Clinical Trials within an NCI Designated Cancer Center

Julie Bauman, MD, MPH
Director, GW Cancer Center

GW Cancer Center

GWCC Mission and Vision

- Mission

To drive transformational research, personalized therapy, family-centered care, and cancer policy in the nation's capital.

- Vision

To create a cancer-free world through groundbreaking research, innovative education, and equitable care for all.

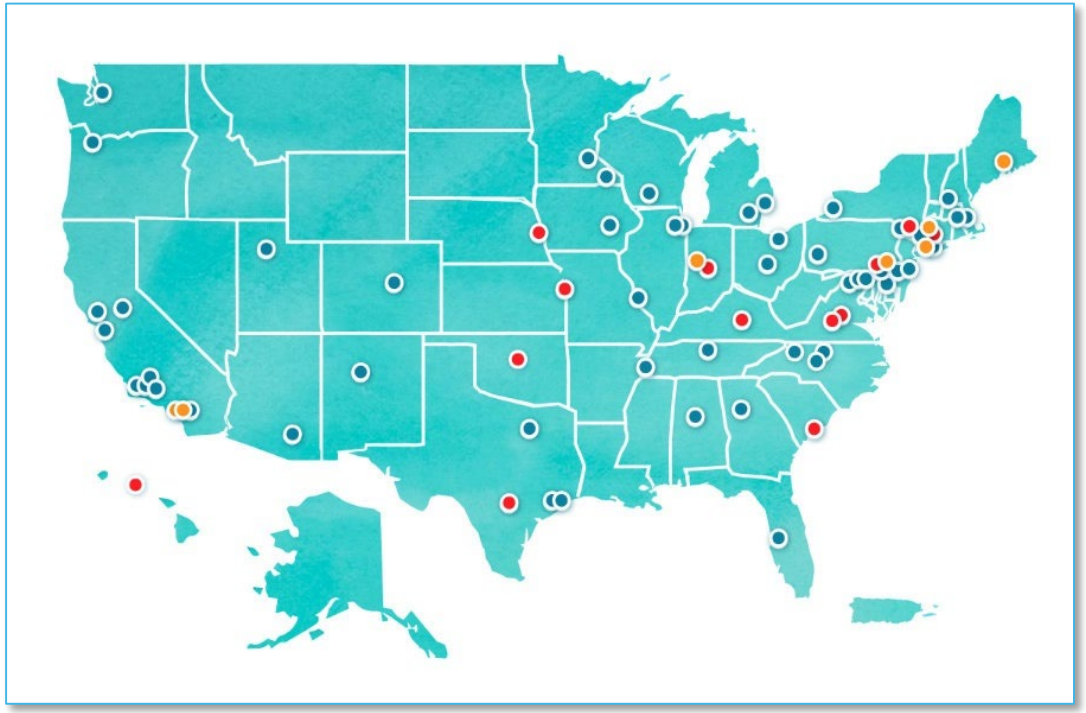
NCI-Designated Cancer Centers

- 1971: Nixon signed National Cancer Act
  - Established 1st 15 NCI-Designated Centers
- Grant recognizing rigorous standards for transdisciplinary, state-of-the-art research focused on preventing, diagnosing, and treating cancer within a U.S. catchment

