

# Leveraging technology to bridge research and care

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December 2024

Highlander Health

# Disclosures

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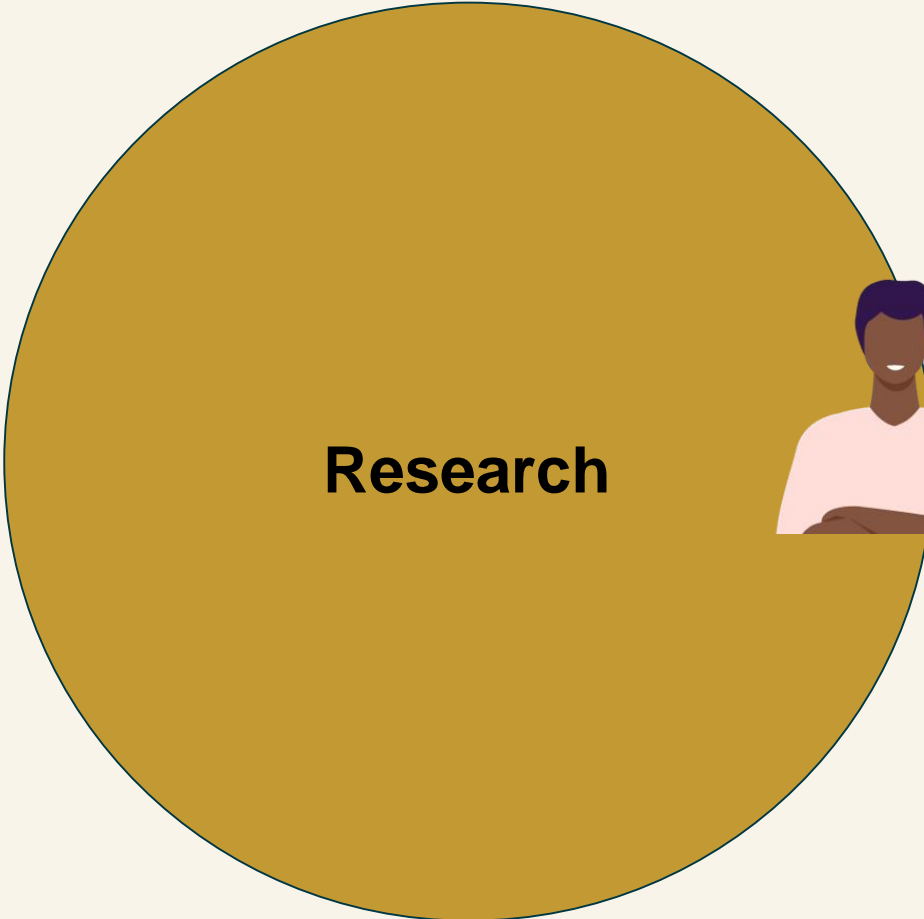
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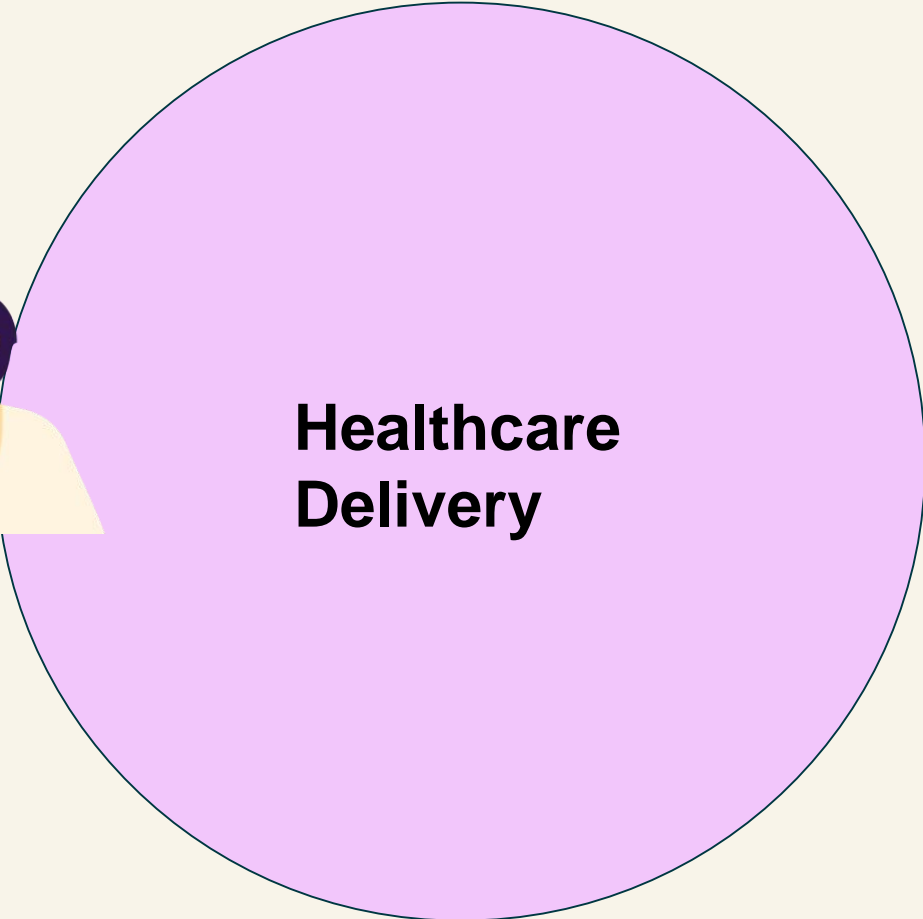
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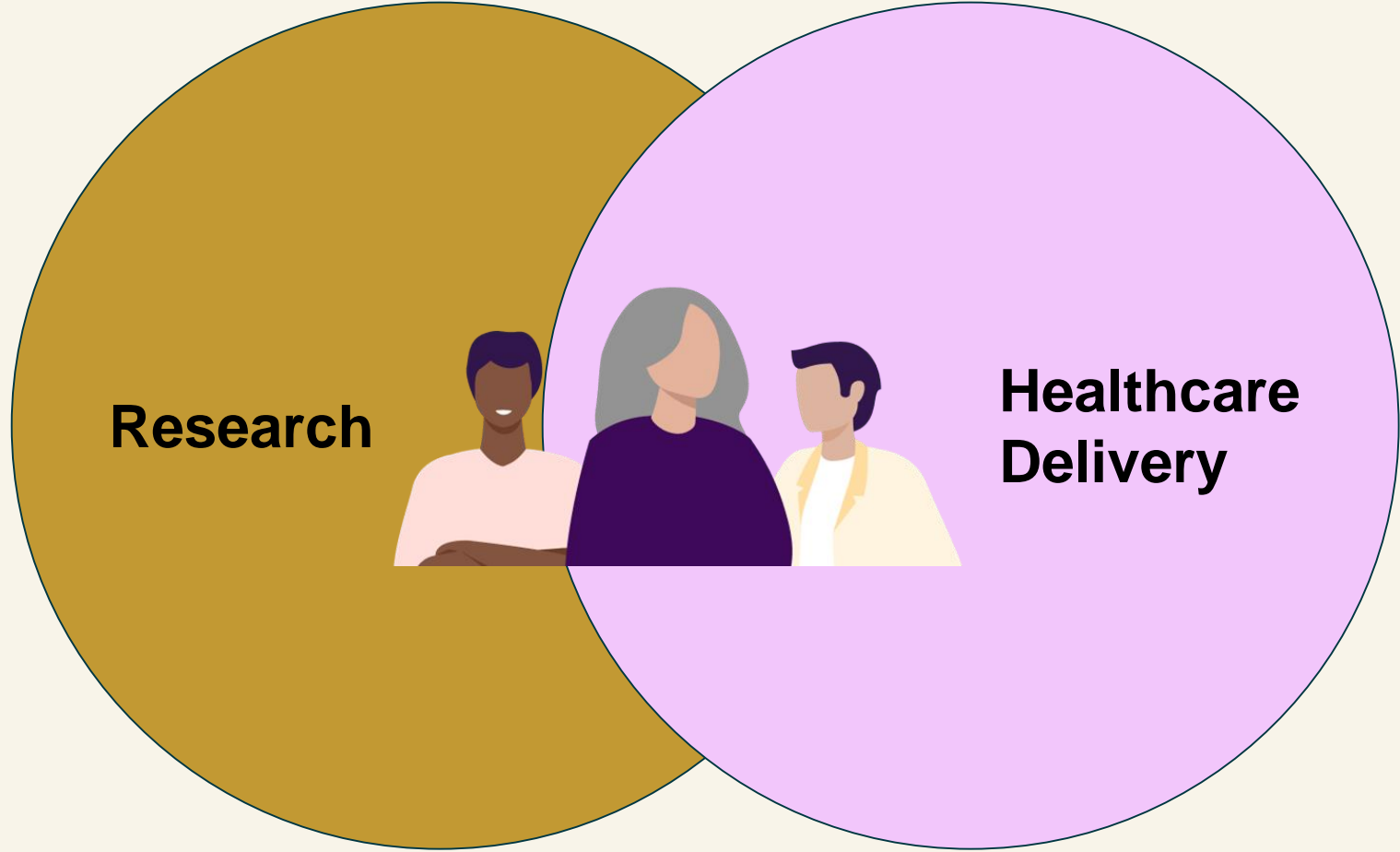
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**Research**

