# Ancillary Supplies for Clinical Trials

## A Project Management Approach


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# About this Ebook

Ancillary supplies, such as medical equipment, visit kits, and lab products, play an essential role in most clinical trials.

> *Does your job description include procuring ancillary supplies? Will it soon? Is it a task dropped in your lap from time to time?*

The selection, procurement, and shipment of ancillary supplies is a specialty in itself. In this ebook, we will show you how applying a systematic, structured approach to identifying and implementing ancillary supply requirements can reduce costs, save time, mitigate risks, and improve study effectiveness.

The best way to do this is by using a traditional project management approach and applying all five project management process groups:

- Initiation
- Planning
- Execution
- Monitoring and Controlling
- Closing

We will go over each of these in detail, and we've peppered the text here and there with real world examples so you can sample the full flavor of ancillary supplies experiences and issues that can come up.

And since it's become common for sponsors and CROs to use vendors to assist with part or all of the ancillary supply aspects of their studies, we have included a chapter containing important questions you should ask the vendor before you step into a relationship.

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# Chapter 1:
## Initiation

Processes performed to define a new project or a new phase of an existing project and gaining authorization to start the project.

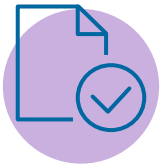
Initiation processes lay the foundation for getting things right. It's important to ask a lot of questions. Here's how to get started:

### Identify a need or request

Ideally, you should identify a need or a request for each ancillary supply very early, before the project kickoff. This will help avoid delays and last-minute requests from sites.

### Assess the protocol to ensure that nothing was missed

Reviewing the protocol is an important part of initiating the project and starting the study. However, during this assessment, required supplies and/or equipment are often overlooked. It is important that a review of the protocol, specifically identifying supplies or equipment needed to conduct the study, takes place. The list should be all-inclusive, even if it is likely or expected that the site should already have these materials available. A comprehensive list based on a protocol review provides an excellent starting point to assess site capabilities during feasibility.



### Review site feasibility/assessment results to verify consistency in equipment

Was the specific make or manufacturer of supplies determined in the protocol? Are all sites using the same quality of supplies or equipment? Every manufacturer has its own set of specifications, and their variance of tolerability can be very different from each other and/or the protocol requirements. Consistency of data is critical to study success and the development of relevant statistical results. So, in turn, the equipment used to collect the data must also be consistent. If different sites are using equipment with varying levels of tolerability, that can significantly impact data output and have a germane effect on the results.

In addition to the consistency of equipment, the ability for the site to house, maintain, and use the materials needed is vital to conducting the study.

> Here is an important question that doesn't always get asked: Does the site have space for the supplies and/or equipment that will be sent to it?

We recently had a client request a specific refrigerated centrifuge, which had been vetted and approved. However, once it arrived at the site, it took up too much square footage. The site's desktops were cluttered and didn't have room even for this compact model. This unexpected development led to a costly process for the sponsor. The centrifuge was returned, and a replacement that met the requirements had to be found, vetted for approval, and shipped to the site. This resulted in loss of time, extra costs, and additional human resources that could have been better used elsewhere.

# Chapter 2:
## Planning

Process required to establish the scope of the project, refine the objectives, and define the course of action required to attain the objectives.

Expect to devote more time to the planning process than you will to the other processes. Don't look for shortcuts or place these elements on the back burner. Good planning leads to good execution.

### Review the list of needed supplies

Are there any needs that aren't listed?
Do you understand exactly what is being asked for?

Take, for example, a fundus camera. Some will call it a mydriatic retinal camera, and some will call it a non-mydriatic retinal camera. And others might call it a fundus camera. All three are actually slight but distinct variations of the same thing and are not identical. Understanding what is being requested is critical.

Where will you procure the items that are listed? Will you get them from a vendor, manufacturer, or distributor? These are crucial things that you need to know. Each operates in its own fashion—dealing with expiration, lead times, supply chain, and export issues in a different way, which may or may not effectively meet your study needs.

