



A guide to outsourcing clinical trial equipment

How to get the most from working with an external
clinical trial equipment partner.



Introduction

MESM is a clinical trials specialist, sourcing and supplying medical equipment and ancillaries to hundreds of research sites globally. Having worked with over 700 studies in over 80 countries, we understand the challenges and complexities that lead companies to outsource these elements of a trial to an expert partner.

In this article, we share some insight and guidance for getting the most out of outsourcing equipment and ancillaries supply to a partner.

Sourcing the correct equipment and ancillaries for a clinical trial always requires careful adherence to protocol, as well as due diligence to ensure all equipment meets the requirements of the study. Something as simple as storing biological samples at an incorrect temperature or failing to use properly calibrated measurement equipment can make or break when it comes to the success of a trial¹. An oversight such as sourcing a freezer with the wrong minimum temperature can affect approval of new drugs, minimising the patent window and severely delaying access to new or improved treatments for patients.

As well as ensuring all the correct equipment is sourced and ready for use at the trial site before the SIV date, study managers must also think about the on-going management of equipment supply and servicing; and ensuring all ancillary supplies are in stock, with maximum expiry dates and a smooth process for reordering. An MESM blog post on managing your ancillaries supply provides more specifics on this topic².

New challenges in clinical trial equipment management

Alongside all the requirements mentioned – which remain vital to running a successful clinical trial – the changing landscape of pharmaceutical research presents new challenges. Whereas clinical trials used to take place at a single institution, research now typically involves multiple sites, sometimes across several countries³. This adds the additional burden of factors including:

- Meeting concurrent SIV dates for multiple sites around the world
- Getting equipment into hard to reach locations
- Communicating with global research teams
- Sourcing country specific equipment variants (e.g. power cords)
- Ensuring the trial complies with all country specific regulations (e.g. Canadian safety certificates, import / export regulations, and more)
- Ensuring country specific equipment reporting requirements are met

The complex research landscape in which we now operate demands a higher level of support and a partnership approach, allowing Study Managers to focus on coordinating study sites, training healthcare personnel, and recruiting participants.

What to look for in a partner

There are several characteristics we recommend looking for when you're choosing a partner for clinical trial equipment supply.

Driven by your objectives

When you start speaking to a potential partner, they should be interested in your study objectives and your required trial outcomes. Lots of companies can source and supply equipment from a list, but the real value comes when a partner takes the time to deeply understand your clinical trial, and provide a consultative service to ensure the equipment supplied is best suited to help meet the stated objectives.

A good partner should be able to advise you on the right equipment for your needs, and be driven by the overall success of your study, not just their ability to supply the equipment needed at the right time and place.

Your equipment partner should be driven by your objectives and take the time to deeply understand your clinical trial



Asks the right questions

Knowing when to challenge you, or raising potential issues before they escalate, is one of the factors that sets a true partner apart from a straightforward supplier. A good equipment partner doesn't just have their eye on fulfilling orders correctly - they are aware of the bigger picture, and will step in early to prevent any potential issues that could affect your trial timeline, participant retention and budget.

End-to-end support

Lastly, a good partner should be able to support your trial from beginning to end. This may include:

- Consulting on the equipment specifications of the clinical trial protocol
- Having the ability to source and supply any required equipment, including getting it into difficult to reach locations
- Providing equipment that is calibrated and ready to use, as well as ensuring annual servicing takes place
- The removal and/or disposal of equipment and consumables at the end of a trial
- Support with end of study reporting

Getting the most from your equipment supply partnership

Investing in building a partnership early on leads to greater efficiency and value over time, as you create a relationship you can return to in the future with the confidence that your equipment partner understands your business or organisation.

Information provision

Start by bringing as much information as you can into the early conversations, to help your equipment partner begin adding value and consulting on how best to deliver your required outcomes. The kind of information you may be able to supply includes:

- Therapy area
- Size of study
- Number of trial sites
- Countries
- Known equipment requirements



Plug your processes together

Finding ways to align your processes will allow you to work more efficiently together. This may involve optimising data management or working in a shared online space to understand the needs of each trial site, in terms of equipment and other supplies.

Working in close partnership (both in terms of communication and alignment of data sources) can help a supplier like MESM forecast requirements for ancillary and consumable supplies – this is highly recommended to ensure you are always fully stocked at all trial sites.

Summary

In the modern clinical trial landscape, the sourcing and supply of equipment to locations around the world is becoming increasingly complex. Specialist partnerships can become an invaluable and essential element of clinical trial planning. It's important to seek a partner with strong credentials, and an approach that will increase your chances of running a smooth and successful clinical trial.

References:

1. CluePoints. 2013. Case Study: Using CluePoints to Detect Miscalibrated Equipment in a Clinical Trial. [ONLINE] Available at: <http://lp.cluepoints.com/detecting-mis-calibration-issues-within-a-large-vaccines-study/>. [Accessed 18 April 2017].
2. MESM. 2016. Managing your clinical trial ancillaries supply. [ONLINE] Available at: <https://www.mesm.com/blog/managing-your-clinical-trial-ancillaries-supply>. [Accessed 18 April 2017].
3. FDA. 2016. Using a Centralized IRB Review Process in Multicenter Clinical Trials. [ONLINE] Available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm127004.htm>. [Accessed 18 April 2017].

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