MEHARRY VANDERBILT ALLIANCE
SINCE 1999

Patient-Centered Clinical Trial Design

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The National Academies of SCIENCES ENGINEERING MEDICINE

Innovation in Drug Research and Development for Prevalent Chronic Diseases Workshop
March 1, 2021

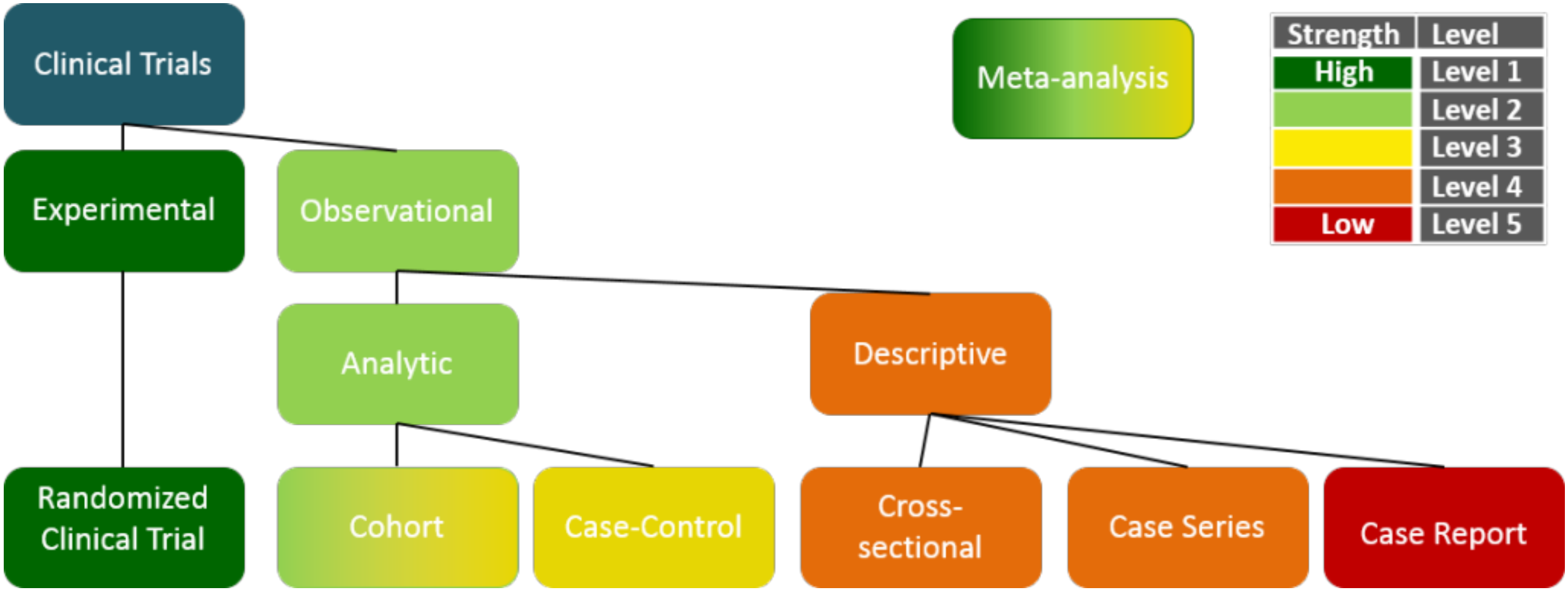
Disclosures

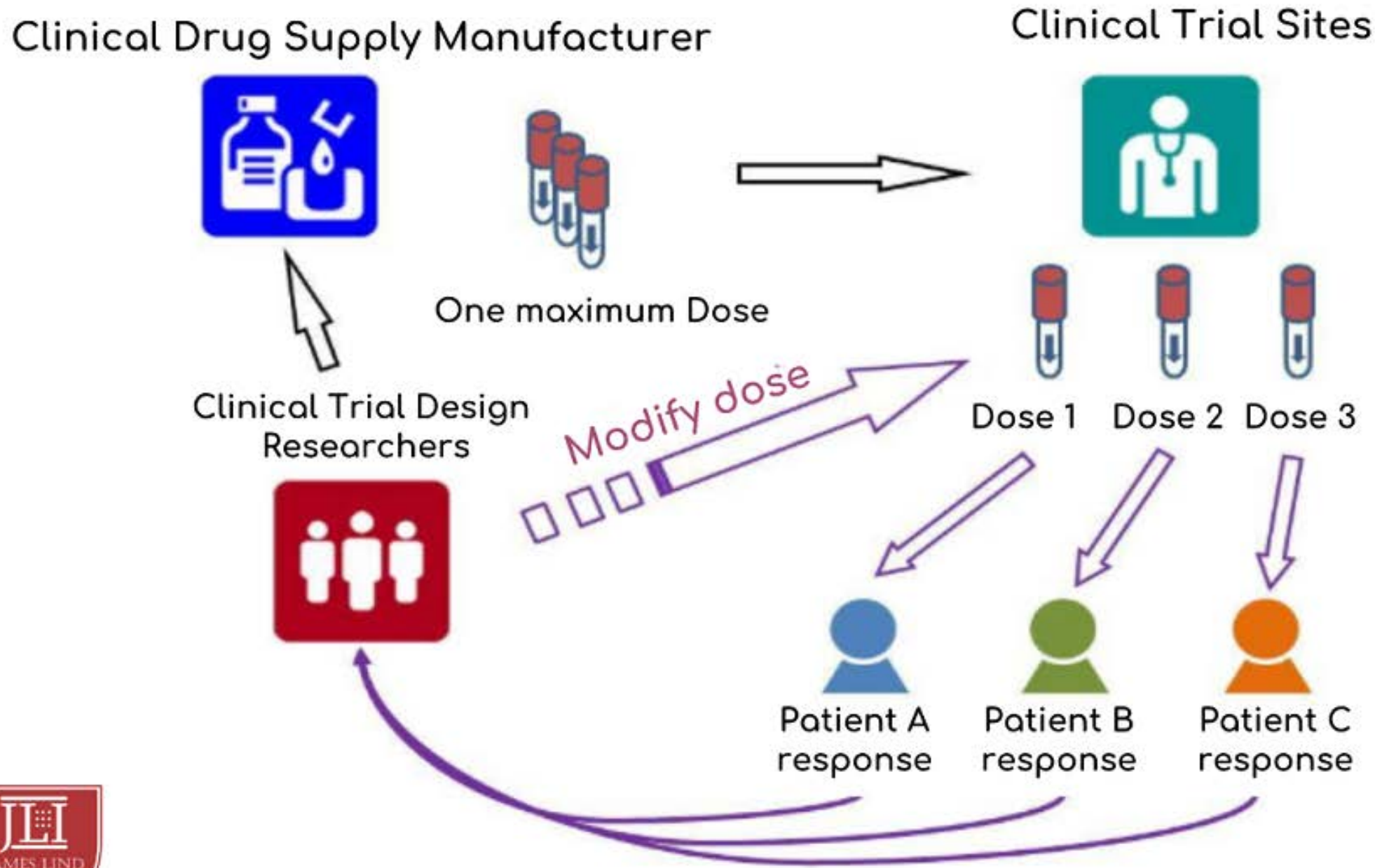
- Consultant
  - Merck
  - Bristol-Myers Squibb
  - Grail Bio, Inc
  - AstraZeneca
  - NIH: Inclusive Participation COVID-19

