

# Hoosier Oncology Overview



hoosier oncology group

leading cancer research  
close to home

## WELCOME TO THE HOOSIER ONCOLOGY GROUP

The Hoosier Oncology Group Inc., is an independent not-for-profit Indiana organization established to evaluate and deliver leading edge cancer treatments throughout the state and literally **leading cancer research close to home** by bringing these treatments to cancer patients within their communities.

### *Our Vision*

The vision of the Hoosier Oncology Group is to form unparalleled relationships between community and academic partners to advance cancer research, education, and patient advocacy.

### *What We Do*

We are a full-service, 360° clinical research organization, providing excellence from conception and study design, all the way through project completion and publication.

Hoosier Oncology Group conducts leading cancer research in communities across the United States and internationally. Our concepts, developed in collaboration with academic and community oncologists, are conducted at more than 50 active research sites.

## OUR HISTORY

The Hoosier Oncology Group was created in 1984 by a small group of community-based oncologists and faculty members at Indiana University, modeled after the North Central Cancer Treatment Group (NCCTG). The concept was to foster relationships between academic and community physicians in Indiana so that patients could gain access to investigational therapies in the setting of a clinical research trial without having to travel to major academic centers for treatment. Whereas the majority of patients were entered locally, data was sent centrally to the Hoosier Oncology Group office where it was accumulated, assimilated and later prepared for presentation at national meetings and subsequent manuscripts.

Since 1984, the Hoosier Oncology Group has initiated more than 130 trials, testing hypotheses in a variety of cancer types and supportive care, involving more than 3000 patients.

The Hoosier Oncology Group has succeeded in creating an extraordinary network of more than 400 physicians and nurses.

### *Our Mission*

*To reduce the burden of cancer through the conduct of high quality research and education, as guided by the collaborative efforts of the Indiana University Melvin and Bren Simon Cancer Center, academic physician scientists, community cancer investigators and patient*

## Historical Timeline

### 1984

- Academic and community doctors decide to collaborate, modeled from NCCTG
- Formed as subsidiary of Walther Cancer Institute

### 1988-1999

- Makes first appearance at ASCO
- Establishes and solidifies its reputation in oncology research emphasizing investigator initiated, phase II trials
- Landmark trials in lung and pancreatic cancers, melanoma and quality of life are launched

### 2000

- Sandra Turner Excellence in Clinical Research Awards established, in memory of Hoosier Oncology Group's first Executive Director, to recognize research professionals
- Patrick Loehrer and Bill Fisher step down after 20 years of service as chair and vice chair
- Chris Sweeney and Robin Zon appointed chair and vice chair

### 2007-2008

- Spun out from Walther Cancer Institute as independent 501(c)3 not-for-profit
- Nasser Hanna appointed chair
- eDC system achieves maturity

### 2009-2010

- Silver Anniversary Year after 25 years as guardian of good research
- Announced research collaboration with The Translational Breast Cancer Research Consortium (TBCRC)
- Memo of Understanding signed between Indiana University Melvin and Bren Simon Cancer Center and Hoosier Oncology Group, formally aligning our research objectives and resources.
- Abonour appointed chair
- Announced research collaboration with the Mayo Clinic Cancer Research Consortium

## LANDMARK STUDIES

- Performed a phase III study comparing the four drug Dartmouth regimen, which had become a standard therapy based upon phase II data, to single agent DTIC in melanoma and documented no added benefit for the Dartmouth regimen in our phase III study
- Led and presented the pivotal phase III studies of two separate agents, gemcitabine and pemetrexed, in NSCLC that resulted in FDA approval of these two important drugs
- Refuted the benefit for consolidative docetaxel in locally advanced non-small cell lung cancer, which had become standard practice
- Developed standard treatment in localized pancreatic cancer (gemcitabine plus radiation).
- Established the role of the anti-depressant, fluoxetine, in patients with cancer