52 Comprehensive Cancer Centers

12 Clinical Cancer Centers

07 Basic Laboratory Centers

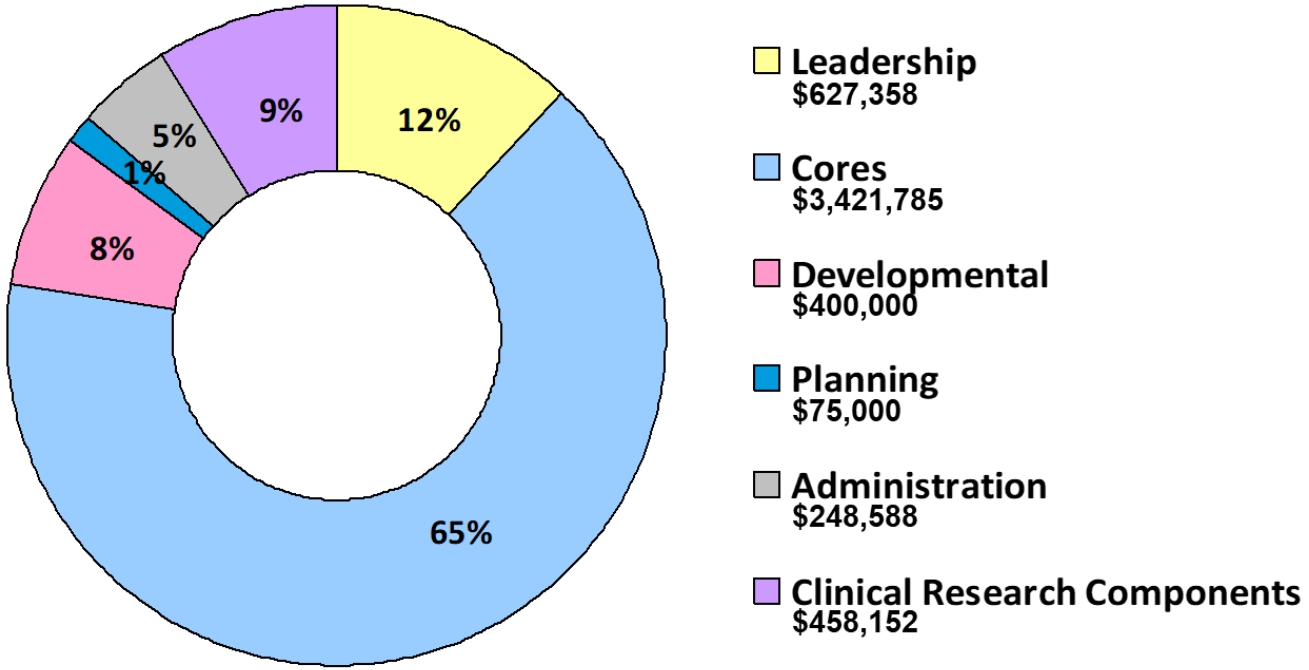


The Application

What they review

- High quality research focused on cancer (grants and publications)
- Broad and deep in all 3 areas: (Basic, Cancer Prevention & Control, Clinical Investigations)
- Collaboration and translation
- Innovative, early phase clinical trials
- Environment that supports both discovery & collaboration
- Impact in the community (Catchment area)

What they Fund



"REVIEW THE SCIENCE, but FUND THE CORES"