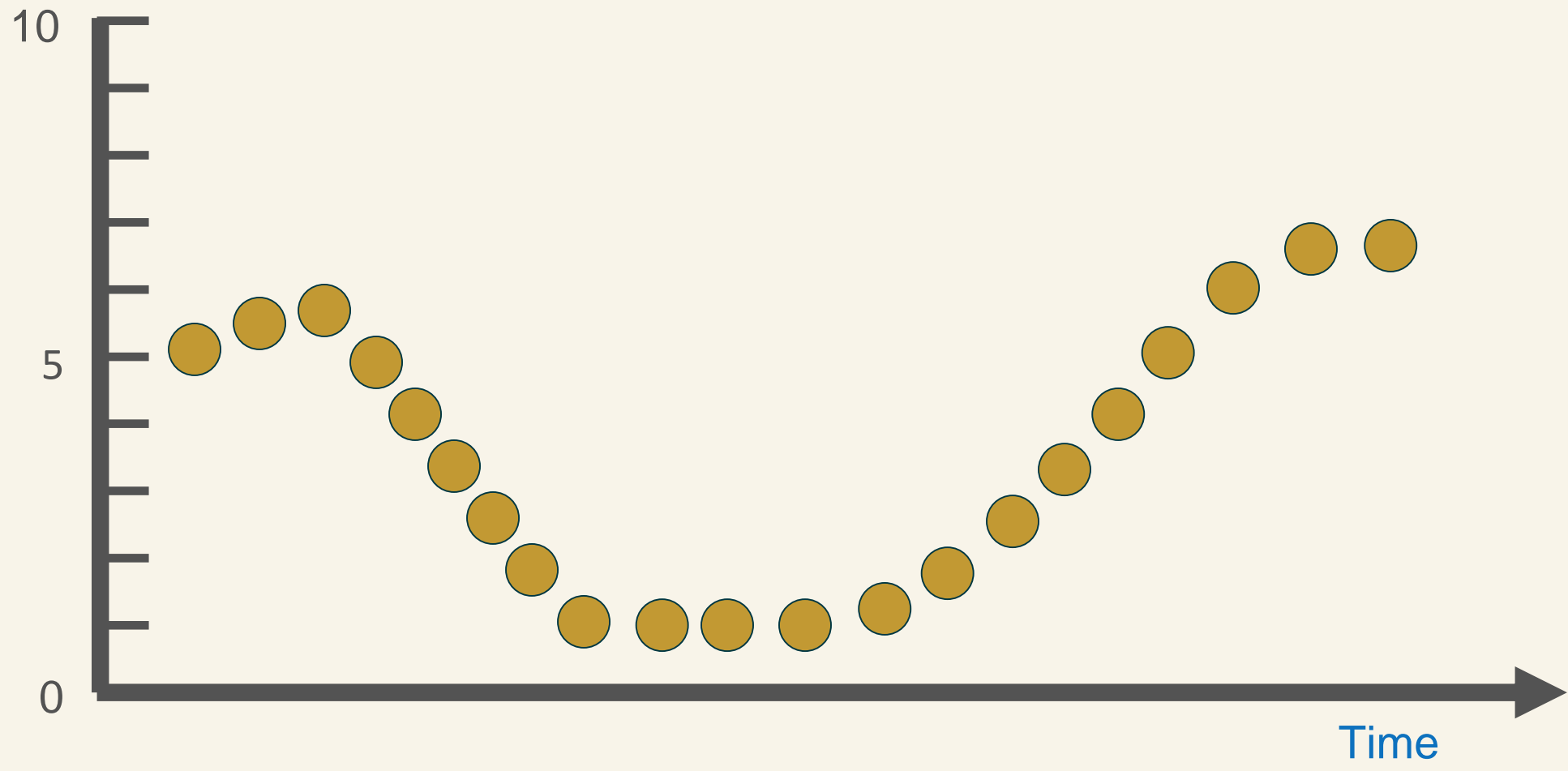


**Healthcare  
Delivery**

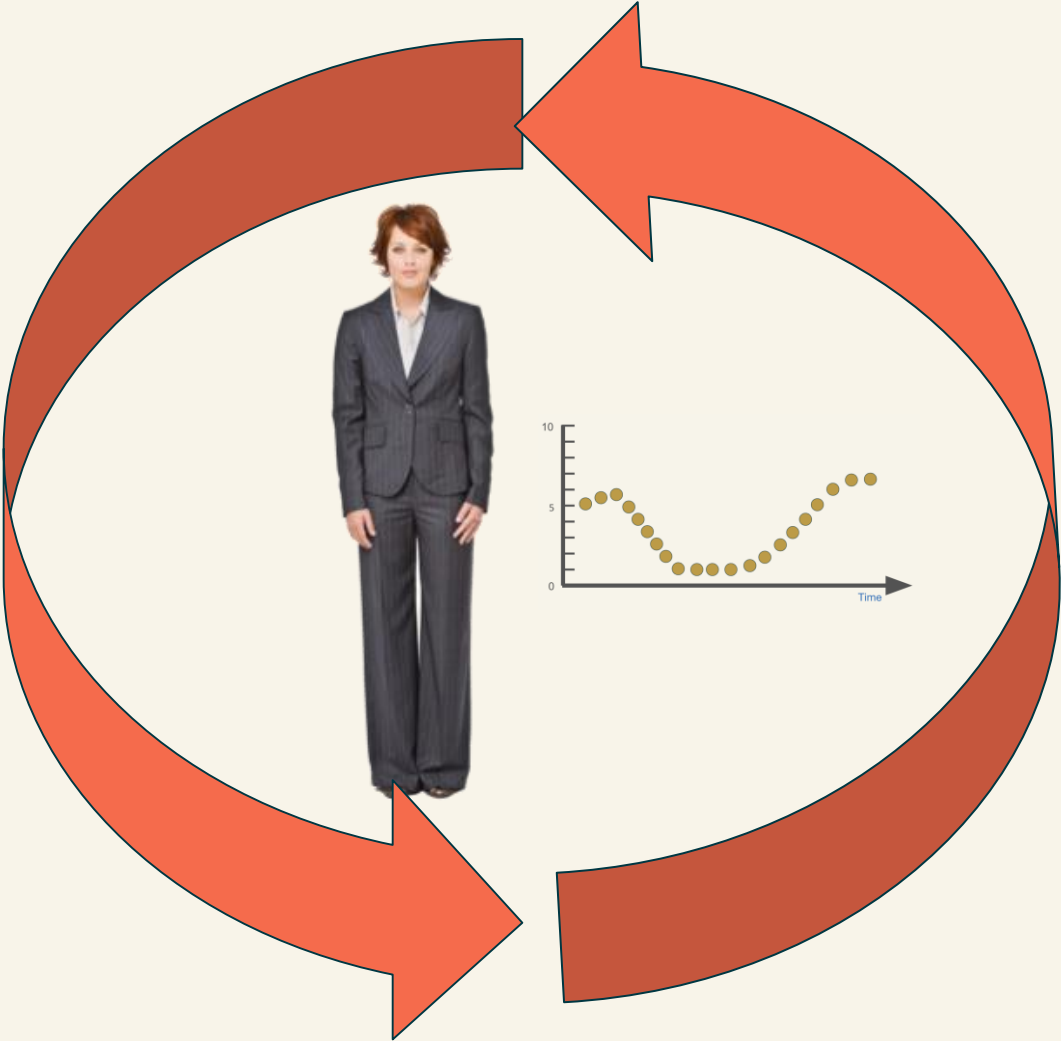
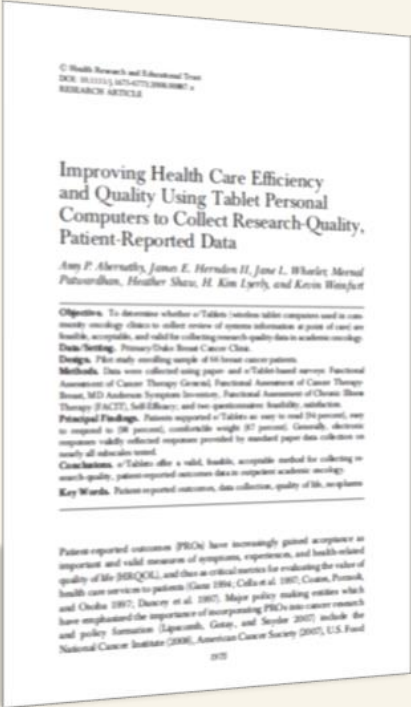


