CCDI Workshop: The Importance of Electronic Health Record (EHR) Data in Clinical Care and Research

November 2, 2022

NIH NATIONAL CANCER INSTITUTE

1. *Welcome and Introductions*
2. *EHR Data Portability and Interoperability*
3. *Structured EHR Data, Data Extraction, and Translation*
4. *EHR-Directed Clinical Trials*
5. *Research Use of EHR Data*
6. *Closing Remarks*

Welcome and Introductions

Jaime Guidry Auvil, PhD

Director, Office of Data Sharing
National Cancer Institute

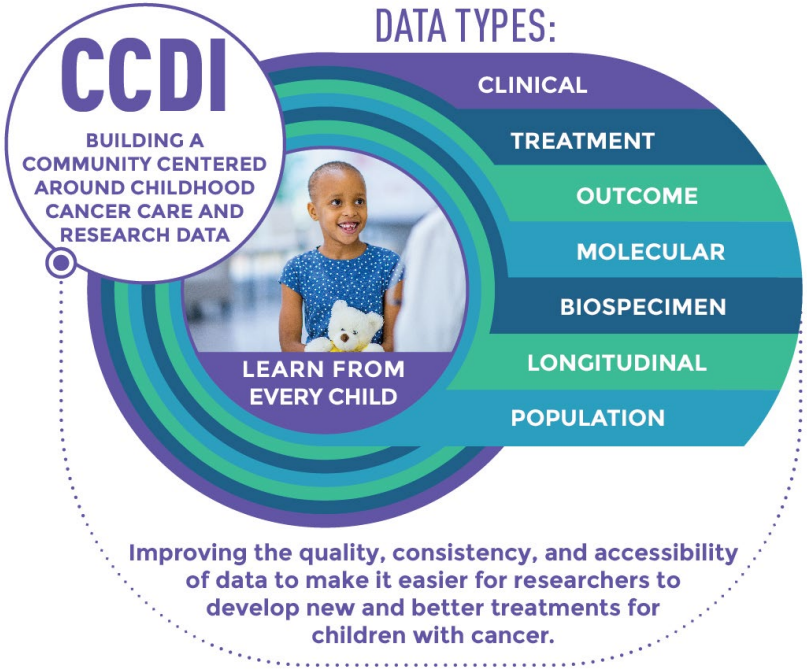
Tony Kerlavage, PhD

Director, Center for Biomedical
Informatics & Information Technology
National Cancer Institute

Welcome and Introductions

Monica Bertagnolli, MD

Director
National Cancer Institute



EHR WORKSHOP OBJECTIVES

- Understand the issues surrounding EHR data portability and interoperability
- Outline potential approaches to structuring EHR data for maximal utility and benefit
- Explore opportunities to capitalize on the use of EHR data for clinical care and research

