We care as much as you.

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Project Management

Project Management is a standardized service that allows for continual oversight and engagement with sites and sponsors on a protocol-specific basis beginning at the concept phase. Coordinating Center responsibility entails providing updates regarding site progress on protocol activation, as well as other critical communications, via scheduled bi-weekly or weekly teleconferences.

Superior Project Management is at the center of good clinical trial work. Novella Clinical’s Project Management (PM) teams plan and execute critical milestones for each study, while providing excellent client service and proactive communication. Our experienced project managers excel in areas including KPI identification and management, risk mitigation and effective budgeting.

Central to the success of a project manager is his or her understanding of, and experience in, the given therapeutic area. Novella assigns project managers based on therapeutic expertise, and our clients have come to expect a thorough understanding of the protocol and the therapy from all of our PMs, ensuring they add value from day one.

With both industry and sponsor backgrounds, our project managers understand product lifecycles and the larger picture. With an average of 11 years in project management, and five years in the industry, Novella’s PMs are therapeutically aligned and vested in each program.

Our key Project Management functions include:

- Oversight of the day-to-day activities of all team members, as well as quality, budget and timelines
- Proactive communication with the client, team members, vendors and sites throughout the study lifecycle
- Tracking and management of predefined metrics, timelines and anticipated trends
- Identification of efficiencies and processes that improve data quality
Advisory Board

Clinical Advisory Boards are established by Medical Device Sponsors to seek expert opinion from clinical subject matter experts who play a key role in advising the company's clinical programs and overseeing the clinical development process.

A Sponsor may choose to appoint an Executive Committee or Steering Committee to provide oversight for the overall direction and strategy for a clinical trial. This committee may include investigators, other experts not otherwise involved in the trial, and usually representatives of the Sponsor. The Executive or Steering Committee may contribute to the design of the study, increase information exchange at an early stage of trial development, increase the efficiency of clinical trial collaboration and, in many cases, contribute to the publication of the study data. These individuals may also participate in open sessions of Data Monitoring Committee (DMC) meetings and communication of DMC recommendations following each DMC review of the trial data.

Novella offers our Medical Device clients the necessary expertise for the successful implementation of Clinical Advisory Boards, Executive Committees and Steering Committees.

Our capabilities include:

- Member Selection
- Identify Clinical Advisory Board, Executive and/or Steering Committee members, with access to a global pool of board certified physicians and key opinion leaders through our Physician Network
- Manage member contracts and payments
- Prepare Physician Payment Sunshine Act reports for Sponsors
- Establishing a written charter, with well-defined standard operating procedures for committee operations
- Board and Committee meeting coordination, including agendas, logistics, hosting, facilitation, and minutes of appropriate sessions

Novella's Oversight Group Management can manage the process from beginning to end, or work with Sponsors on a customized list of services. For further information, contact us.
Contracts & Budgets

On January 6, 2006 the PCCTC executed the Prostate Cancer Clinical Trials Consortium Agreement (Agreement). This membership agreement binds all of our sites as sharing certain goals regarding development of new treatments for prostate cancer. As the PCCTC grew in 2007 and 2009, the Agreement was amended to include the new members. This Agreement has allowed the Consortium to develop unilateral and bilateral Confidentiality Disclosure Agreements (CDAs), an MICTA for Industry Sponsored Clinical Research (MCTA), and an MCTA for Investigator Initiated Clinical Research (IIT MCTA). Having these contract templates has allowed us to negotiate consistent terms of confidentiality, data ownership, publications, and intellectual property across institutions and industry. The first MCTA was executed on April 9, 2007. The Consortium also developed a Coordinating Center Service Agreement (CCSA), which is utilized to contract with industry for clinical research activities to be carried out by the Coordinating Center, ensuring investigators and industry sponsors share responsibilities in development pathways, trial design, data evaluation, and decision-making as well as to improve procedures for project management, protocol development, clinical trial budgeting, and contracting.

ACORN CRO has an experienced contract and budget staff to support both the site and sponsor in contract negotiation and budget management.

Our Contract and Budget Management services include:

- Development of investigator budgets that reflect the nuances of reimbursement at the sites for accurate forecasting of site budgets and anticipated pass-through expenses
- Negotiation of site budgets and site contracts on behalf of sponsors
- Management of site and vendor payments
- Ability to directly pay sites and vendors
- Track site contract deliverables and process payments
- Provide reports to sponsor as requested
Regulatory

The Coordinating Center continues to provide a standard process for timely Regulatory Document Management, allowing sponsors a single point of contact for multi-site start-up. The Coordinating Center notifies the sponsor once a site has completed all the necessary requirements to be considered ‘regulatory ready’ to open the trial and receive study drug. When a study is being conducted under a US Investigational New Drug (IND) application, the Coordinating Center coordinates the submission of the required regulatory documents to the sponsor from all sites.