## RESEARCH EXPERIENCE

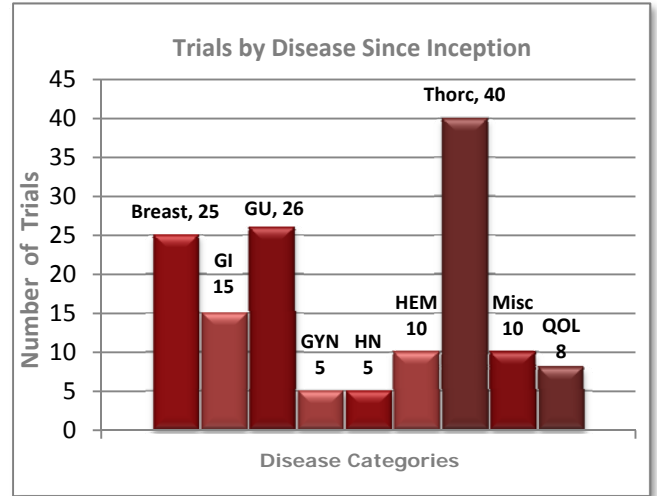
For more than 20 years, Hoosier Oncology has made a name in ground-breaking work. Our research findings have been selected as oral presentations at ASCO for four of the past five years, and we boast more than 60 manuscript publications in major peer-reviewed journals.

We have conducted more than 130 studies.

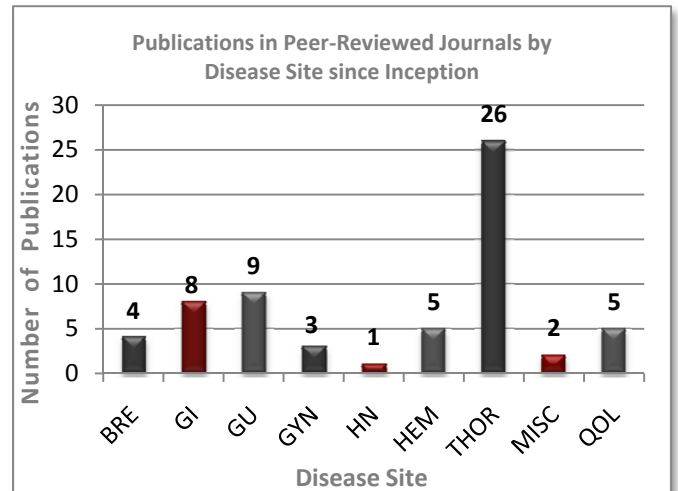
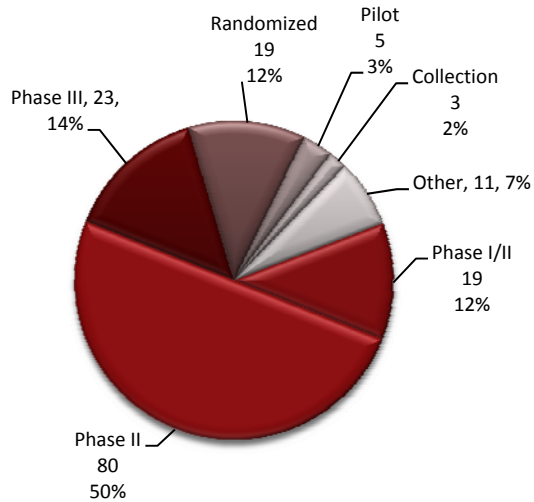
Of these:

- 80 have been phase II studies
- 40 have been thoracic studies

We have enrolled 3000+ patients across 200+ research sites since 1985.



