The Role of Personalized Medicine in Addressing Health Equity

August 12, 2022

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Disparities in Cancer Care Summit

Sara Rogers, PharmD, BCPS and Benjamin Brown are being compensated for their presentation today by AmerisourceBergen however neither AB nor any pharmaceutical company has influenced the content of this presentation nor has AB independently verified the presentation for accuracy.

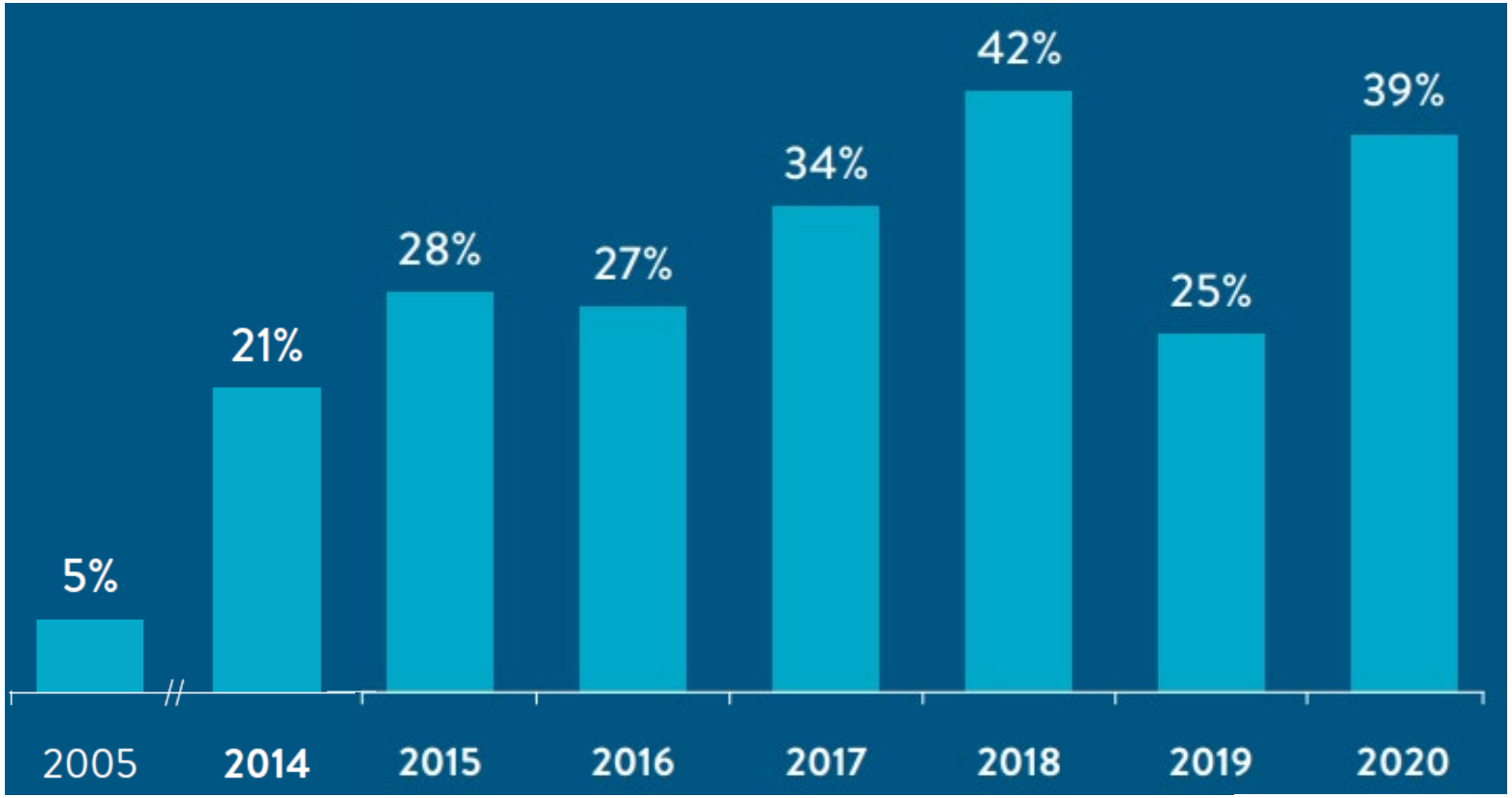
ASP Vision

We shall prevent the premature death of millions of patients by building a healthcare network that represents the ASP core values:

1. Culture of radical innovation towards improving the quality of patient care
2. Unwavering dedication towards solving the Nation's toughest problems in healthcare
3. Diversity of thinking, perspective and ideas
4. Concrete communication and masterful messaging to create persistent public awareness
5. Massive mobilization of national resources to fulfill the promise of precision medicine

American Society of Pharmacovigilance. https://stopadr.org/about-us. Accessed Mar 4, 2022.

Personalized Medicines Account for More Than 30% of FDA Approvals in Recent Years



*Defined as drugs where labeling references specific biological markers, often identified by diagnostic tools, that help guide decisions and/or procedures for their use in individual patients.
Personalized Medicine Coalition. Personalized Medicine at FDA: the scope & significance of progress. (2020)

Pharmacogenetic Biomarkers in 2020

Therapeutic Area	Number of Biomarkers
Oncology	184
Psychiatry	38
Infectious Diseases	35
Neurology	32
Hematology	26
Anesthesia	23
Cardiology	18
Gastroenterology	16
Gynecology	10
Pulmonary	10
Rheumatology	10
Other	29

