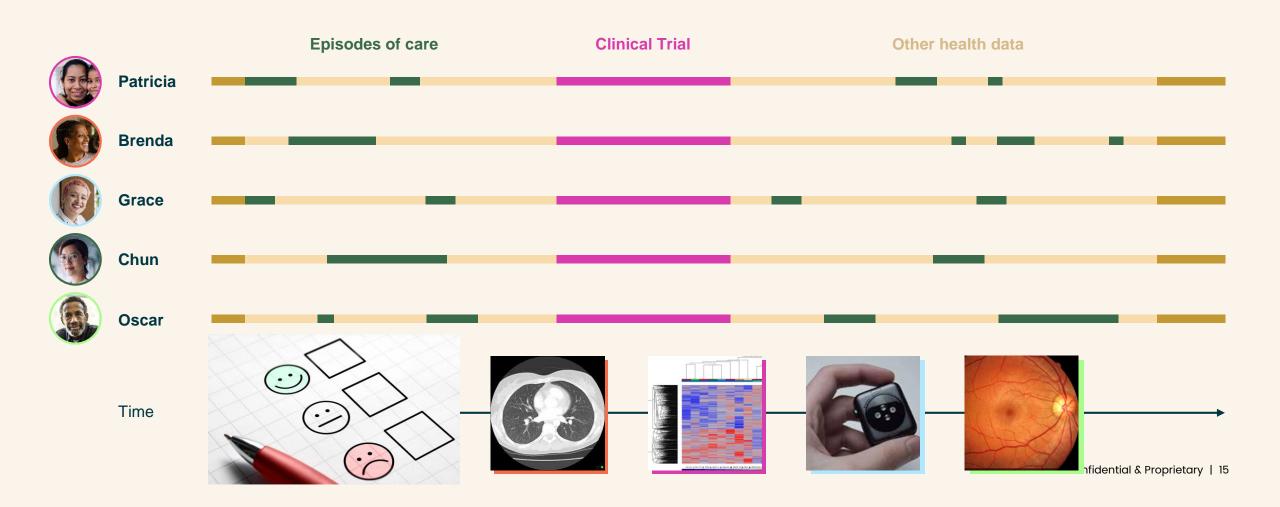
Corresponding Author: Amy P. Abernethy, MD, PhD, Highlander Health, 300 Crescent Court, Ste 550, Dallas, TX 75201 (amy@ highlanderhealth.com).



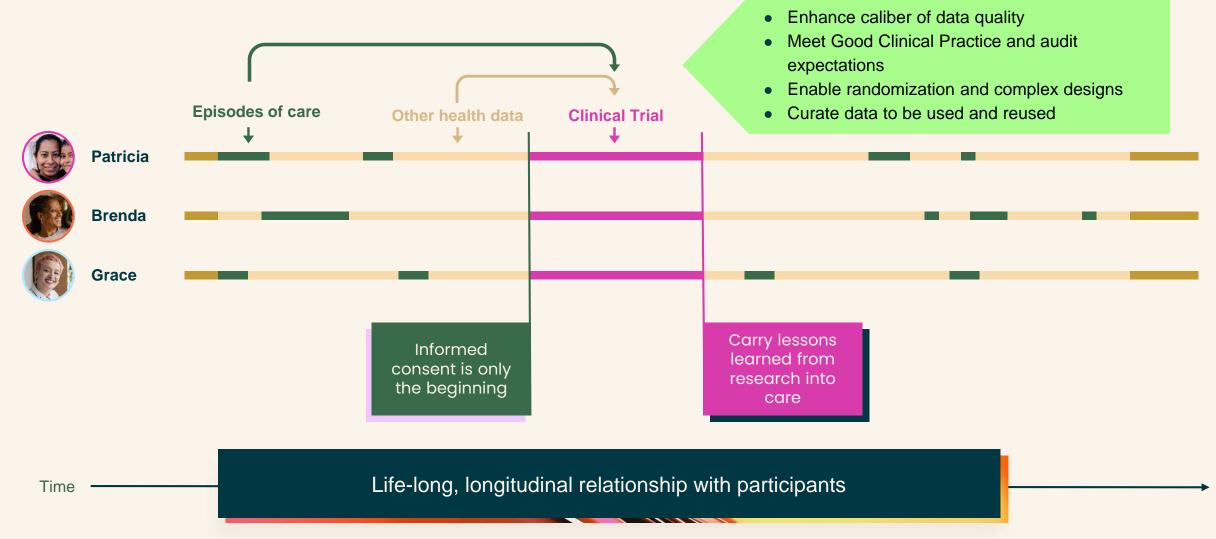
## The future of clinical trials connects into care settings and integrates participant-generated health data



