Oncology Consortia of Criterium

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Background: A Centralized Network Model for Functional Outsourcing in Pharmaceutical Development

Escalating economic pressures, regulatory requirements, and technological demands, coupled with the need for more diverse patient populations and increasing demands on clinicians in their daily practices challenge the "single site" clinical research model. Clinical trial participation has become increasingly demanding for all stakeholders: the sites, sponsors, investigators and patients. Adding to the demands, leading pharmaceutical firms have reversed a downward trend in the number of new drug approvals in the late 1990's by increasing the number of new drugs entering the clinical research arena. The annual rate at which drugs entered clinical testing for the 10 largest pharmaceutical firms increased 52% from 1998-02 to 2003-05.[1] A more recent 2008 PhRMA Biotechnology report found that America's pharmaceutical research and biotechnology companies are testing a record 633 new biotech medicines of which 254 are in oncology.[2] Yet, only 3% of cancer patients participate in clinical trials despite the importance of clinical trials in improving cancer treatment and control.[3] The current decentralized, single site model is creating a "no win or catch 22" scenario; community practices are struggling to initiate or maintain clinical research programs; industry looks for ways to increase the patient recruitment into their trials as well as general trial performance while controlling resource impacts as they downsize their clinical research departments and move down an outsourcing path. The outcome is inevitable; the clinical research model must change. Organizing community-based sites and Institutions into networks is a solution that takes the administrative burden off the sites and the sponsors leaving both to concentrate on the enrollment and evaluation of patients.

The Centralized Network Model

The **Centralized Network Model (CNM**) today is defined as a group of independent, primarily community based research sites that function as one large, synchronized entity bound by a set of strong, core operating procedures. These procedures are implemented and enforced by a central administrative group.[4] The responsibility for most regulatory and administrative tasks associated with conducting clinical research are assumed by the central administrative group allowing the network sites to focus more on their trials and patients. Common organizational network infrastructures include disease state committees which consist of regional research leaders or disease state experts which are usually led by a chief medical officer. The disease committee would review all protocols offered to the network for proper scientific design which truly meets the patient and market needs. The administrative group would assist the committee in optimal and timely site selection within the network using historical enrollment databases and feasibility surveys. Ongoing trials would then be followed by the committee along with the site staff participating on the trial. The central administrative group would provide all site staff access to various database reports on enrollment, safety reports and other pertinent topics utilizing secure communication databases managed by a central IT support team. The communication flow helps to ensure proper trial oversight and ultimately patient safety. Throughout the study various trial processes and administrative tasks such as contracts, budgets, general trial management, safety reporting, regulatory document management, pharmacy services and site reimbursement would all be handled centrally.

About the Parent Company

Criterium Inc. has operated as a complete service CRO since 1991. In that time, Criterium has developed and maintains a site database registry of over 3200 individual listings of PI's and study locations across multiple therapeutic areas. Criterium also organizes and manages individual **oncology consortia** – a centralized academic model following the principles of CNM – in specific oncology therapeutic indications. Often, sponsors have preferred provider arrangements with CRO's, but still want to work with the expert investigators and key opinion leaders in the consortia we have organized. For this reason, Criterium provides a centralized network model approach for specialty site management (and other related services) to CRO's, biotech and pharmaceutical and medical devices companies.

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The Oncology Consortia of Criterium

The Oncology Consortia of Criterium brings together the best possible team of institutions and investigators with similar research interests, to advise the sponsors in the design of trials, to complete translational, phase IB and phase II studies, to be the lead team for the full phase III programs and to represent the sponsors as key opinion leaders at the time of approval. **Criterium offers *the consortia as a solution to meet Sponsors' oncology research needs.***

The Academic GI Cancer Consortium (AGICC) is presently represented by Key Opinion Leaders (KOLs) and top Investigators at 11 of the most prestigious institutions in the USA. The **Academic Myeloma Cancer Consortium (AMyC)** is represented by Key Opinion Leaders (KOLs) and top Investigators at 9 of the most prestigious institutions in the USA. The **Academic Thoracic Oncology Medical Investigators Consortium (ATOMIC)** is represented by Key Opinion Leaders (KOLs) and top Investigators at 8 of the most prestigious institutions in the USA. The **Academic Breast Cancer Consortium (ABRCC)** is represented by Key Opinion Leaders (KOLs) and top Investigators at 9 of the most prestigious institutions in the USA. We currently have master service agreements with all of these institutions. Each member chosen for the consortia is usually located at a hospital associated with an academic institution that has superior infrastructure and staff to meet the requirements for not only translational and investigator initiated studies, but also the design and completion of all phases of clinical trials. The scope of responsibilities for our **consortia** follows:

Consortia Model design, startup, site management and recruitment services offered:

Project Development
Advisory Board (KOL)
Clinical Drug Development Planning
Translational Study Design
Phase I-IV Protocol Design and Writing
Regulatory Consulting
Statistical Consulting
Clinical Study Report and Publication Writing
Site Evaluation
Identify Potential Member and Affiliate Study Sites
Obtain Confidential Agreements
Conduct Feasibility
Conduct Evaluation Visit and Prepare Report
Identify Final Member and Affiliate Investigators
Site Documentation & Contracting
Collect and Validate Pre-Study Documents
Distribute Protocol/Essential and Study-Related Documentation to sites
Distribute IBs or Package Inserts
Informed consent form (ICF) Draft and Translation
Manage Documentation for submission to IRBs
Submission for Institutional Review Board / Independent Ethics Committee (IRB/IEC) approval
Maintain all regulatory documents throughout study
Negotiate Investigator Budgets
Execute Investigator Site Contracts (per study)
Set-up Investigator Study File Binder and related Trial Master File
Oversee the maintenance of the Trial Master file
Provide Document Tracking Report
Archive Trial-related documents

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Site Study Management
Project Management
Recruitment & Enrollment Tracking
Internal Monthly Meetings to manage study progress
Advising & alerting investigators of potential protocol & ICH-GCP violations
On-site QA: on-site training, for "internal quality check of source and data prior to sponsor/CRO monitoring visits"
Coordinate the Reporting of serious adverse events to the Sponsor or CRO and the IRB/IEC
Centralized Site Payments
Recruitment & Retention
Recruitment, Oversight and Follow-up
Screening, Recruitment, Enrollment Tracking using IVR/IWR Applications
Retention

The Consortium - A Unique Model

CNM – A Centralized Network Model provides for a coordinated structure and capabilities for clinical trial development, coordination and management:

- Full service organization positioned to design, perform, and analyze clinical trials focused on GI, Multiple Myeloma, Thoracic and Breast cancers
- Experienced centralized research department that integrates coordinated PM, Finance, and grant management capabilities
- Advanced clinical trial model better suited to adapt to changes in cancer drug development
- This innovative and focused research model speeds decision making by the sponsor on the development of drugs.

Features, Advantages & Benefits

- **Each consortium consists of top Academic Institutions with like-minded, experienced PIs**
  - Produces a tightly knit group with collegial relationship
  - Efficient execution of complicated oncology trials on behalf of the Sponsor or CRO
- **Translational research expertise**
  - Exceptional therapeutic and targeted expertise
  - Design, perform, and analyze pilot phase I/II clinical trials
- **Scientific and operational value-added services from planning through completion and publication**
  - Advanced clinical trial model better suited to adapt to changes in cancer drug development
  - Contribute to translational research and molecular endpoints
- **Experienced centralized network integrates coordinated project, contract and grant management**
  - Reputational advantage associated with Consortia
  - Rapid study development, start-up, and enrollment in all phases of clinical trials

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- **Flexible business model**
  - We can deal with a variety of situations, client needs
  - Sponsor can pose a question and receive multiple solutions to meet their needs

- **Clinical and scientific expertise in protocol development**
  - Our team manages the protocol development
  - Protocol quality is better, development faster

- **Ability to design state of the art targeted and combination therapy studies**
  - Multiple coordinated centers can work as one on IIT-Pilot-Proof of concept studies
  - More credible and reproducible study results on behalf of Sponsor

- **Forum for scientific ideas and more efficient protocol design**
  - Annual and monthly meetings to discuss pipelines, potential drug regimens and combinations
  - Each Consortium becomes your Virtual Advisory Board

- **A group of Key Opinion Leaders in TOP US Academic Institutions who work together in each consortium**
  - Central Master Service agreements, Project Agreements and budget negotiations
  - Studies are up and enrolling patients faster (90 days vs. 180 days)

- **Small Group of KOLs with academic appointments at Top US Academic Institutions**
  - Agile group that can make recommendations and a solid commitment quickly
  - Our staff and investigators are the continuity in a project from start to finish

The great advantage of working with OCC and its consortia is that a sponsor gets a continuous access to Med Ad Board of KOLs from protocol design through data interpretation that is only a phone call or Webinar away. This consulting service is available throughout the active project (usually a clinical trial). This is a more efficient way to benefit from expert advice than the standard approach of recruiting Med Advisors to meet at an expensive venue.

References:
1 Tufts CSDD Impact Report (Sept./Oct., 2007)
2 PhRMA 2008 Biotechnology Report Sept, 2008
3 N. Stark, "A Survey of Survivors," Applied Clinical Trials, July, 2007
4 L. Scheible, "The Clinical Network: A Different Approach," Community Oncology, 3 (11) (2006).