Two Major Components Related to Clinic Trials

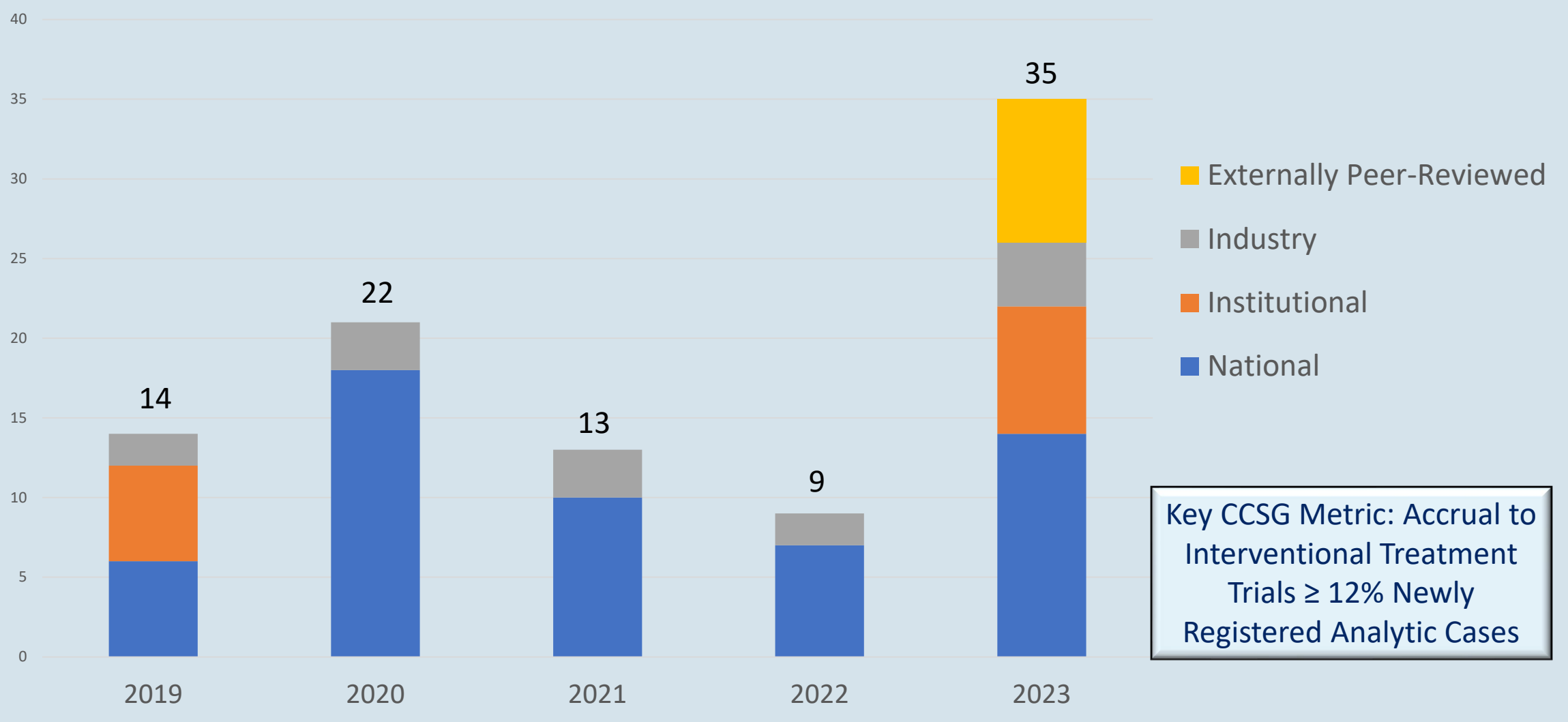
CPDM

- Clinical Protocol and Data Management
- Referred to as the “Clinical Trials Office” or GWCC CTO
- Accrual data is the primary metric