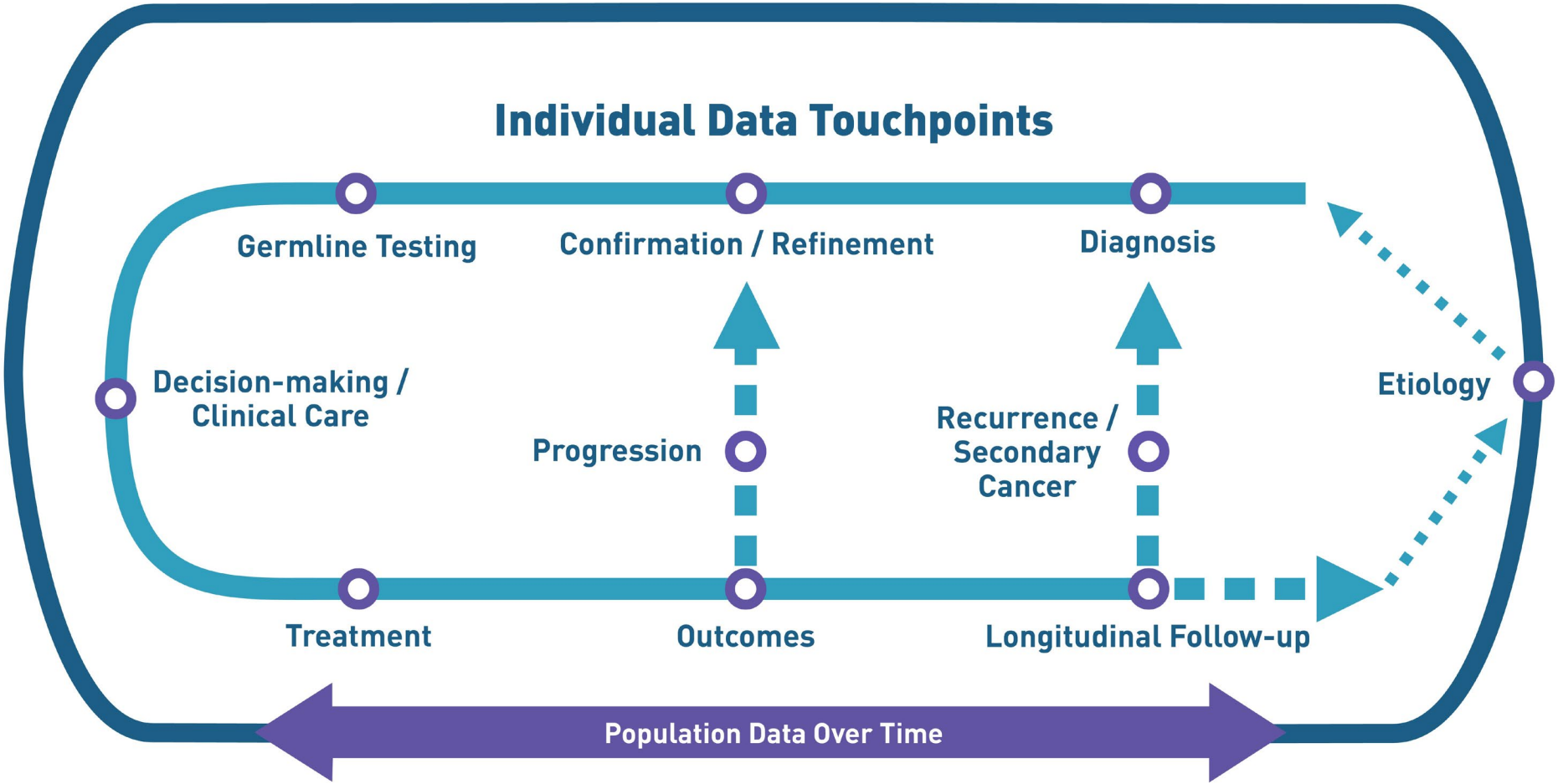
Benefits and Challenges of Using EHR Data

Benefits

- EHRs are data-rich and cover a patient's medical journey
- EHRs are first point-of-entry for patients and their data