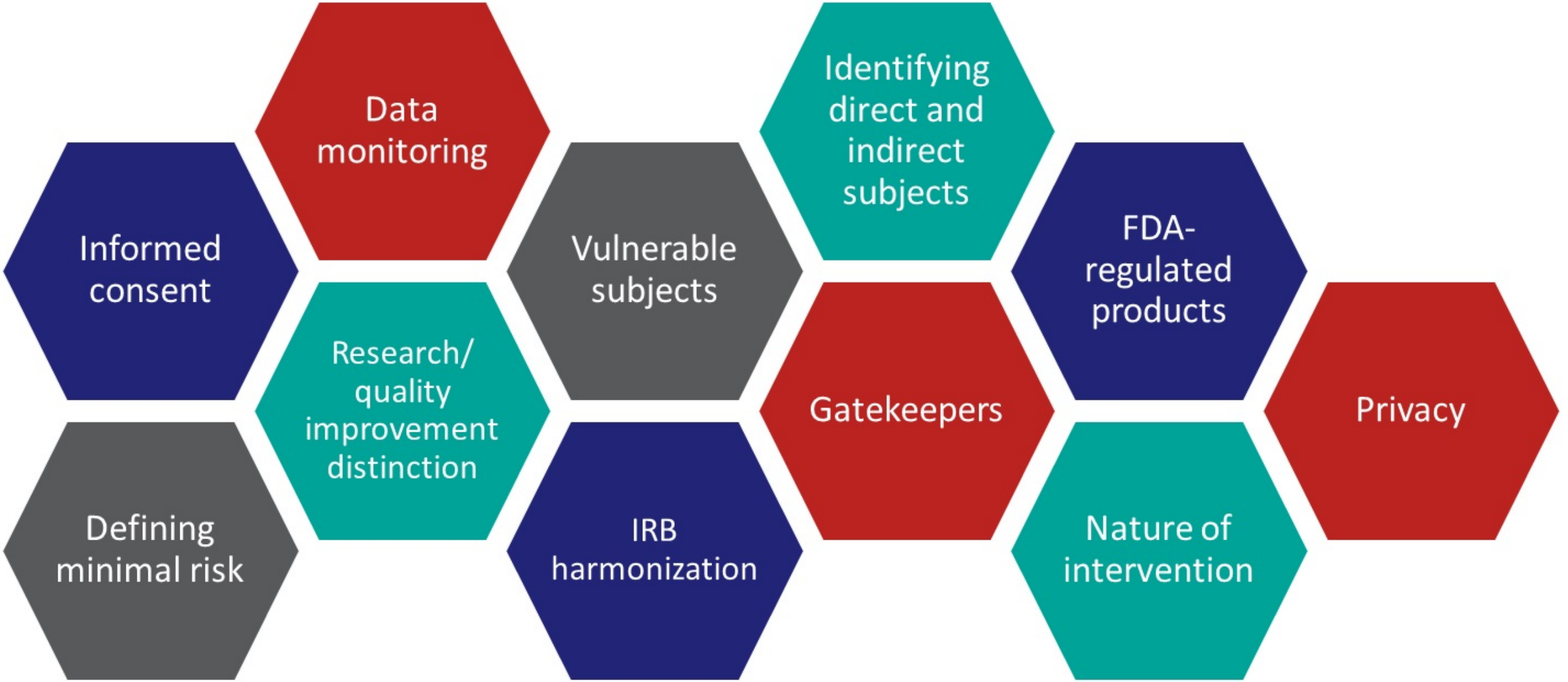
- Honorarium
  - Pfizer/AONN
  - BioAscend

MEHARRY VANDERBILT ALLIANCE

SINCE 1999


Clinical Trials
Experimental
Observational
Analytic
Descriptive
Randomized Clinical Trial
Cohort
Case-Control
Cross-sectional
Case Series
Case Report
Meta-analysis
Strength
Level
High
Level 1
Level 2
Level 3
Level 4
Low
Level 5


Clinical Drug Supply Manufacturer
Clinical Trial Sites
One maximum Dose
Clinical Trial Design
Researchers
Modify dose
Dose 1
Dose 2
Dose 3
Patient A
response
Patient B
response
Patient C
response

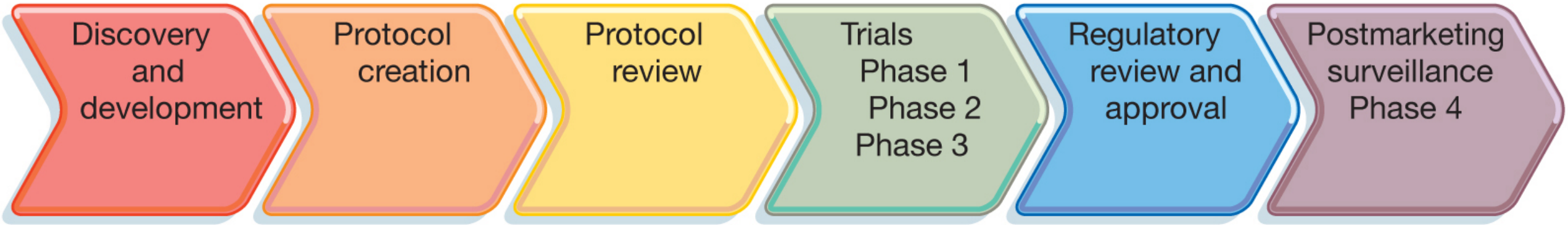


https://rethinkingclinicaltrials.org/cores-and-working-groups/regulatory-ethics/

https://mrctcenter.org/blog/projects/diversity-inclusion-and-equity-inclinical-trials/

Who are we designing clinical trials for??