Do any of these items require reporting? In the United States, we have the Sunshine Act reporting, and outside of the U.S., there are additional reporting structures that have to be followed. We will go into more detail about this in the next chapter.

## Identify the function

This is important for technology, equipment, and complicated procedures. Identifying the function—the action that the product is intended to perform or the objective you are trying to achieve—helps to ensure that supplementary activities or materials are included in the scope.

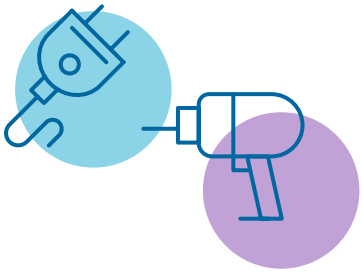
When a protocol calls for a centrifuge, there are many questions to answer: Is it going to be a fixed or a variable speed centrifuge? Is it going to have maximum speed rotation or minimal speed rotation? Are you going to measure it in Gs or RPMs? Does it need to be standard or refrigerated? Is it air jacketed? Is it water jacketed? Do you need to consider humidity levels? Do you want a gravity style or a convection style? Are you doing slides or petri dishes?

Why do you need to know this level of information? If, for example, you're creating slides that will be incubated, you probably don't want a convection style incubator. This is because the movement of the air actually dries out the slide and dries out the study sample. When you look at it under a microscope, it becomes crystallized or starts to look opaque, so it's difficult to read.

Clients have come to us and asked for a specific infusion set. And the reason they might like that particular model is because it is latex-free, DHEP-free, or has a certain number of injection sites, or it's a certain length. The problem is that not all infusion sets are created equal. B. Braun sets usually don't work with a Baxter pump and vice versa. Staying on top of the details as well as the big picture is important.

## Identify the country requirements

Once we have our list of supplies, it is important to identify country requirements.



What kind of power supplies and plug types are used at the site?

Power supplies in the United States are generally 120 volts, 60 hertz. Outside of the U.S., power supplies vary anywhere from 220 up to 240 volts, and 50 or 60 hertz. Plug types can range from A to G. A and B are usually U.S. plugs; an F or G is usually a European plug.

You will also need to check country eligibility. Every country has its regulatory agency and rules. Is the supply you're looking for CE-marked for the European Union? Is it FDA cleared for the United States? Is it TGA compliant in New Zealand? Is it NHS compliant in the U.K.? Make sure you are in compliance with the country's safety group. Compliance is often overlooked.

Recently an Imperial client selected an ultrasonic nebulizer for us to procure. We found that the manufacturer of that nebulizer was not NHS registered, which meant no hospital in the U.K. could use that piece of equipment.

We vetted a different ultrasonic nebulizer, had the original returned, and sent out one compliant with the country regulations that appeared on the NHS registry.

We've seen an entire study held up because of a specific model of a syringe. Although such a common product, this particular syringe did not have FDA clearance for use in the U.S. These delays can be costly.

## Understand the study duration and any expiration


Equipment and supplies in the medical arena often have expiration dates, so it is important to consider the study duration. Is it a two-year study? If so, what is the standard or common life span of the materials that you need to procure?

