Innovative Clinical Concepts, LLC

ICC

Your Clinical Trial Research Services Group

Company Overview

- Innovative Clinical Concepts, LLC is a minority/woman owned Clinical Trials Research Services company whose mission is to provide community based physicians, who have access to large and diverse patient populations, an opportunity to bring new and innovative medicines and medical devices to their patients through the clinical trials process.

Innovative Clinical Concepts, LLC

- **Founded in October, 2003 by industry pioneers**
- **National Clinical Trials Research Services provider**
  - **Provide services the sponsor needs**
  - **Phase II, III, and IV**
- **Experience in a wide variety of therapeutic areas**
- **More than 60 years of cumulative medical and pharmaceutical industry experience**
- **Utilizing tools and methods used in the industry ("don't re-create the wheel")**
- **Developing a reputation of delivering unparalleled service to our clients**
- **Developing a network of community based physicians and study coordinators**

Innovative Clinical Concepts
Overview of services

- **Site selection**
- **Investigator and staff training**
- **Site initiation**
- **Patient/subject recruitment**
- **Study budget management**
- **Data management (Query resolution, SAE processing, etc.)**
- **Study drug management**
- **Site monitoring**
- **Study closeout**
- **Regulatory Readiness**
- **Project management**
- **Quality assurance**
- **Customized services for sponsors**
- **Other**

Why is ICC Unique

- What Drives the Business
  - Experience in managing and conducting global clinical trials in multiple therapeutic areas
  - Strong desire to be involved in the science of clinical trial research
  - Desire to bring education and innovative new medicines and medical devices to underserved patients and community based physicians
  - Flexibility
  - Will surpass client expectations by providing on time delivery, high quality and individualized services
  - Committed to our client's success

Why is ICC Unique

- What ICC brings to the table
  - Bring new opportunities to community based physicians
  - Help sponsors gain a better understanding of ethnic/racial differences in patient therapies
  - Resolve the “one drug fits all” issue
  - Bridge to building better relationships/trust between industry and physicians/patients - (minority)
  - Understand the changing paradigm in medicine
  - ICC is a vehicle to help sponsors achieve FDA Draft Guidance for inclusion of minorities in clinical trials

ICC's Therapeutic Focus

- **Hypertension**
- **Diabetes**
- **Heart disease**
- **Depression**
- **GI disease**
- **Renal disease**
- **Infectious Disease**
- **Obesity/hyperlipidemia**
- **Osteoporosis**
- **Asthma**
- **Sickle Cell Disease**
- **Orthopedics**
- **Medical Devices**
- **Other**

Our Customers

- **Current Customers**
  - **Roche Diagnostics**
  - **Eli Lilly**
  - **ICAGEN/Quintiles**
  - **Proctor & Gamble**
  - **United BioSource Corporation (UBC)**

- **Future Customers**
  - **GSK, BMS, Pfizer, Covance, Paraxel, Medtronics, Abbott, Watson, Indiana University**

ICC Experience: Facts and Figures

- **Bringing value to our clients?**
  - **Recruitment and enrollment Goals**
    - **Exceeded the recruitment and enrollment goals by 134%**
  - **Quality**
    - **Provided process improvement procedure to prevent data collection errors**

      Regulatory requirements
    - **Sample integrity**

ICC Experience: Facts and Figures

- Speed
  - Exceeded all timelines
  - Quick turnaround for second contract
- Project management
  - Developed task list
  - Determined work flow process
  - Determined staffing needs

ICC Experience: Facts and Figures

- ICC's participation in clinical trials studies has varied according to the needs of the sponsors as well as the progress level of the study when ICC was contracted to provide services.
- *In summary:*
- ICC has achieved 89% of its goal for P I recruitment and 97% of its goal for patient enrollment across all studies.
- **Achieved**

	P I Recruitment goal	Patient Recruitment goal
	89%	97%

- **Demographics**

	P I Recruitment	Patient Recruitment
minority	76%	98%
non-minority	24%	2%

- We prepare our investigator sites to have all documents ready to submit for IRB approval (central or local IRB approval) as soon as all parties sign contract documents. This process is designed to minimize cost to our sponsors when individual site budget requirements exceed the dollar amounts offered by the sponsors.

ICC's Value Proposition

- ICC's Value Proposition to our sponsors
  - Bring access to investigators and patients
    - Access to large minority patient populations
    - Potential access to naïve patients
    - Majority becomes minority by 2050
    - FDA Draft Guidance mandate
    - Bridge the relationship gap among industry, physicians and patients
      - Quality data
      - On time results
      - Within budget

Technology

- **Tools**
  - **Web and FAX-based data collection/communication**
  - **IVRS**
  - **Microsoft project management tool**
  - **Microsoft Windows applications**
    - **Office**
    - **PowerPoint**
    - **Excel**

Project Tracking-Timelines

- **Timelines via Gantt charts**
- **Compare actual to planned timelines**
- **Identify tasks ahead/behind schedule**
- **Early prompt for corrective actions**

What's Next

- **Let *Innovative Clinical Concepts* be your preferred vendor for diverse populations**
- You may find additional information about our company on our website at "iclinicalconcepts.com". It is in the process of being updated.
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