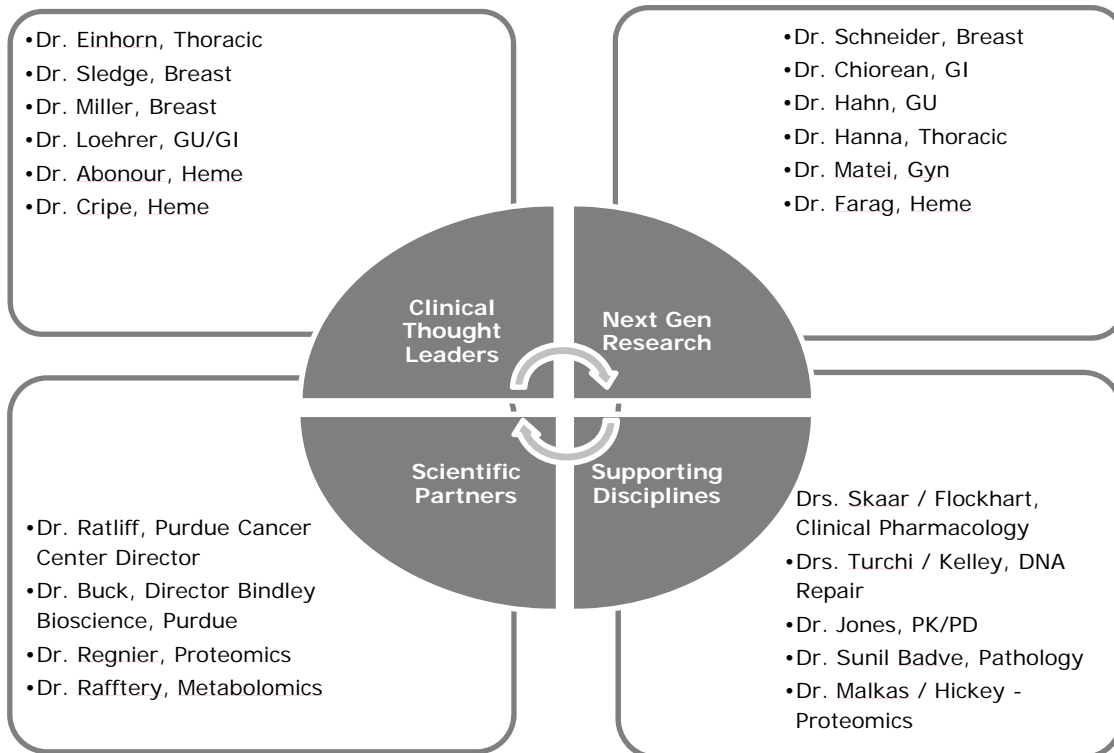
**Distribution of Research since Inception by Type of Trial**