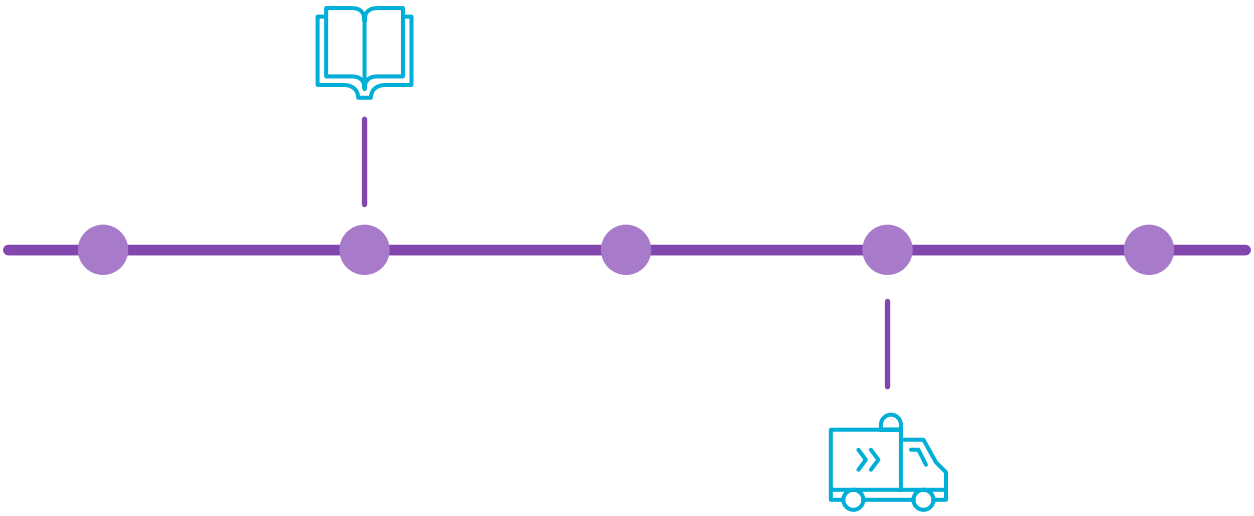
Let's say your study requires blood collection tubes that expire within 12 months. Your procurement and distribution plan should minimize the quantity you're buying up front, so you won't be left with tubes that can't be used before expiration.

> Mesh your study timeline with the products and their expirations. Developing a forecast during the planning stage and managing it throughout the project lifecycle will minimize delays due to having to replace expired supplies at the last minute.

## Identify startup timelines and marry them to procurement/ logistics timelines

Next is the logistics timeline, which can vary greatly depending on the countries and the type of equipment or supplies being used in the study.

Fully understanding those requirements during the planning phase will ensure that you're buying smart. Maximize the utilization of those products to prevent wasting money and causing delays by not having the right supplies when you need them.



## Sunshine Act reporting

As mentioned in the previous chapter, we have found that many studies don't have plans for Sunshine Act reporting.

> The Sunshine Act, specifically the National Physician Payments Transparency Program, was placed into law to disclose the financial relationships between physicians, teaching hospitals, manufacturers, and group purchasing associations.

Understanding your company's interpretation of the Sunshine Act regulations will help you stay on top of this task.

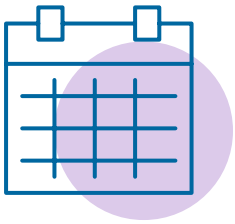
Some people have interpreted this regulation as requiring everything that's distributed to a site to be reported, from disposables, to patient retention tools, to higher expensed equipment. Others have interpreted the Sunshine Act report to be much less strict, narrowed down to only a few supplies. This is primarily self-regulating, resulting in the varied interpretations. Every pharmaceutical organization is responsible for some level of reporting, regardless of its individual understanding of the law. It is important that you plan for these reporting requirements early on, ensuring compliance throughout and after study completion.

Internationally, France has its version of the Sunshine Act, and other countries are making plans to adopt similar regulations.

## Plan your closure activities

Planning for closure is essential to being fully prepared.

Don't wait until your trial is wrapping up to begin planning study closure activities (discussed in-depth in chapter 5). Putting some thought into how you are going to close the study will affect many of your decisions on the front end, particularly in the types of ancillary supplies you might select, your logistics/distribution plan for disbursement, and the timeline for procurement.



For example, are you providing the sites with equipment that needs to be retrieved? If so, build your retrieval plan and budget now, so that the funds and activities are accounted for in the project plan.

Planning for closure now is essential to being fully prepared.

# Chapter 3:
## Execution

Processes performed to complete the work defined in the project management plan to satisfy the project specifications.

You've asked all necessary questions, you've completed your plans, and now it is time to execute.