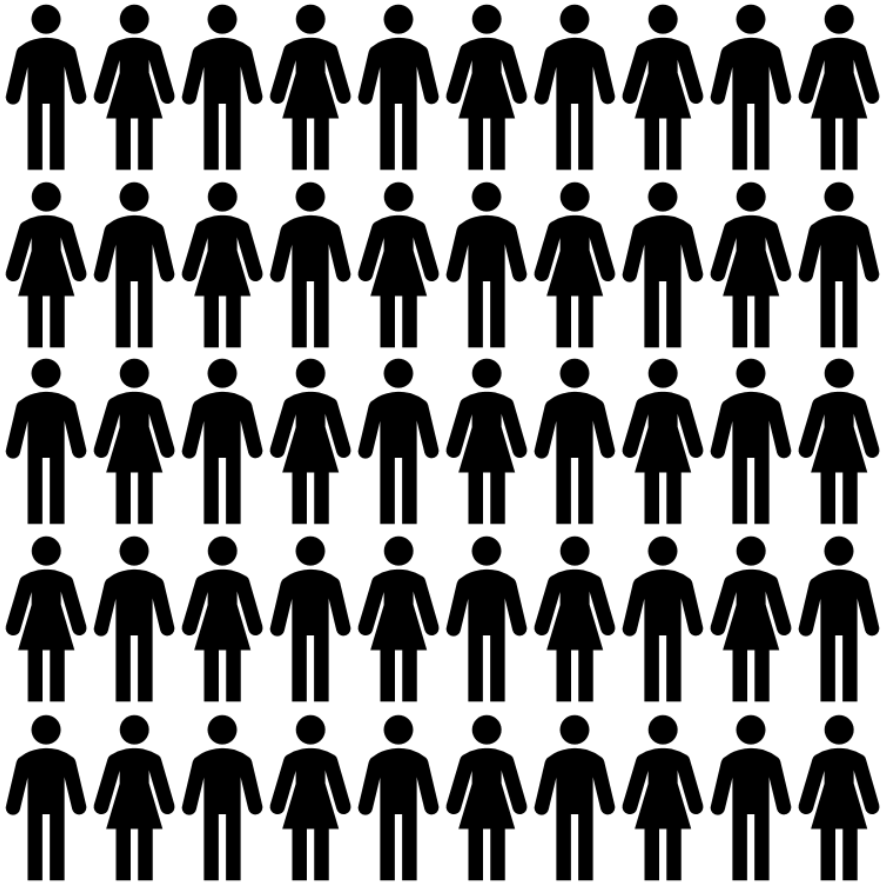
Oncology biomarkers = 184

Non-oncology biomarkers = 247

U.S. Food and Drug Administration. Table of Pharmacogenomic Biomarkers in Drug Labeling. Found at: https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling. Accessed August 17, 2020.

Traditional Prescribing

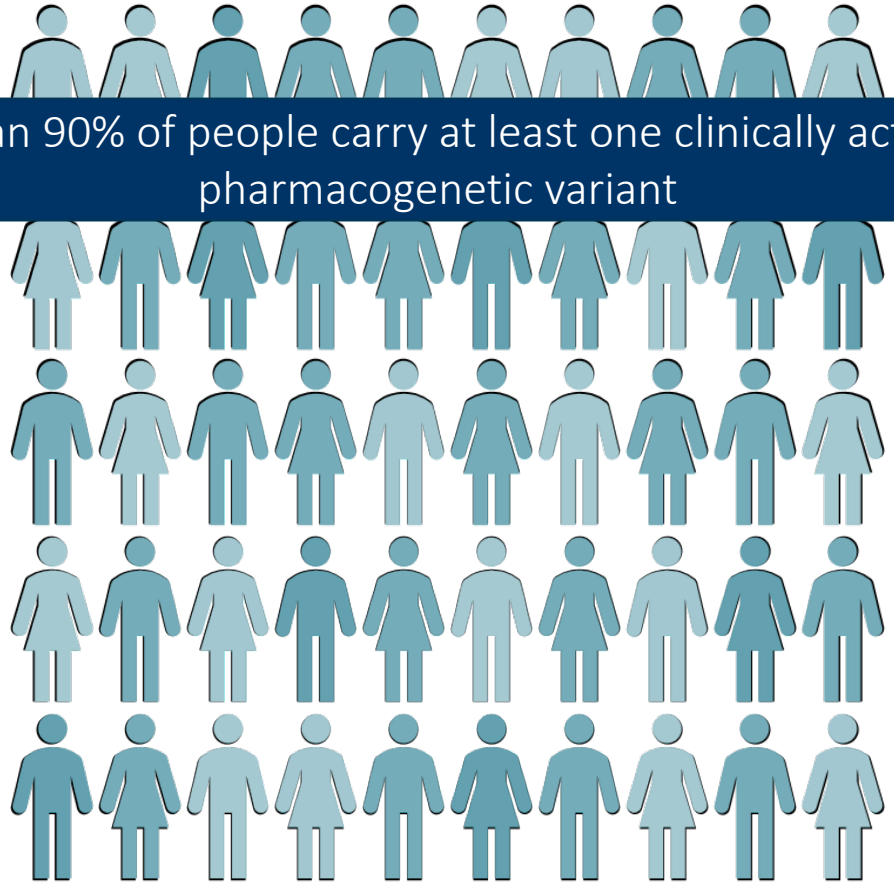
One size fits all

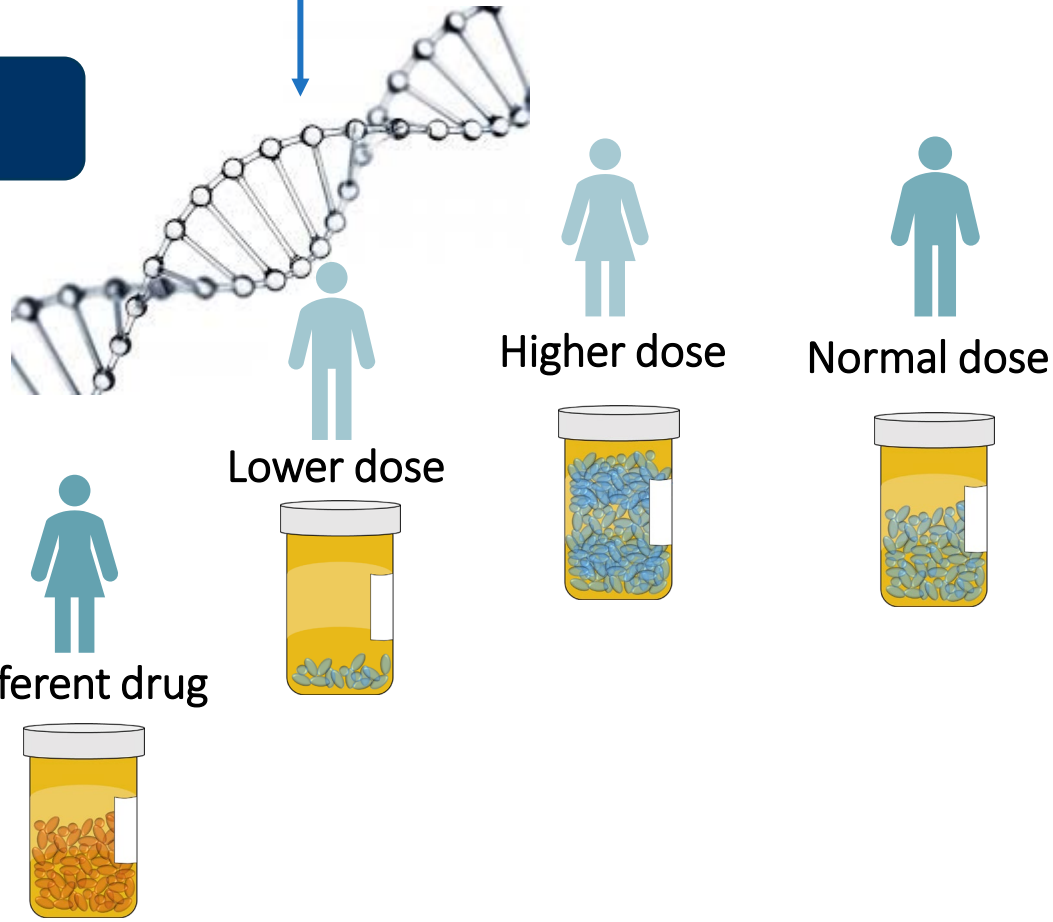


Personalized Prescribing

Adjust based on individual factors

More than 90% of people carry at least one clinically actionable pharmacogenetic variant