Overview of clinical trial process



Wake Forest®
Baptist Medical Center

Comprehensive Cancer Center

Advocates for Research in Medicine (ARM) Program

The purpose of the ARM program is to connect cancer patients and researchers to bring the patient perspective to research activities and ultimately improve outcomes.

ACCC
Association of Community Cancer Centers

https://www.accc-cancer.org/home/about/governance-and-leadership/presidents-theme-2020-2021/research-review/research-review-january-2021

What is a Research Advocate?

- Patients, caregivers & high-risk individuals
- Maintain **patient-centered care** in research
- Role:

  Advise- Voice of cancer patients

  Review- Provide feedback on proposed research

  Implement- Communicate with researchers, patients and the community

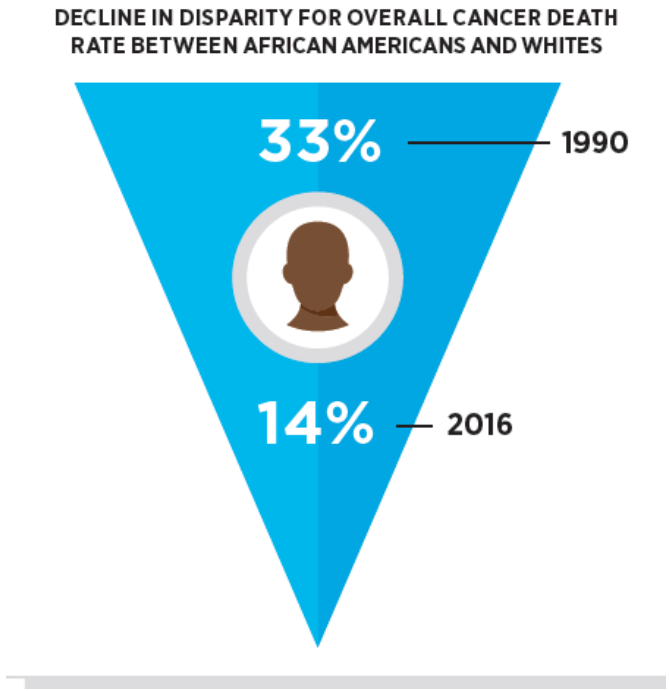
  Disseminate- Share easy to understand research findings with the public

