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THE FUTURE OF CLINICAL TRIAL SUPPLY – TRENDS AND CHALLENGES 2015 REPORT

WITH EXPERT INSIGHTS INCLUDING INTRODUCTION AND ANALYSIS FROM:

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PPD International

PRODUCED IN ASSOCIATION WITH THE 5TH ANNUAL

Clinical Trial Supply Europe

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EXECUTIVE SUMMARY

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We are such a data driven industry. I find the best way to get a point across, influence outcomes, or get decisions made is to provide the facts and the rest will follow.

The data presented here, thanks to the survey that Pharma IQ sent out and then collated, gives us a great overview on what is challenging us, our industry and our partners in the world of clinical supplies. There are some surprises here, some information and perspectives that supports exactly what we thought and some trends that are clearly still plaguing us. We still seek to better control the clinical supply chain, partner better and support our customers in clinical operations through the use of Interactive Response Technology (IWRS/IVRS). We're still adapting to the challenges of maintaining temperature control with our IMP shipments and constantly trying to increase the efficiency and control the cost of our comparator sourcing. BRIC Countries are still on our learning curve as we increase clinical sites in some, decrease them in others and add other difficult countries to our mix of clinical trial markets, like Turkey.

Forecasting and planning is essential in everything we do and we are slowly building this function in our companies with both a resource and automation focus. Finally an area that has evolved over the years and is attracting more attention with better automation and innovation, labeling, from a standardization and "just in time" perspective has popped up as a way to increase speed and flexibility into our clinical supply fulfillment and distribution. The amazing thing about all of this is how we continue to add and improve these initiatives with little to no increase in resources or investment, clearly showing how innovative, collaborative and creative we are as an industry group. I look forward to meeting you at the **event**

Steven Jacobs
Chair Global Clinical Supplies Group

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CLINICAL TRIAL SUPPLY OUTLOOK 2015 SURVEY

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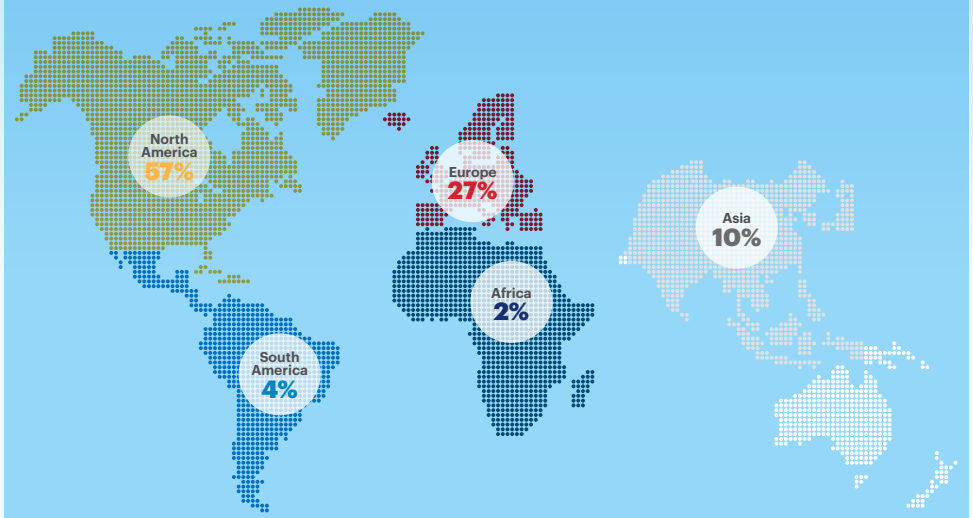
Where They Came From:

In July and August of 2014, Pharma IQ surveyed its members in the Clinical Trial Supply Outlook 2015 Survey to discover the latest trends, priorities and challenges in clinical trial supply. The results of this survey and expert analysis are contained in the following pages



North America provided the largest amount of respondents, this may be unsurprising as is shown on our clinical trial supply map on page 26 the USA is the number 1 location in the world for clinical trials.

In Europe, the best represented country was the UK followed by Germany and Switzerland.

