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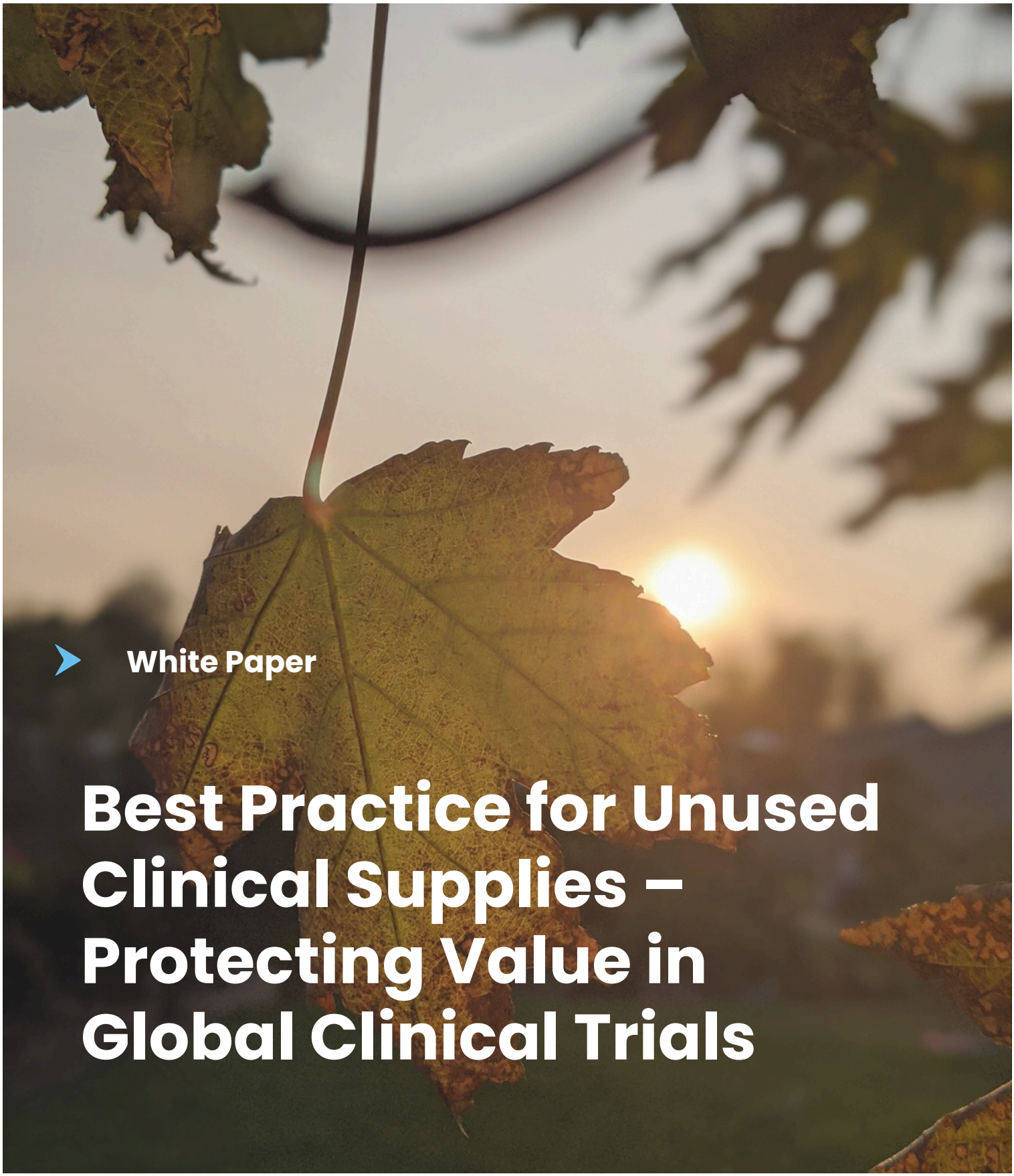
Your Clinical Supply Solutions



White Paper

Best Practice for Unused Clinical Supplies – Protecting Value in Global Clinical Trials

Created by
Ben Everington

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Introduction

Having an excess of commercial product at the end of a clinical trial is very common, and ‘some’ surplus stock in each trial could be best described as unavoidable. As with all critical supply chains, where the performance and outcome have a direct impact on human health, a level of buffer is not only justifiable, but also essential.

However, excessive amounts of leftover products are not what any of us want, and yet again the onus falls on the conscientious clinical supply professional to plan as effectively as possible to reduce our exposure, without risking study continuity.

