COA Patient Advocacy Network

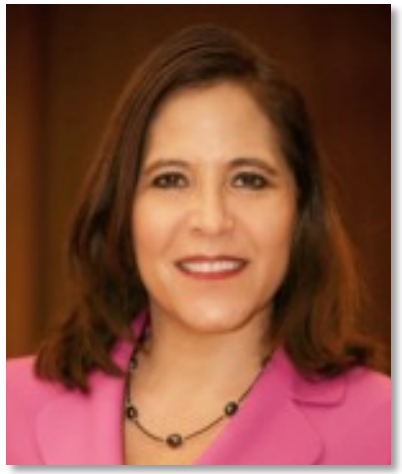
advocacy CHATS

Clinical Trials in the Community Oncology Setting: *Positive Impact on Patient Care*

Collen Lewis, MSN, ANP-BC, AOCNP
Vice President, Nursing & Research
Florida Cancer Specialists & Research Institute

Today's Chat Agenda

- **Updates: Community Oncology Alliance (COA) and COA's Patient Advocacy Network (CPAN)**
  - COA Capitol Hill Day, June 13 - **Patients/Caregivers Join Us!**
- **Introduction Collen Lewis, MSN, ANP-BC, AOCNP, Florida Cancer Specialists & Research Institute**
  - The positive impact of clinical trials for patients and providers
  - How clinical trials address health equity



Rose Gerber, MS
Director of Patient Advocacy & Education
Community Oncology Alliance

Clinical Trials: Role of Community Oncology

Colleen Lewis, MSN, ANP-BC, AOCNP
Vice President Nursing & Research

MAY 17, 2023

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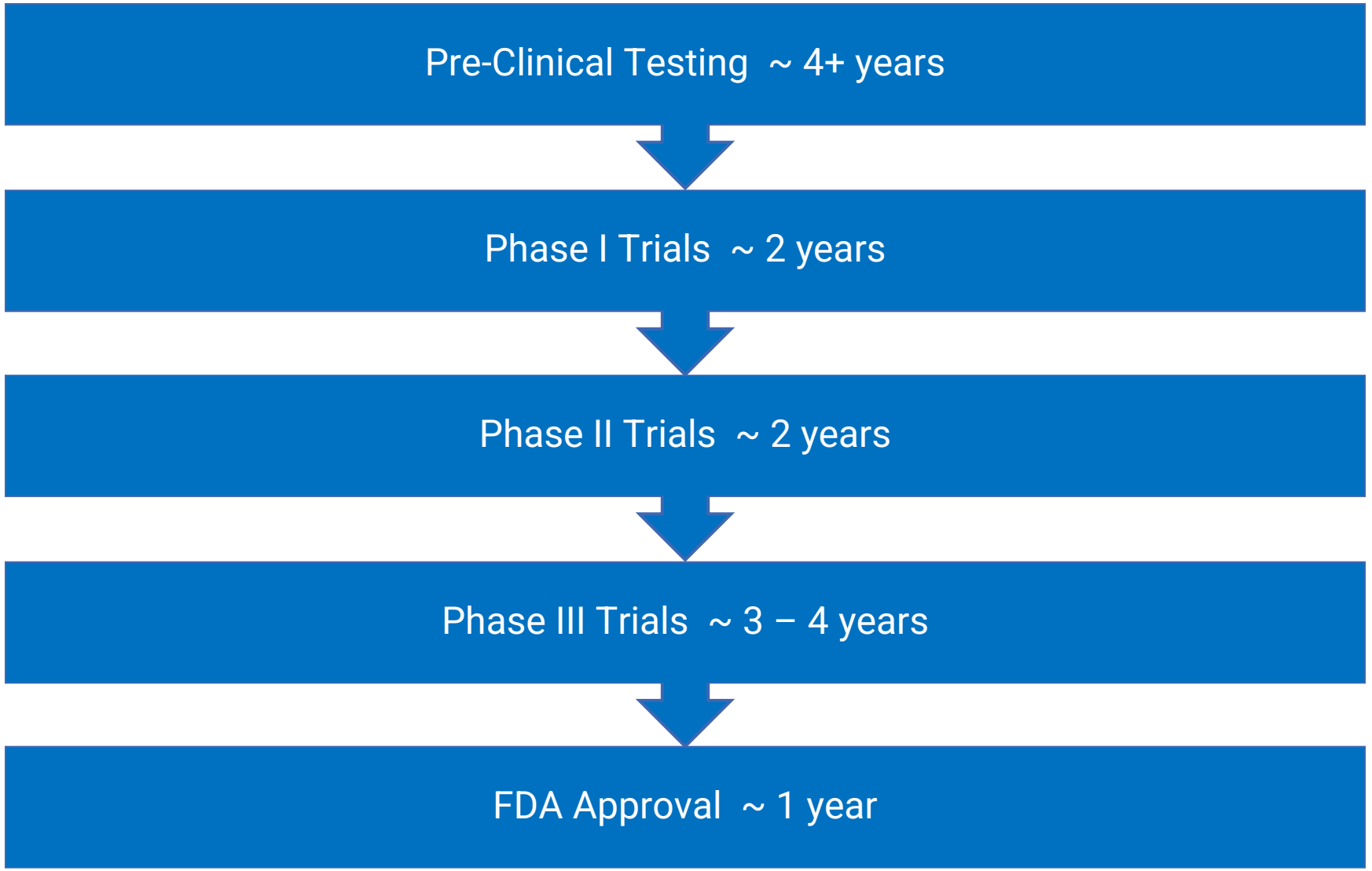
Classic Drug Development Process