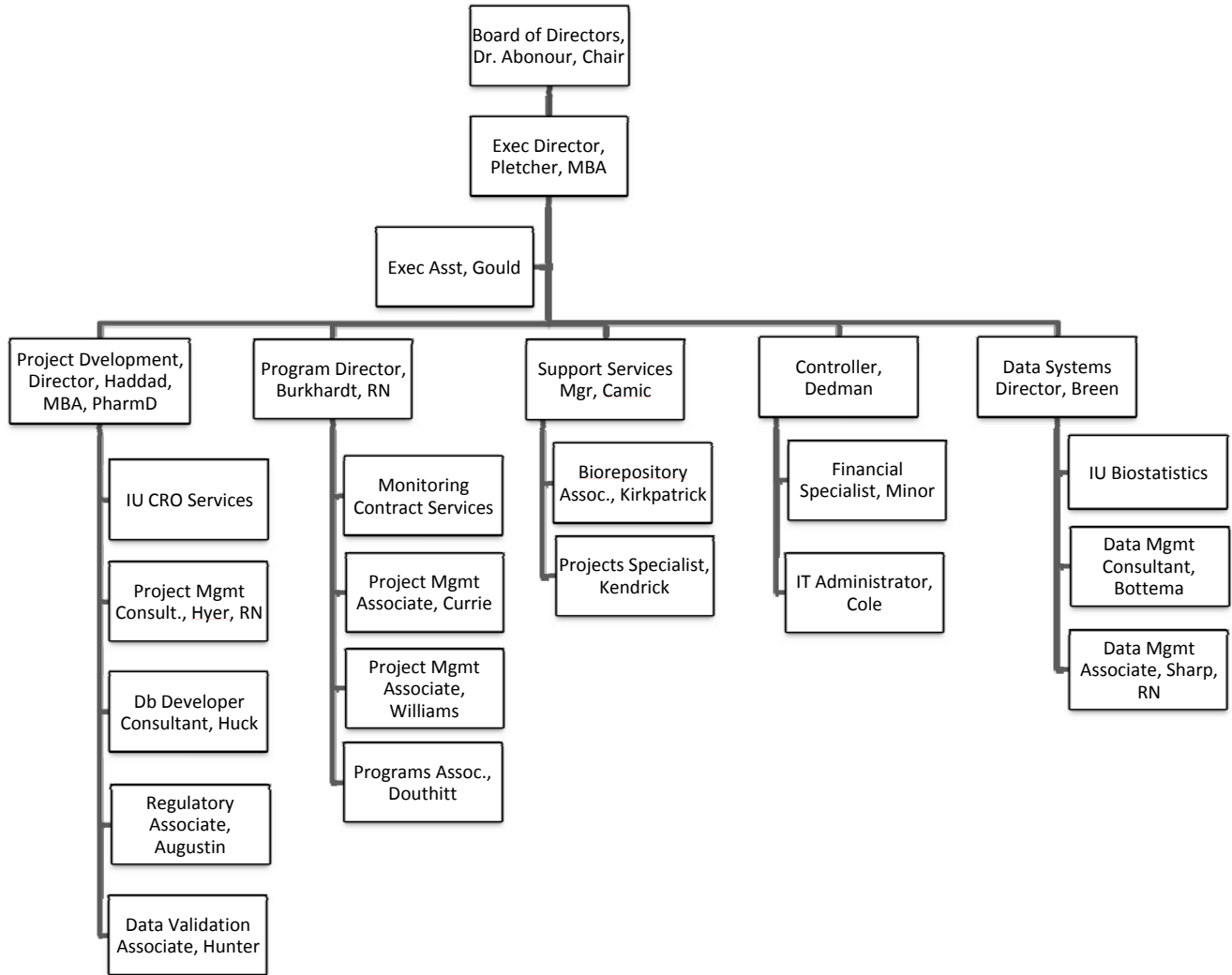
## OUR PROFILE

<p><b>Research Collaborators</b></p>	<ul style="list-style-type: none"> <li>• IU Simon Cancer Center is Research Base</li> <li>• Purdue Cancer Center</li> <li>• 3 Research Collaborations (TBCRC, GU Consortium)</li> </ul>
<p><b>Study History</b></p>	<ul style="list-style-type: none"> <li>• &gt;80% Investigator Initiated</li> <li>• Phase Ib/II are primary focus</li> <li>• Breast, Lung, GU, GI, Heme historical strengths</li> </ul>
<p><b>Patient Accrual</b></p>	<ul style="list-style-type: none"> <li>• Treatment studies avg over 250/year</li> <li>• Sample collection studies avg over 100-200/year</li> </ul>
<p><b>Member Profile</b></p>	<ul style="list-style-type: none"> <li>• 13 Indiana clinics/hospitals</li> <li>• 10 NCI-designated Cancer Centers</li> <li>• 7 Networks</li> <li>• 5 cCOPs</li> <li>• 3 NCCCP</li> <li>• 2 International</li> </ul>

## OUR KEY OPINION LEADERS



## ORGANIZATIONAL STRUCTURE



With more than 180 years combined clinical oncology research experience, our highly qualified staff has the knowledge and expertise to conduct the highest quality research.

### Our Staff Credentials:

- 1 PharmD
- 2 MBA
- 2 RN
- 1 MBBS
- 2 CCRP
- 2 CCRC
- 2 CCDM
- 3 MS
- 1 PhD
- 1 ASCP
- 1 HT
- 1 BSPH

## OUR NETWORK OF INVESTED RESEARCHERS

### Arizona

Mayo Clinic Cancer Center, Phoenix

### Arkansas

Highlands Oncology Group, Fayetteville

### Colorado

University of Colorado Hospital, Aurora

### Delaware

Christiana Care, Helen F. Graham Cancer Center, Newark

### Florida

Shand Cancer Center, University of Florida, Gainesville  
University of Miami, Miami

### Georgia

Winship Cancer Institute, Emory University, Atlanta

### Illinois

Ingalls Memorial Hospital, Harvey  
Kellogg Cancer Care Center, Northshore Univ. Health System, Evanston  
Medical & Surgical Specialists, LLC, Galesburg  
Northwestern University Feinberg School of Medicine, Chicago  
Rush-Presbyterian, Chicago  
The University of Chicago, Chicago

