

Overview

ClinXus is a non-profit community based alliance established in West Michigan to enable biomarker driven and innovative clinical trial designs as recently defined by the United States Food and Drug Administration (FDA) and European regulatory agencies. The alliance is comprised of existing community health care, clinical, research, and educational organizations. It seeks to establish a 21st Century “open-architecture” biomarker driven clinical trials network to serve the increasingly molecular-based medical applications. The ClinXus network is dedicated to improvement of the clinical trial process by applying solutions and services related to innovative patient access, biomarker implementation and trial designs.

Coupled with the strengths and expertise of the organizations involved ClinXus acts as the single point of contact to extend the following coordinated community capabilities and services:

- Protocol and project design, development and implementation
 - Phase I-IV expertise, trial design and coordination
 - Research coordinators/support staff
 - Educational forums for physicians, health care partners and communities
 - Regulatory/compliance consultation
 - Tissue collection and biobanking facilities
- State of the art patient facilities and support
 - Combined hospital capacity of over 1,500 beds
 - 50 bed full service Phase I clinical research unit
 - Access to a well characterized 1.4 million patient population
 - Integrated physician network (with extensive Electronic Medical Record (EMR) utility)
 - Standardized and custom sample acquisition
- Extensive molecular profiling capability
 - Advanced imaging and molecular profiling platforms for biomarker discovery and qualification
 - Discovery core services (including preclinical)
 - The Center for Molecular Medicine (CMM) – a high complexity CLIA/CAP accredited organization focused on the development and application of molecular-based diagnostics
- Full breadth of integrated IT infrastructure
 - Data management services, including data and image warehousing
 - Molecular analysis, interpretation and reporting services
 - Conventional and Exploratory Statistical services, including modeling and simulation, PK/PD analyses
 - Target data assembly from diverse discovery and pre-clinical sources across therapeutic areas

In addition to the large annotated patient population, several diseases are particularly prevalent within the West Michigan community including cardiovascular disease (e.g. drug eluting stents, transplant rejection, atherosclerosis), oncology (e.g. prostate, colorectal, breast, pancreatic), inflammatory diseases (e.g. Crohn's disease, osteoarthritis, rheumatoid arthritis, asthma) and CNS diseases (e.g. schizophrenia, depression, Alzheimer's, Parkinson's). Expertise in ophthalmology, pediatrics, respiratory disease and metabolic syndrome (e.g. type II diabetes, hypertension, obesity) is also immediately available. Across this population, patient access is greatly assisted by the implementation of electronic databases, significantly reducing the time required for prospective identification of potential clinical study participants. ClinXus therefore provides the necessary patient and expertise base to ensure rapid identification through electronic medical records (EMR's) and adequate powering for a clinical research study.

ClinXus will continue to expand alliances and relationships that strengthen its offering related to biomarker driven clinical research and trial design. This includes establishing partnerships with study sponsors and key collaborators to further develop the required infrastructure and meet the demands of accelerated drug development. ClinXus is committed to innovating and streamlining study design and incorporating clinical and molecular end points that go beyond the current standard practice. For additional information please contact:

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