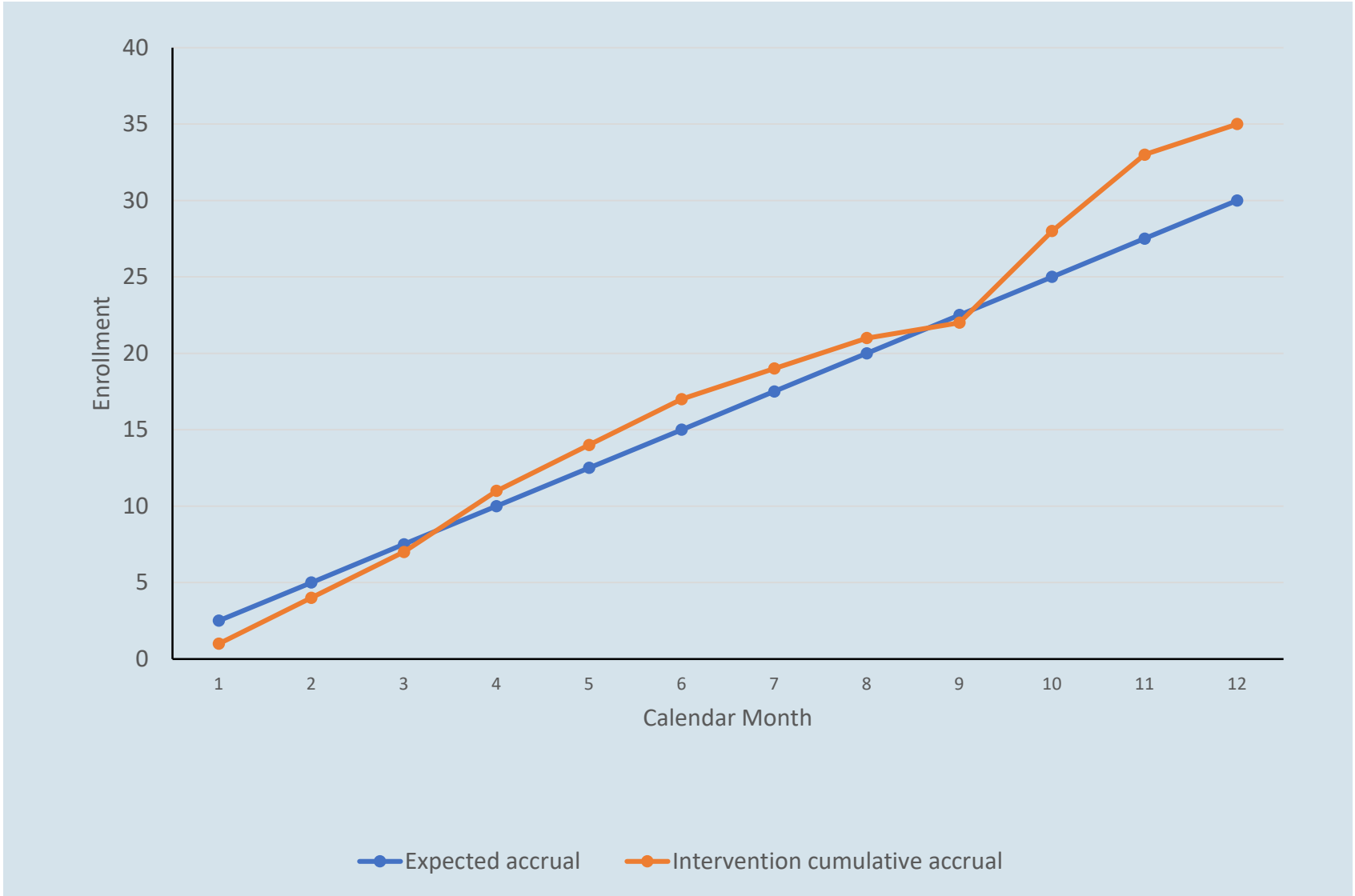
PRMS

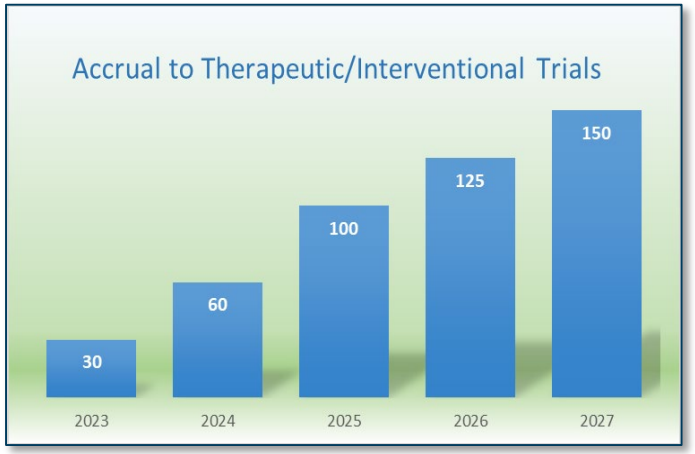
- Protocol Review and Monitoring System
- Includes:
  - Scientific Review (two-stage)
  - Monitoring
  - Data Safety and Management
- Trial data is the primary metric

