Considerations for Laboratory Point of Care Testing in Clinical Trials

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TRIAL SOLUTIONS

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Point of Care (POC) Testing is laboratory diagnostic testing performed near the study subject, avoiding the necessity to send samples for processing at a central laboratory. A POCT analyser or device can also be termed an IVD (In-Vitro Diagnostic) device. IVD devices can be defined as any medical device intended to be used alone, or in combination, in-vitro, for the examination of specimens (including blood, urine and body fluid) derived from the human body solely or principally for the purpose of providing information:

- **Physiological or pathological state**
- **Congenital abnormality**
- **Determining the safety and comparability with potential recipients**
- **Monitoring of therapeutic measures**

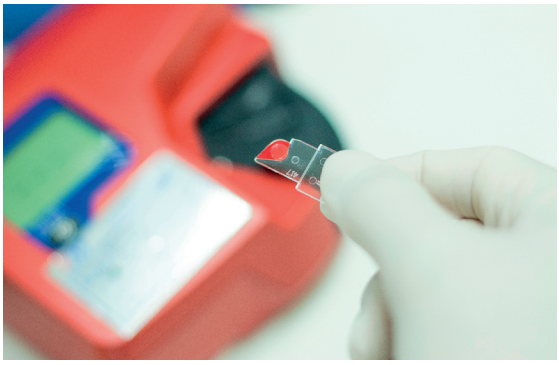
Applications for POC Testing

There are several areas in a Clinical Trial that POCT can prove useful. At each stage, POC testing, and POC testing in conjunction with centralised laboratories, has multiple benefits to relying on centralised laboratories alone. These benefits include speed, portability, convenience, ease of use, standardised results between sites, and small sample size with optimum sample quality.

Pre-Screening and Screening -
This can be varied and in some cases highly specific, for example, when specific assays are developed to aid in the selection criteria by identifying if the participant is a 'responder' or a 'non-responder'. POC analysers are capable of lowering screen failure rates and increasing the rate of enrolment while supporting study subject recruitment by eliminating additional visits.

Safety Testing -
This is usually done prior to the administration of the study drug to ensure the study subject is in an appropriate state of health to participate and to avoid any undue risk to them. This testing may cover a range of analytes and parameters such as:

- **CBC/FBC, with differential count**
- **Liver Function**
- **Basic Metabolic Panel**
- **Lipid Panel**
- **HBA1c**
- **Hemoglobin/Hematocrit**
- **Urinalysis**



Compliance with Study Subject Protocols -
This is usually when it needs to be established that other interfering factors are not present and that the study subject is compliant with the criteria required by the study protocol. Factors that may be tested for using POC testing devices include: Alcohol, Drugs of Abuse, Carbon Monoxide, Cotinine and Liver Function.

Testing Labile Analytes -
Some analytes are highly labile or have a short half life which in most cases means that transport to a central laboratory is not possible or practical. Some examples are CK MB, Troponin I and T, Pro BNP and coagulation screening tests. In such situations POC testing provides the only realistic solution.

Dose Change - Maintaining Therapeutic Range and Blinded Results -

Many drug development protocols require frequent checks of specific endpoint analyte (i.e. Glucose, PT/INR, Hemoglobin, or eGFR) during a site visit. In the course of the study, a dose change may be necessary. With POCT, that change can be made on the same visit and in some cases the change is made based on an encrypted POCT result. Recent publications of approved compounds present evidence of the studies employing POCT with this methodology.

Choice of Clinical Trial CSO

Once the decision has been made to employ the use of one or several POC devices in a trial it is important that these devices are obtained from an appropriate Contract Service Organisation with Clinical Trial POCT experience. Study Sponsors need a variety of services to accompany the POCT application to ensure the smooth running of the trial, maintenance of data and support for sites throughout the study period.

Considerations -

- **POCT devices differ in reportable ranges, specificity/sensitivity and correlation to lab instructions**
- **Some devices many need special arrangements for registration and use in specific countries**
- **All countries have different customs regulations, and some require you to know exactly what components make up the test system with particular reference to biological or genetically modified material**
- **Knowledge of expiry dates of test devices, calibrants and controls are vital throughout the whole supply process. The number of batches should be minimised, known and agreed in advance**
- **Device regulations in the US are based on the complexity of the test device. Some POCT devices can only be used in a setting with a lab licence**

Manufacturer Vs CSO -

POCT manufacturers' focus is on servicing and supporting only hospitals, clinics and physician offices on a routine basis and lack resources to address the special requirements of a Sponsor implementing a new drug development study.

The POCT manufacturers will usually deal with sales only and provide one type of equipment, limiting the selection and support for a study. Manufacturers do not typically rent POCT devices, a service that Sponsors often prefer for a short duration (less than 2 years) clinical trial phase. Choosing to work with a CSO can provide more options and customisation of the solution to meet the protocol requirements. A CSO can work with a variety of POCT manufactures to find the most appropriate product for its intended use. In addition, the CSO can deliver one central call centre along with rent for short or long term. Support capabilities of a CSO will provide appropriate support and include global training throughout the length of the trial.

Requirements of a Suitable CSO for POCT -

It is important that a CSO has appropriate scientific knowledge and expertise, as well as logistical capabilities. Sponsors should ask for case studies that demonstrate the CSO's Biomedical expertise to be able to advise and provide technical support and training. It the event that a device needs to be repaired or replaced during the study, the CSO should have a well-equipped service department to ensure equipment is fully calibrated and maintained. To ensure that sites are equipped for the first patient visit, a worthy CSO should also have experience in logistics to maintain the supply of sensitive reagents worldwide, across difficult borders in a timely manner.

Training

When using POC testing it is extremely important that all necessary training is completed prior to the first patient visit. Training in the use of POC devices must be given to appropriate clinical site staff by appropriately trained Biomedical Scientists. Training must be documented and include:

- **Background information**
- **Sample collection**
- **Storage of test devices**
- **Calibration of analyser**
- **Internal and external quality control checks**
- **Reporting results**
- **Routine maintenance of the analyser or device**

Training can be accompanied at Investigator meetings, via webinar (live or recorded) and/or via face to face site visits. CSO's with clinical trial experience offer all three options to be run individually or in combination to ensure that sites can have ideal outcomes.

In Summary

The CSO for POCT should be employed to advise on choice of analyser, training of staff, ongoing technical support, supply of reagents, routine maintenance and decommissioning of the system at the completion of the trial. Although POC analysers and devices can seem simple, their use is highly regulated and controlled to ensure maximum safety to the study subject.

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