Novella Clinicals Regulatory Affairs department provides comprehensive international support to pharmaceutical, biotechnology and combination product sponsors. Offering both operational and strategic consulting services, our team is experienced in working with domestic and international regulatory agencies as well as IRB/ethics committees.

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Our Regulatory Affairs services include:

- Worldwide regulatory submissions and regulatory liaison activities, including meeting planning, briefing package development and meeting leadership
- Regulatory strategy for clinical, nonclinical and CMC activities
- Regulatory support for advanced therapy product development, including combination products, gene therapy and cell and tissue therapies
- Regulatory document management and document control activities
- Oversight of all regulatory activities
- Single point of contact for all regulatory submissions and activities
- Early core document preparation and approval
- Country-specific documentation
- Rapid review of completed site regulatory documents
Medical Writing

Novella Clinical's medical writing staff plays a vital role in the product-lifecycle model with our clients. Our writers possess the skills and relevant medical/scientific education to produce expertly written documents, and they are integrated with our project teams to ensure accuracy and consistency.

Our expertise includes indication for use statements, product label claims, interim analysis and periodic safety reports, annual IDE updates and final CSR compilations for both sponsors and regulatory agencies. Additionally, for post-market support, we offer medical writing for medical journals, abstracts, registry protocols and CSRs.

Using a flexible approach, Novella offers medical writing as a component of a full-service program or as a stand-alone service. We maintain a library of ICH templates for regulatory submissions, but we can also use client templates and follow client style guides upon request.

Our medical writing services include:

- Preclinical and Clinical Study Protocols
- Clinical study reports
- FDA briefing documents
- Clinical and summary sections of Common Technical Documents (CTDs)
- Clinical and summary sections of Premarket Approvals (PMDAs), 510(k)s, etc.
- Abstracts, posters and journal articles
- Investigator's brochures
- Informed consent forms
- Executive summaries for efficacy or safety
- Patient narratives
- Instructions for use (IFU)
- Clinical evaluation reports
Clinical Data Management

Our overall approach to data collection and management includes careful planning for each clinical trial, applying our SOPs to all phases to ensure data integrity, usage of common data elements compatible with national and international dictionaries, and using integrated advanced technologies and infrastructure for all members of the Consortium, regardless of their local institutional platform or database. (Text from grant)

For more than 15 years, Novella Clinical has been leading the industry in the implementation of eClinical processes in clinical trial technology utilization. Our rich history enables us to provide knowledgeable, targeted solutions for each project. Focused on high quality, timely data capture and processing, our Data Operations group tailors technology strategies to meet the individual needs of each client.

Our dedicated team is comprised of experienced oncology data professionals, who fully appreciate the complexity of oncology protocols. This understanding enables our team to effectively and efficiently create forms and case books for each trial, saving time during the study build phase. Additionally, our oncology knowledge fuels logical form design - reducing queries, minimizing errors and fostering positive relationships with site staff. We also host an extensive library of forms, which serves as an important resource for executing study builds.

Our Data Management Services include:

- Full service or independent data management support
- eCRF design, specifications and completion guidelines
- Protocol amendments, updates and eCRF revisions
- Clinical data review using leading eClinical technologies
- Coordinated data review including clinical, safety and biostatistical teams
- Vendor reconciliation for labs, ECG, imaging, etc.
- Local lab normal coordination
- SAE reconciliation
- Medical Coding of events and medications
- Database lock

Our Statistical and Clinical Reporting Services include:

- Full service or independent biostatistical support
- Protocol development
- Randomization
- Statistical Analysis Plan (SAP) development
- Table, Listing and Figure (TLF) development
- Specialized reporting:
  - DSM/CEC reports
  - Patient profiles
  - Annual reporting
Quality Assurances

Study Design & Protocol Development

ACORN CRO can design studies that will meet a sponsor’s research objectives, and will compare the feasibility of alternative designs to maximize the return on the sponsor’s research investment. ACORN CRO can provide complete protocol development services. With basic research concept or background documents provided, ACORN CRO will develop a high quality protocol draft, revise following review and input from sponsor and key opinion leaders, and finalize a protocol suitable for submission to institutional review boards.

Protocol and CRF Review

ACORN CRO provides biostatistical review of protocols, case report forms (CRF), and other study documents. Review of protocols includes consideration of the appropriateness of the biostatistical content, including consistency of objectives with study measures and planned analyses. It also includes evaluation of the completeness of biostatistical content, and the quality of scientific presentation.