**Research**

**Healthcare  
Delivery**

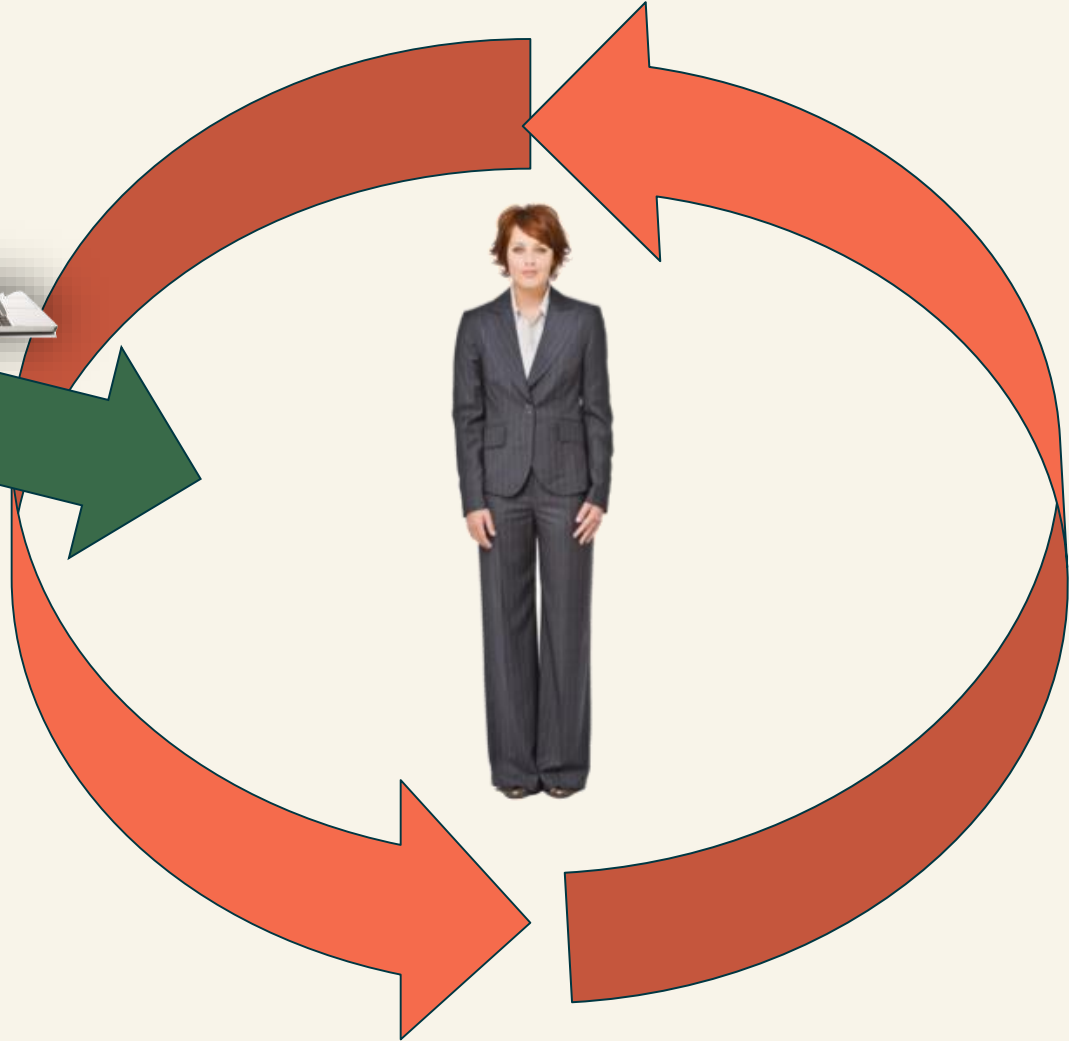
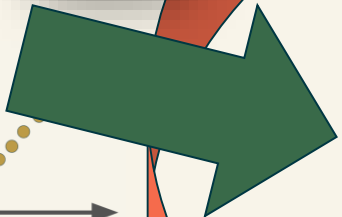