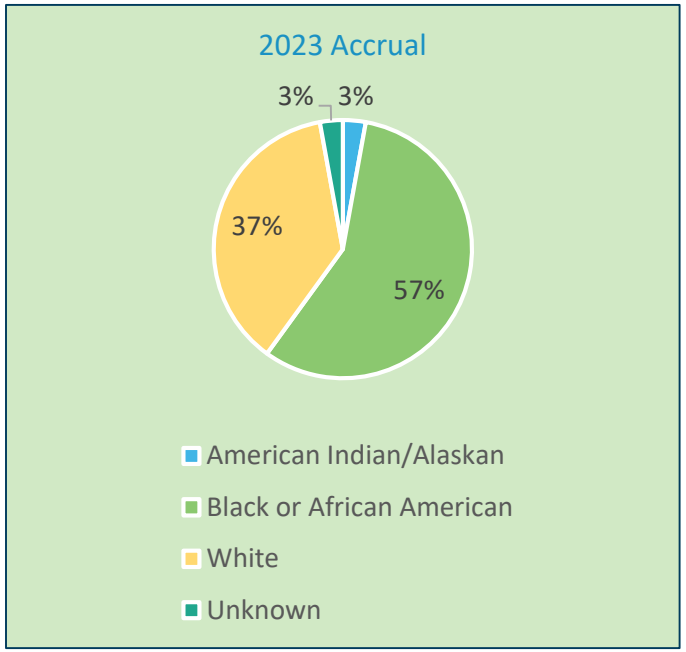
Adult Interventional Accrual Trends



Adult Accrual 2023







GW Cancer Center

Tools for Clinical Research Studies

- Protocol writing
  - MS Word templates available on GWCC CTO webpage
  - Protocol Builder available through GWU SMHS
  - IIT Manager can help edit the document once a good draft has been prepared
- Science
  - GWCC Research Programs and Scientific Seminars
  - GWCC scientists are a valuable resource when evaluating mechanism and molecular endpoints
  - Biostatistics: collaborate early and often!
- Feasibility
  - Disease-Specific Clinical Research Teams
  - Mentors, colleagues and research coordinators to “stress test” feasibility of a study at GWCC

KSIG Webinar- Accruing to Cancer Clinical Trials

Early Phase Clinical Trials- Pediatric Oncology Perspective

AeRang Kim, MD, PhD
Director of Clinical Research
Division of Oncology
Children's National Hospital
Associate Professor of Pediatrics
George Washington School of Medicine
Washington, DC

Children's National™

Unique characteristics in pediatric oncology

- Pediatric cancer is a rare disease
- Most pediatric cancers require treatment at tertiary care centers
- Most pediatric oncology centers belong to major consortia network (Children's Oncology Group (COG))
    - 90% of all pediatric cancer patients in US are treated at a COG institution
    - ~50% are treated on active clinical studies
- ~145 Active clinical oncology research studies open at Children's National

Children's National

Early phase studies (Phase 1 and 2)

- New diagnosis versus refractory/recurrent
- Early phase studies (Phase 1 and 2)
- Novel therapeutics
    - Offered at one or few centers
    - Need for specialized centers- investigational drug services, clinical research coordinators, research nurses, sample processing centers, storage facilities
    - ➢ Referrals (from other pediatric oncology centers)
        - ➢ Patients access to new agents/trials

Children's National™

Need separate pediatric/adult studies?

Different histologies

Different acute/late risks

Formulation

Arbitrary age cut offs

Study Structure?

Cooperative group (PEPCTN)

Multi-institutional

Single-institutional

RECRUITMENT/ ACCRUAL

Patient population

Increase cure upfront

Increase def of molecular subtypes in era of precision medicine

Eligibility

Study Sponsor and Funding

IIT/Grant/Industry

Travel

Study requirements

Regulatory restrictions

→ Smart, innovative, inclusive and flexible design

Investigator Initiated Trials

Pavani Chalasani, MD, MPH
Division Director, Hematology Oncology
GW Cancer Center

GW Cancer Center

- First idea/concept which can be developed into a full project (pre-clinical/ translational/ clinical)
- Investigator's study design, protocol, biomarkers, end points, accruals

Steps in LOI

- How to get ideas
- Next steps
- Funding sources
- Timeline

LOI development

- Get your ideas
- Plan your protocol stages- LOI/Funding/budget/contracts- many of them can be simultaneous