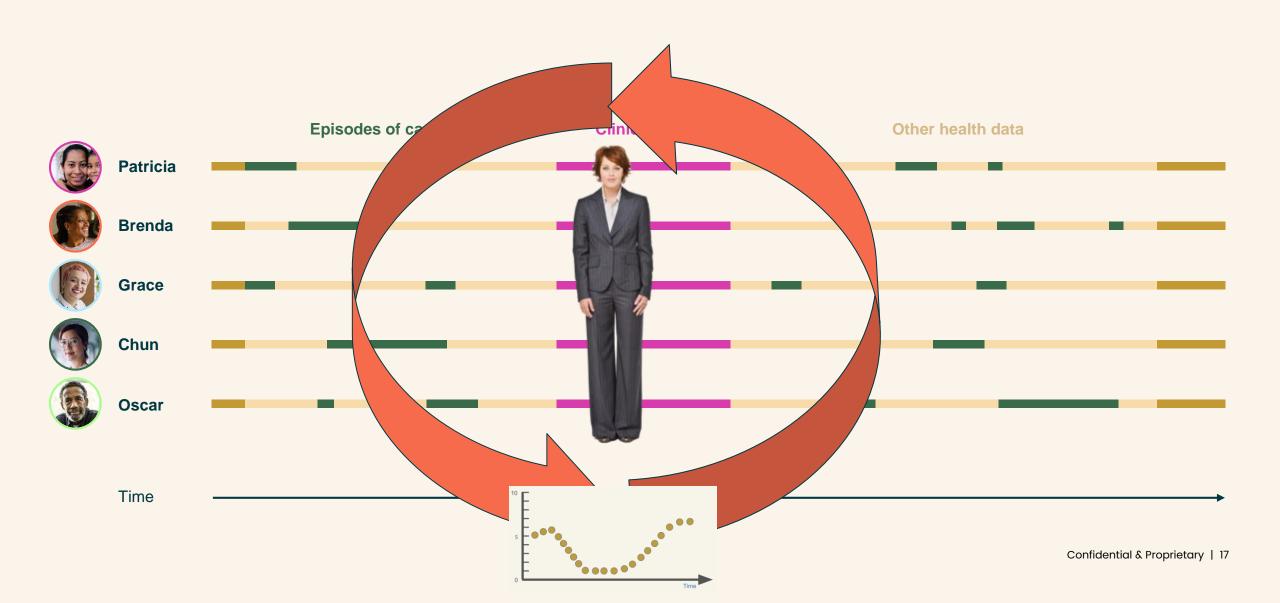
# The future of clinical trials connects into care settings and integrates participant-generated health data



## Longitudinal data connecting research and care

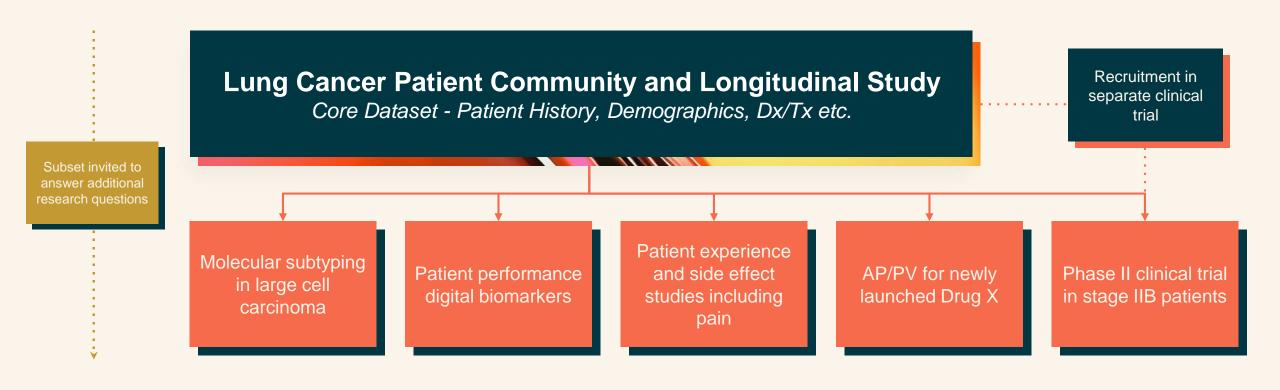


## Longitudinal clinical data bridges research and care

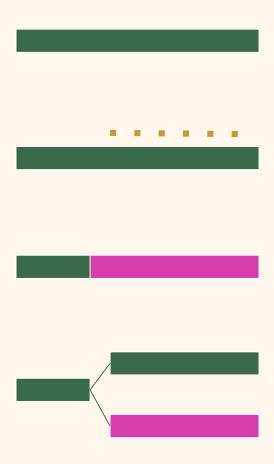


## Methods built into the data infrastructure to enable multiple study types and research applications

Datasets are multiuse, multimodal and multipurpose - can be leveraged for many tasks including discovery, clinical development, implementation, clinical decision support, precision health



## Clinical trials nested in registries



### **Syndicated dataset**

Analyze data to generate new insights into what works and what doesn't

### **Observational study**

Augment baseline data with additional data elements, tests to further study (e.g., pharmacovigilance)

### Single arm trial

Add in an intervention to study plus appropriate risk-based controls (GCP)

### Randomized trial

Leverage core infrastructure to simplify/streamline but randomize between agents and layer in aspects of traditional trial including investigational product and GCP

## Thank you

amy@highlanderhealth.com