### Indiana

Arnett Cancer Care, Lafayette  
Cancer Care Center of S Indiana, Bloomington  
Cancer Care Center, Inc., New Albany  
Central Indiana Cancer Centers, Indianapolis  
Community Regional Cancer Center, Indianapolis  
Evansville Multi-Specialty Clinic, Evansville  
Ft. Wayne Medical Oncology & Hematology, Ft. Wayne  
Good Samaritan Hospital, Vincennes  
Center for Cancer Care @ Goshen Health System, Goshen  
Horizon Oncology Center, Lafayette  
Indiana Oncology Hematology Consultants, Indianapolis  
Indiana University Melvin and Bren Simon Cancer Center, Indianapolis  
Jasper Memorial Hospital, Jasper  
Medical Consultants, P.C., Muncie  
Monroe Medical Associates, Munster  
Northern Indiana Cancer Research Consortium, South Bend  
Oncology Hematology Associates of SW Indiana, Newburgh  
Parkview Research Center, Fort Wayne  
Providence Medical Group, Terre Haute  
South Bend Clinic, South Bend  
St. Vincent Gynecologic Oncology, Indianapolis  
St. Vincent Hospitals, Indianapolis

### Louisiana

Louisiana State University Health System, Leonard J. Chabert Medical Center, Houma

### Massachusetts

Dana Farber Cancer Institute, Boston

### Michigan

Metro Health Cancer Care, Wyoming

### Missouri

Washington University School of Medicine, St. Louis

### Nebraska

Methodist Cancer Center, Omaha  
University of Nebraska Medical Center, Omaha

### New Jersey

Hunterdon Regional Cancer Center (Fox Chase), Flemington  
Southern Oncology-Hematology Associates (Fox Chase), Vineland  
Virtua Fox Chase Cancer Program

### New Mexico

Presbyterian medical Group, Albuquerque  
The University of New Mexico Cancer Center, Albuquerque

### New York

Mount Sinai Medical Center, New York  
Schwartz Gynecologic Oncology, PLLC, Brightwaters  
University of Rochester Medical Center, Rochester

### Ohio

University Hospitals Case Medical Center, Ireland Cancer Center, Cleveland

### Oregon

Oregon Health and Science University, Portland  
Providence Portland Medical Center, Portland

### Pennsylvania

Fox Chase Cancer Center, Philadelphia  
Grandview Hospital (Fox Chase), Sellersville  
Pennsylvania Oncology Hematology Associates (Fox Chase), Philadelphia  
PinnacleHealth Regional Cancer Center (Fox Chase), Harrisburg  
Reading Hospital Regional Cancer (Fox Chase), Reading  
University of Pennsylvania, Philadelphia

### South Carolina

Medical University of South Carolina, Spartanburg  
Spartanburg Regional Healthcare System, Spartanburg

### Tennessee

The West Clinic (ACORN), Memphis

### Texas

Baylor College of Medicine - Methodist Breast Center, Houston  
CTRC at the UT Health Science Center at San Antonio  
Texas Oncology PA, Sammons Cancer Center, Austin  
The Methodist Hospital, Houston  
University of Texas Southwestern Medical Center, Dallas

### Virginia

Virginia Oncology Associates, Newport News

### Wisconsin

Medical College of Wisconsin, Milwaukee

### INTERNATIONAL SITES

#### Peru

Instituto de Enfermedades Neoplásticas (INEN), Lima

#### Poland

Medical University of Gdansk (Poland), Gdansk

#### United Kingdom

St. Barts and The London School, London

## OUR SERVICES

### Research Development

- Protocol Writing
- Budget Development
- Commercialization and Medical Strategy Development
- Scientific Review Committee Approval
- Statistical Analysis Planning
- Non-Standard of Care Review
- Budget Development
- Protocol Advisory Group Review

### Data Systems

- Electronic Data Capture Database Development
- Automated Data Querying
- Electronic Case Report Form Design
- Data Monitoring Plan
- Data Management and Validation
- BioStatistical Analysis