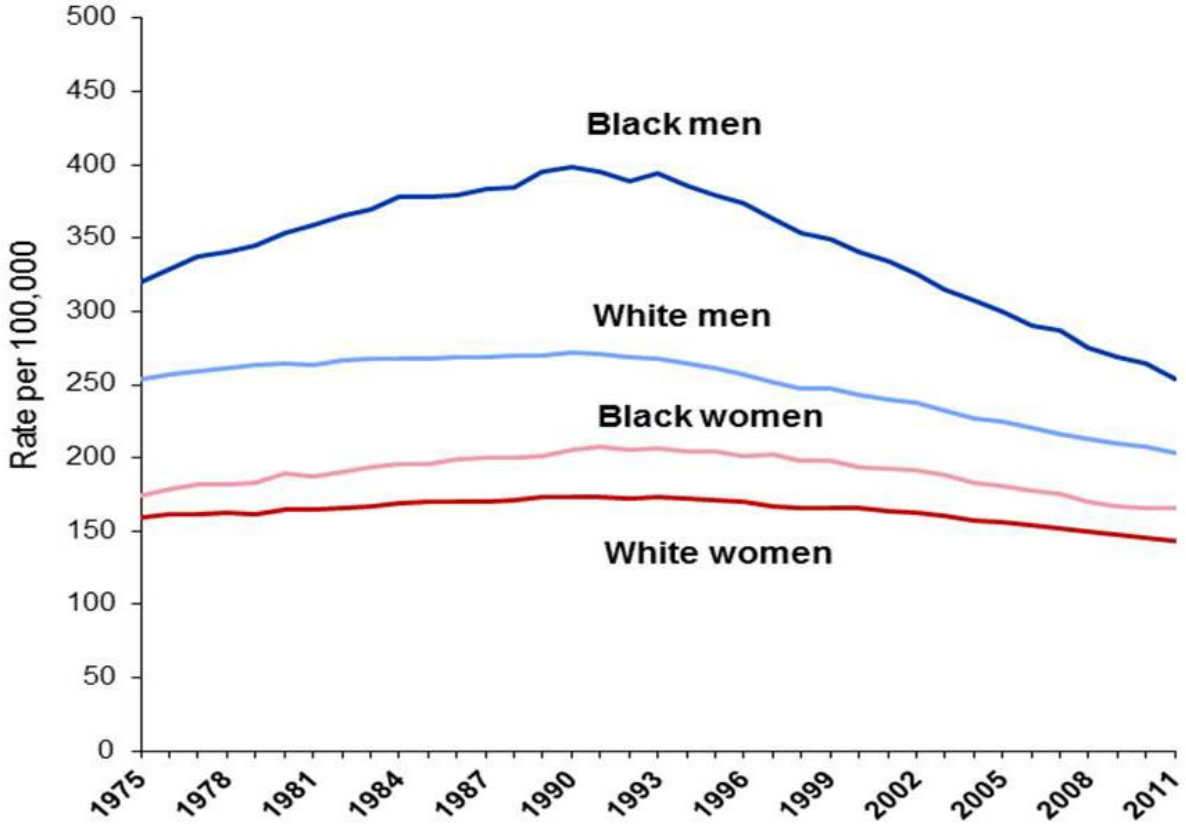
ARM Program

- Personal experience with cancer
- Able to represent broad patient perspective
- Match advocates and researchers
- Formal training provided
  - 8+ hours of initial training, including CITI certification
  - Ongoing continuing education offered
  - Multidisciplinary training topics including:

- Cancer 101
- Research 101
- Clinical Trials
- Health Equity
- Cancer Control
- Advocate Role
- Regulatory Oversight
- Research Funding
- Grantsmanship
- Working with PIs

Trends in Cancer Death Rates by Sex and Race, US, 1975-2011

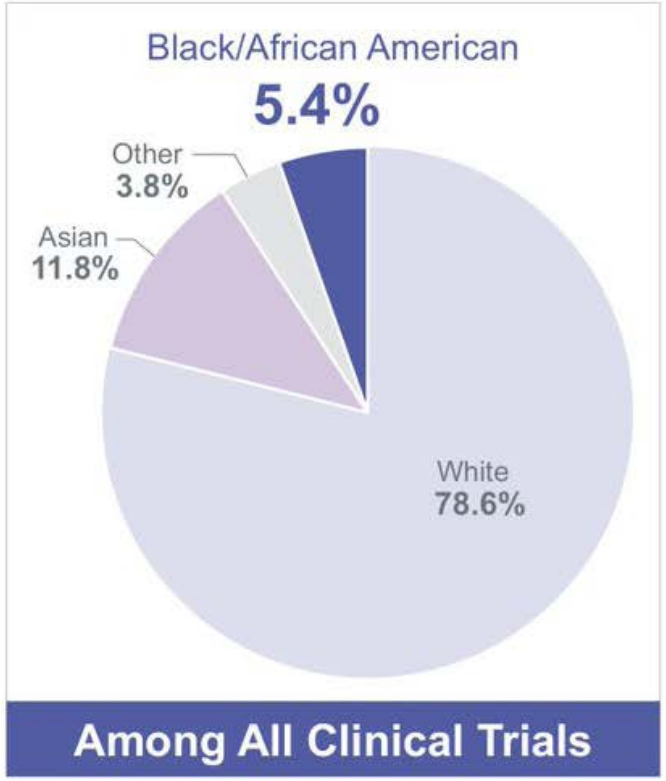




https://cancerprogressreport.aacr.org/disparities/

Under-Representation in Clinical Trials

Black/African American Clinical Trial Participation



Among All Clinical Trials

Specific Therapeutic Areas (2015-16)