# Endeavor to create “research quality clinical data”



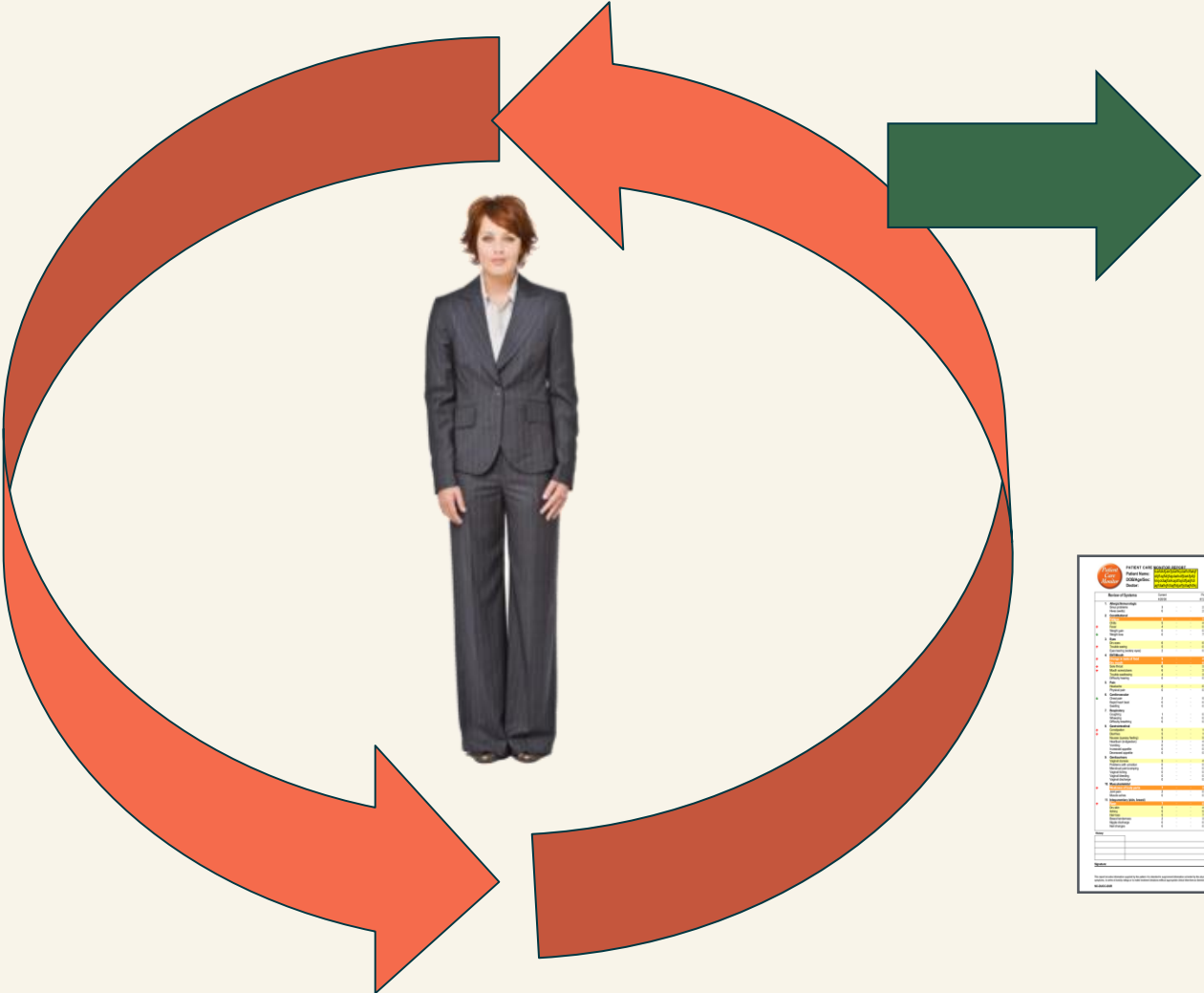
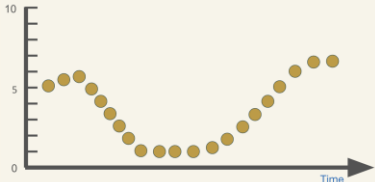
Reliable data is parsed out for clinical trials, clinical care, healthcare quality monitoring, and healthcare improvement simultaneously

# Multiple information sources linked via coordinated databases



# Real-time clinical use improved data quality

Multiple information sources



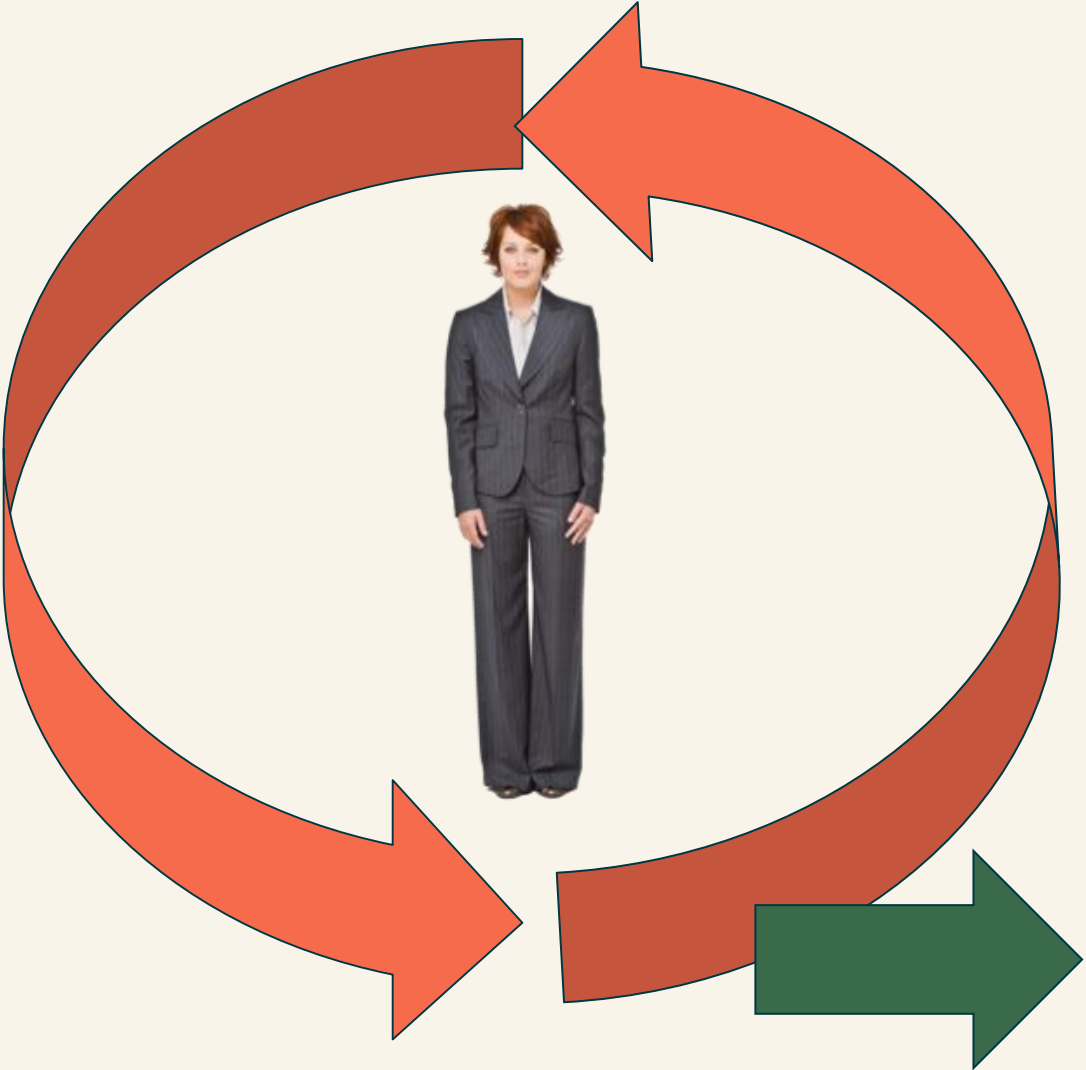
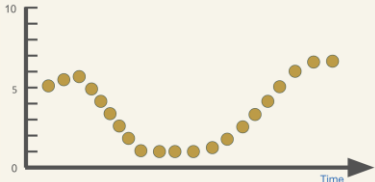
- Longitudinal reporting at point of care
- Clinical decision support
- Patient education
- Triggered interventions