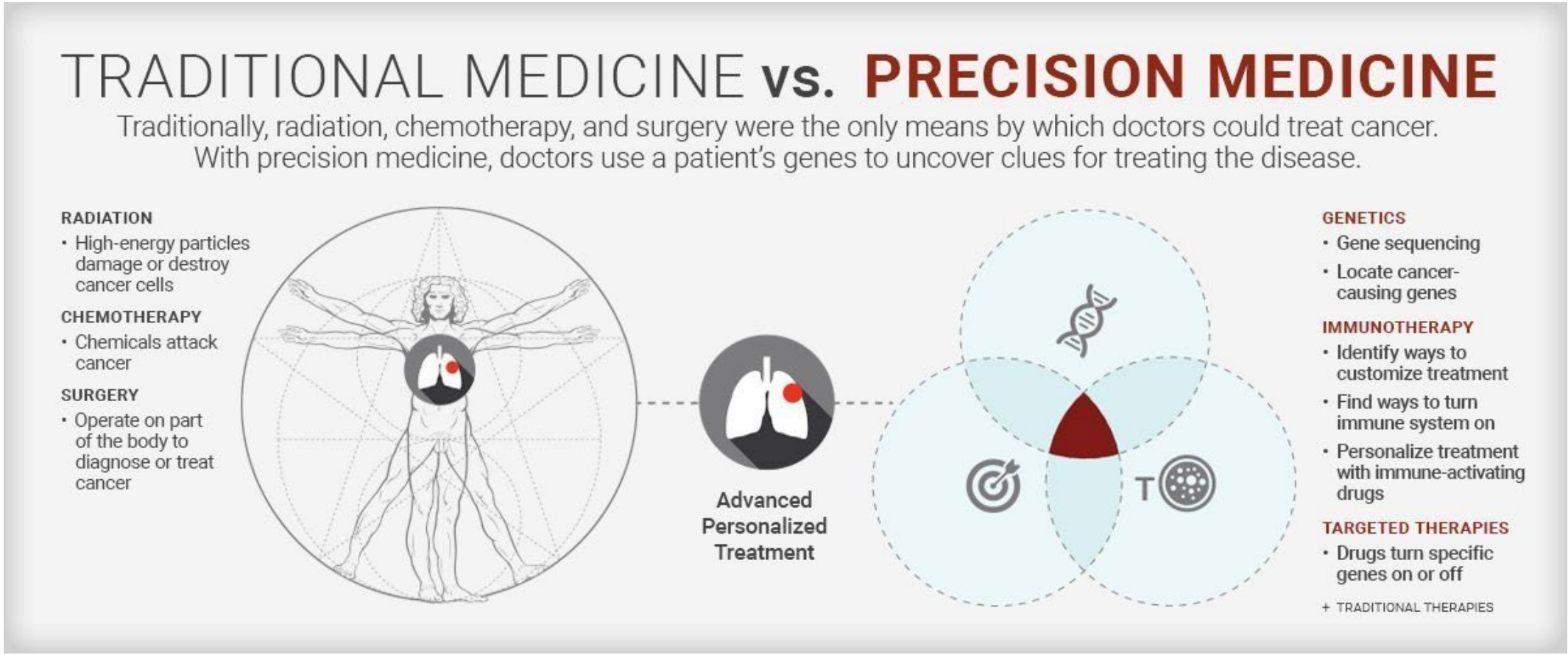
Why is Personalized Prescribing Important?

Expansion of pharmacogenetics education agreed as part of lawsuit settlement

Updated: May. 04, 2022, 11:05 a.m. | Published: May. 04, 2022, 7:00 a.m.

David McIntyre had a fatal reaction to OHSU's chemotherapy for his cancer, his wife, left, claims in a lawsuit filed against the university.

Advancing More Precise Cancer Care



"How Precision Medicine Works." *NewYork-Presbyterian*, 15 Feb. 2022, https://healthmatters.nyp.org/precision-medicine/.

What is Health Equity?

- Health equity is achieved when **every person has the opportunity to attain his or her full health potential** and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.

- Health inequities are reflected in differences in length of life; quality of life; rates of disease, disability, and death; severity of disease; and **access to treatment**.

"Health Equity." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 3 Mar. 2022, https://www.cdc.gov/chronicdisease/healthequity/index.htm.

Drivers of Cancer Health Disparities

1. Access to cancer screenings
2. Access to testing
3. Access to care
4. Access to clinical trials

Addressing Cancer Health Disparities in a Multilateral Collaboration in an Independent Community Cancer Clinic: Translating Words Into Action

March 15, 2022

Kashyap Patel, MD, Hirangi Mukhi, BS, Anjana Patel, BSc, Niyati Nathwani, MD, Dhwani Mehta, MS, Jennifer Sherak, MBA, Natasha Clinton, MSN, APRN, AOCNP, Holly Pisarik, JD, Benjamin Brown, BS, Sara Rogers, PharmD, Mary Kruczynski, Nicolas Ferreyros, BA, Ted Okon, MBA