Respondent's Job Titles

The respondents to the survey held diverse job titles, but the best represented titles were:

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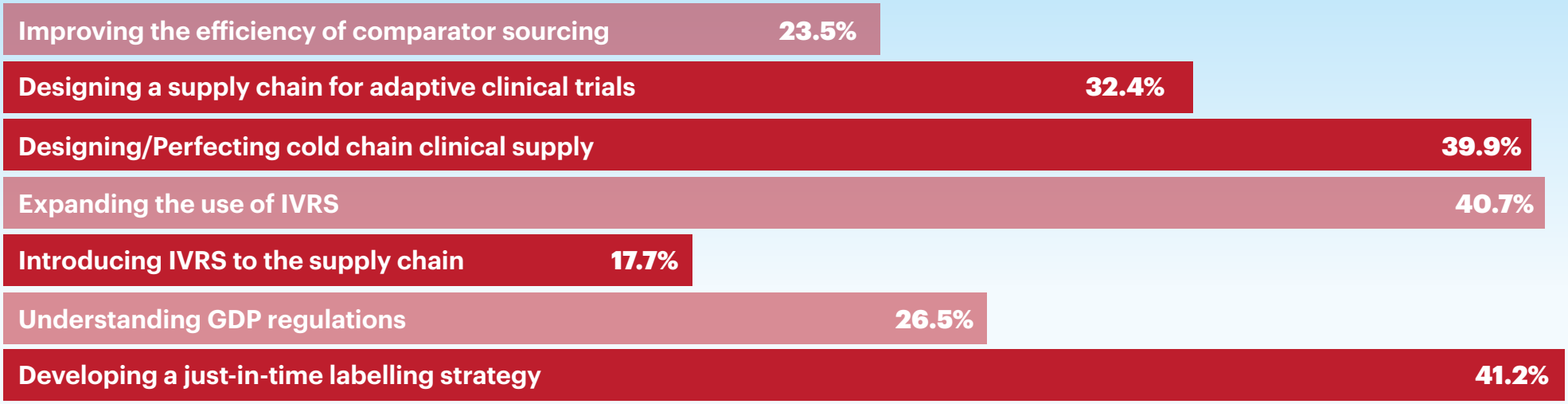
What area(s) are you most focused on improving in your clinical trial supply in the next 12 months?



Insights from Steve Jacobs

As our trials continue to grow in terms of scope and complexity, it is no surprise that we are turning to technology and ways to increase efficiency in getting the rift clinical supplies to the right sites in time for the subjects and patients to be dosed. With IRT (interactive Response Technology), forecasting tools, temperature controlled distribution and finally comparator sourcing, never have our stakeholders and business partners been as important or helpful in aiding us in our quest to get it there and have it ready to be used.

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What are your top 3 challenges with comparator sourcing?