Review of CRFs entails matching of CRF content to protocol and/or statistical analysis plans. It also includes evaluation of the nesting structure of the data as implied by the CRF.

Randomization

ACORN CRO can produce random allocation sequences for multiple group designs, with specified proportions assigned to each group, and with the number of stratification variables allowed by the sample size. The allocation sequence can be generated in blocks, with varying block length to reduce the risk that assignment will be determined and known by research staff.

Analysis Plan Development

ACORN CRO can produce or assist in the production of statistical analysis plans (SAP) for studies of varying complexity. Typical SAPs are free standing documents with abbreviated study background, a complete description of raw and derived variables, and specification of all descriptive and inferential procedures to be conducted. The SAP also specifies scheduled interim and final analyses by accrual or calendar schedule, the assessment points (for repeated measures) and the cohorts to be included in each analysis. For intervention studies, the SAP generally includes table shells, definition of figures to be generated, and listings to be produced (TRLS). For observational and retrospective research, TRLS generally include labeling and description of tables without production of table shells.

Analysis and Interpretation

ACORN CRO has expertise in the application of a wide range of statistical methodologies, including the following:

- Descriptive analysis of continuous, count, categorical, and censored outcomes
- Comparison of group means (univariate, multivariate, and repeated measures analysis of variance)
- Multiple linear regression
- Multiple binary and multinomial logistic regression
- Ordinal regression
- Linear mixed models for assessment of longitudinal data
Statistical Analysis

The Coordinating Center serves the Consortium’s stakeholders by providing the infrastructure and procedures necessary for ensuring QA, quality control (QC), and study monitoring. All protocols where data are managed through the Coordinating Center have a detailed Data and Safety Monitoring Plan. The Data and Safety Monitoring Plan describes sample size, critical and non-critical data fields to be audited, frequency of audits, tentative site visit schedule, corrective action, and any other relevant information for each clinical trial. [Text from grant]

Novella Clinical’s quality management processes are integral to all aspects of our business. Our independent Quality Assurance (QA) department performs regular quality assessments of our services to ensure compliance with FDA (21 CFR 312) and international GCP regulations, ICH, ISO, our SOPs and our commitment to clients.

Our experienced auditors conduct trial master file audits on a rolling basis, ensuring GCP, documentation processes and file structure as well as providing peace of mind for clients. In addition, QA operates a robust vendor qualification process and regularly administers vendor audits through a variety of mechanisms to ensure all Novella’s vendors meet or exceed our stringent standards.

In fact, Novella’s commitment to quality facilitated our North American headquarters to earn ISO 9001:2008 certification in 2004 and recertification in 2010. Today each Novella location operates under our centralized quality management system.
Our Mission

In 2005, the Prostate Cancer Foundation (PCF) and the U.S. Department of Defense (DOD) Prostate Cancer Research Program (PCRP) initiated the Prostate Cancer Clinical Trials Consortium (PCCTC) in response to gaps identified in prostate cancer clinical research by physician investigators and prostate cancer advocates. The PCCTC is now a major multicenter clinical research organization consisting of a nationwide network of physicians at 13 academic institutions specializing in cutting-edge prostate cancer research with a single coordinating center located at Memorial Sloan-Kettering Cancer Center (MSKCC). To secure and expand its enhancements to the clinical trial environment and to become sustainable following DOD/PCF funding cycles, the PCCTC has recently establish an independent entity, the PCCTC, LLC. The PCCTC has established itself as the nation's premier prostate cancer clinical trials group and remains poised to make a significant impact on the lives of patients by keeping the drug pipeline filled with promising novel agents.
Our History

In 2005, the Prostate Cancer Foundation (PCF) and the U.S. Department of Defense (DOD) Prostate Cancer Research Program (PCRP) initiated the Prostate Cancer Clinical Trials Consortium (PCCTC) in response to gaps identified in prostate cancer clinical research by physician investigators and prostate cancer advocates. The PCCTC is now a major multicenter clinical research organization consisting of a nationwide network of physicians at 13 academic institutions specializing in cutting-edge prostate cancer research with a single coordinating center located at Memorial Sloan-Kettering Cancer Center (MSKCC). To secure and expand its enhancements to the clinical trial environment and to become sustainable following DOD/PCF funding cycles, the PCCTC has recently established an independent entity, the PCCTC, LLC. The PCCTC has established itself as the nation's premier prostate cancer clinical trials group and remains poised to make a significant impact on the lives of patients by keeping the drug pipeline primed with promising novel agents.
Management Team