- EHR data can provide immense value to clinical care, research, and public health

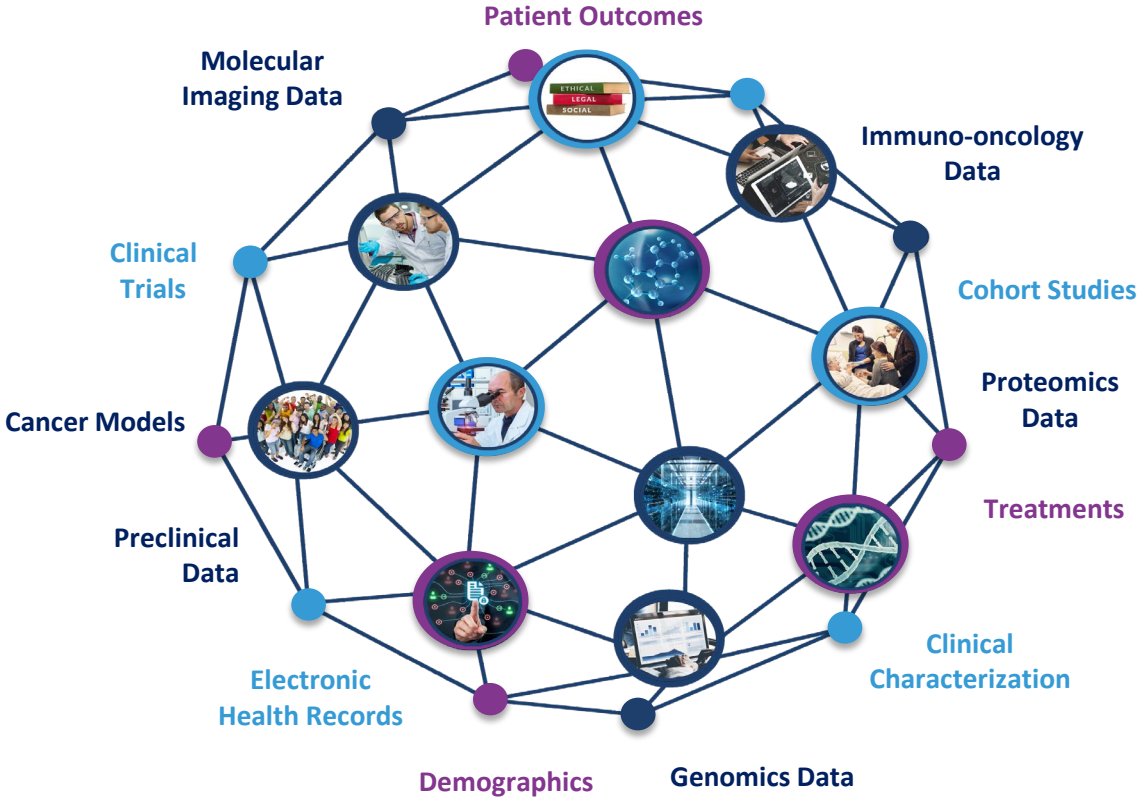
Challenges Prevent This Value from Being Realized

