Clinitude

CIS²

A New Era in Site Support: The CIS² Approach by Clinitude

Clinitude Integrated Site Support

Introduction

Clinical trial sites are essential for successful studies. Sponsors carefully evaluate them, considering expertise, data quality, and recruitment abilities. Patient involvement is crucial too. While innovations in clinical research improve trial management and data quality, their impact on trial sites is often neglected. This leads to challenges for trial sites in meeting the growing demands from stakeholders compared to other participants benefiting from these advancements.

If we pay more attention to the concerns of our trial sites, we'll better understand their challenges. A trial coordinator's job goes beyond a desk, involving tasks like patient recruitment, compliance, and training. While we have methods and technologies for managing trials, it's time to prioritize supporting trial sites. Clinitude Integrated Site Support Services can help simplify your study team's workflow, making it as easy as riding a bike.

ABOUT US

The Clinitude Integrated Site Support (CIS²) was launched in 2020 and successfully piloted at a prominent research center in Belgium. The initiative coincided with the approval of multiple vaccine studies during the challenging times of the COVID-19 pandemic. Facing the urgency to process and prepare data swiftly, the CIS² team significantly alleviated the administrative burden on the research center. As a result, the center emerged as the leading global recruiter for vaccine trials, achieving outstanding results with high-quality data.