Jake Vinson  
Executive Director

Michael J. Morris, MD  
Medical Director

Mary Warren  
Budgets & Contracts Manager

TBD  
Business Manager

Julie Filipenko  
Clinical Informatics Project Manager

Kristofer Prepelica, PhD  
Communications Coordinator

TBD  
Program Manager

Abheem Simmons  
Project Coordinator

Kin Tse  
Project Coordinator

TBD  
Project Coordinator
Board of Directors

Lorem Ipsum
Executive Director

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Scientific Advisory Board

Howard I. Scher, MD
Mary-Ellen Taplin, MD
Michael Carducci, MD
Tomasz Beer, MD
Charles Ryan, MD

Evan Yu, MD
Daniel George, MD
Celestia Higano, MD
Elisabeth Heath, MD
University of California Los Angeles (UCLA)

[Weill Cornell]
Marga Oortgiesen, PhD
James E. Williams, Jr., COL (Ret)
Charles Sawyer, MD
Levi Garraway, MD, PhD

Elizabeth Mansfield, PhD
Marc Buyse, ScD
Richard Simon, DSc
Our Participants

Memorial Sloan Kettering Cancer Center

Dana-Farber / Harvard Cancer Center

Duke University Cancer Center

Johns Hopkins Sidney Kimmel Cancer Center

Oregon Health and Science University Knight Cancer Institute

University of California San Francisco Helen Diller Family Cancer Center

University of Washington Fred Hutchinson Cancer Research Center

University of Wisconsin Carbone Cancer Center

Wayne State University / Kresge Cancer Institute

Weill Cornell Medical College

UCLA Jonsson Comprehensive Cancer Center
Our Participants

- University of Texas, MD Anderson Cancer Center
- University of Michigan Cancer Center
- Chicago Prostate Cancer Association
- Johns Hopkins Sidney Kimmel Cancer Center
- Rutgers Cancer Institute of New Jersey
Drug Development

The individual research objectives of our member institutions are well represented in our clinical trial portfolio and unified by our translational, team-based approach to developing therapies based on the underlying biology of the disease at specific points in the disease continuum. Specific therapeutic areas to which the Consortium has given priority include AR modulation, targeted therapies, antibody-drug conjugates (ADCs), radiopharmaceuticals, and immune response modulators. Equally important is that the Consortium places great emphasis on novel trial designs, endpoint development, and the analytical validation of biomarkers to ensure that the decision to advance or to discontinue the development of an agent is made objectively and rapidly.
Biomarker Development

To enable member institutions to drive the Consortium’s as well as their own research agendas, the Consortium has developed mechanisms to expedite and simplify the process of working as a multicenter consortium—mechanisms for finding the most deserving new therapies for clinical trials, designing trials with meaningful endpoints, obtaining the necessary regulatory approvals, and tracking results for prompt analysis and publication. Notably, our evolving procedures for project management, protocol development, and contracting have enabled the Consortium to activate trials within an average of 192 days after initial letter of Intent (LOI) submission over the past two years, as compared to the more than 500 days it takes for NCI Cooperative Groups to do the same.
Regulatory Compliance

We, as Coordinating Center, and all of our member sites, understand the importance of FDA compliance. Before trial activation, the sponsor or investigator is required to give a determination of the applicability of filing an IND application for the study, according to the FDA's current guidance on IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer.

Consortium studies, particularly investigator-initiated trials, may be IND-exempt. Those that do not meet exemption criteria will have INDs held by trial sponsors that could range from industrial firms to the lead site or lead investigator of a Consortium study. To date, most sponsors have been from industry or CTEP; however, going forward, an industry sponsor, lead site, or lead investigator will have the option to transfer study oversight responsibilities to the Consortium via the CCTC. The Coordinating Center will ensure that proper processes are in place for compliance with FDA requirements. To this end, Consortium leadership has collaborated with the FDA's Center for Devices and Radiological Health (CDRH) in the development and analytical validation of predictive biomarkers in prostate cancer.
Research Administration

To enable member institutions to drive the Consortium’s as well as their own research agendas, the Consortium has developed mechanisms to expedite and simplify the process of working as a multicenter consortium—mechanisms for finding the most deserving new therapies for clinical trials, designing trials with meaningful endpoints, obtaining the necessary regulatory approvals, and tracking results for prompt analysis and publication. Notably, our evolving procedures for project management, protocol development, and contracting have enabled the Consortium to activate trials within an average of 192 days after initial letter of intent (LOI) submission over the past two years, as compared to the more than 500 days it takes for NCI Cooperative Groups to do the same.
Industry Expertise

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