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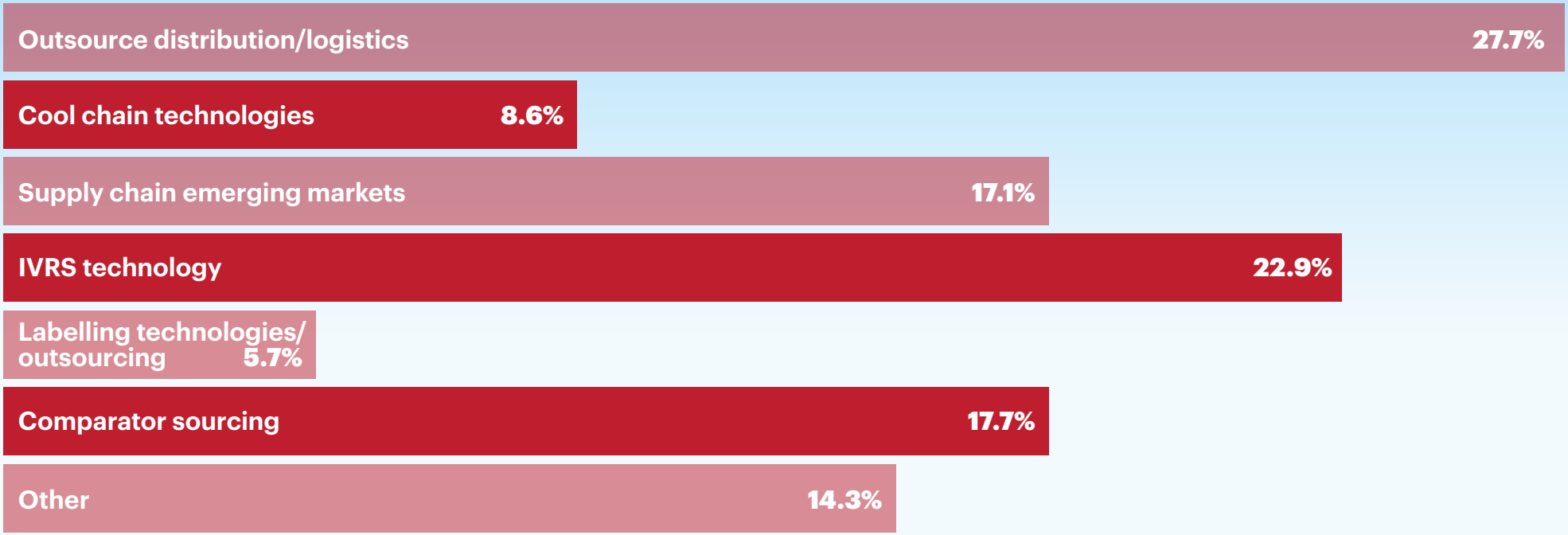
Which Area(s) are you looking to invest in in the next 12 months?



Insights from Steve Jacobs

With constantly shrinking sponsor company numbers, due to mergers and acquisitions, partnerships to improve distribution, logistics and IRT is no surprise. What was a surprise was how little investment, or known investment is occurring in environmentally friendly supply chain initiatives. I suspect this will change in about 3 to 5 years, but will always be late to the dance behind ways to improve IMP supply chain efficiency.

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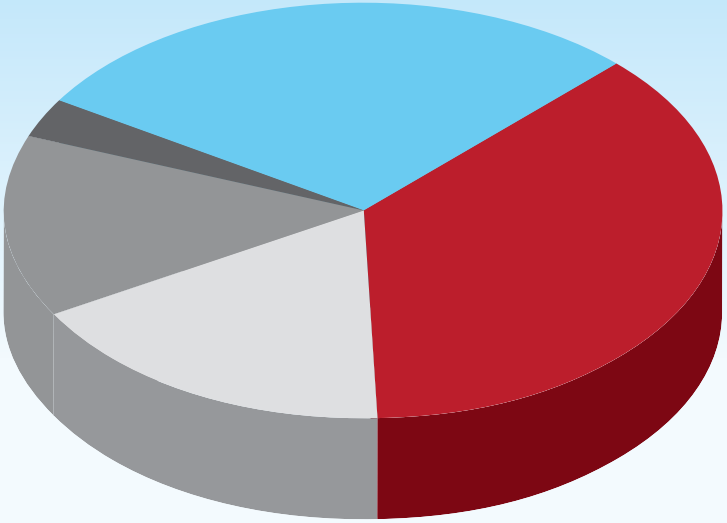
How much are you looking to increase your investment into the clinical trial supply function in the next 12-18 months?



0-25%	37.1%
26%-50%	17.1%
51%-75%	14.3%
76%-100%	2.9%
Investment levels are likely to remain the same	28.6%

Insights from Steve Jacobs

I was proud to see many folks are seeing some investment in people and systems to help us improve the quality, speed and efficiency to our clinical supply chain. I am hoping to see more in the future, but the number one will always be enrollment and clinical trial completion