## Procure supplies

Procuring supplies should be relatively efficient if properly planned for. You should know what you are getting and from where. Hopefully, you have already answered some of the detail questions, such as:

- Will you get them from different vendors and manufacturers, with multiple shipments sent to a single location?
- Will you have them drop shipped to sites?
- What are your lead times? Keep in mind that special orders can take six to eight weeks and sometimes up to 14 weeks.

If not, finalizing these details can be critical for they may significantly affect timelines. We have found that special orders delay many studies because the orders were not placed early enough.

For example, we had a situation where a client needed 250 ml bags of sodium chloride, which are getting harder to find. The client specified 250 ml bags, but due to manufacturing limitations, the lead time was extraordinarily long. In consulting with our client, we determined that 500 ml bags could be substituted for the way in which they would be used, thus reducing lead time.

Knowing where your sites will be is essential to the procurement process. If the FDA has not cleared a product, you will have no success getting it into the U.S. Even if you make assurances that the final shipping destination is outside of the U.S., it will not be allowed in.

What are the best packaging and quantities available? Make sure you know the best minimums and maximums for your sites. Sites can be very limited in terms of space. It is also likely that your study is not the only one they are conducting. Clearly labeling your study supplies and shipping only what they can comfortably store will foster site success in managing their role in the trial.

## Set up inventory management procedures

Inventory management procedures must be taken into account. For example, once stock of a supply reaches a minimum number, it should trigger an automatic reorder of an established quantity. What will those numbers be? All of this should be determined in advance.

Expiration management is also part of this process. Studies have been delayed simply because syringes that were in stock had reached expiration dates. The problem is exacerbated if the syringe is a special order item, which further increases timeline delays.

Many sponsors and CROs prefer to have vendors manage this process for them. A good partner will help you identify and mitigate risks associated with these pitfalls.

## Definition and responsibilities of consignee for international shipments

Clearance of your ancillary supplies through in-country customs may require substantial advance preparations including a thorough knowledge of the laws, proper documentation, and a clear and well-defined process.

With traditional exports, the consignee can be the buyer or the seller of the goods, or the business or person that receives the goods.

However, clinical shipments do not fall under the traditional import/export process, because only a service is being provided. No sales transaction is taking place in the country.

When exporting your ancillary supplies to another country, it is critical that your recipient outside of the U.S., the consignee, is registered with the country's customs department as an importer.

If your consignee is not a registered importer, the shipment will be placed in customs clearance delay or a hold pattern until a proper, registered importer is assigned in country. If the consignee is not a registered importer, then one must be identified in order to clear the shipment on its behalf.

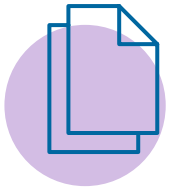
## Definition and responsibilities of the importer of record

The importer of record (IOR) is a critical concern, and many people miss this. The IOR is the legal entity responsible for ensuring that the imported goods comply with local laws and regulations. He or she files completed duty entry and associated documents and pays assessed import duties and other taxes on these goods. Country customs will assign tax ID numbers to an individual, firm, or legal entity that will be responsible for articles of trade from a foreign source into their domestic market.

The role of the IOR varies from country to country. In some, the sponsor is the only identity that can assume the role of an IOR, while in other countries, the IOR can be a third party, such as a clinical research organization or a distributor. Effective communication with the IOR in every country in which the clinical studies will be shipped will prevent time-consuming and costly delays.

In addition to speaking the local language and providing hands-on support, your registered importer will be key in maintaining good working relationships with the regulatory and customs officials in country. He or she can also provide early warnings about proposed or impending changes that can impact your specific clinical supply supplies and logistics.

## Paperwork preparation



Each of your international documents will require detailed information, and documentation often includes a pro forma or a commercial invoice.

Pro forma invoices are used in advance of shipment, while commercial invoices are customs documents. Both describe the goods coming into the country and require similar details of information.

Details include:

- Who are the business parties involved?
- Who is the owner of the goods?
- Who will receive the goods–the consignee?
- Who is the registered importer for the goods?
- Commodity description of the goods.
- Harmonized Tariff number assigned for each of the commodities.
- Declared value of the goods.