- Data are collected across disparate settings over time, without consistent alignment or standardization
- Data and systems are not interoperable, in myriad, complex ways
- These inconsistencies require error-prone, labor-intensive manual efforts and tremendous resources to resolve
- Patients and families do not have sufficient access to and appropriate control over their data

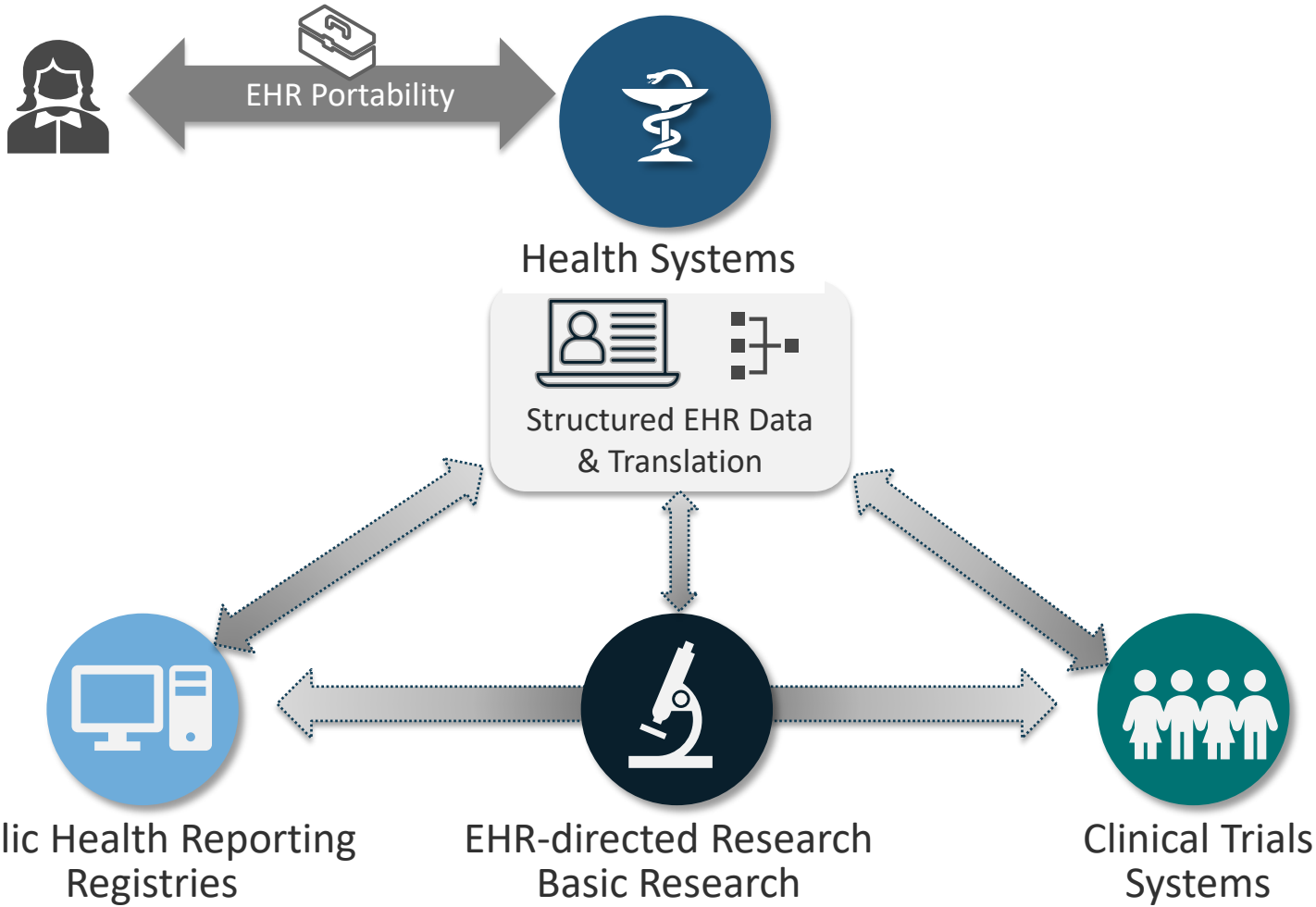

Individual Data Touchpoints
Germline Testing
Confirmation / Refinement
Diagnosis
Decision-making / Clinical Care
Progression
Recurrence / Secondary Cancer
Etiology
Treatment
Outcomes
Longitudinal Follow-up
Population Data Over Time

EHRs in the Context of a **Federated** Cancer Data Ecosystem