### Program Management

- Interest and Feasibility Surveys
- Study Procedure Manuals
- Site Monitoring
- Sponsor Communications
- IRB Approval
- Continuing Reviews
- Bimonthly Coordinator Conferences
- SAE Reporting
- IND Management
- Study Drug Storage and Distribution
- MS Project trained Project Managers

### Support Services

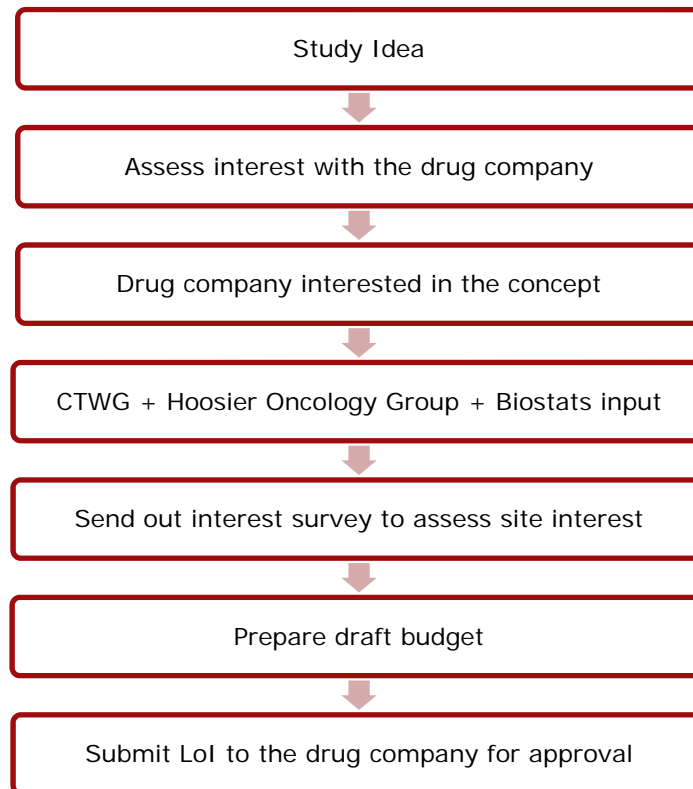
- Correlatives and Pharmacogenomic Planning
- Kit preparation
- Sample tracking, collection and storage
- Contracting with Sites
- Communications

## Research Development

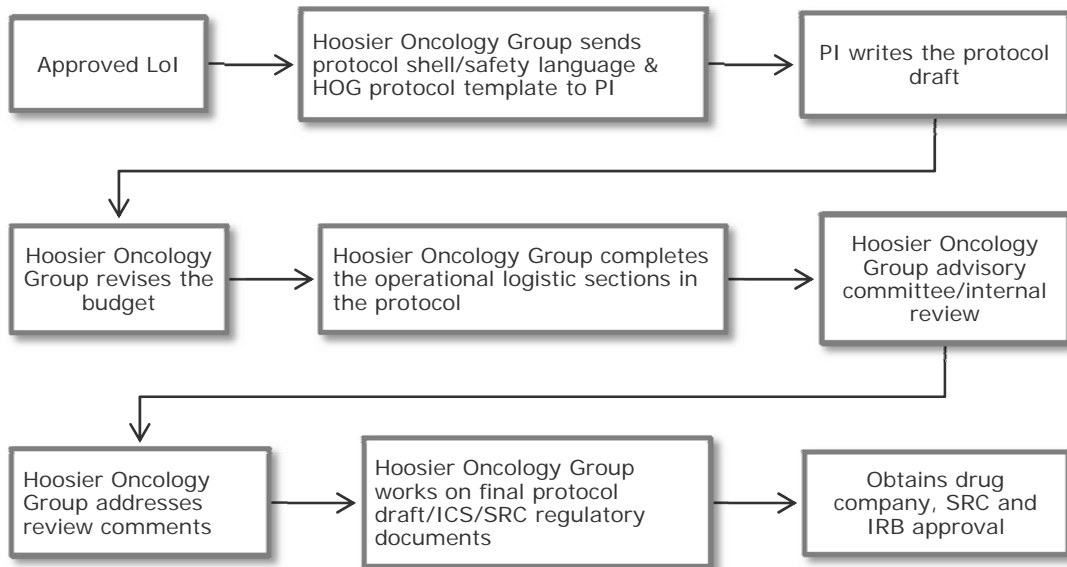
- Consultation on clinical protocol design
- Organization of meetings to review and discuss concepts among investigators
- Facilitate Letter of Intent (LoI) writing, submission and approval
- Serve as liaison between the investigator and sponsor/funder to obtain drug and funding support for the concept
- Prepare, submit and negotiate budget and contract with the pharmaceutical sponsor/funder
- Protocol and informed consent writing
- Statistical support
- Facilitate review and approvals of the protocol from various review committees such as Scientific Review Committee and Institutional Review Board.

