Clinical Ancillary Management (CAM) services

Strategically managing your clinical ancillaries from study setup through execution to closeout

The rising complexity of clinical trials has resulted in an increase in the volume of ancillary materials needed and the number of vendors that supply them. In addition, the shift of responsibility for ancillary procurement from the investigator site to the sponsor creates numerous new challenges and supply chain risks. Clinical ancillaries may play a secondary role in each sponsor's budgets; however, a site missing a critical ancillary could delay patient treatment and negatively impact your trial. To make matters more complex, the global supply chain is under increasingly intense pressure, emphasizing the need to strengthen supply chains for both primary and secondary sources so that you're ready even before something goes wrong. Getting the right package with the right labeling to the right location on time requires expertise, time, and attention to detail.

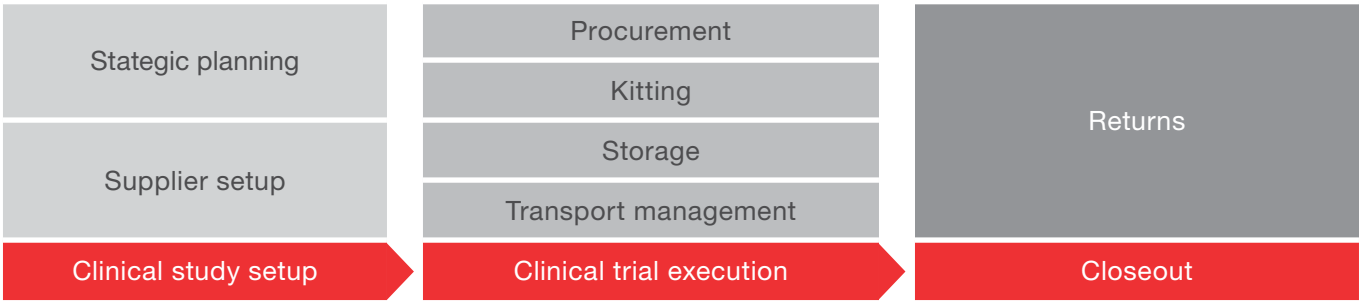
What are clinical ancillary materials?

An ancillary material is anything that is required in a clinical trial to support the successful administration of the Investigational Medicinal Product (IMP) over the life of the study. Ancillary materials can include, but are not limited to:

Laboratory	Medical	General	Educational	Other
Equipment and supplies (freezers, storage cabinets)	**Diagnostic equipment and supplies** (glucose meters, blood pressure monitors)	**Clinical supplies** (alcohol swabs, syringes)	**Materials** (brochures, instructions)	**Digital** (smartphones, tablets)

Comprehensive and specialized clinical ancillary supply chain management

Thermo Fisher Scientific's Clinical Ancillary Management (CAM) service is a comprehensive, specialized supply chain management service that provides a team of supply chain experts who work with you to solve challenges from the early planning days of clinical study setup, through clinical trial execution, all the way to trial closeout. Through our comprehensive sourcing models and proactive monitoring of our global supplies network, combined with global distribution and support with import and export requirements, we are able to anticipate shortages and proactively look for alternatives to ensure that your ancillary supplies arrive where they are needed, when they are needed. We also take a patient- and clinician-centric approach to kitting and supply management to help ease the burden and increase retention within your trials.

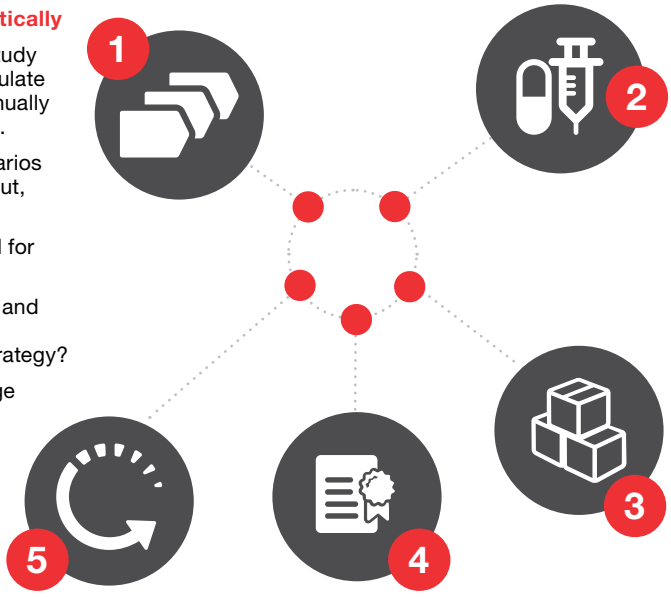


Our CAM team will be with you every step of the way. To get you started, here are five tips for thinking through management of your clinical ancillaries.

1. Plan strategically and tactically

Consider the details of your study design and requirements, simulate different scenarios, and continually monitor and adjust as needed.

- What ancillary supply scenarios could impact waste, stockout, and expiry across depots?
- What materials are required for the study?
- How will patient enrollment and geography impact your distribution and demand strategy?
- What variables could change and how might that impact your supply strategy?



2. Think about your supplies in detail

Think about your supplies in detail rather than generally to reduce time, resources, and project costs, and engage others for input.

- How will the supplies be used?
- What are you administering?
- Who is administering the drug (patient or medical professional)?
- What adjunct product(s) might be required?
- Is there a size, thickness (syringe), or dosage consideration?

3. Consider site space and capabilities

Keep in mind site space and capabilities during the planning process.

- Search for options that are available in similar units of measure or are easy to subdivide into smaller packs for waste reduction.
- Create your own single-serving packs per patient when possible.

4. Understand regional nuances

Regulatory and customs requirements change constantly and vary from country to country.

- What are the customs clearance requirements and what might need to differ from country to country to comply with local regulations?
- Are there translation needs for patient inserts, instructions, labels, etc.?
- What are each country's regulatory requirements and how might some pieces of your study need to be modified slightly to comply?

5. Plan for recalls and returns

Ancillaries are commercially available items, so recalls can and do happen. Build a plan for what to do in the event of a recall or surplus items after study closeout.

- What is your ancillary supplier's recall process and tracking system?
- What are your options for any surplus items remaining after study closure?

Set up your Clinical Ancillary Management services today.

Contact your local Thermo Fisher Scientific representative to learn more.

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