Prodia the CRO

YOUR RELIABLE PARTNER IN CLINICAL STUDIES

COMPANY PROFILE

The first Indonesian CRO which provides
excellent and comprehensive services in Clinical Trials

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Prodia the CRO

YOUR RELIABLE PARTNER IN CLINICAL STUDIES

CORPORATE VALUES

Our corporate values are:

1

Customer Oriented

Always ready to serve sincerely, dedicatedly, honestly to our customers.

2

Quality Oriented

Quality as a way of life is paramount.

3

Balance

Always to endeavor balance between elements, always pursuing satisfaction for all parties.

4

"The spirit of Prodia"

Spirit to do the best, to achieve success, to improve oneself and spirit to make dreams come true.

5

Integrity

Committing to maintain integrity and put it on interpersonal relationship.

6

Change

Open for changes.

VISION & MISSION

Our Vision

Becoming the leader of CRO and the most reliable partner in providing drug development service.

Our Mission

Helping our clients bring their new products to market at the earliest through a combination of integrated and wide range of services.

FULL SUPPORT FOR CLINICAL TRIAL

Prodia the CRO is a Contract Research Organization (CRO) based in Indonesia which provides GCP-based Clinical Trial supports through our integrated and wide range of services.

Prodia the CRO has accumulated many experiences providing services to local as well as multinational companies with commitment to reach quality through qualified and dedicated resources. It provides customers in GCP trials with competitive cost, firm timeliness, high compliance to ICH-GCP guidelines.

ROLE AND RESPONSIBILITIES IN CLINICAL TRIAL

REGULATORY AUTHORITIES

Authorization

Sponsor

Prodia the CRO
YOUR RELIABLE PARTNER IN CLINICAL STUDIES

- Feasibility Study
- Trial Sites & Investigator Selection
- Subject Recruitment
- Study Document Development
- Clinical Trial Submission
- Study Coordinator
- Good Clinical Practice (GCP) Training
- Investigational Product (IP) Management
- Clinical Study Monitoring
- Biometrics
- Quality Assurance and Audit
- Bioavailability & Bioequivalence Study

Central Laboratory / Prodia Clinical Lab

LABORATORIUM KLINIK Prodia
Untuk Diagnosa Lebih Baik
Dengan Layanan Sepenuh Hati

- Facilities
- Personnel
- Certification
- Quality

Investigators

- Qualified
- Trained team
- Acceptance of monitoring, audit & inspection
- Proper storage of logistics
- Etc.

Ethics Committee (IRB)

- Independent
- Composition
- Written approval
- Documented decision

Subjects / Patients

INTEGRATED AND COMPREHENSIVE SERVICES

Study Document Development

Prodia the CRO supports a clinical trial for the development of the necessary documents for capturing and documenting all aspects of a clinical trial. Prodia the CRO can meet custom development needs when establishing client documents which is specific for a clinical trial.

Clinical Trial Submission

Approval process from Ethics Committee and Regulatory Authority somehow varies among countries and become critical point in clinical trial. The presence of a local CRO which understands the local regulations become indispensable.

Clinical Study Monitoring

Without a good study monitoring, the best preparation will not produce a high quality study. Your project will be handled by GCP-certified CRAs with specialized skills, knowledge, abilities and experiences.

Investigational Product (IP) Management

The availability and continuity of IP are the important things to be assured during a conduct of clinical trial. Prodia the CRO will be involved in managing and assuring the IP stock, storage and deliverance to the support of a clinical trial site.

Data Management & Analysis

Biometrics services by Prodia the CRO will provide you with well-trained and detail-oriented staffs, continuous monitoring, audit tracking, accurate clinical statistic, well clinical interpretation and integrated logic clinical summaries.

Medical Writing

Prodia CRO offers extensive medical writing services for your study such as: study synopsis, protocols and amendments, clinical study reports, abstract, and or manuscript publications. We work closely with competent medical writers with sufficient expertise in this field and highly adapt to your needs. Writing your documents will certainly be structured according to procedures and comply with the ICH-GCP guidelines.

Quality Assurance and Audit

Prodia the CRO has certified auditors who will complete your needs in auditing procedures to ensure that a site is comply with the protocol in conducting a study. The Quality Assurance and Audit process will be in accordance with the regulatory audit requirements.

Prodia Central Laboratory

Prodia Central Laboratory support clinical trials by collecting up to analyzing the specimens, preparing the specimen kits. All study procedures are conducted in compliance with ISO 9001 and ISO 15189. Prodia Central Laboratory is the first and the only CAP-accredited laboratory in Indonesia.