- Underlying data science infrastructure
- Enhanced cloud-computing
- Services linking clinical, image, & molecular data
- Standards & tools for data interoperability
- Data repositories
- Public Health registries



Discovery Science → Clinical Studies/Care → Surveillance


EHR Portability
Health Systems
Structured EHR Data
& Translation
Public Health Reporting
Registries
EHR-directed Research
Basic Research
Clinical Trials
Systems

Session 1: EHR Data Portability and Interoperability

EHR Data Portability and Interoperability

Gregory J. Aune, MD, PhD
Greehey Children's Cancer Research Institute

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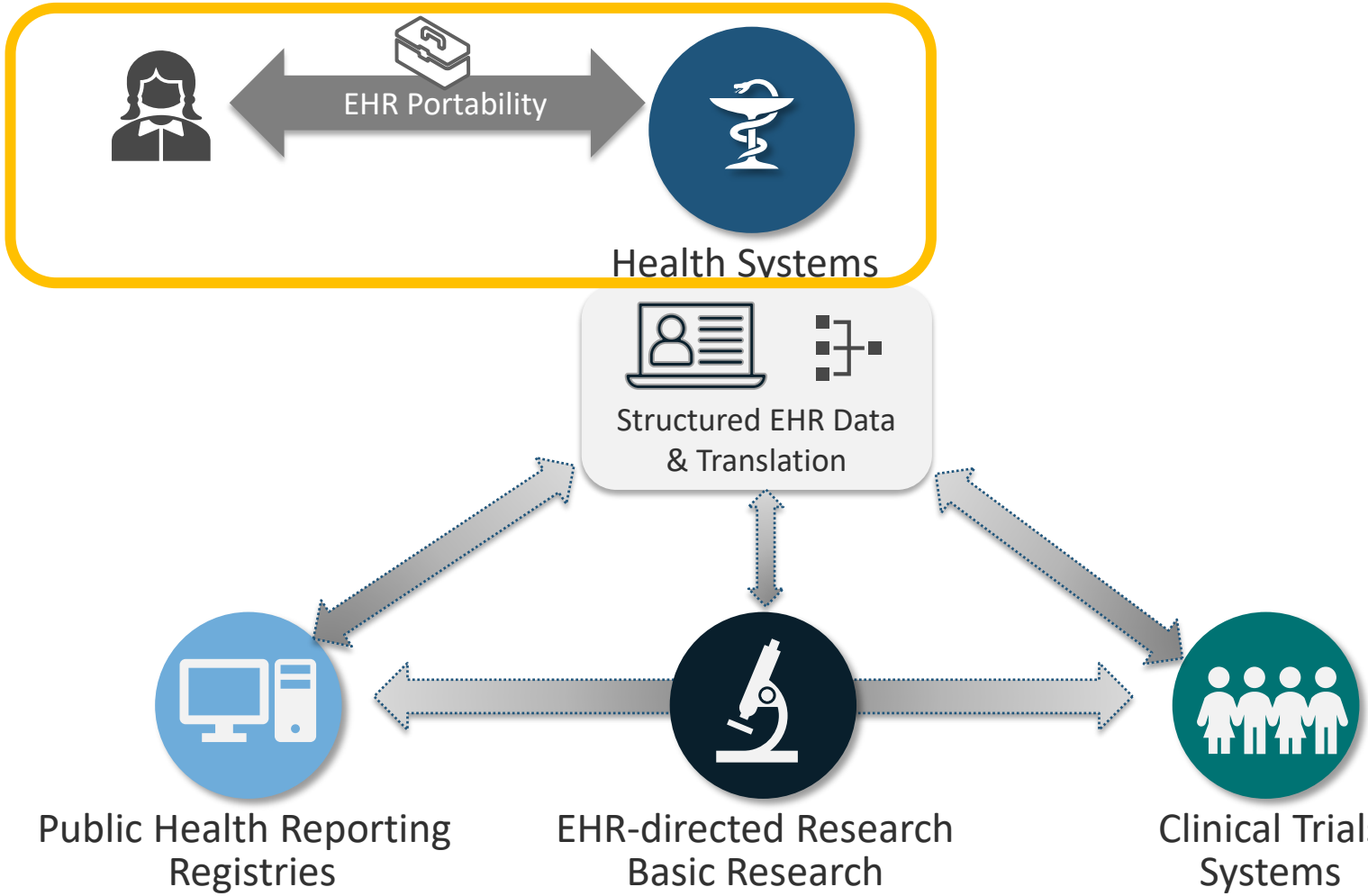
PicnicHealth