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

Multiple information sources



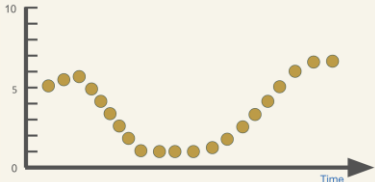
Real-time clinical use

Meaningful use of data in local health system

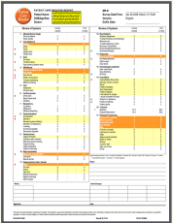
- Quality monitoring
- Improving operations

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

Multiple information sources

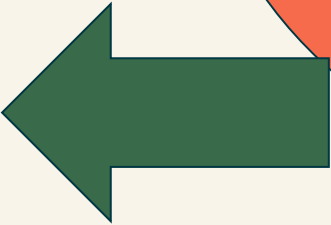


Real-time clinical use




A screenshot of a clinical dashboard with multiple colored sections (yellow, orange, red) and various data points, representing real-time clinical use.

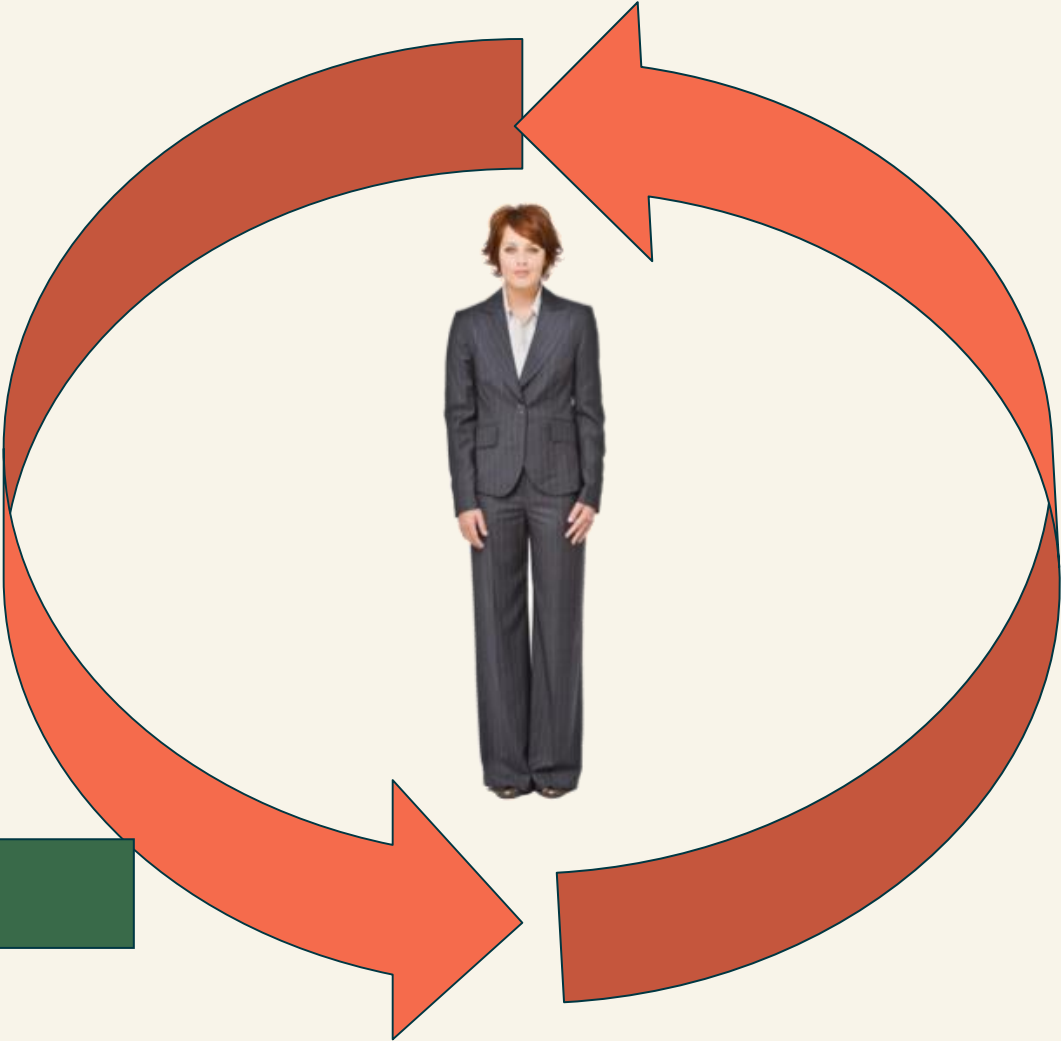
Clinical research and healthcare innovation