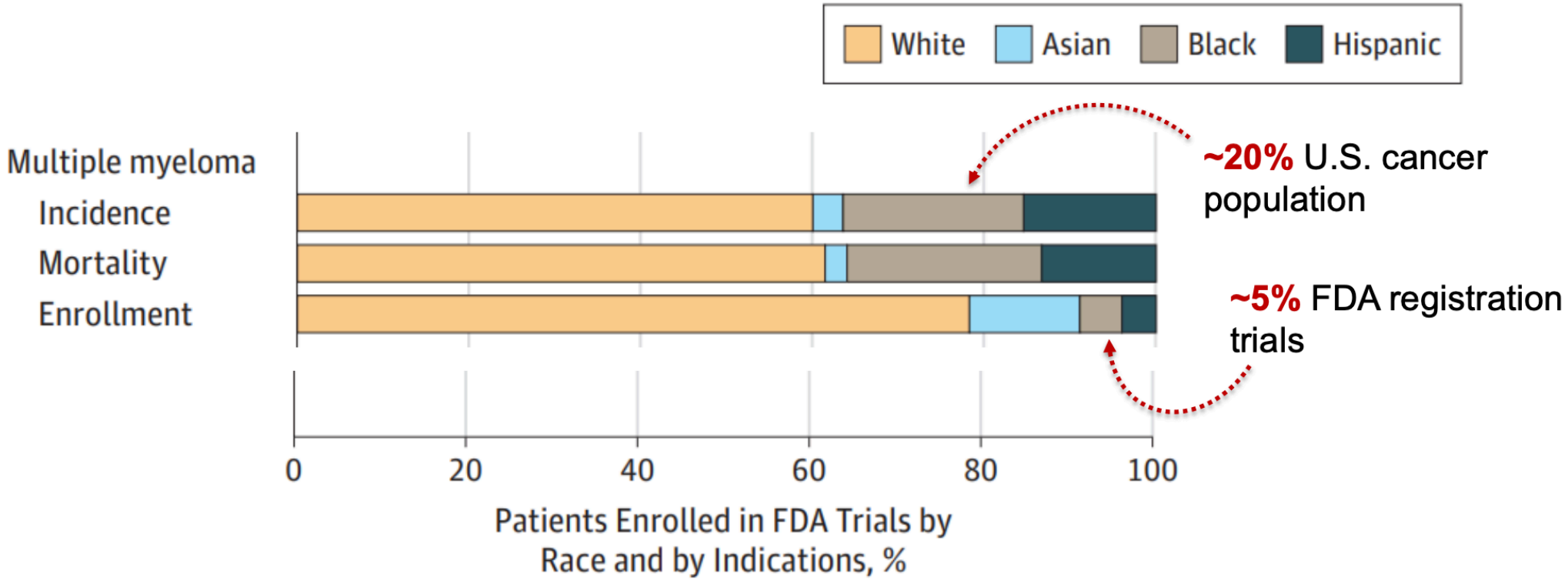
Black/African American	Black/African American
2.5%	**2.74%**
Cardiovascular Trials	**Oncology Trials**

- **White participants represent about 78.6% of all clinical trial participants.**
- **Asian, Black/African American, and other groups represent 11.8%, 5.4%, and 3.8%, respectively.**

When looking at specific therapeutic areas, Black/African Americans only represent 2.5% cardiovascular and 2.74% of oncology trial participants from 2015-2016 *(FDA Global Trial Participation 2015-16)* despite the prevalence of cardiovascular disease and aggressive cancers in this minority *(Coakley, Fadiran et al. 2012)*.