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Phases of Clinical Trials

1

- Evaluate safety
- Determine the appropriate dose for further evaluation
- Identify side effects

2

- Determine effectiveness of a treatment in a specific cancer type

3

- New drug or therapy is compared to standard therapy in randomized trials

4

- Post FDA approval, further monitor and evaluate effectiveness and side effects

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Phase I Trial

- First step in transforming laboratory research to clinical care – “bench to bedside”
- Goals of Phase I trials
  - Find a safe dosage
  - Decide how the new treatment should be given
- Average number of participants 15 – 30
- More efficient designs are emerging

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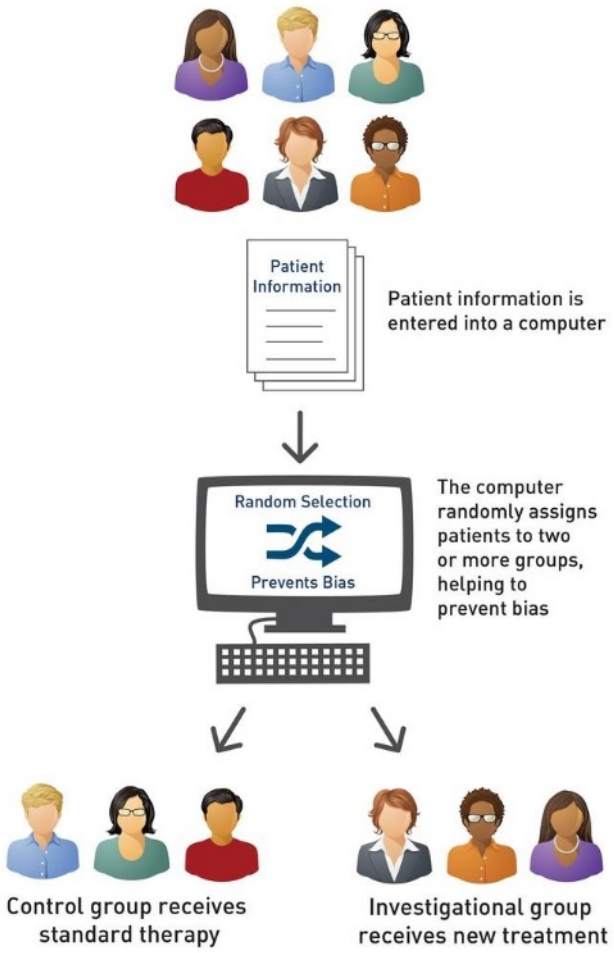
Phase II Trials

- Designed to test the effectiveness of a drug in a larger population (usually < 100)
- Use the dose determined to be safe in Phase I trials
- Narrow the focus to people with specific diagnoses
- The treatment is assessed for effectiveness as well as additional safety data