Evidence-Based Oncology, August 2022, Volume 28, Issue 6

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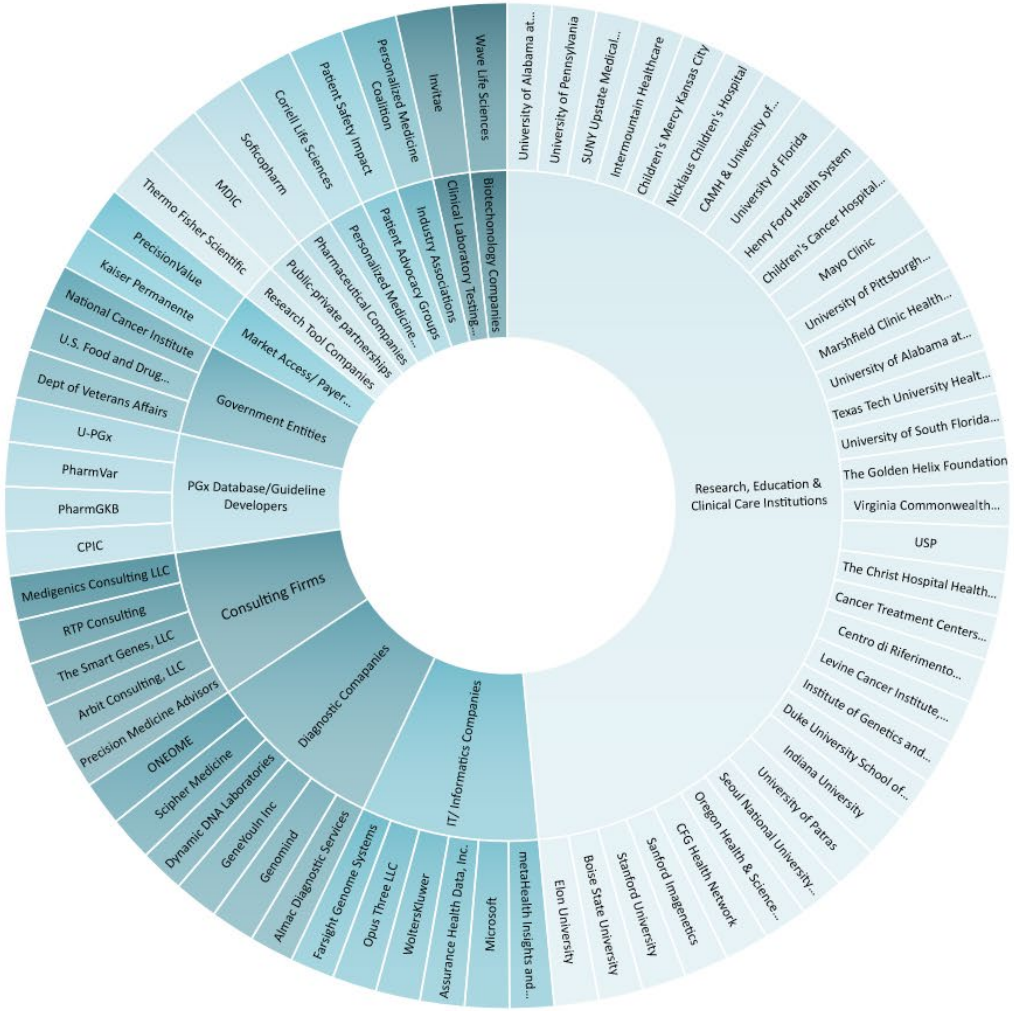
A Collaborative Framework

Pharmacogenetics Testing Community

- Standardizing Laboratory Practices in Pharmacogenomics (STRIPE) Initiative
  - Align stakeholders to develop a standardized approach to evidence evaluation for drug-gene associations
  - Elucidate level of evidence thresholds for clinical, payer and regulatory organizations
  - Solve shared technology, education

American Society of Pharmacovigilance. “STRIPE Collaborative Community” https://stopadr.org/stripe. Accessed May 3, 2022.

Member Affiliations Across Health Sectors



- Biotechonology Companies
- Clinical Laboratory Testing Services
- Consulting Firms
- Diagnostic Comapanies
- Government Entities
- Industry Associations
- IT/ Informatics Companies
- Market Access/ Payer Organizations
- Patient Advocacy Groups
- Personalized Medicine Providers
- PGx Database/Guideline Developers
- Pharmaceutical Companies
- Public-private partnerships
- Research Tool Companies
- Research, Education & Clinical Care Institutions

FDA NEWS RELEASE

FDA Participates in New 'Collaborative Communities' to Address Emerging Challenges in Medical Devices

- Collaborative Community on Ophthalmic Imaging
- National Evaluation System for health Technology Coordinating Center (NESTcc) Collaborative Community
- Standardizing Laboratory Practices in Pharmacogenomics Initiative (STRIPE) Collaborative Community
- International Liquid Biopsy Standardization Alliance (ILSA)
- Xavier Artificial Intelligence (AI) World Consortium
- Case for Quality Collaborative Community
- Heart Valve Collaboratory (HVC)
- Wound Care Collaborative Community
- Pathology Innovation Collaborative Community (PICC)
- REducing SuiCide Rates Amongst IndividUals with DiabEtes Digital He(RESCUE) Collaborative Community
- MedTech Color Collaborative Community on Diversity and Inclusion in Medical Device Product Development and Clinical Research (MedTech Color Collaborative Community)
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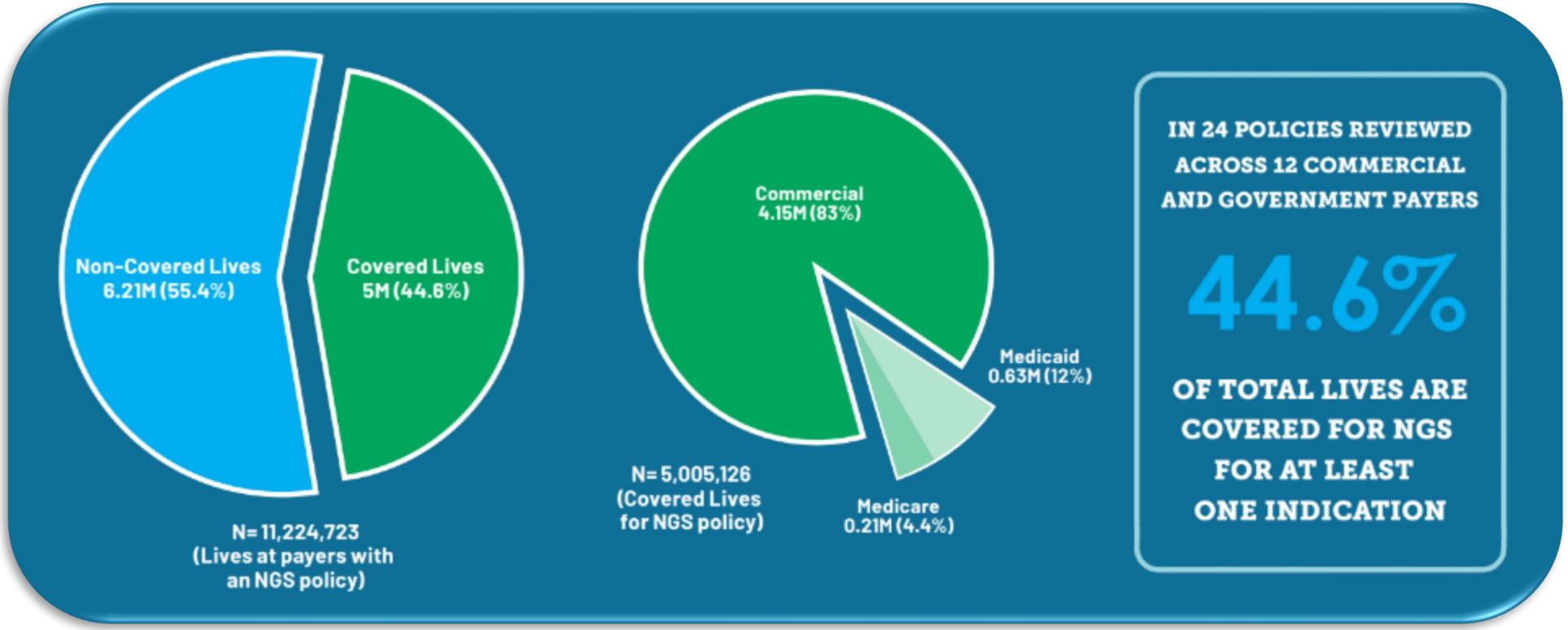
Patient Access

