Procurement pitfalls and hurdles of lab equipment for clinical trials

Over \$78 billion is spent every year in the clinical trial market in the pursuit of bringing new drugs and medicines to market. Equipment procurement can often be an issue, with project managers already under pressure to oversee clinical trials across multiple sites and numerous continents. Fortunately, external support is available from the marketplace, but there are a number of pitfalls to consider.

Which equipment? The procurement dilemma

The first challenge when evaluating equipment for clinical studies is to understand which equipment will meet all requirements. Having a full specification of the proposed equipment and written confirmation that it meets all requirements is essential. The rhetoric and reality can regularly be distant strangers with a major problem being the fact that other issues, including cost, can take priority over specification. A common example of this is the use of domestic fridges in place of medical refrigeration units in an attempt to make a cost saving. Unfortunately, the inability of a domestic fridge to perform as accurately as a medical fridge can compromise trial results, ultimately leading to high financial loss.

Changes in the marketplace have brought an increase in external expertise and support. The main focus of this expertise is on smooth project management through planning and the selection of equipment. When considering your partner, evaluate the following key points: equipment specification, product lead times, role and responsibilities of each company. Payment terms, total delivery and collection costs, annual service and calibration options, breakdown and response times, local languages for technical support, equipment installation and training of operators and the storage conditions required for equipment and consumables on-site should also be negotiated. This will enable you to choose the best options, without any surprise overrun of costs or disappointment in performance.

Logistics and local sourcing

A key decision when procuring equipment for a global study, is to compare the benefits of acquiring equipment centrally or locally. If equipment is to be exported, then the supplier should have experience of importing into the required countries and be able to identify the logistics and import partners required to operate within these countries. Clarity on the local taxes and duty costs is also essential. Experienced partners with local knowledge can guide you through the import process, managing the importation lead times, essential documents such as licenses, and handling the costs of carriage. When looking at acquiring product, always consider the lead times and local taxes associated with both options. Most local providers do not stock product, often making the lead time longer than it takes to import equipment.

Late delivery can delay the start-up of the study, causing resource and cost implications and the pressures of searching for temporary solutions



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Maintenance and calibration

Most lab equipment requires maintenance or calibration every 12 months. It is important to know beforehand the date of the last service and the service intervals for each piece of equipment in a study. Location influences both service availability and cost and is therefore an important consideration. The travel time of an engineer can be far more expensive than the actual calibration or maintenance, whilst the geographical location of the site can significantly restrict the availability and lead time for obtaining a service. If the equipment is hired from your procurement partner, clarify what service backup is included in the rental fee. Always ensure on-site service is available to minimise delays. Response times should be stated and contracted at the start of the study for any service/breakdown work to be carried out. Any rental or pre-owned purchased equipment should be calibrated and serviced prior to despatch to the trial site. It is important to review the warranty period on purchased equipment and agree the terms of breakdown cover. Ensure your supplier provides a full list of all equipment by location, service and calibration plans and access to all certification documentation.

End of study responsibilities - the options

At the end of the study it is important to decide upon the retirement of the equipment through storage, reuse, recycling, donation or destruction.

Do consider:

- A good supplier of both rented and purchased equipment should be able to remove equipment from site, re-calibrate, package and store ready for the next trial
- If the equipment is no longer required, the supplier should offer to recycle the equipment on your behalf
- If equipment is hired, your provider should collect the equipment in a timely manner.

Conclusion

Finding knowledgeable, customer-focused support not only reduces costs across the course of the trial but can reduce errors, provide a proactive solution to problem solving and add value to a study. Ultimately a good partner allows project managers to concentrate on the complexities of running successful clinical trials.