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

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
Clinical Trials:
Role of Community Oncology

Colleen Lewis, MSN, ANP-BC, AOCNP
Vice President Nursing & Research
Classic Drug Development Process

1. Pre-Clinical Testing ~ 4+ years
2. Phase I Trials ~ 2 years
3. Phase II Trials ~ 2 years
4. Phase III Trials ~ 3 – 4 years
5. FDA Approval ~ 1 year
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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*FLORIDA CANCER SPECIALISTS & RESEARCH INSTITUTE*
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
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

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
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.
Several names used

- Biomarker testing
- Genomic testing
- Molecular testing
Precision Medicine FDA Approvals
PATIENT-FACING CLINICAL TRIAL MATCHING

Increasing Specificity of Patient Data Decreases Number of Trials Identified

Patient data
- Age, diagnosis, location
- Stage of cancer, common somatic mutations
- Prior lines of therapy, comorbidities, performance status
- Distance patient is willing to travel, preferred type of therapy

Trials for which Patient is Likely to be Eligible and Interested

All Open Trials

https://www.fightcancer.org/figure-10-patient-facing-clinical-trial-matching
Steps to Biomarker-Driven Targeted Cancer Therapy to Improve Patient Outcomes

- Development of reliable, valid, and relevant biomarker tests
- Patient is diagnosed with cancer and a biopsy is performed
- Provider orders appropriate test and the clinical facility is equipped with testing infrastructure
- Patient’s insurance provides test coverage
- Test is performed, interpreted, and identifies a therapeutic selection biomarker
- Patient receives targeted therapy
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

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
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.
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
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
Community Based Oncology

Centered Around You

World-Class Medicine  Clinical Research  Find a Location  Value-Based Care
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

Thank You to Colleen Lewis & Our Listeners!
Don’t miss our Survivorship Chat on
Wednesday, June 21st at 12:00 pm ET