Next Generation Sequencing

FOR	Somatic (acquired) Cancer	Germline (inherited) Cancer
NGS is reasonable and medically necessary and nationally covered for a patient	With recurrent, relapsed, refractory, metastatic, or advanced stage II or IV cancer AND Not been previously tested with the same NGS test for the same cancer genetic content AND Is seeking further cancer treatment	Ovarian or Breast Cancer AND A clinical indication for germline testing for hereditary breast or ovarian cancer AND A risk factor for germline breast or ovarian cancer AND Not been previously tested with the same germline test using NGS for the same germline genetic content
And the lab test using NGS must have:	FDA approval or clearance as a companion in vitro diagnostic AND FDA-approved or cleared indication for use in that patient's cancer AND Results provided to the treating physician for the patient using a report template to specify treatment options	FDA approval or clearance AND Results provided to the treating physician for the patient using a report template to specify treatment options
Non-Covered Indication	Any patient NOT meeting the requirements above	
MACs may determine coverage	Recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer AND Not previously tested with same test using NGS for the same cancer genetic content AND Seeking further cancer treatment	Any cancer diagnosis AND A clinical indication for germline cancer AND A risk factor for germline cancer AND Not been previously tested with the same germline test using NGS for the same germline genetic content

Payer policy data from Policy Reporter, a TrialCard company. Retrieved from Policy Reporter PolicyCore database https://www.policyreporter.com/resources/coverage-at-the-forefront-of-genetic-testing. 2022, June 29.

NGS Covered Lives By Payer Plan Type



Payer policy data from Policy Reporter, a TrialCard company. Retrieved from Policy Reporter PolicyCore database https://www.policyreporter.com/resources/coverage-at-the-forefront-of-genetic-testing. 2022, June 29.

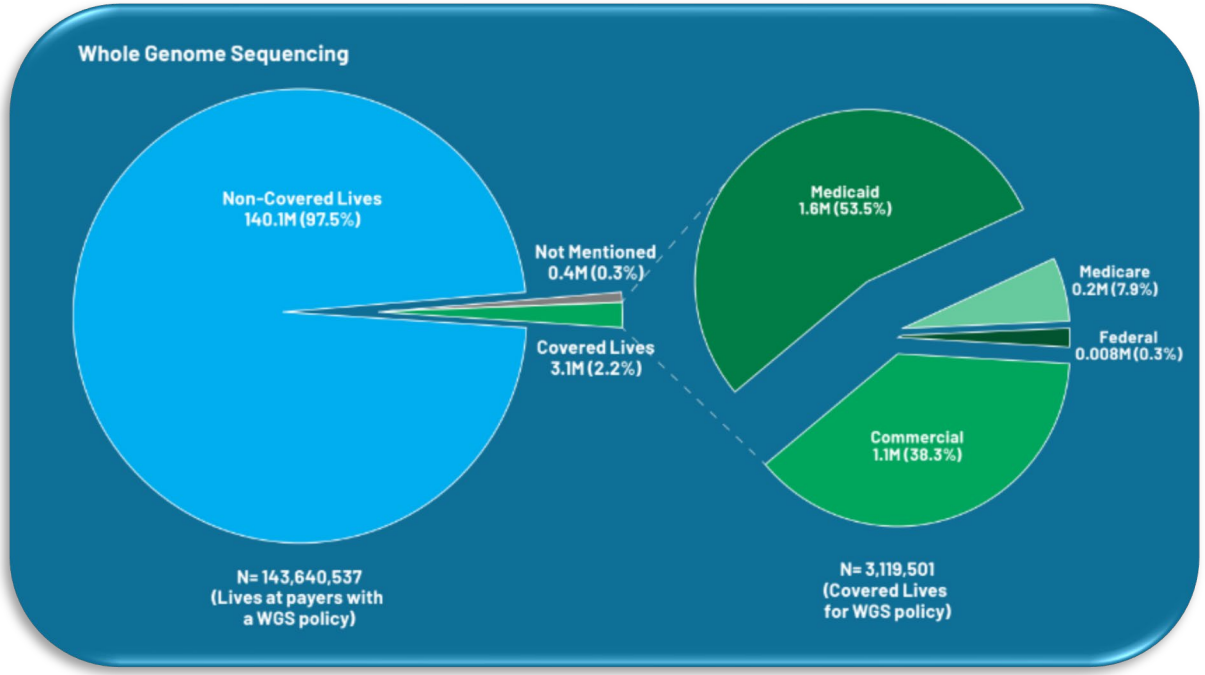
Comprehensive Testing

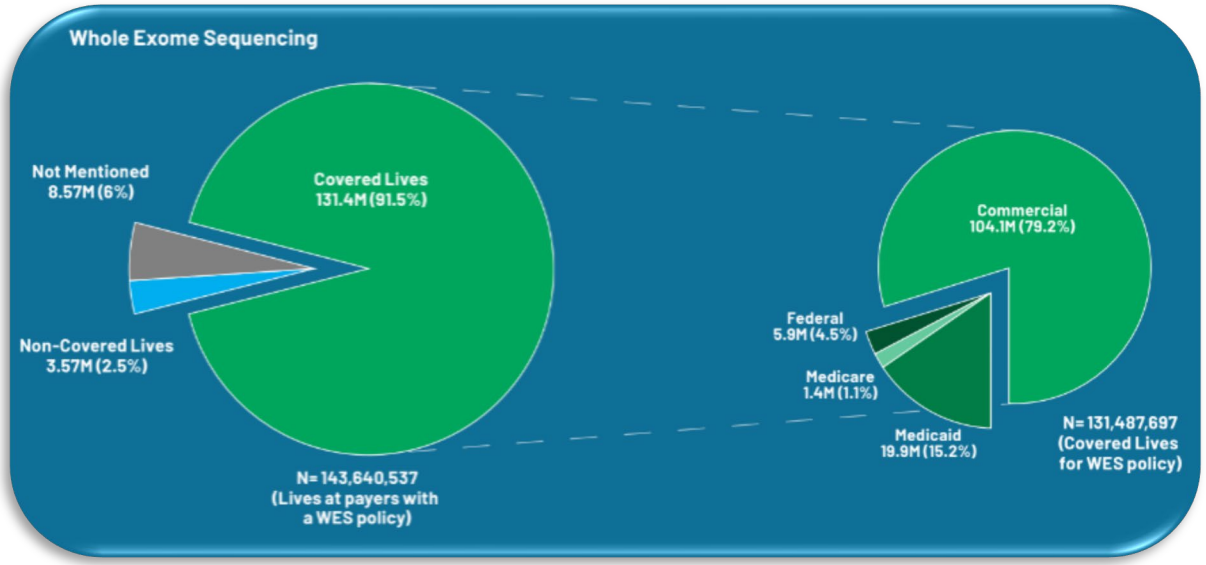
- Comprehensive genetic testing can diagnose disease states beyond oncology