SANOFI

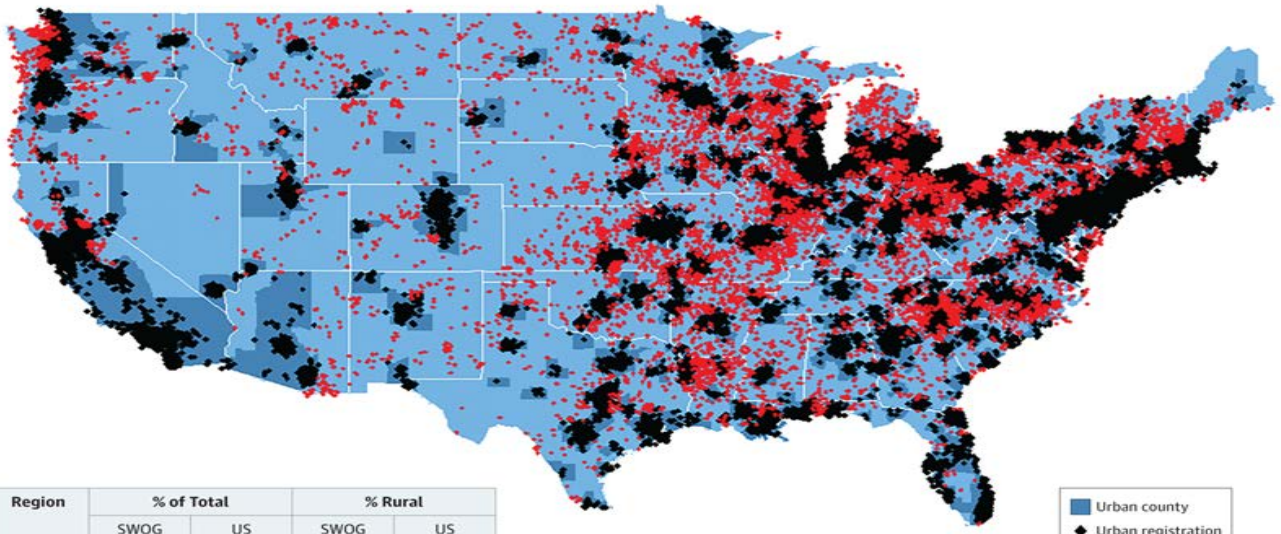
Relative Differences in Incidence, Mortality, and Enrollment in **Multiple Myeloma** Clinical Trials Leading to FDA Drug Approval for Specific Indications*



** Loree et al., JAMA Oncology, 2019*

Clinical Trial Enrollment

Geography matters!



Region	% of Total		% Rural	
	SWOG	US	SWOG	US
West	23	23	13	11
Midwest	39	21	23	22
South	24	37	23	24
Northeast	14	18	14	16

Patient Income Level and Cancer Clinical Trial Participation

A Prospective Survey Study

Joseph M. Unger, PhD[1]; Julie R. Gralow, MD[2]; Kathy S. Albain, MD[3]; et al

Author Affiliations

Addressing Financial Toxicity

VOLUME 36 · NUMBER 33 · NOVEMBER 20, 2018

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Addressing Financial Barriers to Patient Participation in Clinical Trials: ASCO Policy Statement

Karen M. Winkfield, Jonathan K. Phillips, Steven Joffe, Michael T. Halpern, Dana S. Wollins, and Beverly Moy

Author affiliations and support information (if applicable) appear at the end of this article.

Published at jco.org on September 13, 2018.

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ABSTRACT

Research conducted through clinical trials is essential for evaluating new treatment modalities, establishing new standards of cancer care, and ultimately improving and prolonging the lives of patients with cancer. However, participation in trials has been low, and this is attributable to various factors including patient financial barriers. Such financial barriers include the rising cost of cancer care; a lack of transparency in coverage policy; and the perception of ethical, compliance, or in-

Precision Oncology

BJC
British Journal of Cancer

EDITORIAL

Are we inadvertently widening the disparity gap in pursuit of precision oncology?

British Journal of Cancer (2018) 119:783–784;

editorial

STATE OF CANCER CARE IN AMERICA

Mind the Gap: Precision Oncology and Its Potential to Widen Disparities

Ryan W. Huey, MD[1], Ernest Hawk, MD, MPH[1], and Anaeze C. Offodile II, MD, MPH[1,2]

Engage the Community!!

Community Engagement Studios (CE Studios)

- CE Studios are 1-time, facilitated, consultative meetings with an investigator's patient population or community of interest
  - Each has a unique Community Expert panel (8-12) recruited via patient networks, social media, support groups, etc. Compensation is $50.
  - The research team receives a written summary and key recommendations from the CE Studio team following the studio.