Clinical Trial Consulting

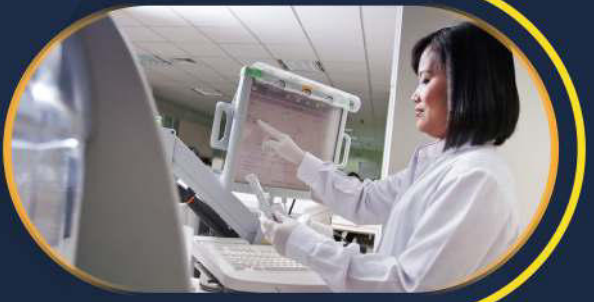
Prodia the CRO has more than 10 years experience in conducting clinical trials. Prodia the CRO as your reliable partners, provide comprehensive counseling about the system and essential aspects of clinical trial in Indonesia. We are more than welcome to help our client encounter any regulatory or technical challenges in the clinical trial.

Product Registration Consulting

Registering product to the Regulatory Authority is a crucial step and somewhat challenging. Prodia the CRO is your capable partner who will provide insight and information regarding product registration for both drugs and medical devices to speed up launching your products to the market.

Bioavailability & Bioequivalence Study

Prodia the CRO has alliances with BA/BE laboratories to provide one stop services



CENTRAL LABORATORY SERVICE

(Supported by Prodia Clinical Laboratory)

EXPERIENCED, ADVANCED TECHNOLOGY, NATIONWIDE NETWORKS:

Being one of the largest and the best clinical laboratories since 1973, Prodia clinical laboratory serves many trials through its more than 250 outlets in Indonesia, provides many services in laboratory testing including central laboratory services.

Our evidence of commitment in quality as a central laboratory in Indonesia for global service (clinical trial worldwide):

- The first and the only clinical laboratory in Indonesia accredited for College of American Pathologists (CAP), an internationally recognized accreditation that is accepted as the gold standard for quality.
- The first clinical laboratory in Indonesia certified with ISO 9001 and NGSP Level 1
- Accredited for ISO 15189
- Member of Clinical and Laboratory Standards Institute-CLSI
- Extensive internal quality control procedures (performed by Technical Quality Assurance Unit)
- Extensive external quality control procedures (RCPA Quality Assurance Programs - Australasia, EQAS - Bicrad, PNPME - Dept. of Health Republic of Indonesia)
- Comprehensive quality assurance programs and compliance to GLP procedures
- EQAS Biored: "Best 100 performance lab worldwide" in quality assessment

CENTRAL LABORATORY SERVICE AND FACILITIES:

Prodia Branches

The Broadest Menu of Laboratory Tests:

Having a menu of more than 500 kinds of tests, from routine standard safety testing to esoteric testing.

Routine Tests:

- Hematology
- Coagulation
- Clinical Chemistry
- Urine and Feces
- Molecular
- Osteoporosis
- Others tests

Specialized Tests:

- Tumor Marker
- Endocrinology
- Microbiology
- CSF analysis
- Trace Element
- Biomolecular
- Personalized Medicine

Rapid Turn Around Time

Prodia achieves extremely rapid turn around time by implementing the latest generation instruments with high throughput. Prodia is supported by integrated system through Laboratory Information System (LIS) and Laboratory Automation System (LAS)

Specimen storage

Prodia's repository services provide both long-term and short-term specimen storage under optimal conditions for specimen integrity. Prodia maintains specimen at -20°C and -80°C for bank serum, genomic DNA, PK samples, etc. The controlled storage environment has on-site backup system to overcome disruption of electrical service.

Flexible Logistics

Preparation, packaging and delivery of all supplies and materials necessary for specimens are managed within the laboratory. Having close cooperation with major courier service allows us to supply trial sites with sampling materials comply with current International Air Transport Regulations (IATA compliance). Materials can either be provided as visit-specific kits or generic supplies, yet remains convenient and easy to use.

PRODIA THE SMO

Site Management Organization In Indonesia

Who is Prodia the SMO?

Prodia the SMO works to support sites and investigators in conducting qualified clinical trials. Prodia the SMO also provide wide range of services to fully support the development of trial site capacity.

Why choose Prodia the SMO?

- Established good network with hospitals and clinicians in Indonesia
- Continuous trial site capacity building on potential clinical trial sites
- Experienced in establishing and managing Clinical Research Supporting Unit (CRSU) by developing the procedures, facilities and other resources at the sites.
- Provision of committed and highly qualified site staff
- Database of experts trainers in clinical trial training
- Promote effective and efficient study conduct
- Commit to confidentiality and quality

Why SMO is Critical to Clinical Trial?

- Compliance to protocol, Good Clinical Practice (GCP) and other regulations.
- Limited time allocation of the investigators. Most Principal Investigators are Key Opinion Leader in their field. Hence, they are often extremely busy persons and therefore need support from a committed and qualified study staff to support the clinical trial.
- Difficulties in finding competent and committed staffs resulting in delay of recruitment and increase of clinical trial budget;
- Tortuous and time-consuming clinical trial process at the site;
- Limited knowledge on clinical trial, procedure and facilities at site resulting in long overdue paperwork, longer clinical trial application process and ineffective clinical trial conduct.