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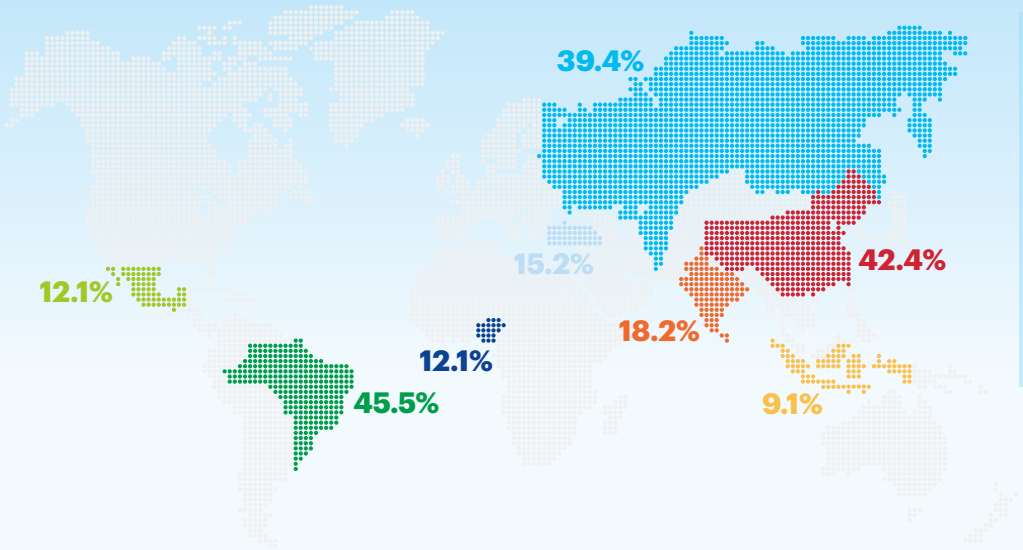
Which emerging market(s) do you find the most challenging from a CTS perspective?



Insights from Steve Jacobs

The BRIC countries continue to plague us with India less so, probably due to a drop in use of their country due to patent infringement issues of drugs in development. Other countries have started to be more troublesome, like Turkey and many other new emerging markets as the BRIC countries can no longer be called emerging markets, just fast changing ones. The word on the regulatory affairs street is that both Russia and China have started to decrease the difficulty of getting clinical trials launched in their countries to get more revenue and eventually more newly marketed biotech and pharmaceutical products.

Brazil	45.5%	Indonesia	9.1%
India	18.2%	Nigeria	12.1%
Russia	39.4%	Turkey	15.2%
China	42.4%	Other	21.21%
Mexico	12.1%		

Other areas specified were: MEA, Vietnam, Serbia, Saudi Arabia, North Africa, Georgia, Iraq, Iran, Philippines

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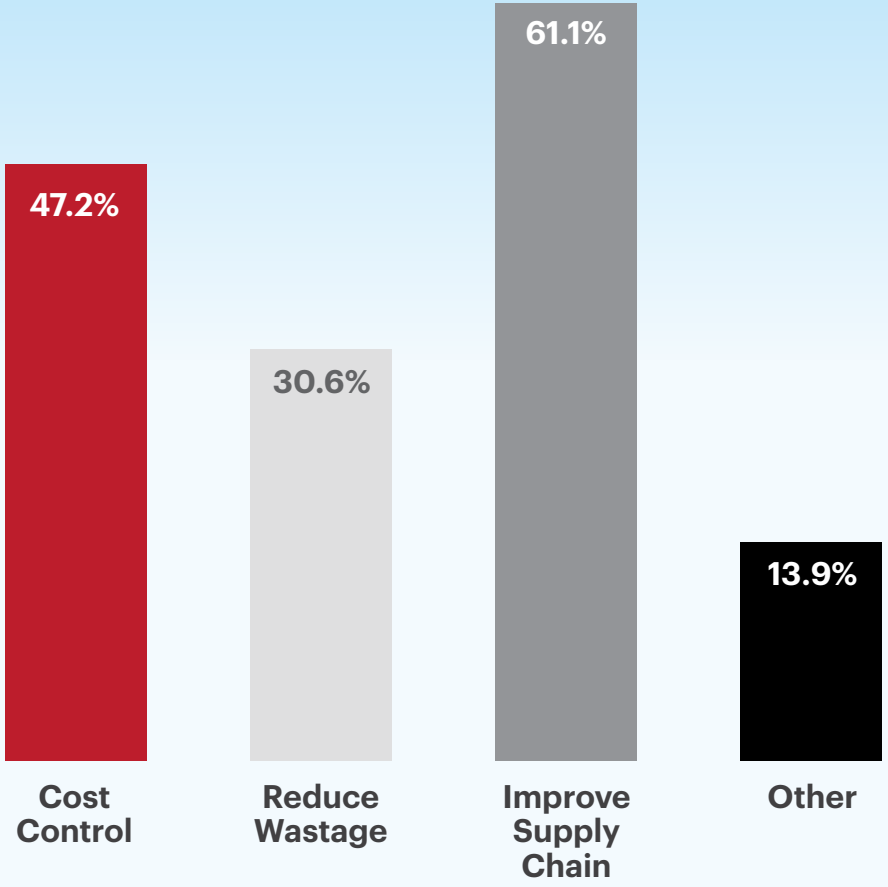
What are the most important outcomes of the implementation of forecasting?



