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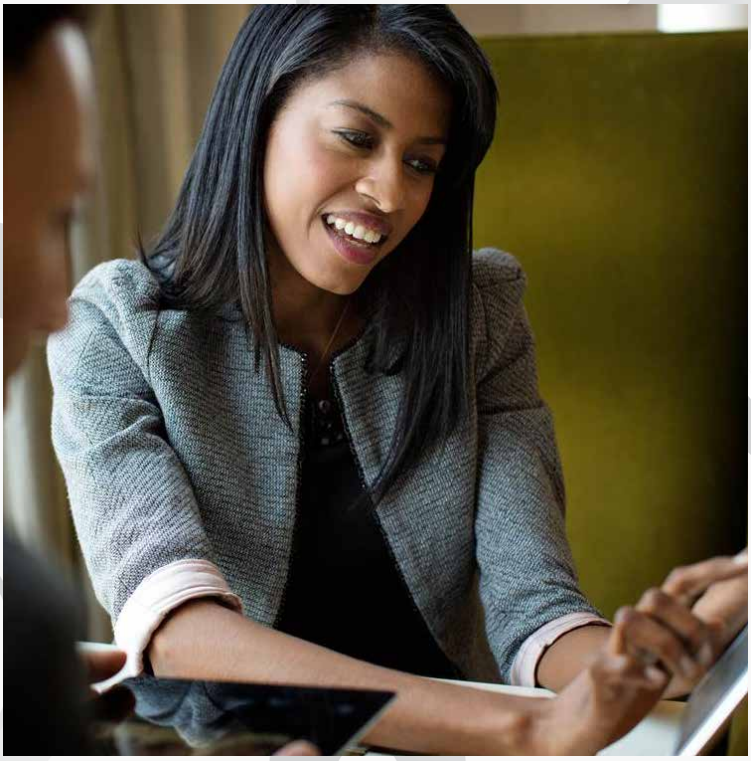
Ancillary Supplies: Clinical Trial 'Must-Haves' that Require Early Planning



Ancillary supplies are a necessary component in every clinical trial, though these products are often perceived as secondary in importance to investigational medicinal products (IMPs). Janet Williams, senior director, global supply chain management, and Julie Hoffman, senior director of commercial strategy and execution, discuss why ancillaries are as essential as IMPs, and why sponsors should devote as much attention to early planning for ancillary supplies as they do for study drugs.

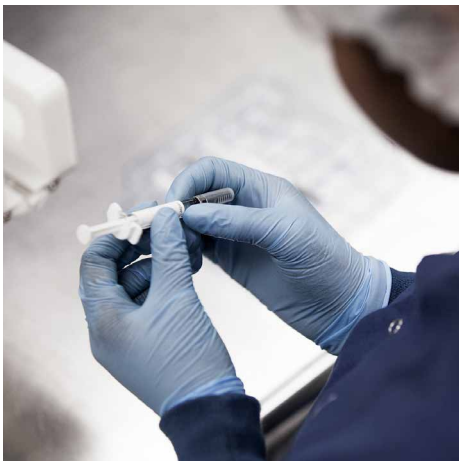
What are clinical ancillary supplies, how have they evolved over time and why are they important?

Janet Williams: While sponsors understandably focus their attention on supplying investigational drugs, clinical trials also require a wide variety of equipment, instruments and consumables – collectively known as ancillaries. These include laboratory, medical/diagnostic and drug delivery equipment and instruments, general clinical supplies and educational materials. Ancillaries are must-haves: a trial cannot begin unless both the investigational drug and ancillary components are in place.

Examples of commonly used ancillaries include freezers, refrigerators, centrifuges, computers, ECG machines and glucose meters, as well as consumables such as alcohol swabs, gloves, face masks and test strips. Paediatric trials may call for additional ancillary items, such as teddy bears and colouring books. While every trial is different, diabetes, vaccine, cardiovascular and oncology trials typically require a high level of ancillary products.

While not technically ancillaries, the study team manages other materials separately. These materials include documents such as trial procedures, investigator literature and brochures for study volunteers.

As trials have become increasingly global and complex, ancillaries have grown in volume, type, visibility and expectation. Ancillaries have become more sophisticated as sponsors embrace patient-focused treatments and precision medicine. Today, for example, ancillaries can include electronics such as e-diaries, smartphones, tablets and wearable devices that go home with study patients, as well as digital devices specially programmed to track medication usage, or to make medication administration simpler.



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With respect to clinical ancillary management, could you discuss the role of planning?

Julie Hoffman: Sponsors should begin planning for drug product and ancillaries at the same time, especially given the complex administration of some investigational drugs. Sourcing ancillaries requires an understanding of the study design and requirements, an in-depth knowledge of international regulations, and rigorous proactive planning to ensure that the most appropriate equipment and materials are purchased at a competitive price, and are provided to the right sites in the right volume at the right time.