Phase III Trials



- Enroll more patients (hundreds - thousands)
- Compare an investigational treatment to the current standard
- Participants are usually randomized to the investigational or control group
- Conducted at multiple sites around the country / world

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https://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/randomization/clinical-trial-randomization-infographic

Reasons Patients Decline Trials

- Fear of side effects - feeling that research is too risky
- Loss of control - discomfort with the idea of a placebo, randomization, or have a desire to retain the ability to select their own treatment
- Logistical challenges – trials are not conveniently located, require too distant travel or take too much time
- Costs Concerns - concern around insurance coverage and additional costs

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Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer - A Landscape Report AACR 2022

Common Myths

Patients need to be near a big hospital to take part in a cancer clinical trial

Clinical trials are a last resort treatment option

Patients may receive a placebo only, not treatment

Participation in trials is not important

Patient concerned about staying informed by care team while on a trial

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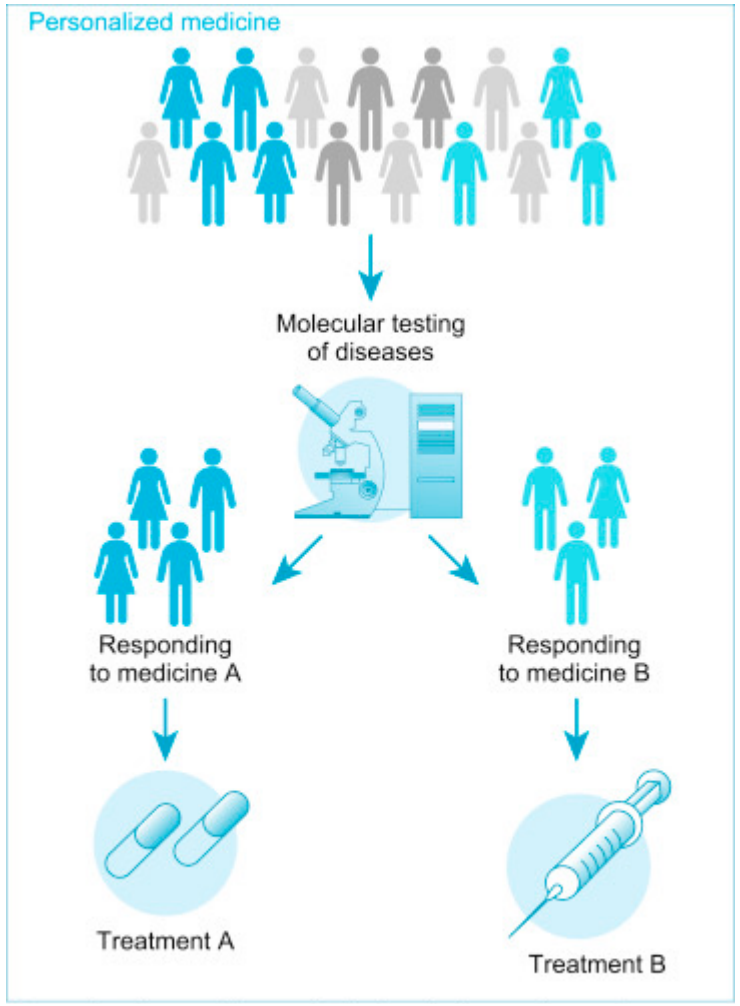
Personalized Medicine

