



Contract Research Opportunities in SA Family Practice

Managing your practice as a study site

Managing a practice as a study site is not always easy. Investigators have to be very well-organised and they may have to set aside specific days or time slots for research. They have to plan well and may also have to employ dedicated and trained, temporary, staff to assist them with the extra work-load. There is a different pace (mostly more efficient) when seeing trial patients as opposed to non-trial patients. In fact, most doctors who frequently engage in contract research prefer seeing trial patients because, to them, it is practising medicine like in the "old days" - no managed healthcare, more time to see patients, being on the edge of medical development and better and quicker payment.

However, the "slower" and more rewarding research practice may be more demanding at times and may interfere with the "other side" of your practice where you are forced to see as many patients as possible. Recruiting and retaining patients are also time-consuming activities and require a good system where patients can be interviewed and screened immediately at their first visit or contact. There may, for instance, be more patients responding to the local trial adverts than you expected and you may need assistance to interview and screen them immediately. If recruitment is slower, the current database may need to be screened for possible trial candidates. Furthermore, patient compliance on trial medication needs to be pro-actively monitored. Patients often need to be reassured, motivated and reminded of their follow-up visits, especially as they may not feel ill and following the protocol may be the only reason for the visit. They may also have more and specific queries - they may want to report serious adverse effects, want to know if they may take certain medication for other illnesses concurrently, or they may have queries on how to take trial medicines or how to complete diaries.

Service delivery is, therefore, very important to successfully recruit and retain patients for a trial and all practices are not necessarily geared to handle these demands. Employing a study site co-ordinator (SSC) can be of invaluable

assistance to clinicians, enabling them to recruit more patients faster, retain patients and to ensure protocol compliance. Moreover, they ensure that the paper work and correspondence with regulatory bodies is completed and completely correct. This article outlines the services that can be rendered by Site Management Services and their SSCs.

Which services are rendered by Site Management Services?

1. Provision of trained and experienced study co-ordinators on a contract basis to investigators.
2. Provision of payment to independent SSCs or the site's own SSC on behalf of a site.
3. Provision of assistance with site set-up and site organisation.
4. Provision of administrative assistance as well as nursing assistance.
5. Provision of unblinded administrators of medication.
6. Training of site study staff in clinical trial methodology - either in groups or one to one.
7. Recruitment assistance.
8. Regulatory assistance.

Study site co-ordinators

Study site co-ordinators (SSCs) are provided to support investigators to meet their recruitment targets and collect high quality data. Being dedicated to the study, they will assist in its efficient running. SSCs who can speak native languages will be able to assist with informed consent, identify specific protocol requirements, or refer questions to the clinical monitors as necessary. SSCs are all fluent in English and are able to provide assistance in all aspects of study communication.

How can SSCs help with recruitment?

The patients can already be identified while waiting for ethics committee approval. Therefore, when the study is ready to start, one should be in a position to immediately start the screening and recruitment processes.

The SSC can identify a pool of potential patients who meet the inclusion criteria from medical records. When

the study is ready to start, the SSC can arrange bookings for the identified patients to attend the screening visit. If investigators are considering recruitment from colleagues in the local hospital or from neighbouring hospitals, the SSC can help with liaison.

The unavailability of study staff can often restrict the number of patients or rate of recruitment. By providing an additional dedicated member to the study team, patient recruitment can be maximised.

Other benefits of using SSCs

The investigator can decide which duties will be delegated to the study site co-ordinator, giving him/her complete control of the integrity of the data generated by the site. The SSC can relieve the investigator of some routine and administrative functions allowing the investigator more time with the patient.

The SSC can assist with CRF completion, making corrections and reducing the number of queries generated by the site. The assistance of the SSC for routine corrections and queries will significantly reduce the time that the investigator needs to spend on these tasks. The SSC can also act as a contact person for the clinical monitor and assist with the monitoring visit, allowing the investigator's participation in the monitoring process to be more focused. If the SSC is a qualified registered nurse, duties like phlebotomy and administration of intravenous medication, ECGs, blood pressure and lung function tests can also be delegated.

Investigator responsibilities

For the duration of the study, the study site co-ordinator is responsible to the principal investigator (PI) at the site, working alongside other site clinical staff. The PI retains complete responsibility for all study data generated/documented and all activities undertaken by the Study Site Co-ordinator. In compliance with ICH/GCP, the investigator will be asked to sign an agreement indicating which duties have been assigned to the SSC. This can be modified if, during the study, the

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investigator identifies additional tasks that he/she wants to delegate.

What else can SSCs do?

Their work can include both clinical and administrative responsibilities, depending on the requirements of the study. Typically, a SSC has a clinical background and may be involved in:

- Pre-screening medical records for suitable patients.
- Ensuring that informed consent is done according to ICH GCP.
- Scheduling patient visits.
- Assisting in the running of study clinics.
- Conducting clinical measurements e.g. pulse, BP, venepuncture, urine analysis.
- Completion of case report forms, including transcription of data from source documents.
- Assisting with subject questionnaires.
- Assisting with drug dispensing / accountability.
- Ordering and maintenance of study supplies.
- Maintenance of investigator site file.
- Preparation for monitoring visits and facilitating monitoring visits.
- Non-clinical CRF corrections and data queries.
- Acting as a contact person between the investigator and the monitors.
- Documentation and reporting of adverse events and serious adverse events according to the correct procedure and within timelines.

COST to investigator

The cost to the investigator depends on study procedures and time spent on patient related activities, but is always discussed with the investigator on a study specific basis. It is currently calculated at an average of R100 per hour with most patient visits taking 2-3 hours maximum. The payment per hour may, however, be more, depending on the number and type of procedures the SSC needs to do in that period of time. The SSCs are paid per patient visit to ensure effectiveness and good time management.

In conclusion

SSCs prevent crisis management on site and relieve investigators of time-consuming administrative duties associated with clinical trials.

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Quintiles South Africa



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For more information on the course please contact:

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Sr Michelle Botha 012 671 6185 or michelle.botha@quintiles.com

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Do you need a study site coordinator for your practice?

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