Tasks of Study Coordinator

SCs have significant roles in the following clinical study activities including:

- Working with the institutional official in contract negotiations
- Developing a detailed cost analysis, negotiating the budget with the Sponsor (i.e. pharmaceutical company or granting agency)
- Review and familiarize themselves and other staff with the protocol
- Provide prospective investigators with copy of protocol
- Prepare for and attend IRB meetings
- Participate in Investigators meetings
- Schedule on site visits with sponsor
- Setup study files and prepare study records, forms, and letters
- Enroll subjects
- Oversee study activities
- Oversee secure storage of investigational product
- Adverse event and Serious Adverse Event Reporting
- Maintain accurate and complete records
- Close the study and store study records
- etc.

The Advantage of collaborating with Prodia the SMO

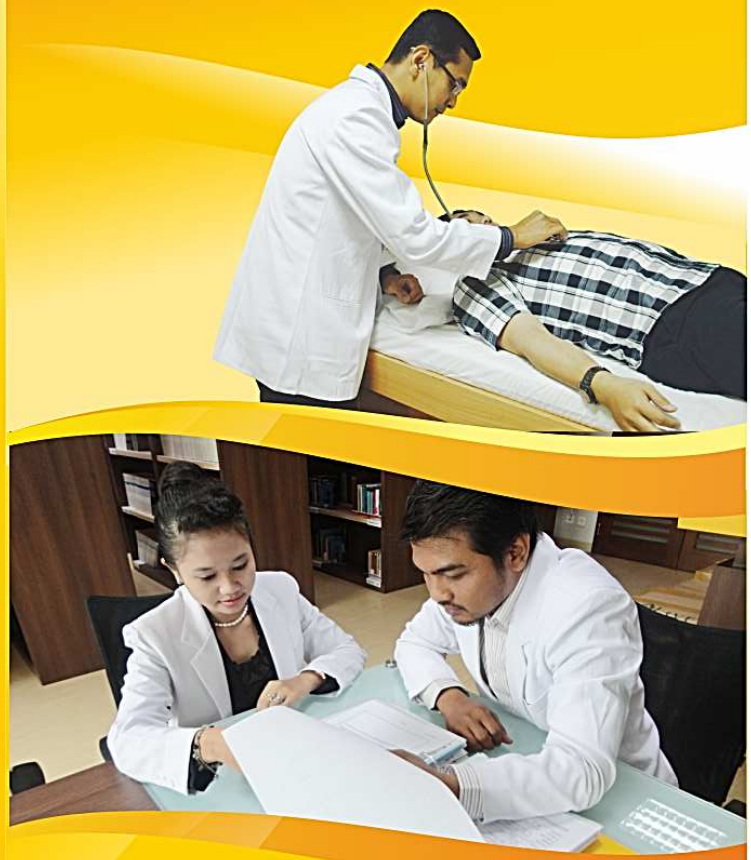
- Prodia Site Management Organization (SMO) will support to provide **qualified Study Coordinators** who have educational background in health sciences, well-trained, GCP certified, good documentation practice, good verbal and written communication, good organization skill, can manage teamwork with peers in order to provide high quality clinical trial project implementation according to clinical trial protocol , GCP standard and applicable regulations
- Prodia SMO also will support to maintain the same standard for multi-centre trial through our experiences and well trained Study Coordinators.

Competent Study Coordinators can increase Quality of Study

2014 FROST & SULLIVAN INDONESIA CONTRACT RESEARCH ORGANIZATION OF THE YEAR

Prodia the SMO

STUDY COORDINATOR



Filling the Gap toward High Quality Studies

Operating Constraints at Trial Sites

Clinical research is a complicated undertaking, with multiple partners. Complex relationships exist between the sponsor and each individual study site.

Principal Investigators (PIs) are the persons responsible for the trials but some challenges they face are:

- Time allocation of Investigators. Most PIs are Key Opinion Leaders in the field, their time occupied with clinical, academic, managerial tasks other than clinical research.
- No / limited dedicated staff for clinical trials
- 'Favourite Investigator' issue (causing limited choice of PIs)
- Low interest for research (limited choice of investigators, low number of GCP certificate holders)

Impacts of Sites Limitations

Low compliance to protocol, quality and timeliness, causing:

- Prolonged subject recruitment time
- Insufficient number of trial subjects
- Dragged trial period
- Expenditure increase

How to Improve Quality of Study?

Support PIs and Investigators
with
Study Coordinators / Clinical Research Coordinators

How Study Coordinators can improve the Quality of Studies?

Study Coordinators (SCs) are the main liaison between the investigators and the study subjects, and between the site and the sponsor; they also handle a great deal of the study activity at clinical sites. The SC is the person in charge of managing the individual study site.

The SC supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study. They help assess study feasibility: handle, prepare, and track document submission; and manage the day-to-day logistics of everything.

Although the PI is responsible for the conduct of the trial, the **SC is the heart and soul of the research study** and ultimately, it is the SC who carries forward the research goals, thereby **playing a significant role in the success of the research study**.

PI and SC need to work well with a variety of departments in site to complete the study protocol successfully (see figure).

On-site relationship