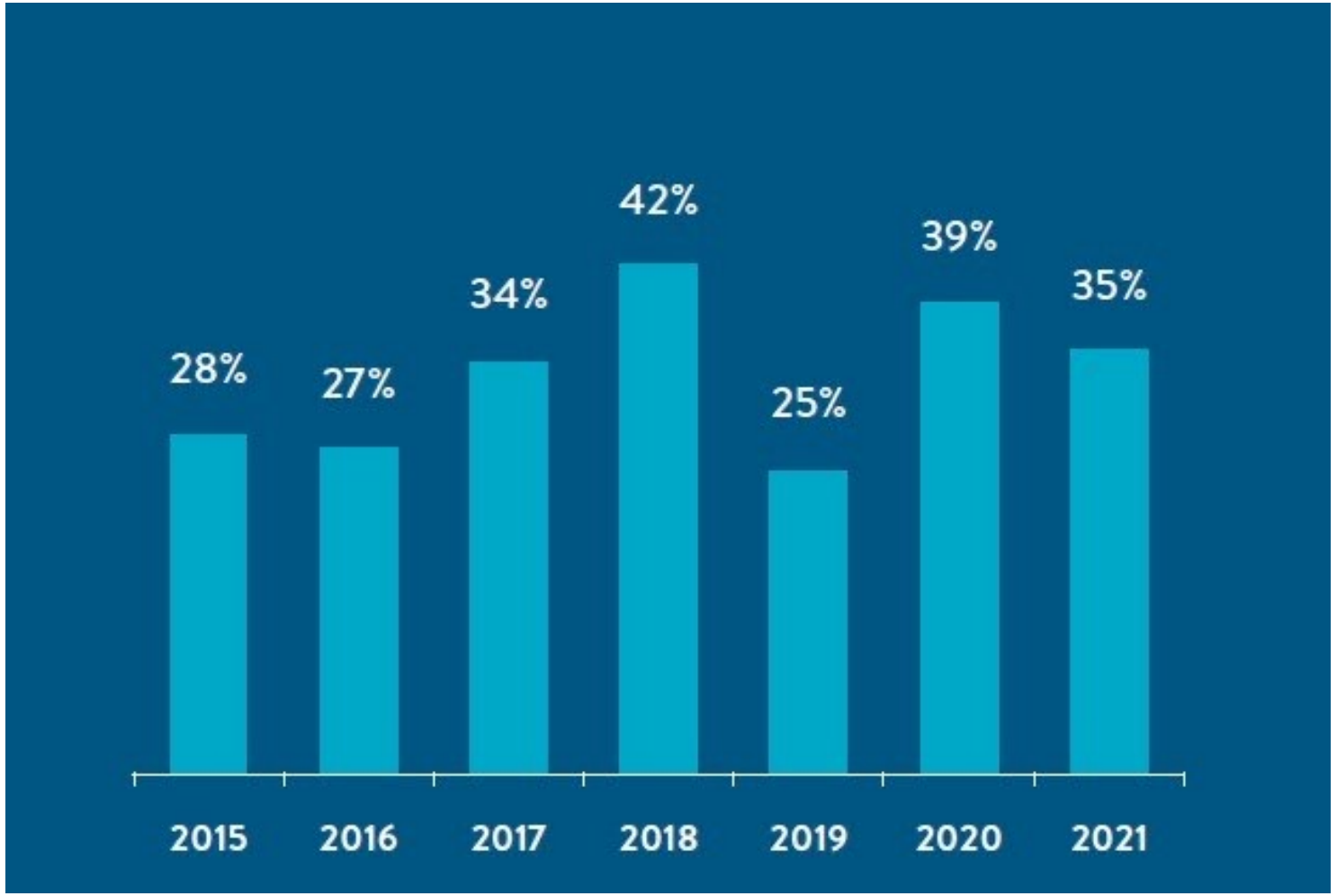
Several names used

- Biomarker testing
- Genomic testing
- Molecular testing



https://doi.org/10.1016/B978-0-12-420196-5.00017-4

Precision Medicine FDA Approvals



https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/Personalized_Medicine_at_FDA_The_Scope_Significance_of_Progress_in_2021.pdf