Suzanne George, MD
Alliance for Clinical Trials in Oncology

Vasiliki N. Rahimzadeh, PhD
Assistant Professor
Center for Medical Ethics and Health Policy

Sanford M. Simon
The Gunter Blobel Professor, Head of the Lab of Cellular Biophysics, The Rockefeller University President, The Fibrolamellar Registry

Sharon F. Terry, MA
Chief Executive Officer
Genetic Alliance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Key Goals for Session 1

1. Define patient, family, and physician needs within EHR data portability
2. Outline challenges specific to:
    a) Access to EHR data by patient, families, and treatment teams
    b) Consent practices and trust around privacy issues (age of majority, long-term follow-up)
    c) Pediatric and AYA navigation and survivorship
    d) Ability of patient or family to ensure accuracy of EHR data
    e) Institutional or regulatory policies (IRB, HIPAA)
3. Address misplaced burden of consent and data consolidation for portability
4. Describe possible solutions (empowering patients/families to control their data, clinical care team communications)

Session 2: Structured EHR Data and Data Extraction & Translation

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Structured EHR Data, Data Extraction, and Translation

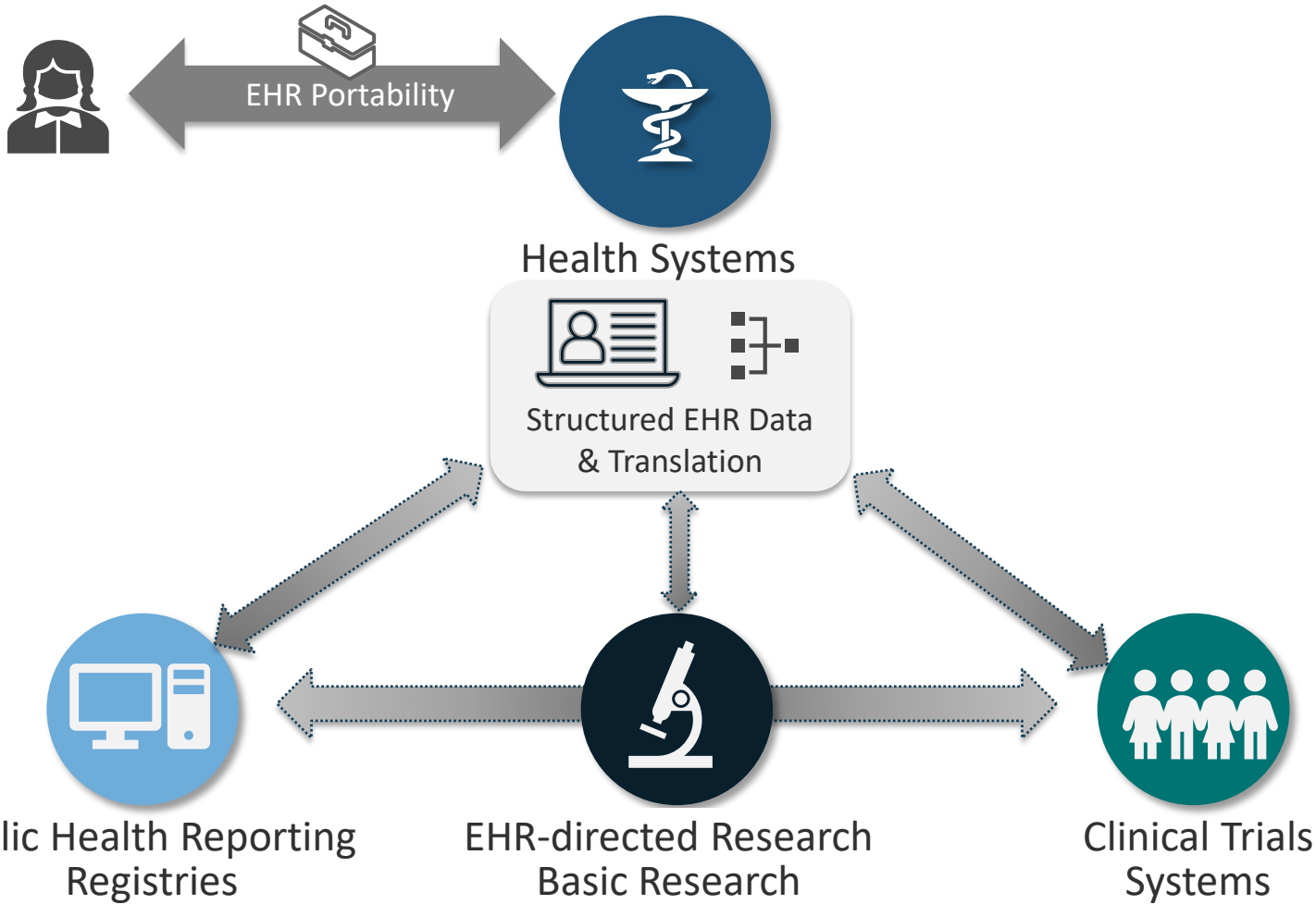
Allison P. Heath, PhD
Children's Hospital of Philadelphia

Lela McFarland
Enterprise Data Architect
ECS Federal

Travis Osterman, DO, MS
Assistant Professor, Department of Biomedical Informatics, Division of Hematology and Oncology Vanderbilt Health

Andre Quina
MITRE Health

Samuel Volchenboum, MD, PhD
Pediatric Cancer Data Commons, University of Chicago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Key Goals for Session 2

1. Define the need for EHR data models, elements, translation, and transport
2. Outline challenges specific to:
    a) Lack of data structures and consistent use of standards
    b) Pediatric and AYA coding complexity, accuracy for rare cancers
    c) Commercial and institutional implementation of standardized data
    d) Regulatory policies for data structure and transport (ONC)
3. Describe possible solutions (standards such as FHIR, USCDI, mCODE)

Session 3: EHR-Directed Clinical Trials

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EHR-Directed Clinical Trials

Richard Aplenc, MD, PhD
AVP and Chief Clinical Research Officer, The Children's Hospital of Philadelphia, Perelman School of Medicine at the University of Pennsylvania