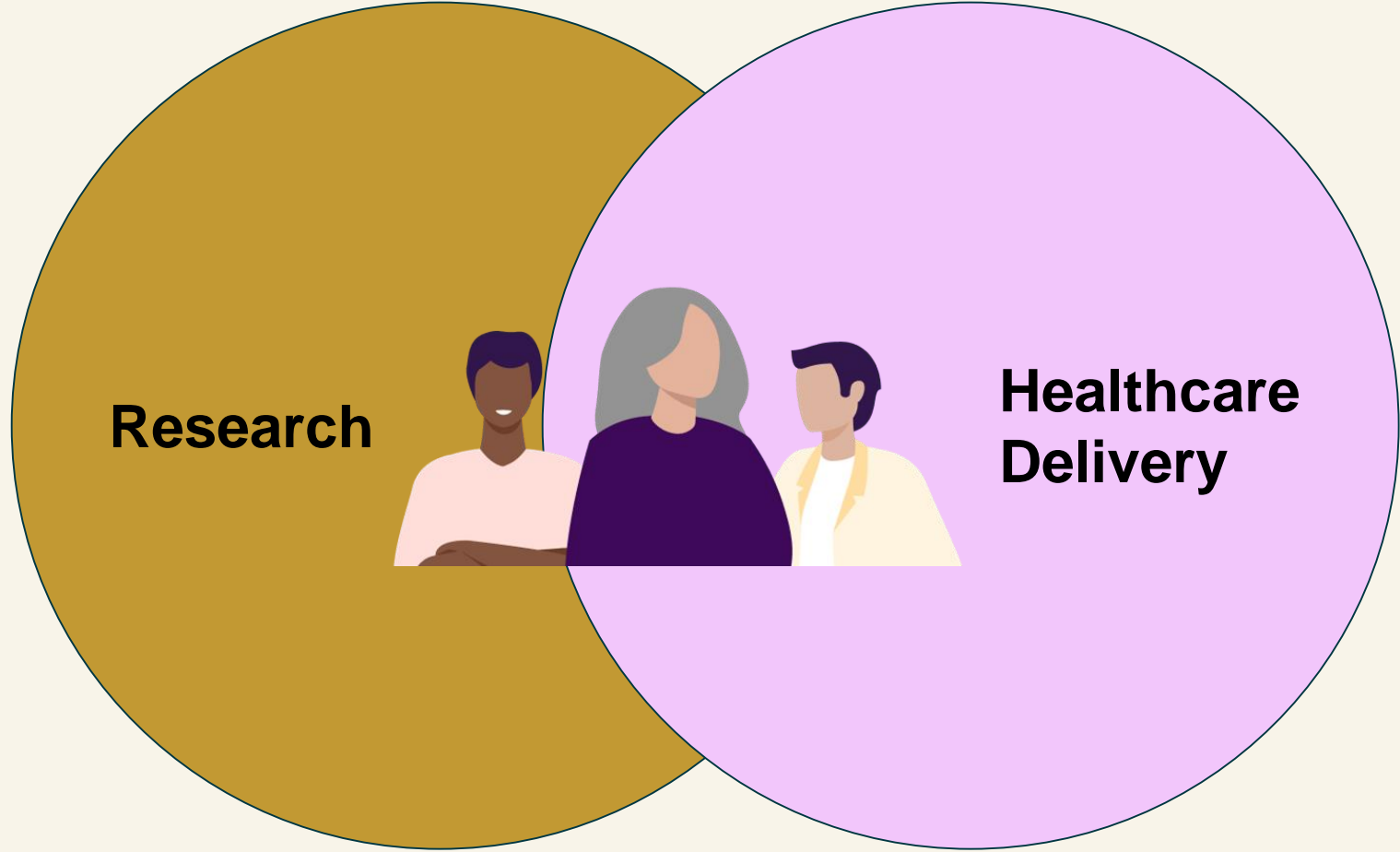


Health system impact



A screenshot of a data table with multiple columns and rows, representing health system impact data.





**Research**

**Healthcare  
Delivery**

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. Krumholz, 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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Published online August 5, 2024.

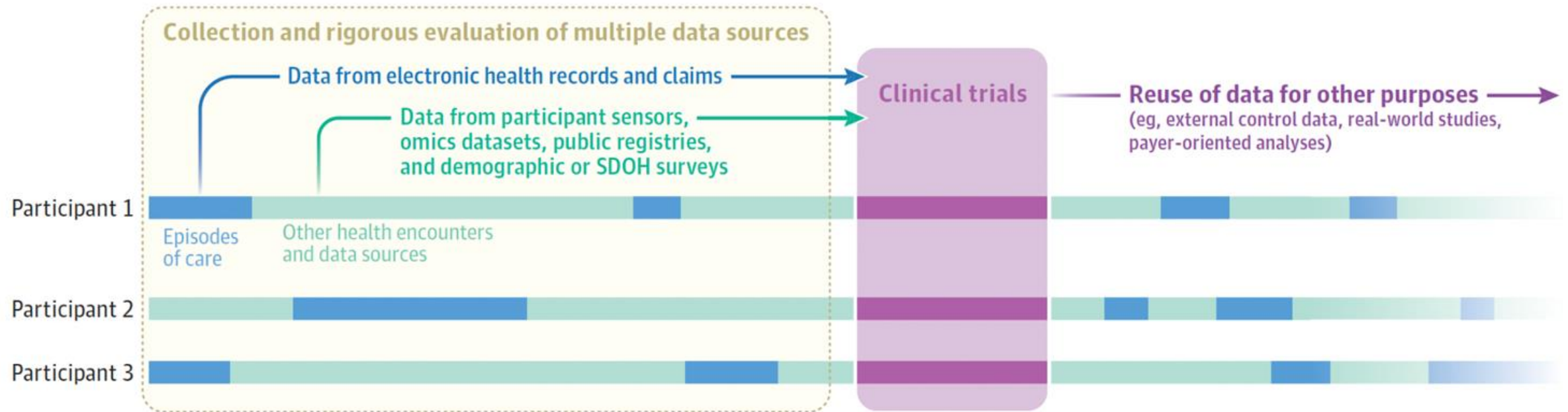
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**Author Affiliations:** Author affiliations are listed at the end of this article.

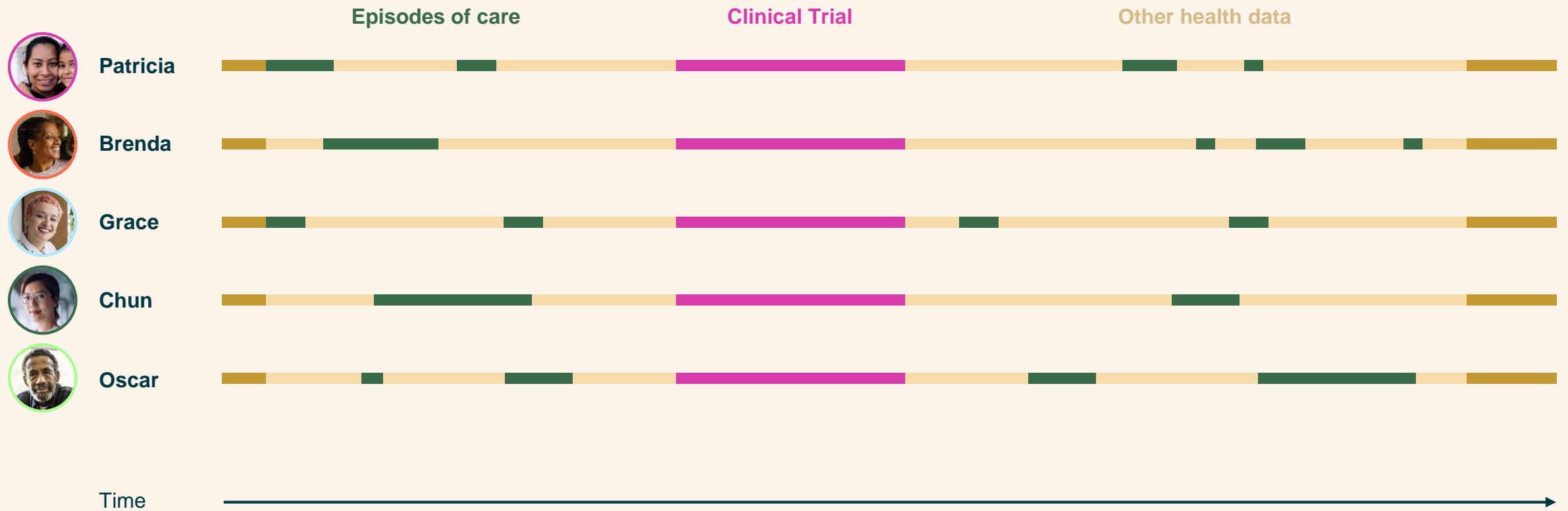
**Group Information:** The full list of the Participants of the JAMA Summit on Clinical Trials appears in the Supplement.