The proper customs value to be supported on pro forma or commercial invoices is the transaction value, which is the price actually paid to have the goods manufactured or the amount that the manufacturer invoiced a client to produce the goods.

## Additional considerations

Pro forma and commercial invoices include international commercial terms (called incoterms). These terms name who will be responsible for the liability of the shipment from the time it leaves the door of the shipper to the time it arrives at the door of the consignee in the destination country. They spell out the respective roles of the exporter and the importer and who owns each responsibility at each geographic point, including the cost of freight/transportation, documentation, duty, VAT, and clearance charges.

It's very important to understand who the responsible party is that will assist the courier or the carrier for clearing the goods in country and who will be responsible for paying the customs, duties, and back-clearance charges imposed on the goods.

Even though there is no sales transaction taking place, the import shipments will be assessed duties and VAT taxes.

Prior to customs clearance, your supplies may also require a certificate analysis, a certificate of conformity, or a country of origin certificate. Ancillary supplies that contain or involve electronics, measurable or measuring devices, or Class II medical devices typically fall under these certification processes.

These certificates will vary by country. Before exporting your supplies, consider requesting pre-approval of your documentation with your in-country registered importer. Your importer will seek counsel from his or her assigned registered customs broker before the exportation. This communication is time well spent.

When the goods arrive, the registered importer will seek power of attorney with his/her broker in country to assist in the clearance process with the courier, carrier, and customs.

> The importance of the country of origin certificates for ancillary supplies cannot be overstated. These documents are required to prevent importation of non-approved materials.

**An example:** You have shipped ancillary supplies containing batteries that were manufactured in China. Prior to exportation, some countries will request these batteries be removed from the ancillary supply. That is because their country's import laws and regulations don't allow these batteries or the licensing requirement is too involved to be worthwhile.

Such issues vary within specific countries and regions of the world.

It's important to communicate about standard operating procedures, which play a major role in your success. And it is best practice to ensure in advance that everyone involved in your supply chain knows what ancillary supplies are expected to arrive in country and when.

When forecasting the quantity of ancillary supplies needed for a study, restrictions on returns and destructions must be taken into account. Consider, for example, Taiwan prohibits the export of unused trial materials. With proper planning, this will not become an issue for sites that have neither the desire nor the resources to deal with excess trial materials.

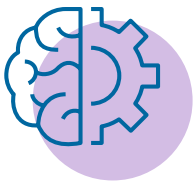
Finally, there are regional idiosyncrasies. Differences in language, working patterns, culture, and religion add additional layers of complexity that are challenging but not insurmountable. Navigating these challenges successfully requires a sustainable approach that mitigates risk from the beginning to the end of your supply chain.

Differences in language, working patterns, culture, and religion add additional layers of complexity that are challenging but not insurmountable.

You need to be able to rely on your core group of local partners and staff in the country where you're importing. Vet the local in-country partners and staff carefully. Even when working with a skilled and dependable group, it is important to confirm and reconfirm everything in advance. Going the extra mile to reconfirm arrangements and details may appear to be overkill, but doing that prevents last minute surprises and provides peace of mind.

# Chapter 4:

## Monitoring and Controlling



Throughout all phases, includes: Tracking, reviewing, and regulating the progress and performance of a project, identifying any areas in which changes to the plan are required, and initiating the corresponding changes.

Even though monitoring and controlling is a formalized step within the project management guidelines, it should be ongoing. This process gives you the ability to course correct as you go.

### Advance identification of problems that may arise

Planning includes considering problems that could come up. What is the identification process if there are problems? What is the communication plan? What is the escalation plan to get a resolution in place?

Recognizing potential problems early is critical to driving resolution so that timelines, costs, and risks are minimized. We have seen problems arise with something as simple as a data logger. Data loggers are small electronic devices commonly used to constantly monitor the temperature of a medication when a patient takes it home.