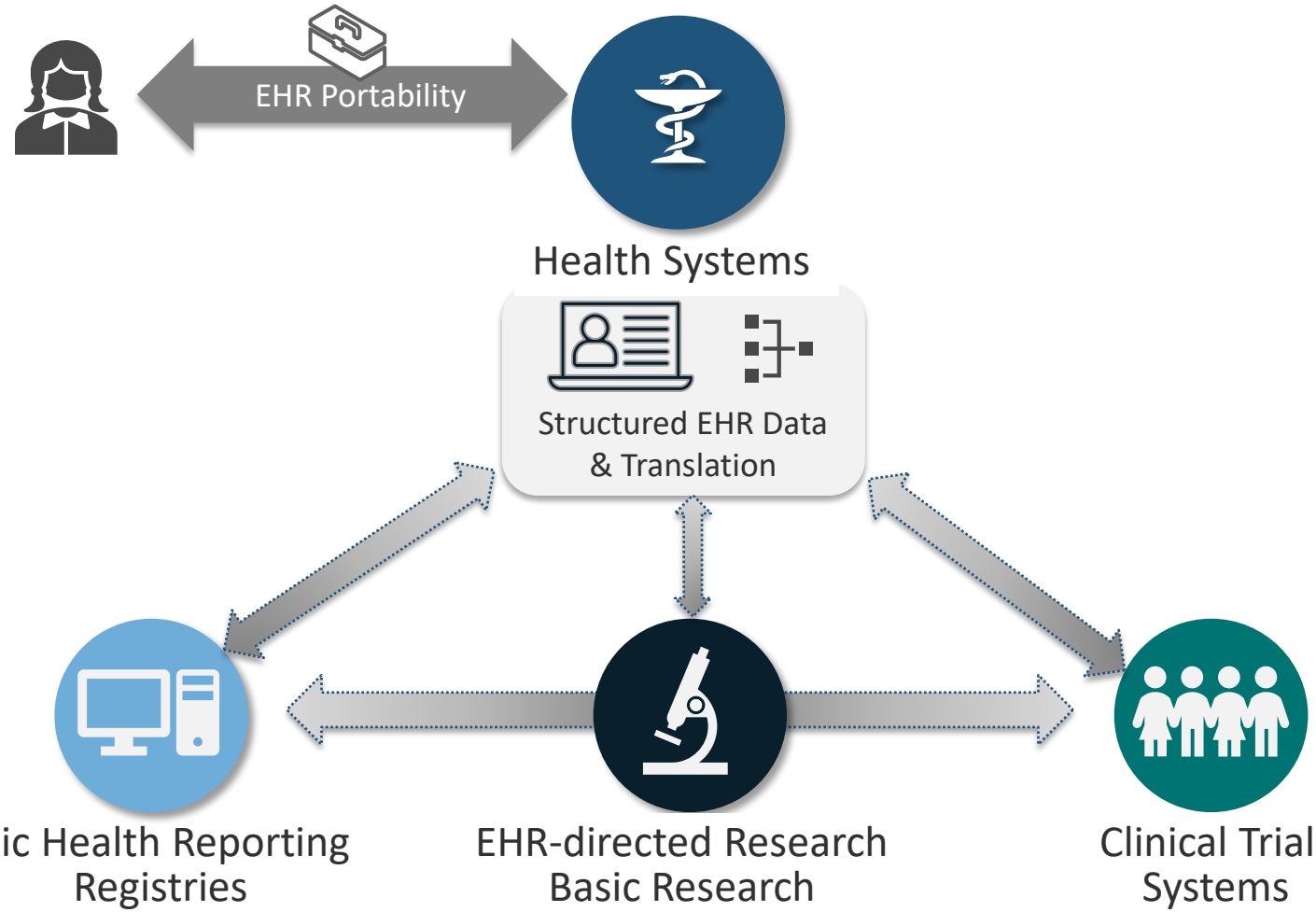
Keith Goodman, D.B.A, VP of Technology
Cancer Research and Biostatistics
SWOG Statistics and Data Management Center

Katherine Janeway, MD, MMSc
Associate Professor of Pediatrics, Harvard Medical School
Senior Physician, Dana-Farber/Boston Children's Cancer and Blood Disorders Center Director, Clinical Genomics, Dana-Farber Cancer Institute

Hugh P. Levaux, PhD
Vice President, Head of Clinical Research Growth Strategy
Flatiron Health

Gwen Nichols, MD
Chief Medical Officer
The Leukemia & Lymphoma Society (LLS)

Steven Piantadosi, MD, PhD
Brigham and Women's Hospital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Key Goals for Session 3

1. Define opportunities for use of EHR data in clinical trials
2. Outline challenges specific to:
    a) Obtaining patient treatment (and other relevant data) from EHR
    b) Defining synthetic control arms and cohorts for new studies
    c) Structured eligibility criteria and trial matching
    d) Pediatric and AYA rare cancers and small populations
    e) Regulatory and commercial requirements for data quality (FDA, Pharma)
3. Describe existing and potential solutions (tools, approaches, data elements)

