

## An Insight into the role of an ACM Project Manager

Once you decide to entrust the central laboratory services required for your study to ACM Global Central Laboratory, our first priority is to assign you with your dedicated Project Manager, and Deputy Project Manager. Your dedicated Project Manager acts as a central point of contact for your operational team on the assigned as well as future studies. This offers the opportunity for the building of a positive relationship between ACM and you as a client, allowing for improved communication and consistency across trials moving forward. Your Project Manager's role is to work collaboratively with you to review your clinical protocol, define the objectives, set timeframes, and to achieve the deliverables within the desired period.

Our first aim is to jointly identify the central laboratory objectives for the study. This is achieved by compiling a service level agreement (Global Laboratory Specification Document – GLSD) which lays clear from the outset our services and the deliverables we will achieve over the course of your study. All internal set up is based on this document which, on agreement, is signed off by the ACM Project Manager, the Data Management and Quality Assurance Departments, as well as the sponsor in order to ensure consistent and accurate expectations in terms of services agreed to be undertaken.

Internal and external set up procedures which follow from finalising the GLSD and are complete prior to the first patient being recruited, include, but are not limited to, the following:

- Assistance with import/export licenses – We are able to provide assistance to you or your CRO with the application of import/export licenses should any of your sites be located within regions requiring such documentation.
- Investigator Manual design - This document is designed as a guide for the sites, and can be as simple or as detailed as you wish. It contains information such as contact details, public holidays, testing schedule, guidelines for completing requisition forms, sample collection instructions, shipping instructions, reference ranges and accreditation certificates.
- Kit design – Our aim with kit design is to make kits as easy as possible for the site staff to use. We customise the kits to the testing required at each visit, and also supply the additional items needed such as courier airwaybills and bags.
- Requisition (Request) Form design – This form allows us to record the patient and visit details for each sample which arrives in our laboratory. Again, we make this form as clear and concise as possible so that site staff find it easy to use. This helps to minimize data queries resulting from missing or discrepant information. It is printed on 3-part NCR paper to allow copies to be saved at site, and also sent with the sample shipment thus meeting shipping regulations as well as providing a complete and accurate data trail.
- Sourcing of non-routine supplies – Many protocols, in addition to testing for routine safety, call for more esoteric tests which can require various different reagents and sample processing procedures. We are able to source any non-routine supplies for you and can supply them directly to sites.
- Set up of courier documents – We use several different courier companies depending on the courier most suitable for your trial. We base the decision on a site's location, our experience with them on a regional level and in the case of dedicated couriers – cost!
- Communication – The key to a smoothly run trial is always good communication. Your dedicated Project Manager ensures that communication, both internally between our different departments, as well as externally with site staff, CROs teams and your operational team is always at an optimum.

Our Project Management team are available 24 hours a day/ 7 days a week. We are very aware that the clinical trials industry can work to extremely short deadlines with delays being costly. Our flexibility allows us to work to these deadlines, without compromising on quality and keeping your trial on schedule. Outside of office hours, an on-call Project Manager is always available, to ensure any questions or issues regarding your study are dealt with on a real time basis.