In one study, some sites did not know how to download the information from the data logger once the patient returned it. This was unexpected, and the client had to create written instructions to provide each site to get usable data for that portion of the trial. This introduced delays that could have been avoided. However, because the problem was recognized with the first few patients, swift action was taken to avoid a lengthy and potentially costly resolution.

## Getting ahead of amendment requirements

Protocol amendments happen! We have seen them on many, many trials—sometimes six, seven, and even eight during the course of a trial. Statistics say that on average, an amendment can add a million dollars to the cost of a trial.

> If you know that an amendment is imminent, understanding the changes that will be implemented, and specifically how those changes affect the processes and procedures that require ancillary supplies, will position you to make proactive decisions about supplies that may now be necessary for study conduct.

## Product replacement plans

What is your product replacement plan? A min/max thermometer calls for a different replacement plan than, say, the calibration of a scale at a site.

If your study duration is two years and your min/max thermometer is good for 12 months, it will likely need to be replaced. Making sure in advance that you have a plan to replace it will prevent a gap in monitoring refrigeration of medication at the site.

Similarly, planning for the calibration of a scale will make sure the site continues to operate seamlessly. Is your plan to have a technician on site calibrate the scale, or is it best to have a replacement scale sent prior to the scale's calibration expiration? We prefer to contract or repair through local contacts near the sites, especially with larger items. Smaller items can be easily shipped, and we often opt for what we call a repair/replace—we send a replacement that is calibrated, and the site returns the used device.

# Chapter 5:
## Closing

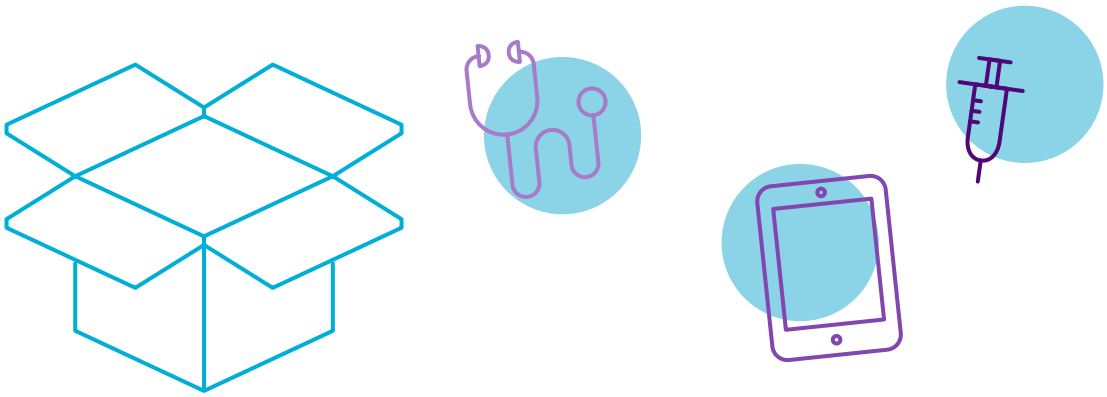
Processes performed to finalize activities across all process groups to formally close a project or a phase.

This is a critical part of ancillary supplies. The study is done, and you have unused supplies at sites and in storage. Ideally, during the planning phase, you determined which supplies (if any) will be returned and where they will go.

### Equipment return/retrieval

At the end of a study, supplies are often eventually given away. Sometimes they end up sitting underneath desks or stacked in closets. Clients have told us that they have storerooms full of equipment that they don't know what to do with.

Consider what supplies and equipment are remaining at sites. Determine what will remain there and what you would prefer to have returned. Then decide who will perform the retrieval activities and what those activities will involve.



## Disposition plans

If you need to destroy any of this equipment (for example, if it is contaminated, still being tested for market, or the protocol simply calls for it), you will have to find a source to carry that out. In some cases, you will need a letter of destruction, and sometimes it has to be a certified letter.

You may plan to store, resell, or donate your equipment. Some equipment may require calibration or minor repairs. If you plan to store your equipment for later use, a location must be determined. There is always the possibility of donating the supplies to groups that help set up clinics around the world.