This White Paper looks at the challenges faced by our clinical supply community, why ‘waste’ is increasing, and what are some meaningful steps to reduce, and repurpose, excess medicines.

The likely culprits....

Perhaps the most obvious cause of leftover drug is the product reaching its expiry date. At the outset of any new study, when enrollment rates are an assumption rather than a data set, we must decide how aggressive we are going to be with the initial purchase of comparator. Over-optimism of enrollment rates can be a costly mistake, especially if your comparator is found to be lacking in the expiry date department.

Increasing complexity in clinical trial design (the thread which runs through several of our recent White Papers) creates risk. The more variables you need to plan for, the larger your safety net will become. Simply: more therapeutic areas, more drugs, more countries and more trial sites, equate to an increased likelihood of unused product.
Modern clinical trials are rarely static, and as the adage goes, "the only constant is change", which applies to trials from FPI to LPO. A protocol change, a cancelled cohort, or other supply chain constraints, can all contribute to a larger pile of unused drug than our best laid plans had allowed for.

The Falsified Medicines Directive in the EU (which I believe we are all aware of by now, but if not, please read our White Paper) dictates that all drug that is being consumed in a clinical trial, or drug that is leaving the EU, should be 'decommissioned'. This decommissioned status is non-negotiable, and we all must comply, but there is a potential hidden cost to decommissioning earlier than necessary. Beyond 10 days of the decommissioning taking place, drug cannot then be re-commissioned. This eliminates any possibility of drug being resold into commercial channels, which significantly limits the avenues available to a sponsor for recouping value from their asset.

Why efficient purchasing of medicine matters

Starting with the most obvious – **cost**. Trials are expensive and comparator spending is often a high-profile part of any Sponsor's budget. It is also the lowest hanging fruit when a company is looking for efficiencies and savings. When we are dealing with comparator drug, any discarded product is easily quantifiable, as it has a clear commercial value, which is the price you paid for the product.

Sustainability has, rightly, become a greater focus for all of our organizations in recent years, regardless of our size or profile. Each pack of destroyed drug has an **environmental impact** when considering the manufacturing process required to make the drug itself, not to mention the plastic, cardboard, glass, and so on, that goes into primary, secondary and tertiary packaging. The argument of 'it was already manufactured' doesn't stand up to scrutiny, and we must recognize that our clinical demand does impact commercial manufacturing.

Whilst some waste in clinical supply chains is a necessity for patient safety, excess waste can create a **negative patient impact,** albeit out of our direct line of sight. Every pack that we don't use in a clinical trial could have been used by another patient in a more traditional healthcare setting.

Finally, there is the **expectation that we put on ourselves**. The intrinsic motivation that we individuals involved in clinical supply chains should perform our roles as best we can, by executing our clinical supply chains with the right balance of risk and continuity, and to demonstrate that our plans are well thought out, efficient and sustainable.

Wastage vs. Resilience

Hands up anyone that has been asked to explain to a commercial colleague why buffer stock, or overage, is required for a clinical trial?

I have a feeling that a few hands may have just gone up....

'Waste' can be a misleading term, as it implies that an item serves no purpose, and is entirely obsolete. What a well-planned level of overage actually provides is a resilient supply chain, peace of mind, and patient safety. All of that combines to give you clinical trial continuity. For the well-informed Sponsor, that is money well spent.

The challenge is finding balance, and there is no exact equation that can be applied to tell you that you got it right or you got it wrong. Clinical supply strategies vary, by necessity, and where a trial dictates that all global sites need to be seeded in the high likelihood of high enrollment, excess product is going to be higher than a study with a longer screening period (that would more easily allow for 'Just in Time' distribution). One study design may legitimately need a 100% comparator overage, whereas another needs only 25%. Identifying that appropriate overage is where we can help ourselves.

The line that must not be crossed is where we think of surplus stock and supply resilience as one and the same. The two things are related, but they are not directly proportional to one another.

How Sponsors can limit exposure to over supply – practical guidance

Forecasting discipline is at the heart of many supply chain efficiencies, and this topic is no different. A proactive approach to the available data is the best way we can be informed. This needs to be interpreted in conjunction with the advice of a reliable and strong comparator vendor, though. A forecast on its own tells part of the picture, but insights into expiry dating and likely lead times is a layer of detail that produces a robust supply schedule.

Ordering in tranches is another important step. It is tempting to let optimism get the better of us and assume that our trial will get off to a smooth and uninterrupted start, but in reality, we see trials delayed more often than we see them starting early. If expiry dating is only around the 12–14-month mark, it is prudent to allow more deliveries and more packaging runs than if you are blessed with 24 months of dating. Extra packaging runs does mean more cost, but if the comparator you are purchasing is expensive, then it pales in comparison to destroying 200 vials that have expired.