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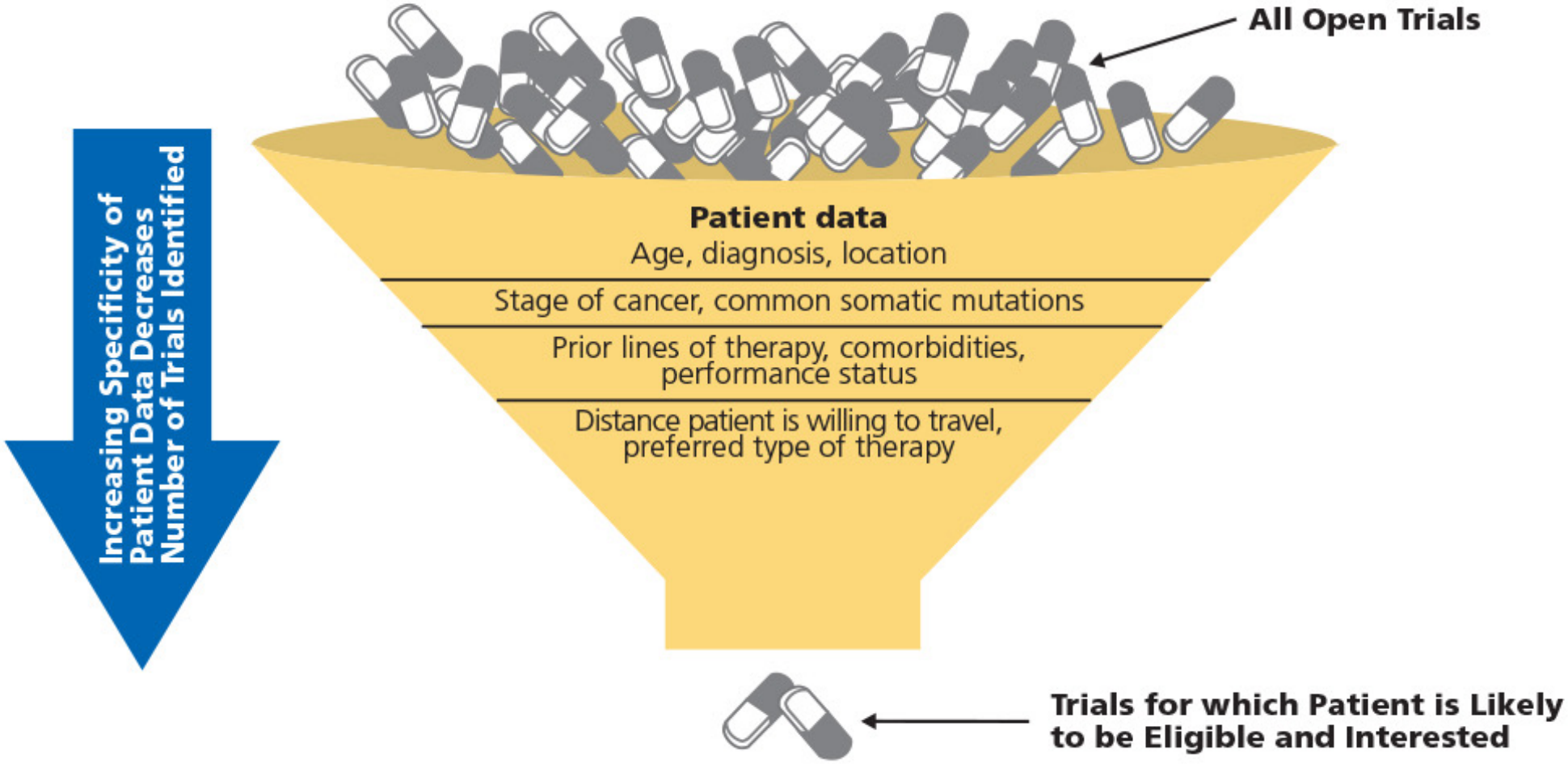
PATIENT-FACING CLINICAL TRIAL MATCHING