- Whole exome sequencing (WES) is a laboratory test used to determine the nucleotide arrangement of the protein-coding regions of the genome

- Whole genome sequencing (WGS) determines the order of the nucleotides in the entire genome.

WGS & WES Coverage by Payer Plan Type





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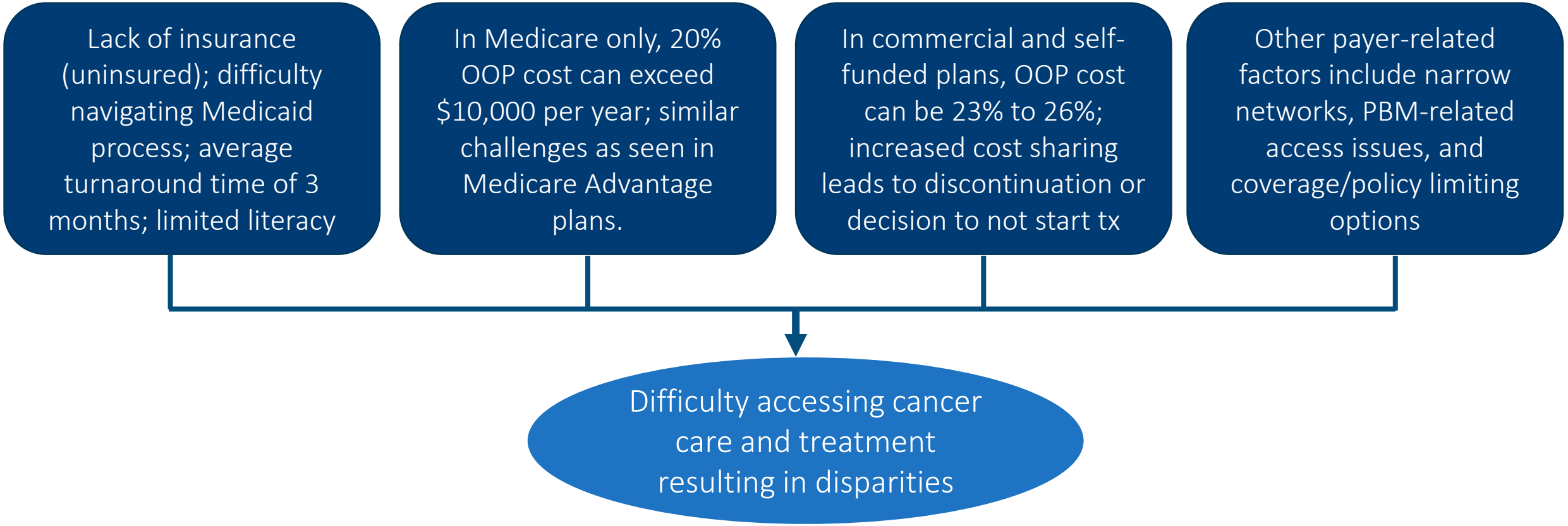
Inconsistent Use of Genomic Testing in US Even Among States With Favorable Coverage Policies

1. Medically appropriate genomic testing is inconsistently utilized across U.S. states;
2. Payer genomic testing coverage policies vary considerably among states;
3. Favorable coverage policies do not always correlate with higher utilization rates across states; and
4. Inconsistent coverage and reimbursement policies remain barriers to genomic testing access, but do not entirely explain inconsistent utilization.

Understanding Genomic Testing Utilization and Coverage in the US. https://personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Understanding_Genomic_Testing_Utilization_and_Coverage_in_the_US2.pdf. Accessed 2022, July 29.

Financial and Payer Related Factors Limiting Access to Cancer Care



Adapted from Kashyap Patel et al. Addressing Cancer Health Disparities in a Multilateral Collaboration in an Independent Community Cancer Clinic: Translating Words Into Action. American Journal of Managed Care. 2022 Mar 15