40%

increase in study coordinator's availability for direct patient care

PHASE III STUDY

1,250

PATIENTS

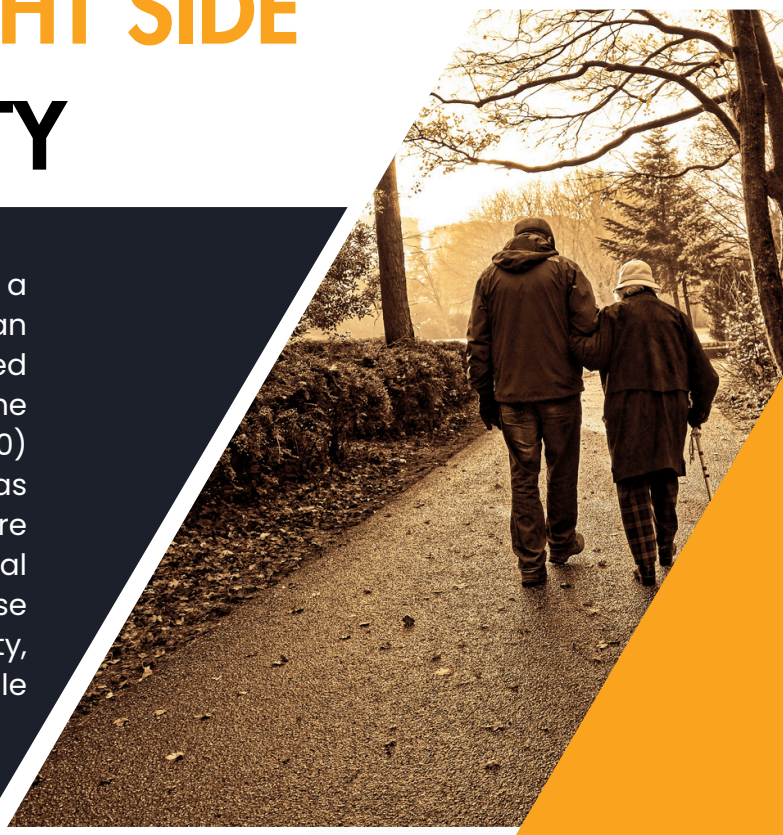
>300

essential documents handled

300

queries resolved per day

FINDING THE BRIGHT SIDE OF ADVERSITY



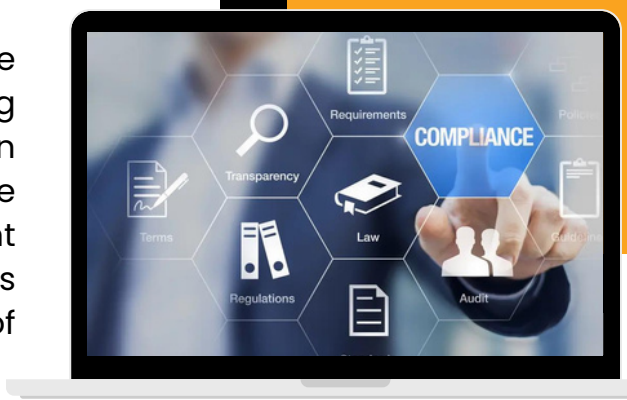
When a site is chosen to participate in a trial with a complex protocol, investigators often see it as an opportunity to contribute to an advanced treatment for improved quality of life. However, the clinical trial coordinator currently handling ten (10) different kinds of such protocols would not see it as a walk in the **"PAAIRC"**. These responsibilities are not an imposition but rather a fundamental component of a clinical trial. The challenges arise from the numerous tasks in each activity, compounded by insufficient resources to handle them efficiently.

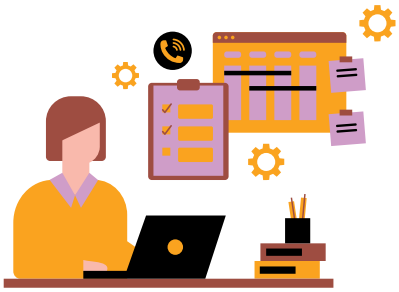
"Like a walk in the P.A.A.I.R.C."

- **P** — **Protocol Compliance**
- **A** — **Administrative Activities**
- **A** — **Assessments for Patient Visits and Follow-Up**
- **I** — **Initiation & Start-up**
- **R** — **Recruitment and Patient Retention**
- **C** — **Contracts and Budget Negotiation**

P Protocol Compliance

The CIS² team ensures clinical trial sites follow the protocol by providing assistance and conducting data quality checks. They act as a bridge between the trial's protocol and site staff, facilitating effective communication, maintaining data integrity, patient safety, and adherence to regulatory standards, thus contributing significantly to the overall success of the clinical trial.





Administrative Activities A

As a study coordinator, you are responsible for various administrative tasks alongside your study duties, including:

- Ensure timely sign-off on training logs, CVs, and safety reports from investigators and study team members.
- Collect required study documents, maintain the Investigator Site File (ISF), and schedule new visits and follow-ups, if needed.
- Attend to CRA onsite visits, participate in study teleconferences , and conduct remote SDV.
- Gather source documentation after patient visits, perform data entry in the EDC, and address queries promptly, adhering to tight timelines.
- Coordinate collection of patient-related outcome (PRO) questionnaires, ensuring timely completion, and following up on non-compliance.

A Assessments for Patient Visits and Follow-up

Tracking each subject's assessments throughout a trial is challenging. The CIS² team significantly aids in data entry, data quality checks in the eCRF, and creating study worksheets and materials for patient visits, ensuring assessments align with the study protocol. Their support ensures that patient visits and follow-ups run smoothly, enabling the sites to provide efficient and high-quality care while adhering to the study's requirements.

Initiation & Start-up

I

Site support services are vital for initiating clinical trials, ensuring regulatory compliance, and streamlining the trial launch process. They assist in developing scientifically sound and ethical protocols, securing regulatory approval, conducting site feasibility assessments, and providing training on protocol adherence. and regulatory appliance. They also coordinate start-up activities, assist with project management, establish data management systems, monitor processes, and contribute to patient recruitment and retention strategies. In summary, site support services facilitate collaboration among sponsors, Contract Research Organizations (CROs), and research sites, ensuring ethical trial conduct, regulatory adherence, and a focus on data quality and patient safety.

R

Recruitment & Patient Retention

Site enrollment and subject retention not only measure site performance but also impact the trial site's budget. Managing patient recruitment and retention is challenging, requiring resources for follow-up and patient retention. The CIS² Team makes a substantial contribution to recruitment and patient retention in clinical trials. They identify and implement effective recruitment strategies, and suggest ways to maintain participant engagement, thus enhancing overall trial success and efficiency, and ensuring the continuity of valuable research efforts.

