



A review of clinical trial equipment guidance

Understanding the guidance available for study
managers and procurement teams



Introduction

Sourcing the right equipment for a clinical trial is an essential part of ensuring the success of the research. But despite the complexities of managing clinical trials, there are only a few guidelines available on running them,¹ and there is very little information about how to source the appropriate equipment.

In this article, we aim to provide an accessible summary of existing advice on equipment sourcing for clinical trials. We also offer some of MESM's own expertise based on our years of experience supporting study managers and vendor managers on all aspects of managing equipment for clinical trials.

Current guidance

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has published guidelines on designing, conducting and reporting clinical research trials involving people.

They recommend that the guidelines are followed when clinical trial data will be submitted for consideration by regulatory authorities. Clinical trial monitors must verify that the investigator has suitable qualifications and resources to run a trial. Any equipment and facilities must be adequate so that the trial can be properly and safely conducted, and they must remain adequate for the duration of the trial.² Trial investigators must provide documents (e.g. certificates, accreditation documents) for medical, laboratory or technical procedures and tests so that the trial facility can show that it is competent to perform any necessary tests.

The Medical Research Council has also published guidelines highlighting the importance of adequately maintaining equipment. They recommend that there should be procedures for ensuring there is training and support for staff who are using, servicing and calibrating the equipment.³ In cases such as this, working with an equipment partner can help to streamline processes. For example, among its other services, MESM can provide products pre-calibrated and will provide training for staff on using the equipment supplied.

The European Medicines Agency have published guidelines for laboratories analysing samples for clinical trials. Any equipment that will be used to analyse samples obtained during clinical trials must be fit for this purpose. Adequately qualified staff should maintain the equipment regularly and any maintenance checks they perform must be documented. Any calibration, inspection or maintenance of equipment should be in line with the standard operating procedures or the manufacturer's instructions and the results of these inspections or activities must be recorded. Calibration should be performed following national or international standards.⁴



In addition to the previous points, ensure cold storage used to house biological samples must be fit for purpose. MESM regularly supports customers in ensuring cold storage meets the requirements of the trial protocol – this is particularly important in the case of very low temperature freezers, where it's essential for the integrity of the trial that samples are constantly stored at the right temperature.

When running phase 1 clinical trials, the type of equipment and facilities needed will depend on the type of trial the investigator is conducting for the sponsors. The Association of the British Pharmaceutical Industry (ABPI) guidelines for phase 1 trials state that it may only be necessary to have basic facilities for storing and dispensing an investigational medicinal product (IMP) providing that's it's already packaged and labelled. If the investigator is acting as the sponsor for the trial they will need to ensure they have any necessary equipment and facilities.⁵

When the trial is underway, each clinical area must have a resuscitation trolley containing equipment and medicines for use in a medical emergency. The trolleys must be checked at least once a week and every time they are used. All checks should be documented.⁵

The type of equipment that's needed for a clinical trial should be documented in the trial protocol. This is another area where a dedicated equipment partner can support – for example by consulting on which equipment and ancillaries to include in the protocol, to ensure the best possible results for the study. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines recommend that trial protocols should set out any sources of financial and non-financial support. The protocol should outline the specific types of support, which includes any equipment, and the length of time that the support will be given for.⁶



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Cost considerations

Advances in technology often happen very quickly so it's important to ensure that there will be enough budget to cover the cost of any upgrades in equipment that may be necessary during the trial. It's important to review any equipment that will be needed to ensure that it complies with Portable Appliance Testing (PAT), so it will be necessary to allow enough time for testing to be performed at the coordinating centre or trial site.⁷

From an equipment procurement standpoint, MESM strongly recommends planning for equipment costs with a view over the full duration of a study; rather than choosing equipment suppliers based on per/unit costs alone. It's important to take any additional equipment related costs into account – beyond individual unit price – such as maintenance, technical support and end of study services (e.g. equipment removal and disposal). Consider working with a supplier whose costs include those additional services, as this has the potential to deliver cost savings over the course of a trial, as well as driving efficiencies by reducing the potential for delays caused by faulty equipment or other equipment related issues.

Summary

The key factors to remember when sourcing equipment for a clinical trial are:

Ensure you understand the guidance

Consult all available guidance relating to the type of trial you are conducting, to minimise delays and ensure you are tracking all required equipment information that you may need to provide at the end of a study.

Make sure the equipment is correct

Interrogate the clinical trial protocol to ensure the equipment sourced is fit for purpose – this may require seeking further information from the protocol authors, but will save time and additional costs in the long run.

Plan for your needs over the full duration of a study

Don't just look at individual unit costs for equipment, but consider the long-term value of the service you receive relating to equipment – including whether it provides for maintenance, technical support, calibration services, equipment removal, end of study reporting and so on.



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