For maximum efficiency, clinical ancillary management should take place through every stage of the clinical trial life cycle, from start to close-out. The planning process begins with a consultation to identify the ancillaries required for the trial based upon the investigational drug and study design. The ancillary supply management team then reviews the list of countries in the trial to assess the availability of ancillaries in

those countries, evaluates suppliers and product alternates, and determines whether there should be central or local sourcing.

Using this information, the team creates a preliminary distribution plan and an initial demand plan. The plans include buffers and an initial cost estimate. From there, the team builds and executes a working demand-and-supply plan, adjusting as needed to reflect changes in study variables. These efforts continue through study closeout to ensure minimal waste.

What are the most common ancillary-sourcing mistakes made by sponsors? What do you wish sponsors knew?

JH: Many sponsors plan for ancillaries too late. They wait until the last minute, because they think sourcing is easy and that ancillaries are commodities one can just order from Amazon.

The reality is that sponsors need to plan for ancillaries the same way they plan for drugs, because the two go hand-inhand. Sponsors should factor in the same considerations – import/export challenges, translation needs, information delivery, regulatory guidelines and timelines – to ensure that ancillaries reach sites on time.

The level of complexity involved can quickly outstrip a sponsor's resources, so many sponsors outsource ancillary materials management to experienced clinical supply service providers. In the end, it doesn't do much good if you have drugs on-site but you can't administer the product because, for example, you don't have the right infusion pump.

JW: Sponsors should know that failure to plan for ancillaries can result in shortages that can endanger a study. Our ancillary supply team has had to contend with many challenges on behalf of large and small sponsors that encounter unanticipated problems.

Among those challenges: sourcing ancillaries locally in difficult countries such as South Korea, rescuing studies from underperforming vendors, and replacing suddenly recalled inventory in the field. On several occasions, the team has also had to make last minute changes in a study's sourcing strategy due to unforeseen circumstances, and establish a relationship with a new vendor in order to obtain a specific item deemed necessary for a trial.

Would you address the ancillary needs of pharmaceutical companies versus biotech firms?

JW: Big pharma companies want transparency in the ancillaries they're purchasing, and in overall spend for this category. They're better equipped to pivot when circumstances change in the ancillary space.

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Biotechs are in a different position. They need knowledge, experience, capabilities, suppliers and networks – all of the infrastructure they don't have. They outsource because they want knowledgeable personnel to manage the ancillaries in the study for them, to tell them what they should do and how they should do it.

How has Covid-19 affected ancillary sourcing, and is it likely to have a lasting impact?

JH: Covid-19 has had a strong impact on the overall ancillary supply chain, and it will be quite some time until full recovery. Many ancillary products are manufactured in China, where the emergence of the virus drove initial ancillary shortages. China responded to the health crisis by restricting the export of such products to ensure a sufficient supply for in-country use.

Europe, the Middle East, Africa and the US are looking for products now, but there remains an insufficient supply overall, even though China is producing and exporting again. As one would expect, hospitals are first in line to receive much-needed ancillary supplies. Clinical trials aren't a top priority. Needless to say, this increases the challenges of supplying ancillaries for new and ongoing studies.

In summary, what advice would you offer sponsors about supplying ancillaries for clinical trials?

JH: Pay as much attention to ancillary products as you do to IMPs, and plan for both at the same time. Keep in mind that you can't begin a trial or administer medication without the ancillary components.

Early on, consider the countries participating in the study and identify the ancillaries needed. Determine whether you need to source centrally or locally, and consider the challenges involved. Ensure that you have approved ancillaries for every country in the study.

Outsource to a clinical supply service partner with the resources necessary to handle distribution of both IMPs and ancillaries. This limits the number of handoffs across the supply chain, while ensuring that both IMPs and ancillaries reach sites when they're needed so trials aren't delayed.

JW: That service provider's team should include ancillary supply management specialists that monitor changing circumstances, and can identify workable alternatives should they be needed. Backup plans are essential, as it's impossible to know when a crisis could affect sourcing of ancillaries. Consider the impact of Covid-19.

As always, keep the budget in mind. The budget for ancillaries is frequently over-looked, especially when studies are outsourced or when sites purchase their own

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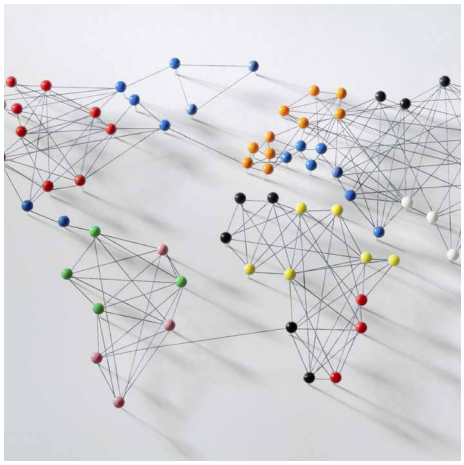
ancillaries, as they frequently choose to do. Failure to keep an eye on the budget can drive risk, as well as unwelcome last minute changes to the overall clinical study budget.

Once again, plan early and often for ancillaries, the same way you plan for study drugs. Ensuring that ancillaries and drugs both reach sites on time is critical, because patients are waiting.



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