Contracts & Budget Negotiations

C

Often the most time-consuming aspect of study start-up. Depending on the specific study and the involved departments, this stage can extend for months, involving numerous iterations between the site and sponsor. On top of this, trial budgets are almost also inflexible that the sites are left to adjust allocations in accordance with the agreed trial agreement. This further leads to an imbalance between actual trial activities versus the study team allocation.

The CIS² team also play a crucial role in effectively managing contract and budget negotiations for sites by thoroughly reviewing and summarizing clinical trial contract terms and assisting in budget negotiations, streamlining financial aspects and securing appropriate funding and resources.

CIS² CORE SERVICES

The Site Support Services is a separate part of Clinitude designed to help trial sites manage studies more effectively, especially when dealing with complex studies. The CIS² team is here to support the site staff by handling tasks that can be dealt with remotely, without disrupting the sites' day-to-day activities. Working behind the scenes, the team takes care of the administrative burden to improve the site's overall performance and streamline procedures. The CIS² team is integrated into the study team, undergoes site-specific training, and functions based on the site's support requirements. Among the services and potential benefits of integrating the CIS² team in your study sites are the following:

STUDY START-UP SUPPORT

- Facilitate and ensure timely completion of feasibility questionnaires.
- Responsible for assessing site team availability onsite for site selection visits and/or initiation visits.
- Full administrative support in the:
  - preparation, management and execution of submission packages to corresponding EC's, IRB's and/or RA's or other boards where approval/feedback is needed, including all necessary notification and safety reporting.
  - Preparation, collection and provision of all essential documents for the Study CRO and/or Sponsor and ensure all documents are up to date in accordance with the regulation.
- Review and ensure all necessary site trainings are in order and is up to date.
- Supporting in planning resources e.g., additional nurses are needed in high recruitment clinical studies.

PATIENT R&R (RECRUITMENT AND RETENTION) SERVICES

- Reach out to potential patients in the patient pool in case of new studies and support in the pre-screening activities.
- Managing patient visits + (re-)scheduling according to clinical study protocol (includes planning of DCT visits with vendors)
- Scheduling patient visits with other departments e.g., when radiology is involved or other technical activities within the study protocol.
- Reaching out to patient for reminders on their treatment and follow-up schedules
- Calling patient during Safety follow-ups

PATIENT PARTNER SOLUTIONS

- Providing ²4/7 helpdesk/technical support for e-PRO, wearable or home-use medical devices or equipment.
- Addressing patient's questions regarding visit schedules, assessments, and basic protocol information.

TRIAL MANAGEMENT SUPPORT

GENERAL ADMINISTRATIVE AND LOGISTIC SUPPORT

- Management of electronic patient medical records
- Encoding of standard of care in health insurance databases, as applicable
- Redaction of discharge summary for subjects GP
- Support in training activities for site study team
- Mailing list support
- Management of study binders including regular quality check
- Attend and provide summary report of sponsor/CRO calls.
- Management of study supplies
- Assist in the planning and plotting of monitoring visits
- Support in financial activities related to clinical study site payments
- Organize / support Archiving activities

E-PRO MANAGEMENT

- Helpdesk support for patients to handle all their questions (patient e-diaries or questionnaires).
- Monitoring, managing, escalating safety data in ePRO devices/data.
- Organize delivery - pick-up return of e-PRO devices including coordination with Vendors.
- Perform remote visits (if possible) and/or Remote interview-based completion of patient questionnaires (in case of phone visit or remote visits of patients)

STUDY DATA HANDLING ACTIVITIES

- Set-up E-CRF – Database for investigator initiated / academic trials
- Set-up study documents and worksheets
- Handling and responding all queries
- Developing and/or supporting in the development of study specific source documents
- Data entry in eCRF (with an integrated quality control)
- Extra review/monitoring of critical data and follow-up of critical data (endpoints, safety)
- Coordination or managing protocol deviations, safety reports and other critical data, including follow-up
- Compilation and submission endpoint reports as applicable
- Compilation and submission of SAE reports including FU reports
- Collection of signatures for study documents