Community Engagement

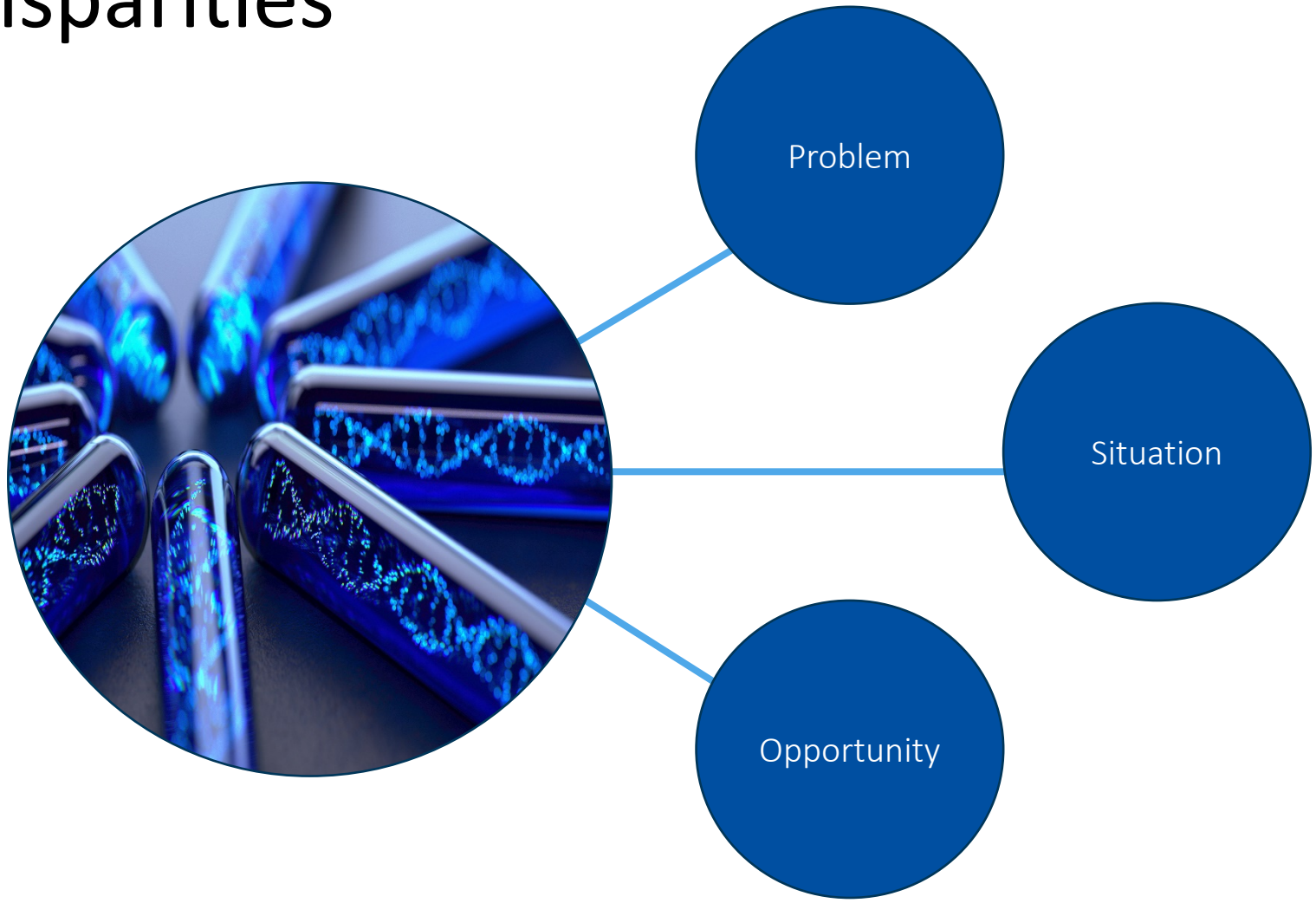
Patient Perspectives

- Diverse community dialogue participant group
  - Felt strongly that patients should be informed of testing
  - Many were willing to share in the cost of testing with their insurance company
  - Patients want transparency in what happens with their data

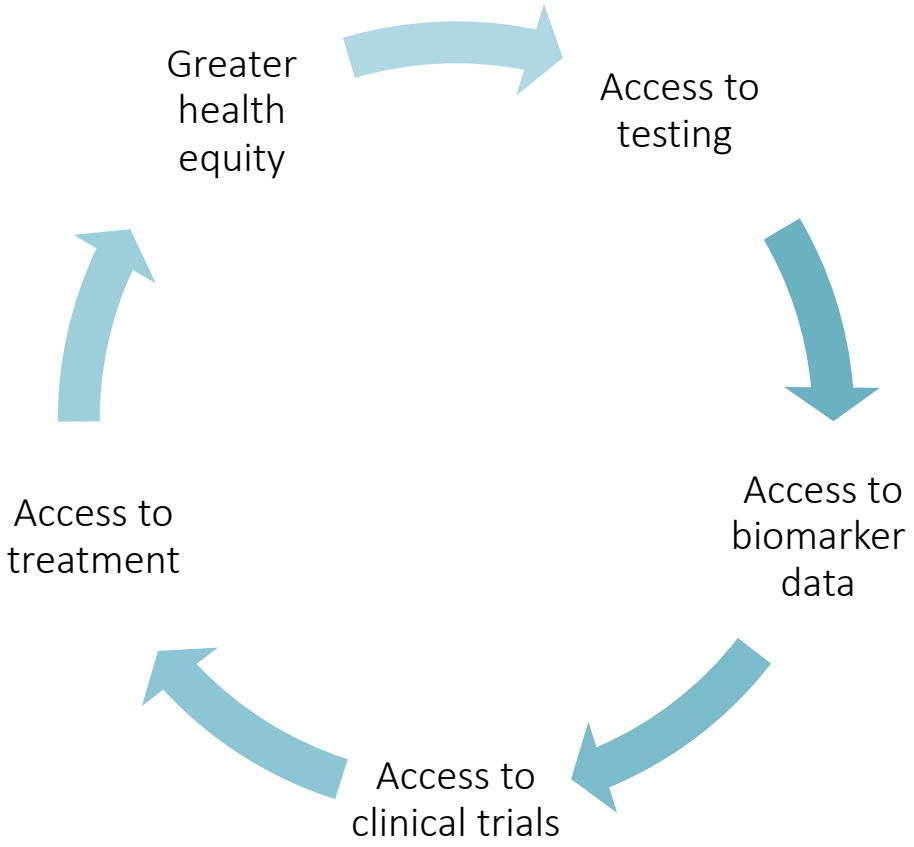
Determeyer P, Crowder J, O'Mahony E, Esquivel B, Atwal H, Atwal PS, Rogers SL. Application of the community dialogues method to identify ethical values and priorities related to pharmacogenomics. Pharmacogenomics. 2021 Jul;22(11):693-701.