Insights from Steve Jacobs

Forecasting and planning have been the industry darlings for a few years now and with technology improving are taking center stage to increase clinical supply chain efficiency and cost savings. The challenge remains finding the right system for you and then ensuring the best training takes place to create the most system super users to aid in successfully decreasing costs while increasing time savings and quality.

Other specified outcomes were: Eliminating Out of Stock Situations, uncertainty of need of clinical samples, Reduce Stock Outs, Security of supply and Lead time reduction, minimize out-of-stocks at clinical sites

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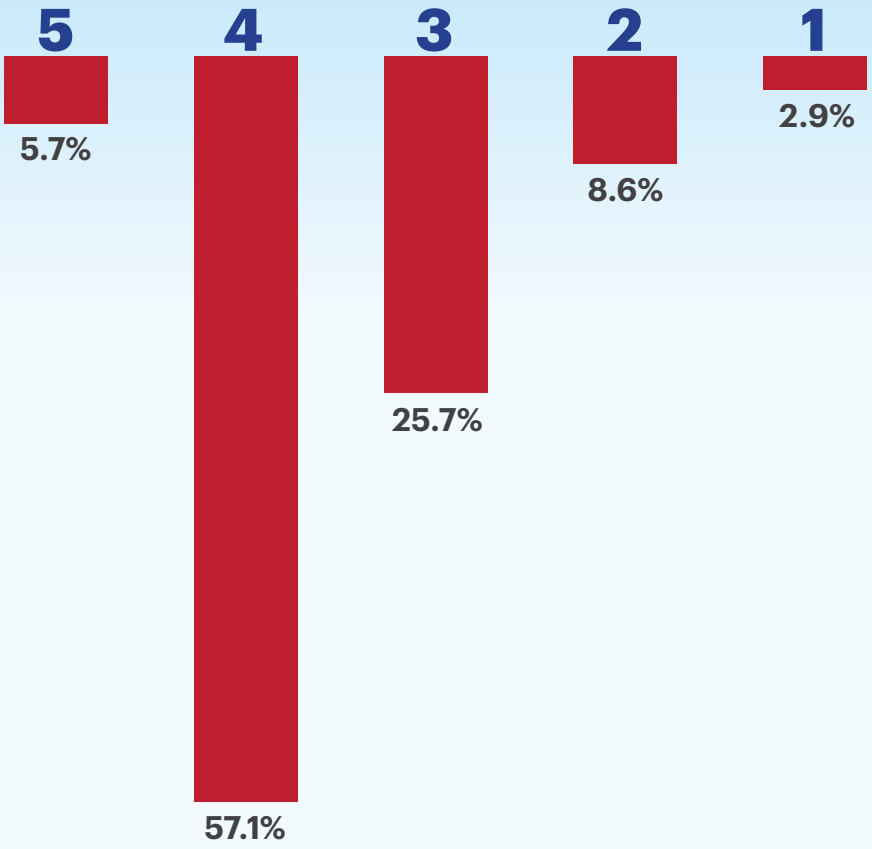
How important is packaging and labeling for your company in the coming 12 months? Rate from 1-5 where 1 is not a priority and 5 is Top priority



Insights from Steve Jacobs

Clearly not the top priority, it's good to see packaging and labeling is still important. I remember, many years ago, one of my clinical operations colleagues telling me clinical supplies was not "Rocket Science". I think we have proved our colleagues and stakeholders, who may have said that long ago, wrong on that perspective. Not only has the complexity of the IMP supply and distribution chain increased exponentially, we now realize any little slip will lead to unacceptable delays in development.