QUALITY SUPPORT

- Support the clinical research coordinator and the PI in the oversight activities
- Write or support in writing/updating/maintaining your institutional SOPs
- Ensuring updates of research staff resumés, training records and other employee records
- Support in incident management
- Support in CAPA resolution

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CIS²

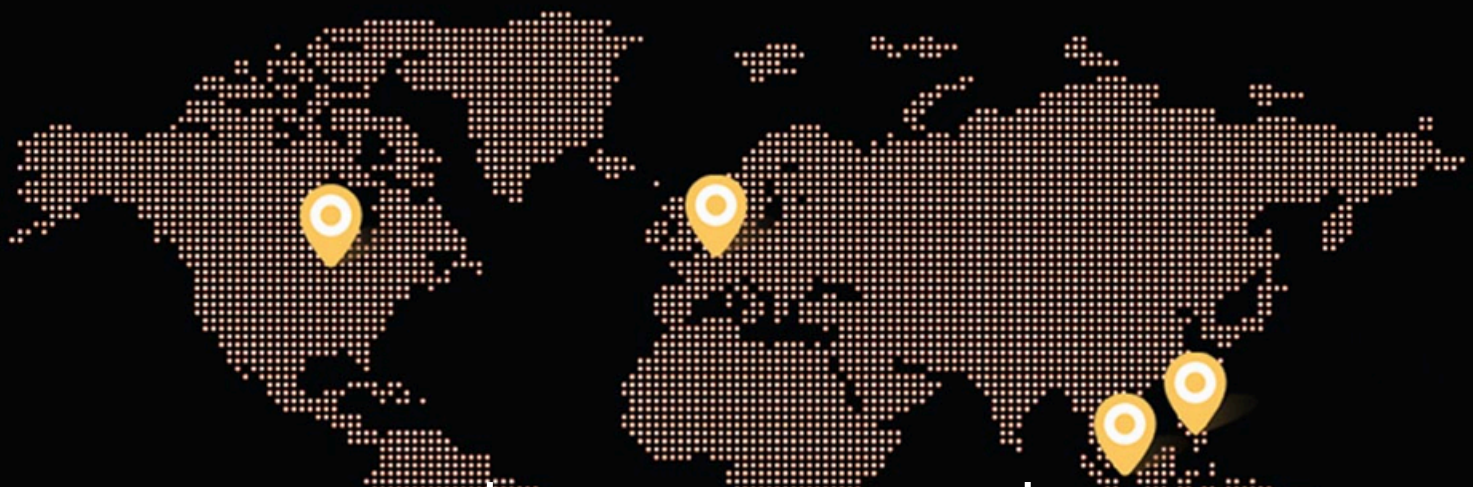
Unlocking Efficiency: How CIS² Services as Site Support Solutions Transform Clinical Trials

Site support solutions play a crucial role in clinical trials by assisting site staff and reducing the burden of administrative tasks. These innovative tools revolutionize trial processes, allowing research teams to prioritize advancing medical knowledge and enhancing patient outcomes. By streamlining complex administrative aspects, such as electronic data capture systems and automated scheduling, these solutions enable site staff to dedicate more time to patient care and scientific work, optimizing overall trial operations.

Real-time access to data enables quick decision-making, improving trial completion rates. The meticulous coordination by the CIS² team ensures data privacy and compliance with regulations, fostering trust among participants.

In summary, the CIS2 team not only eases the administrative burden on site staff but also paves the way for more successful, efficient, and patient-centric clinical trials. As we continue to harness the power of technology and innovation in the world of healthcare, these solutions stand as crucial assets in our quest to improve global health and well-being.

Contact Us!



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"Don't settle for ordinary. Choose extraordinary. It's always a choice."

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