Cancer Health Disparities

Access to Testing is Vital to Reducing Cancer Health Disparities

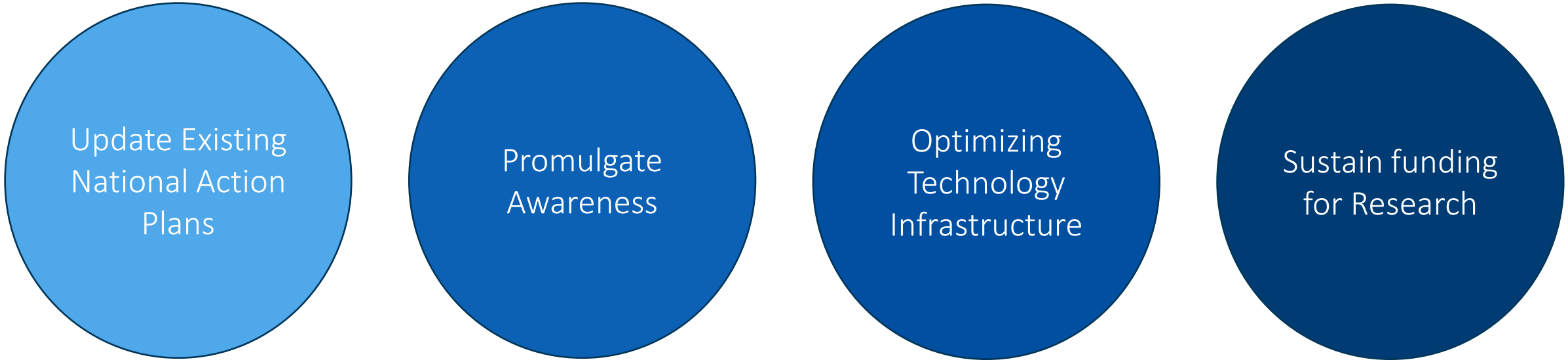


Testing Provides a Clear Pathway to Health Equity



Advancing Health Policy

Identifying Critical Patient Safety Priorities



Progressive Public Policy

SWALWELL, EMMER INTRODUCE BIPARTISAN LEGISLATION TO HELP PREVENT ADVERSE DRUG EFFECTS

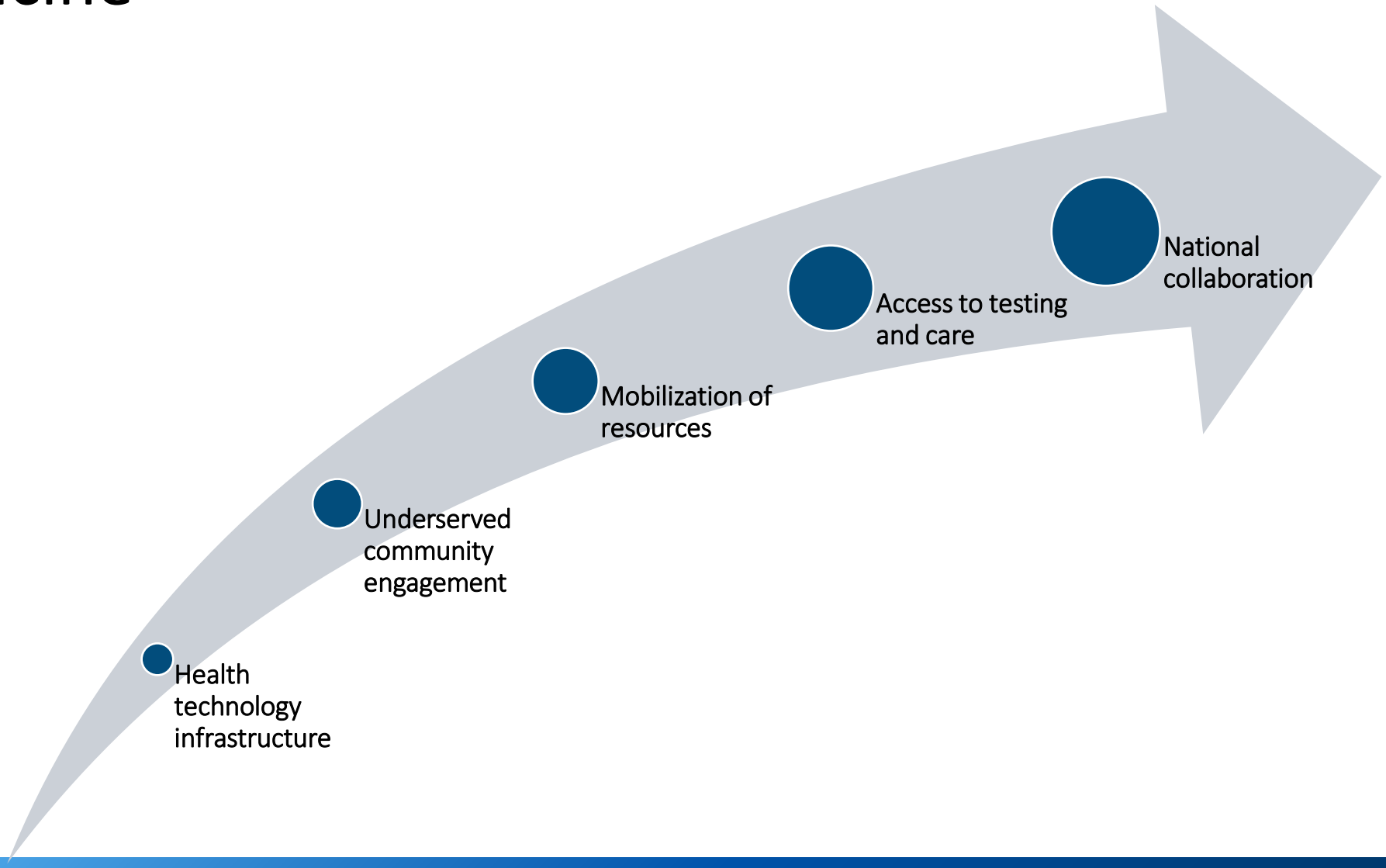
February 28, 2022 | Press Release

WASHINGTON, D.C – Today, Representatives Eric Swalwell (D-CA) and Tom Emmer (R-MN), co-chairs of the Personalized Medicine Caucus, introduced bipartisan legislation to better address drug-gene interactions to ensure that all Americans have access to the treatment that is best for them.

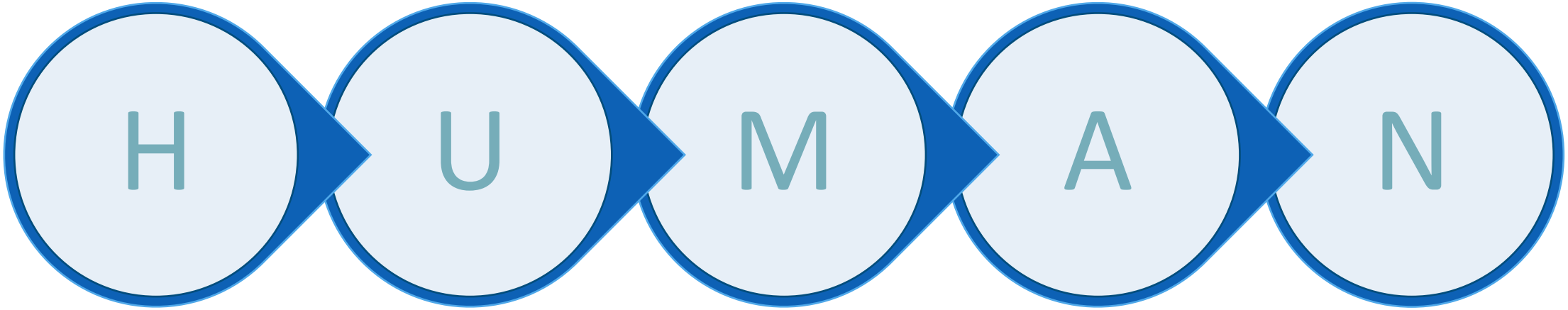
American Society of Pharmacovigilance to Co-Host Virtual Congressional Briefing with Invitae and the Personalized Medicine Coalition on March 29 - in Cooperation with the Honorable Eric Swalwell and Tom Emmer

Translating Words into Action

Five Pathways for Health Equity using Personalized Medicine



Each of Us Needs All of Us to Advance Personalized Medicine for All Mankind



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