

### WHO WE ARE

CREA-N is a Clinical Investigator Site Network committed to providing oversight and a range of site management services for the successful conduct of clinical trials.

We offer quality clinical research services across the lifecycle of a trial ensuring optimal use of resources. By collaboratively working with a network of private healthcare facilities, we have created a platform that supports the development of evidence-based medicine in response to communities' unmet medical needs. We strive to offer above industry standards site management services through our network of investigators, trial managers, and study coordinators dedicated to efficiently execute studies across multiple therapeutic areas.

## **OUR MISSION**

To make clinical trials accessible to patients traversing socioeconomic, geographical, and cultural boundaries.

To continue expanding our network by developing strategic long-term collaboration with sites across Africa.



#### **OUR SERVICES**

#### Our services include:

- · Regulatory and start-up management
- Site contract, budget, expense management
- · GCP training and documentation review
- Subject recruitment and retention management
- · Study management
- · Quality Control
- · Participant safety oversight
- · Audit and Inspection readiness
- · Document storage and archiving
- · Pharmacovigilance and Safety Surveillance
- Clinical Trial Logistics & supply management

# Other services provided by a team of qualified vendors include:

- · Accredited central laboratories
- · Phase I units
- · Insurance brokers (Indemnities)
- Event managers (Accommodation and Investigators' Meetings)



#### **CREA-N Clinical Investigator Site Network Models:**

- 1. Our trained trial coordinators and site managers are equipped with the knowledge of coordinating projects, overseeing quality programs, and managing the accounting for network sites according to set standard operating procedures.
- 2. We conduct our services through the affiliated research sites that are members of our network. These sites function independently from CREA-N for day-to-day management and they staff their own coordinators and site managers. Their quality standards are checked against CREA-N's guidelines and international operating procedures.

#### **Clinical Trials Support Services**

As an African-based investigator site network, we guarantee our clients quality trials that meet both local and international standards. Our clear understanding of the African clinical trial landscape equips us for appropriate planning and development of sound strategies applicable to local country realities and contexts.

We guarantee our clients streamlined regulatory and ethical submissions to avoid delays and minimise timelines for study start-up.

At CREA-N, we provide structured training to our network of site management associates, clinical site managers, and clinical research coordinators among other site staff ensuring that they are compliant with Good Clinical Practice (GCP) guidelines, applicable local ethics and regulatory standards. We have comprehensive and detailed Standard Operating Procedures (SOPs) to guide and train all the staff into consistently meeting the global standards.

#### Participant Recruitment

Our participant recruitment approach combines referrals from a network of private medical facilities, general practitioners, collaboration with patient involvement groups and a CREA-N database to reach a diverse pool of potential study participants and ultimately accelerate recruitment timelines. Using deidentified records from its network of primary healthcare facilities, we perform pre-screening and precision matching of trial participants to specific study protocols covering a broad range of therapeutic areas.

#### Patient and Public Involvement

At CREA-N, we recognise that the foundation of a clinical trial is the willingness of participants to invest their time and effort for a study. By working collaboratively with patients, we leverage their perspectives to prioritise patients' needs from study design to knowledge dissemination. We can therefore optimise study feasibility, facilitate successful recruitment and retention of study participants through patient-centeredness.







#### **Quality Assurance**

At CREA-N, we have established quality assurance and quality control systems to fully satisfy our stakeholders needs and expectations. Our network of site staff is equipped with the understanding of QA policies and SOPs to ensure that trials are compliant and data is gathered, recorded and reported in accordance with the protocols, GCP guidelines and the applicable regulatory requirements.

#### Clinical Trial Logistics & Supply Management

CREA-N has efficient clinical trial logistics and supply processes led and supported by experienced professionals, who make sure your materials are where you need them, when you need them.

A key factor in study success is the management of supplies, which begins with the creation of a supply strategy and ends with the return and destruction of the supplies. We assist in obtaining import licenses and customs clearance of clinical supplies and also coordinate with third-party vendors and technical systems, to verify that study drugs are available in sufficient quantity and quality at the various stages of clinical distribution. We provide full traceability of this process to avoid information gaps and reduce risks such as the out of stock or expiration of the supplies.

By working with us, we guarantee the success of your study by providing comprehensive, timely and cost-effective clinical supply chain services.

#### Pharmacovigilance and Safety Surveillance

CREA-N's pharmacovigilance associates can assist you to develop, negotiate, and implement Risk Management plans which will ensure that patient safety is at the forefront of all clinical trial phases. This also includes the later stages once a therapeutic receives regulatory approval, during the post-approval and for the entire duration the product is on the market. CREA-N is committed to provide monitoring services that will ensure the long-term continual safety of the patients.







#### Benefits of the Clinical Research Health Network - CREA-N:

- 1. Rapid patient recruitment as CREA-N reduces the time taken during the recruitment process.
- 2. Patient compliance throughout the study is better due to efficient follow up by CREA-N associates deployed at clinical research sites.
- 3. Significant cost and time saving advantages for the sponsors and Clinical Research Organisations conducting a multi-centric clinical trial.
- 4. Accurate, detailed and consistent documentation throughout all stages of the clinical trial.
- 5. A reliable network of associates with supporting relationships that extends to sponsors, CROs and other healthcare professionals.
- 6. Streamlined study start-ups which help in reducing the trial timelines.
- 7. CREA-N is committed to actively involving patients and the public in our research, which is key to improving recruitment and retention rates in health and social care research.

#### Clinical Research Health Network

Taking clinical trials to the next level while maintaining exceptional quality standards across all site networks.



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