PRODIA THE SMO INTEGRATED SERVICES IN SUPPORTING CLINICAL TRIALS

Feasibility Study

Feasibility Study that conducted properly and accurately is one of the key factors to reach the most effective clinical trials. Prodia the CRO will help you to identify strategies to mitigate the costs and risks associated with the proposed trial.

Site and Investigator Selection

Selection and assessment of sites and investigators are indispensable for the trial to ensure their compliance with protocol, ICH-GCP, all applicable regulations and time constraint.

Development and Management of Clinical Research Supporting Unit (CRSU)

A success on clinical trial conduct requires a good site management system, procedure and sufficient facilities. Prodia the SMO provide full support in developing and managing the One-Gate-CRSU which in correspondence to Joint Committee International (JCI) & KARS (Hospital Accreditation Committee).

PRODIA THE SMO INTEGRATED SERVICES IN SUPPORTING CLINICAL TRIALS

Provision of Site Staff

A qualified personnel measured by education, training and experiences is one of the key success in the conduct of clinical trial. Prodia the SMO may assist in the provision of committed and qualified Site/Study Staff to ensure the day-to-day conduct of clinical trial running according to GCP.

Trainings

All personnel involved in clinical trial must be qualified by training. Trainings offered are Good Clinical Practice (GCP), Protocol Development, Manuscript Writing and Study Coordinator training. Prodia the SMO may help you in organizing and providing these trainings for all the study personnel before the start of clinical trial.

Subject Recruitment

Subjects is the center point of clinical trial. Therefore, meeting the recruitment target within the timeline is paramount to ensure the reliability of clinical trial result. Prodia the SMO provide full support in ensuring the recruitment process meets the targeted number of subject and timeline.

ADVANTAGES

COMMITMENTS TO QUALITY AND CONFIDENTIALITY

Quality and integrity is our philosophy.

CUSTOMER-ORIENTED SERVICES AT COMPETITIVE COST

Offering high quality services at competitive and reasonable cost.

EXPERIENCES WITH LOCAL, REGIONAL & INTERNATIONAL COMPANIES

Experiences in Clinical Trial Study / Central Laboratory Services with Pharmaceutical / Biotech Company or other CROs, both local and regional / international are evidence of qualification.

ESTABLISHED NETWORKING WITH HOSPITAL AND INVESTIGATORS

Involvement in many scientific researches in various disciplines. As such an elaborate database on potential investigators and their interests are available.

EFFECTIVE PROJECT MANAGEMENT WITH GUARANTEED QUALITY, SPECIFIC TIMELINESS AND REPORTS

Ensuring and keeping the trial on track.

EXCELLENT DEDICATED TEAMWORK

- ☑ Experienced and qualified staff complying with ICH-GCP guidelines requirements.
- ☑ Assistance in the implementation of regulatory and ICH-GCP requirements.

PRODIA CENTRAL LABORATORY EXPERTISE IN LOCAL, REGIONAL & INTERNATIONAL TRIALS SINCE 1973

PARTNERING WITH US

Establishing alliance with local CRO may seem more realistic and provide many advantages. Business alliance with local CRO creates global networks, where sponsor have the flexibility to pick and choose the regions or services they desire.

Local CRO's has knowledge of regulatory and guidelines, has strong relationship with investigator and physicians, established networks with local clinical research centres, and supported by sufficient resources (including workforce and financial).

Prodia the CRO offers a wide range of CRO services which is supported by plenty of resources, including CRA, SOPs, network and databases. Its clients are spread among continents, not only pharmaceut cal/biotechnologist companies, but also other international CRO's.

Clinical trials outsourced to Prodia the CRO may free you from the burden in conducting trials.
Services are tailored to meet your needs. "Partnering With Us" bring success to your trial.

CLINICAL TRIALS IN INDONESIA

Unity In Diversity

Indonesia as a large country located in South East Asia with population of around 268 millions is very attractive and promising for pharmaceutical/biotechnologist companies to conducts clinical trials. Indonesia is the fourth world's most populous country. Diversity of our ethnic and the abundance of subjects who have never received medication or any previous treatments (naive patients) are ideal for many of your studies. Beside that, Indonesia has also a high compliance to Good Clinical Practice standard in all clinical trials supportive teams.

The large pool of potential research participants and the lowercost of research provide opportunities to accelerate recruitment and shorten the timeliness.

Conducting Clinical Trial In Indonesia:

- High Percentage of Specialized Patient (Diabetes, Cardiovascular, Metabolic, Pediatric, Geriatic, Osteoporosis, Infection, etc)
- Potential Market for Approved Drug Usage
- High Recruitment Rates
- Support of Central Laboratory: Prodia Clinical Laboratory
- Competitive Cost
- High Percentage of Drug-naive Patient Population
- Comply with ICH - GCP
- Ethnic Diversity
- High Population
- Availablity of CRO: Prodia the CRO
- Full Support from Indonesian Indonesian Regulatory Authority

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ISO 9001
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