As mentioned above, planning for the disposition at the beginning of the study is usually best. This will ease the process and help prevent delays in removing the supplies from sites and getting them to their new destinations. Clients regularly ask us to help with disposition of unused supplies, and we find buyers for them. Unfortunately, when the request comes in at the end of the study, it can take a long time to finalize arrangements. In one study, the buyer eventually backed out because of the length of time it was taking, so the unused, expensive pieces of equipment were left sitting on the site's shelves until a different buyer could be found.

# Chapter 6:

## Working with an Ancillary Supplies Vendor

Determine if a vendor can help you achieve your goals effectively by finding out the answers to the following questions:

**What is the vendor's or supply chain's relationship with manufacturers?**
There should be no agenda to push you into procuring supplies that aren't a perfect fit for your study. One manufacturer might have a shelf full of a specific model of infusion pumps gathering dust, which could inspire the vendor to tell you that the pump is exactly what you need. Make sure your study's needs, not the vendor's or manufacturer's, are placed first.

**Does the vendor maintain a warehouse?**
If yes, ask if it's climate controlled and has the appropriate storage space for the kinds of equipment or supplies you need maintained.

**Where are its warehouses located?**
Make sure that the warehouse to be used is reachable by the majority of carriers. Warehouses in rural locations may have problems with regular pickups and deliveries. Also validate that the warehouse is in a region of the country that facilitates importing and exporting. Often those closest to major cities or airports have the best functionality.

**How do I access my inventory?**
Does accessing your inventory require a phone call or an email message to the vendor? It is best if you can see it for yourself at any time independently, for example, through an online portal.

**How is inventory managed?**
If you have to consider expiration dates for your supplies, verify that the vendor will only send product out that has the appropriate lifetime left on that supply. Many suppliers subscribe to a FIFO system, which is "first in, first out" regardless of your specific study needs. This can often result in very short shelf life at the site, and if the patient's visit is not for a while, it can cause expiration issues.

**What types of repackaging support do they offer?**
What if you have a product that comes in cartons of 1,000, and you only need to send 10 to the site? The vendor should have the ability to repackage it appropriately. But before that is done, the vendor should be able to tell you whether the product will maintain its properties if it's repackaged. For example, if it's sterile, it must maintain its sterility, or if it is CE marked, it must remain in its original marked packaging.

**What logistics support do they provide for shipments?**
It is important to have a vendor that not only gets the supplies you need but can also get them to their destination for you.

Despite the most careful preparations, unforeseen customs issues can arise. When this happens, know in advance whether resolving customs issues becomes your problem, or if your vendor will handle the matter to a successful conclusion on your behalf. Understanding your role and your vendor's role will prepare you for timely resolution of customs issues.

From the outset, make sure you fully understand your vendor's capabilities and range of services. Asking these questions will help you map out areas of responsibility and ensure no time is lost in procuring and shipping your supplies.

Understanding your role and your vendor's role will prepare you for timely resolution of customs issues.

Working with an effective vendor for ancillary supplies will gain you instant access to expertise and systems that are in place and working effectively. This will add efficiencies to your study and also free up your time and your company's internal resources to concentrate on other tasks.

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Hope is a respected operational executive with nearly 10 years of clinical research experience. She leads a team of cross-functional project managers as well as manufacturing and support personnel to provide production, procurement, assembly, and logistics services for client study materials in support of global clinical trials. In addition, Hope directs Imperial's client interaction, workload management, and work process improvements, and ensures continued revenue growth through exceptional customer service and relationship development efforts. Hope is author of the ebook *Effective Project Management for Clinical Trials: A Business Approach.*

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Dan has been in global trade for more than 20 years. He currently assists Imperial's clients with technical knowledge and training regarding a wide range of global trade topics including transportation and logistics, customs clearance, export documentations, valuation compliance, country of origin, and more. Dan oversees more than 50,000 shipments into more than 100 countries annually.


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