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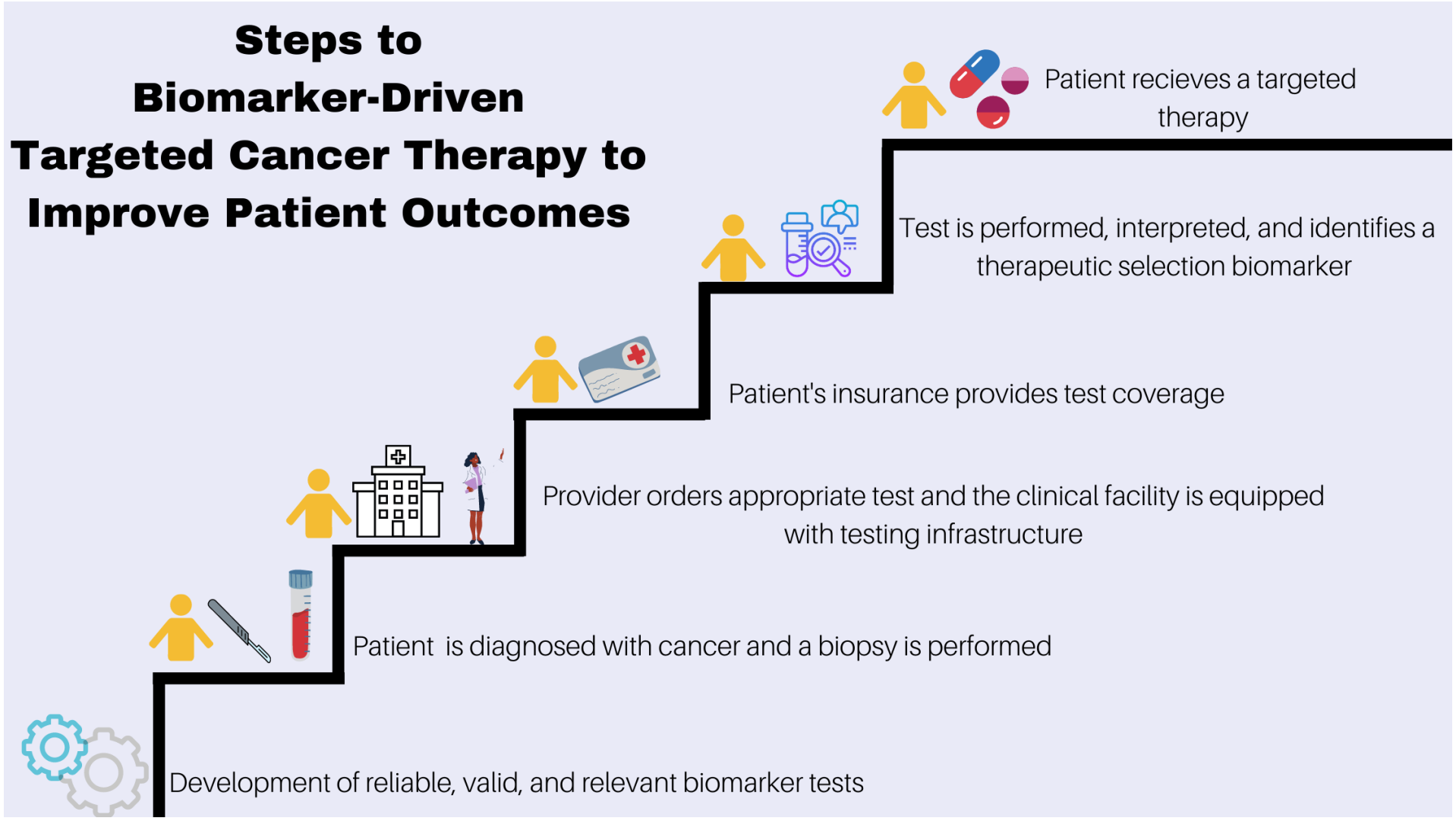
https://www.fightcancer.org/figure-10-patient-facing-clinical-trial-matching

Steps to Biomarker-Driven Targeted Cancer Therapy to Improve Patient Outcomes



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https://www.fightcancer.org

Health Equity – Biomarker Testing

- Results can drive treatment decisions
  - Targeted therapy
  - Clinical Trials
- Notable racial/ethnic and socioeconomic disparities in access
- Insurance / payor coverage limiting factor

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https://www.fightcancer.org/sites/default/files/health_equity_in_biomarker_testing_and_targeted_therapy_.pdf

Enhancing the Diversity of Clinical Trial Populations

Updated FDA Guidance
April 2022

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Race and Ethnicity Diversity Plan

Sponsors of clinical trials to report to FDA:

- Describe in detail the operational measures that will be implemented to enroll and retain underrepresented racial and ethnic participants
- Describe specific trial enrollment and retention strategies, including but not limited to site location and access, sustained community engagement, and reducing burdens due to trial/study design/conduct.
- Describe metrics to ensure that diverse participant enrollment goals