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

Figure 1. Two-Concept Vision for Modernizing Clinical Research Data Across Participants' Data Generation Timelines

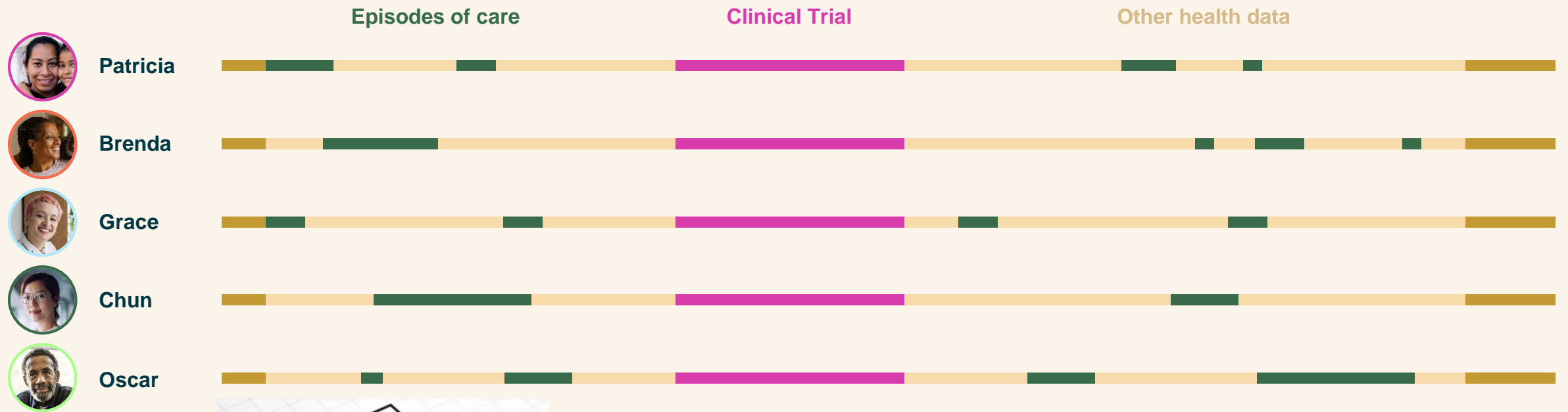


# The future of clinical trials connects into care settings and integrates participant-generated health data

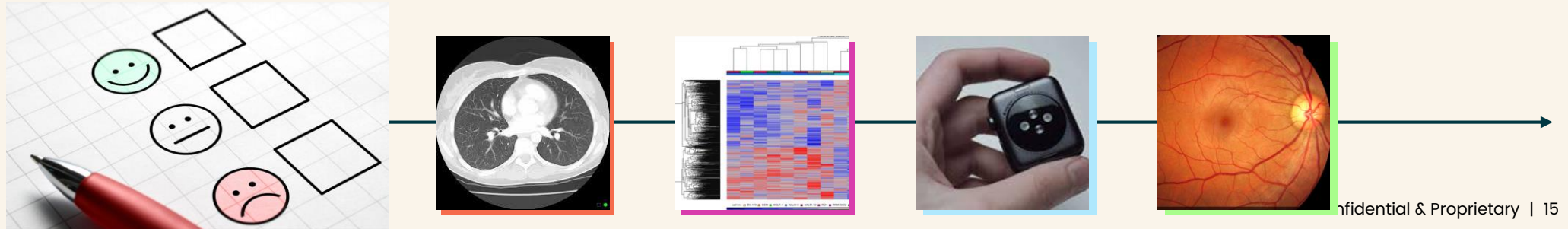




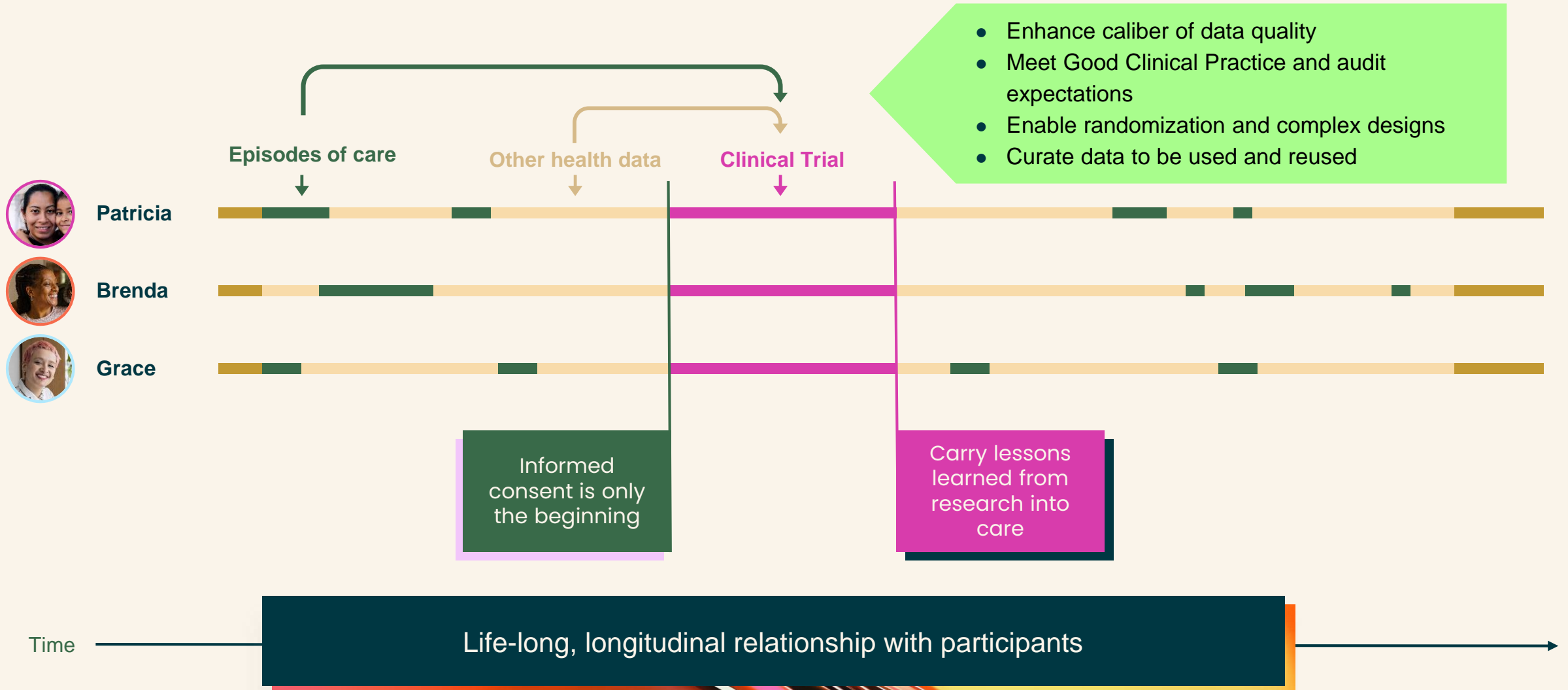
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Time