Session 4: Research Use of EHR Data

Research Use of EHR Data

Amanda Haddock
President, Dragon Master Foundation

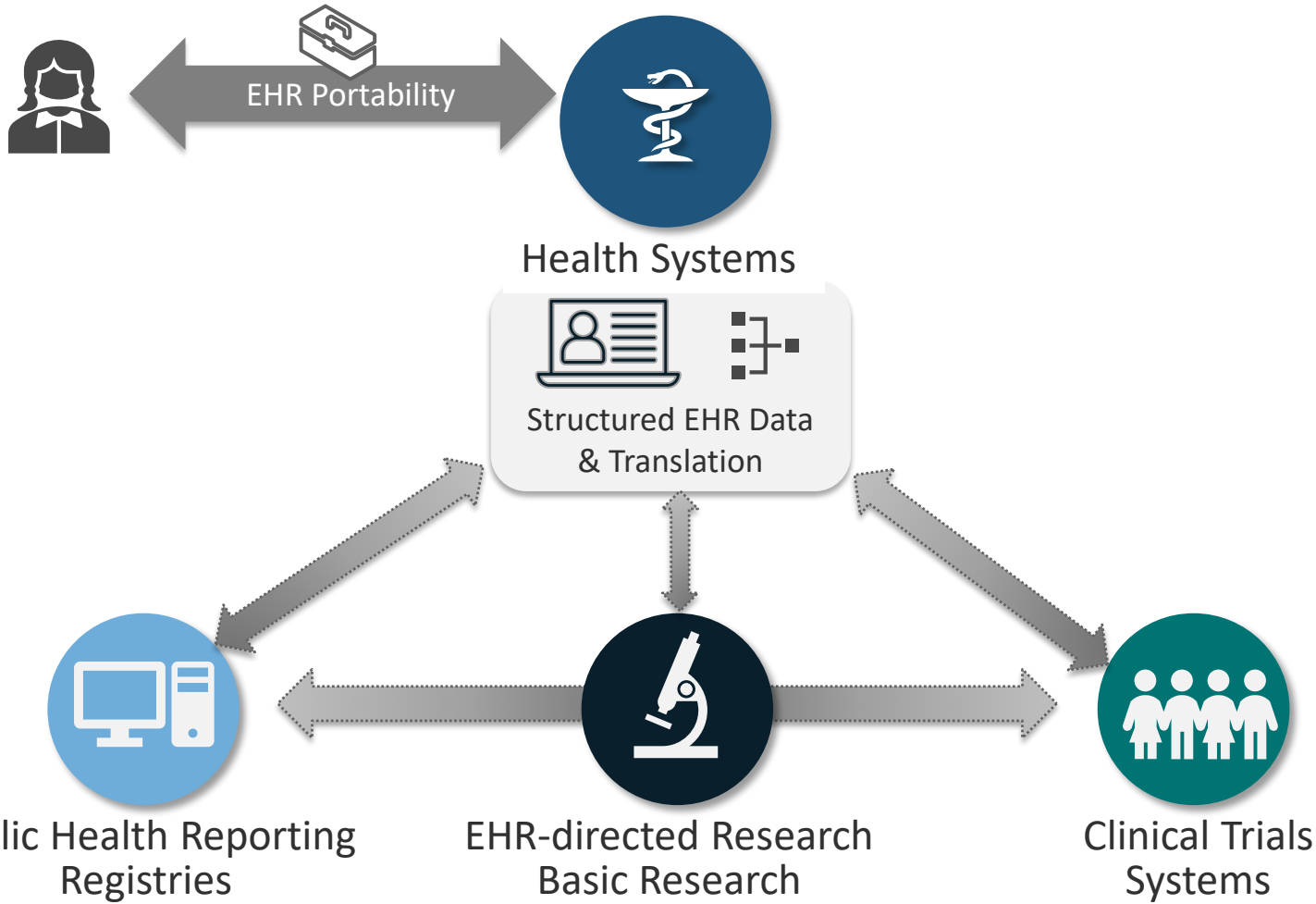
Andy McMurry, PhD (Bioinformatics)
Research Scientist and Faculty Boston Children's Hospital Harvard Medical School

Daniella Meeker, PhD
Associate Professor University of Southern California, Department of Population and Public Health Sciences, Keck School of Medicine

Tamara P. Miller, MD, MSCE
Emory University and Children's Healthcare of Atlanta

Corrie Painter, PhD
VP External Research & Partnerships, Precede Biosciences Strategic Advisor, Broad Institute

Jinghui Zhang, PhD
St. Jude Children's Research Hospital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Key Goals for Session 4

1. Define distinct needs and issues incorporating EHR data into research and public health reporting
2. Outline challenges specific to:
    a) Researcher access to EHR data
    b) Structure and translation of EHR data to match research needs (basic science, population studies, evidence-based knowledge)
    c) Integration of EHR data with research data
    d) Variability in accuracy, specificity, and volume of information available in EHRs
    e) Institutional and regulatory limitations affecting research and public health
3. Describe possible solutions

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www.cancer.gov/espanol