Building in flexibility during the design process can also be helpful. These opportunities do not present themselves often, but where supplies may be pooled between studies, or even between cohorts, there is the possibility of re-directing stock rather than leaving it to gather dust. Innovative labelling and distribution strategies help to enable the maximum number of outlets to repurpose stock within your own clinical pipeline.

As already alluded to, delaying irreversible steps until needed can help Sponsors retain as many options as possible for repurposing drug. Not decommissioning drug (in line with the FMD) until it is necessary will increase your chances of re-selling commercial drug, and it may be the difference between a re-sale and a frustrating destruction.

The same logic can be applied to packaging and labelling. I tread carefully with this advice, as a significant trial risk is when comparators are not packed, released and distributed in a timely fashion, but once a commercial drug has had a clinical label applied to it, then it's only viable avenue for being repurposed is a clinical setting, which rules out all commercial markets.

What can be done with comparator drug that is no longer needed?

Vendors can, and should, be proactive in assessing potential avenues for repurposing drug. If a study is coming to an end, or if the Sponsor has communicated in advance that there may be excess drug, then your vendor should be constantly vigilant for these avenues.

For re-purpose into a clinical supply chain outside of a Sponsor's own pipeline, you will rely heavily on your vendors ability to explore the clinical landscape, and on their own network of customers and ongoing trials.

Resale into commercial channels is the much more likely result, as commercial medicine generally retains some level of value whilst it is usable. This is where buyback schemes can, on occasion, be the right solution, but Sponsors need to be mindful and ensure the drug has not been altered in any way that would exclude its onward commercial sale, such as clinical packaging, labelling, or decommissioning.

When it comes to budgeting accurately, Sponsors should be wary of taking 'buyback' initiatives at face value. Whilst they do work in certain cases, it's best not to assume that a buyback scheme means you will be able to re-coup all of your spend on unused product, as the reality is often that a much lower price per pack is offered, and schemes are not universally applied to all excess stock. What sounds like a great idea on the surface, can often be underwhelming in practice.

For example, if your excess drug now only has 6 months remaining expiry, it almost certainly cannot be used in a clinical supply chain, and if it has been packed and labelled for a trial, it also cannot be used in a clinical supply chain, and if it has been packed and labelled for a trial, it also cannot be used in a commercial supply chain. If there is no avenue for the drugs onward use, then there is no meaningful value that can be attached to it.

An increasingly popular method of repurposing drug is donation to an approved scheme, where medicine can be directed to patients that otherwise would not be able to access it. Whilst this doesn't recoup any of the cost of the drug, these schemes are essential in helping patients in communities with less established healthcare systems. There are many initiatives of this type, both domestic and international, which Midwinter can recommend if Sponsors are looking for a reputable, ethical and compliant avenue for donation.

With all of the above points fully explored, destruction should be the last resort.

Summary

Some redundant commercial drug products are the cost of supply continuity and peace of mind.

The objective for all of us involved in supply chains is to distinguish ‘necessary protection’, from ‘avoidable loss’.

In many ways, increased waste is a byproduct of the development of more flexible trial designs and the desire for achieving better, safer, patient outcomes. This makes the practice fully justifiable, but as always, it rests on the clinical supply professional to decide the right amount of force to apply to the scale when balancing excess and resilience. Good planning and clear communication will help you to make informed and sensible decisions at the outset of your study, and we hope this White Paper has highlighted a few methods that can be employed if the surplus you encounter is beyond your expectation.

If you have any questions on this topic, please feel free to get in touch with me directly at ben.everington@midwinter-solutions.com.

Meet The Team

Mark Waters
Chairman

Ben Everington
Managing Director

Tony Phillips
Director and Responsible Person

Tim Morgan
Director and Head of Supply Chain

Lianne Kloppenburg
VP of Client Services

Charlotte Fretwell
Global Account Manager

Wayne Deans
Client Services Director

Deborah Hemming
Finance Director

Glen Jones
Clinical Trial Project Manager

Shaun Slater
Clinical Trial Project Manager

Ron Yau
Snr. Quality Manager and Responsible Person

Thomas Ross
Senior Finance Manager

Dan Pritchard
Snr. Project and Operations Manager

Anthony Williams
Clinical Trial Project Team

Chris Roby
Quality Team

Becky Kelleher
Finance Manager

Elly Reynolds
Project Manager

Beth O'Neill
Project Team

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Tel : +44 (0)1283 496920 Email: info@midwinter-solutions.com
Website: midwinter-solutions.com

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