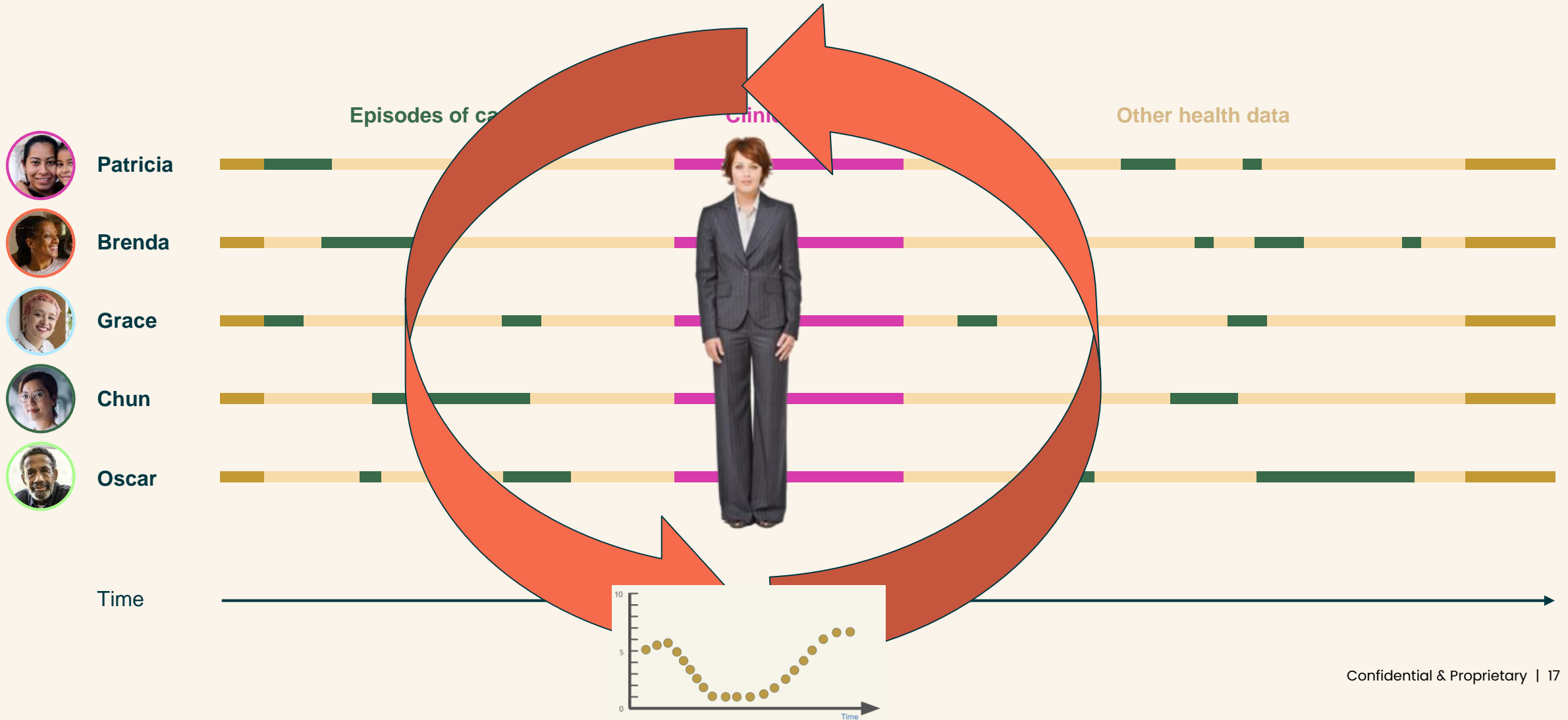


# Longitudinal data connecting research and care



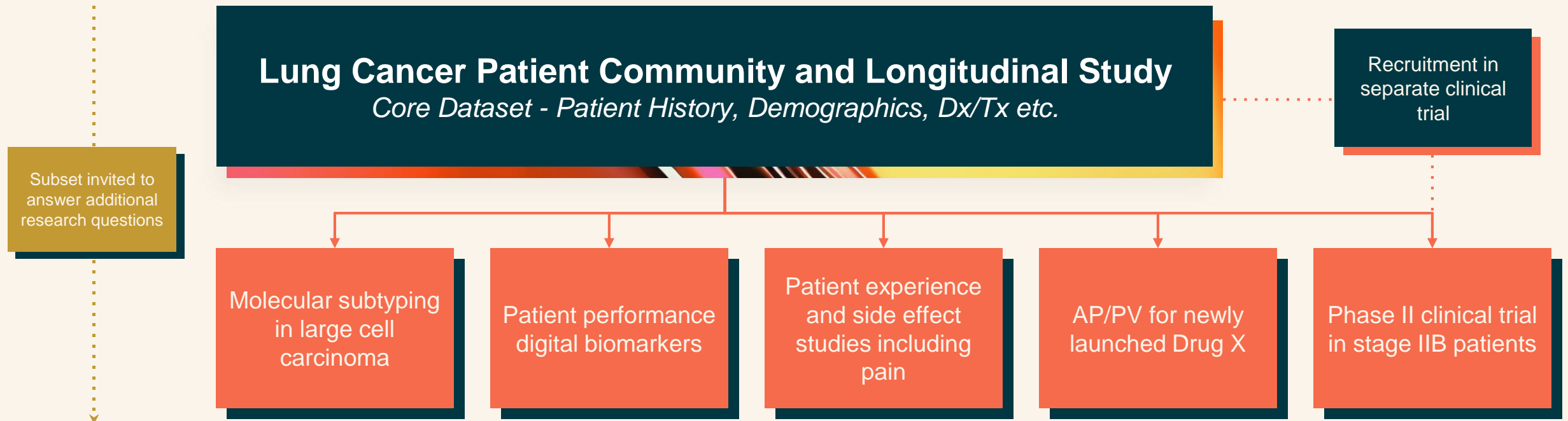


# Longitudinal clinical data bridges research and care

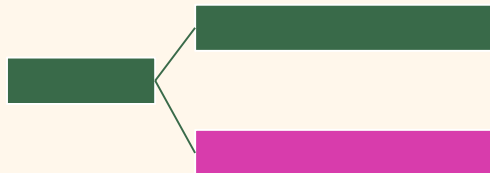
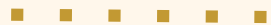


Methods built into the data infrastructure to enable multiple study types and research applications

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



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