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### CONCEPT TO LOI SUBMISSION



## *LOI TO IRB APPROVAL*



## *Contracts*

- Hoosier Oncology Group contract staff executes all Clinical Trial Agreements on behalf of institutional participants
- Institutional Participant Agreements between Hoosier Oncology Group and participating sites allows Hoosier Oncology Group to act as members' agent
- Protocol-specific work orders provide detailed budget information for timely site reimbursement
- Hoosier Oncology Group staff execute confidential disclosure agreements with all parties as necessary

## *Budgets*

- Hoosier Oncology Group negotiates budgets directly with industry
- Proposed budgets are reviewed and approved by executive director
- All payments to sites flow through Hoosier Oncology Group operations office

## Data Capture and Quality Assurance

All Hoosier Oncology Group led studies utilize Web-based electronic data capture (EDC) system that is supported by OmniComm Systems.

### ELECTRONIC REGISTRATION/RANDOMIZATION SYSTEM

- Validates user's institutional and study access
- Verifies relevant IRB approvals
- Verification of subject's eligibility criteria based on a study-specific electronically defined eligibility checklist
- System randomization supports blinding and stratification factors

20. Platelets >= 100 K/mm<sup>3</sup>?  Yes  No

NOTE: Values must be obtained within 14 days prior to registration for protocol therapy.

Platelets Date (DD-MON-YYYY):

Platelets Value (K/mm<sup>3</sup>):

The in-house eDC database developers utilize a large library of common electronic case report forms for rapid eDC development, however, the system also allows for easy development of protocol-specific electronic case report forms.

### SEVERAL LAYERS OF DATA VALIDATION

- Interactive edit checks
- Automated batch-run consistency checks for complex edits
- SCDM-certified data coordinators assigned to each trial

In addition, the eDC system features:

- Integrated query management system
- Online portal web site with customizable dashboard metrics
- Integrated CTCAE v3 dictionary for collection of adverse events, mapping to MedDRA available for adverse events

Metrics	
<a href="#">Customize</a>	
<b>Enrollment Dashboard</b>	
Total Enrolled Patients	28
Patient Enrollment Target	71
<b>Project Milestones</b>	
Latest Subject Enrolled-Actual Date	19-JAN-09
<b>Clinical Data Status</b>	
Number of CRFs Source Verified	258
Number of CRFs Frozen	59

### BIOREPOSITORY SUPPORT

- eDC system allows tracking of each aliquot of biospecimens from collection through processing, storing and distribution
- The sample tracking database is linked to the clinical database so that de-identified clinical data may be provided with the biospecimens
- Biospecimen analysis data can be captured through the eDC system, or received as raw data for statistical analysis

## *Analysis*

- Supported by Indiana University School of Medicine Division of Biostatistics
- Complete statistical capabilities including statistical design, data monitoring, safety analysis, and abstract/manuscript preparation
- Led by Susan Perkins, Ph.D., and supported by Ph.D.- Master's - Bachelor's - level statisticians and data analysts

## *Security and Regulatory*

- FDA 21 CFR Part 11 compliant
- HIPAA compliant
- Audit log system to track all changes to data
- Offsite database hosted by OmniComm Systems with secure servers and daily backups
- Firewall and Intrusion Detection System routinely monitored for any anomalies