- Community engagement faculty and staff from 30 CTSA institutions have received training to implement the CE Studio and 17 currently have an active CE Studio program.

Vanderbilt Institute for Clinical and Translational Research

VICTR

Define | Align | Connect | Plan

246 Studios to date:

- 133 for our CTSA
- 17 for the Recruitment Innovation Center
- 9 for training/demo
- 9 for STRIDE (Collaborative Innovation Award)
- 78 for the Precision Medicine Initiative (*All of Us* Research Program)
- Includes 19 Virtual CE Studios

>700 Patient/ Community Experts

Development of an Actionable Framework to Address Cancer Care Disparities in Medically Underserved Populations in the United States: Expert Roundtable Recommendations

Stakeholders who implement this framework.

Health care leaders, patient advocate groups, community outreach leaders, community-based organizations, lay, nurse and clinical navigators, researchers, industry, govt and policy leaders

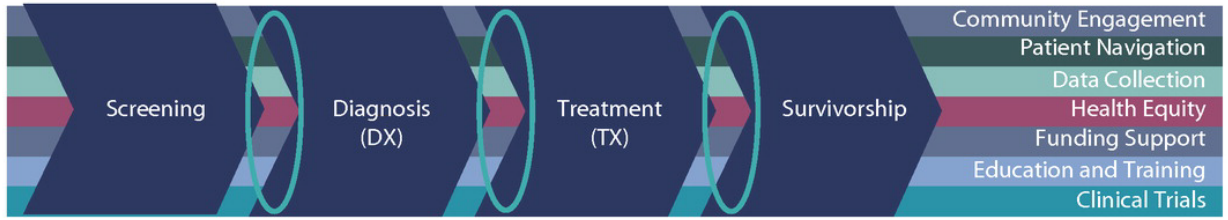
Medically underserved populations.

Racial/ethnic minority groups, rural populations, aged, adolescent/young adult], LGBTQ, differently-abled, immigrants and refugees, and under and uninsured communities.

Winkfield KM et al., Journal of Oncology Practice. Jan19, 2021.Open access and online@ https://ascopubs.org/journal/op

Development of an Actionable Framework to Address Cancer Care Disparities in Medically Underserved Populations in the United States: Expert Roundtable Recommendations

Key Findings: High Impact Practices



Community Engagement

• Engage non-traditional stakeholders • Build advocacy coalitions • Engage patients through trusted community partners • Leverage Technology and engagement platforms

Patient Navigation (PN)

• Standardize best practices for lay navigation (focus on DX through Survivorship)
• Include PN in cancer TX guidelines, clinical trial protocols, CMMI and clinical care teams
• Establish community-academic partnerships to support PN • Enhance/Ensure reimbursement; emphasize and coordinate PN efforts across institutions

Data Collection

• Develop toolkits to collect SDOH data • Collect sexual orientation/gender identity (SOGI) data • Work with payors to access claims data that highlight gaps in the CCC • Gather data directly from patients to inform programs • Conduct benchmarket projects; share and expand

Health Equity

• Implement the HHS action plan to reduce racial and ethnic health disparities • Build addressing SDOH impact into accreditation programs with teeth • Develop health equity scorecard for health systems • Build capacity for trusted community engagement

Priority Actions Between CCC Domains

Screening to Diagnosis

- Add patient navigators to identify, and address barriers
- Assess SDOH before first appt with provider
- Focus on information that a patient needs that day
- Ensure that patients have access to a portal and know what to do next
- Provide cancer screening services, use mobile units to reach communities
- Ensure systems are built within EMRs to enable active follow up (by PN) of abnormal screening results
- Systematically implement shared

Diagnosis to Treatment

- Develop PN practices across institutions that ensure "warm hand offs"
- Critical: Same trusted PN is needed from screening through treatment
- Track patients through second opinion to ensure follow up
- Metric tracking of days from DX to TX must trigger active outreach
- Focus on measurements with data/IT systems ; entire care team needs to understand their roles
- Provide patients with oncology urgent care services for common

Treatment to Survivorship

- Establish an advisory council with patients and community leaders to address local barriers and resource needs
- Develop community outreach programs with a focus on Survivorship
- Build and expand on partnerships with community leaders and Community Health Workers to provide training resources

Thank you!!

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