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Recruitment

- Hold recruitment events on nights and weekends and in non-clinical locations (e.g., places of worship, social commercial venues, public events)
- More inclusive strategies for public outreach and education (e.g., patient- focused research)
- Consult patient advocacy groups and medical associations to educate patients about potential trials
- Engage communities through focus groups, medical societies, and disease registries

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Retention

- Design clinical trial protocols along with patients, patient advocates, and caregivers
- Allow patients to access labs / clinics close to home for some research requirements
- Hold clinical trials in locations with higher concentrations of racial and ethnic minorities
- Use electronic informed consent, while considering the needs of patients without internet access

FDA.gov

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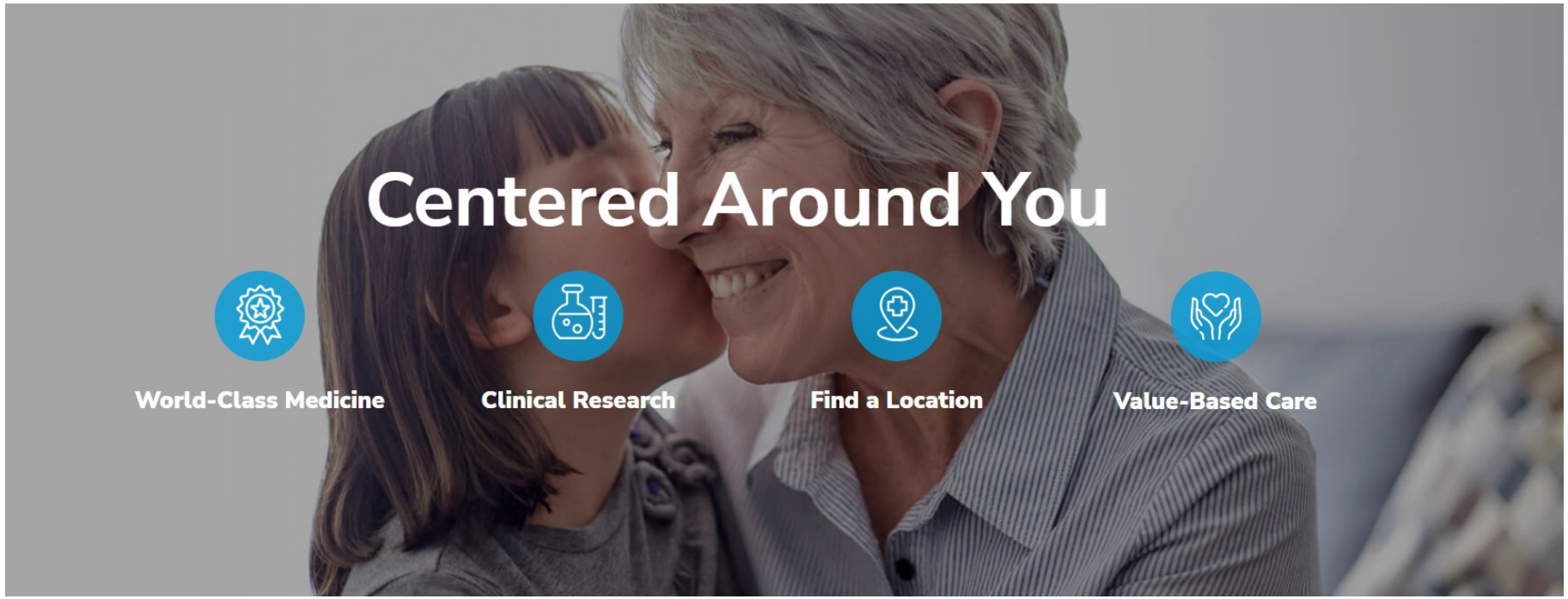
Community Based Oncology



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Improved Clinical Trial Access

- Critical component to advancing health equity
- Increase community-based research sites
- Make trials more accessible in rural and underserved areas
- Utilize technology – trial searching and matching, trial conduct
- Increase access to biomarker testing - legislation

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https://cancerprogressreport.aacr.org/disparities/cdpr22-contents/cdpr22-disparities-in-clinical-research-and-cancer-treatment/

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Thank You to Colleen Lewis & Our Listeners!

Don’t miss our Survivorship Chat on

Wednesday, June 21st at 12:00 pm ET