## *Regulatory*

- Hoosier Oncology Group maintains shadow binders of all regulatory documents of our sites. We keep them current with the standard updating requirements (CV's within two years, current lab certifications and references ranges, etc.).
- Hoosier Oncology Group centrally manages and complies the regulatory items for our sites. We ensure they are in compliance for each trial and ensure we receive all updates.
- Hoosier Oncology Group regulatory staff exercises quality checks and audits of onsite data.
- IND management

## *Serious Adverse Event (SAE) Reporting*

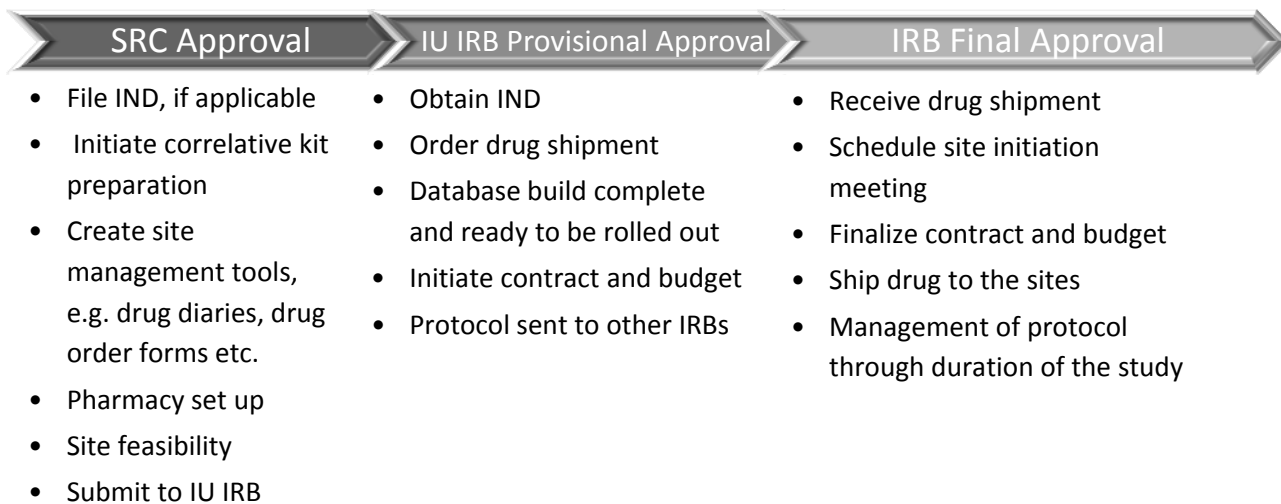
- Review and assessment of all SAEs occurring at participating sites
- All required regulatory reporting of SAEs to FDA and pharma is completed by Hoosier Oncology Group staff, including initial and follow-up reports
- Outside safety reports are distributed to all participating sites
- Comprehensive safety data is provided to Clinical Trial Monitoring Committee for safety review

### *Biorepository Services*

- Storage of correlative samples collected on Hoosier Oncology Group trials from participating institutions. Biospecimens are stored in the Hoosier Oncology Group biorepository in a manner to ensure specimen integrity. The storage of samples can be at either -80°C or ambient.
- Trained and dedicated personnel managing the biorepository. Only authorized individuals have access to the biorepository.
- Biorepository Standard Operating Procedures were written following the NCI's Best Practices guidelines.
- The Hoosier Oncology Group supplies all sites with appropriate materials needed for bio-specimen collection. Included items are cryovials, formalin fixed containers, blood tubes, pipettes, labels, shipping supplies etc. Each sample collection kit is study specific as well as time point specific.
- All bio-specimens are tracked electronically using the Hoosier Oncology Group sample tracking database. Samples are tracked from the point of collection, to receipt in the Hoosier Oncology Group biorepository and then to the destination for analysis. This sample tracking database is linked to the clinical database so that associated de-identified clinical data may be provided with the bio-specimens to the researchers.

### *Project Management*

We offer full cycle management of protocols from LOI through initiation through data analysis.



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[www.hoosieroncologygroup.org](http://www.hoosieroncologygroup.org)