

## Clinical Trials in the Community Setting *Cutting Edge Treatment for Cancer Patients*



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## Today's Chat Agenda

- Community Oncology Alliance (COA) and COA's Patient Advocacy Network (CPAN) Updates
- Overview of the Patient Experience and Clinical Trials
- Clinical Trials in the Community Setting
- Closing Comments/Meet our June Guest

Learn more:

COA's Patient Advocacy Network: [www.coaAdvocacy.org](http://www.coaAdvocacy.org)  
Community Oncology Alliance: [www.communityoncology.org](http://www.communityoncology.org)  
American Oncology Network, LLC: [www.aoncology.com](http://www.aoncology.com)

# Clinical Trials in the Community Setting

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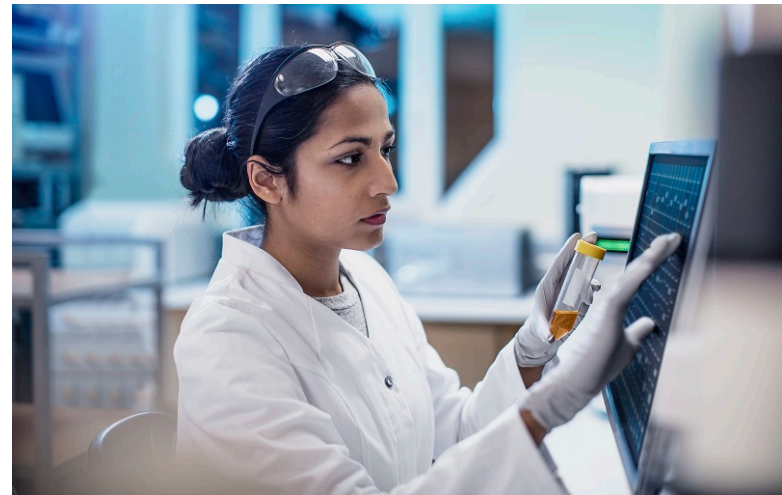


# Importance of Clinical Research

Uses clinical evidence and data to determine which medical approaches work best for certain types of illnesses or specific groups of people.

Advance scientific knowledge to improve patient outcomes.

Provides patients early access to investigational therapies



# Types of Clinical Research



1. Preventative
2. Screening & Diagnostic
3. **Treatment (Intervention)**
4. Quality of Life

# Drug Review Process & Safety

- **Pre-clinical testing**

- US Food and Drug Administration (FDA) decides if reasonably safe to move to human testing

- **IND (Investigational New Drug) Applications**

- Pre-clinical data & clinical protocol (scientific plan)
- FDA and IRB approval before moving to human testing

- **IRB (Institutional Review Board)**

- IRB panels include scientists, non-scientists, patient advocates
- They approve the scientific plan (protocol) that includes schedules of tests, procedures, length of study, written consent forms that contain risks and benefits to patient participants
- Provides oversight to clinical trial from start to finish

- **DSMB (Data and Safety Monitoring Board)**

- Independent experts that monitor safety and efficacy data

# Road to Drug Approval



\*Controlled trials are standard treatment with or without investigational therapy to compare outcome

# Community Clinical Research Sites

- Oncology practices may start research programs with dedicated staff or partner with hospitals and research organizations for infrastructure to become a “site”
- Sponsors of the clinical trial will select “sites” with confidence they will manage the trial with highest quality standards
  - Number of practices will vary and based on numbers of patient participants





# Who pays for my care while on a clinical trial?

Routine Cancer Care Cost: Costs related to treating cancer, whether on a clinical trial or not	Research Cost: Costs related to participating in a clinical trial
Doctor visits	Study drug
Standard of care treatment	Lab tests performed purely for research
Treatments to manage/improve symptoms of cancer or treatment	Imaging needed solely for the clinical trial
Lab tests and imaging (CT scans)	Other tests performed purely for research (eye exams, electrocardiogram)

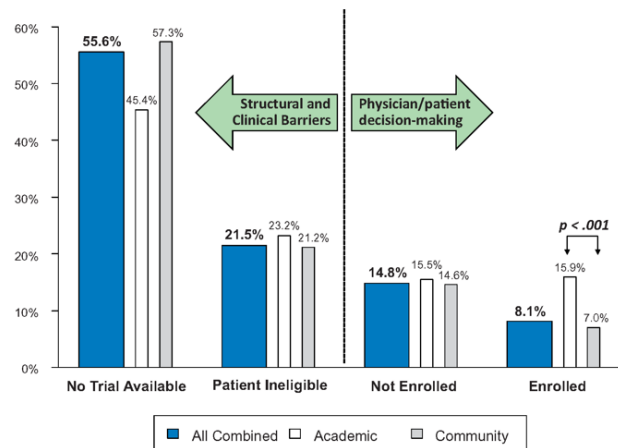
The Patient Protection and Affordable Care Act (ACA) is a federal law that regulates health plans and insurance coverage. It includes the requirement that private insurers cover the **routine patient costs associated with participation in approved clinical trials**

# Barriers to Participation

<5% of adult cancer patients will participate in a clinical trial

70% report they are very willing to participate in a clinical trial

**Figure 4.** Magnitude of barriers for each domain for academic sites, community sites, and all sites combined. The P ...



## ■ Structural

- Does your cancer center participate?

## ■ Clinical

- Did I meet the qualifications to participate?

## ■ Attitudinal

- Do I want to participate?
- Did my doctor recommend I participate?

# Finding a Clinical Trial

- Talk to your doctor and your healthcare team
- Search [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- Disease specific advocacy organizations
- Other resources:
  - [www.Cancer.net](http://www.Cancer.net)
  - [www.FDA.gov](http://www.FDA.gov)
  - [www.Cancer.gov](http://www.Cancer.gov)
  - [www.Cancer.org](http://www.Cancer.org)
  - [www.SarahCannon.com](http://www.SarahCannon.com)

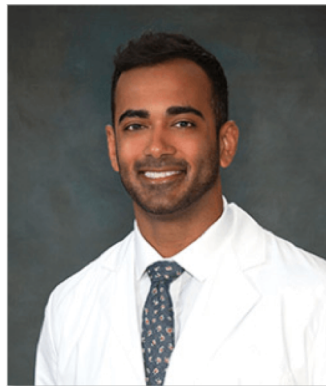


**Thank You to Katie Goodman, RN & Our Listeners!**

**Don't miss our next advocacy chat**

**Wednesday, June 9<sup>th</sup> at 12:00 pm ET**

**Cancer Education and the Power of Social Media**



**Sanjay Juneja, MD - TheOncDoc  
Hematology Oncology Clinic of  
Baton Rouge, LA**