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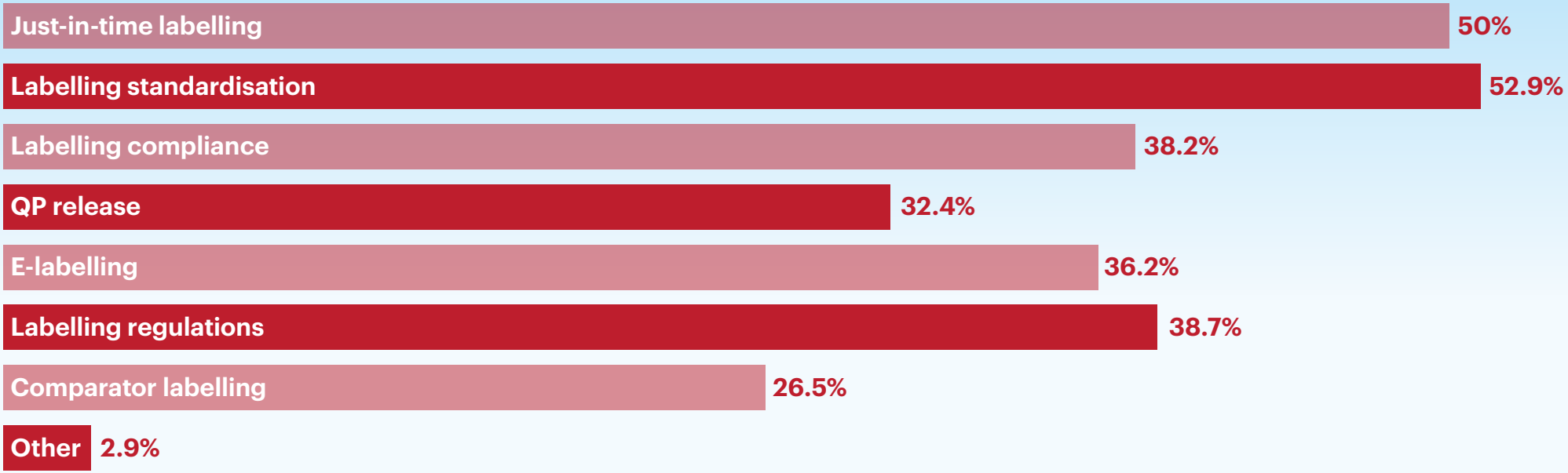
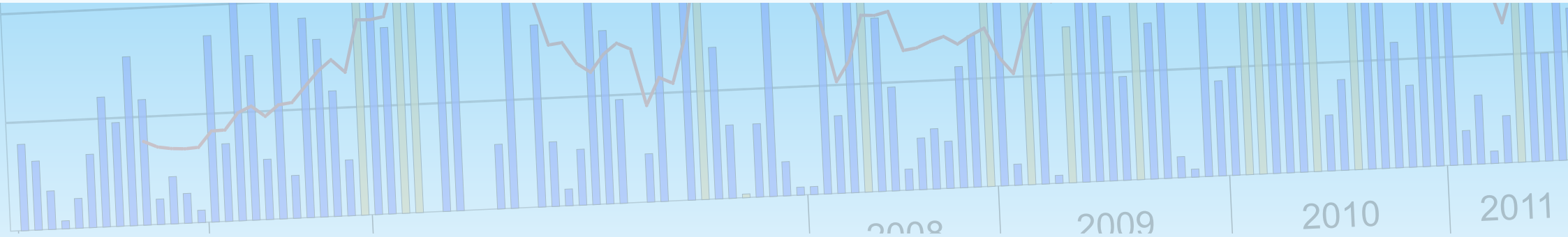
What areas of packaging and labeling is your company most interested in?



Insights from Steve Jacobs

When you're looking to increase speed and efficiency while maintaining quality, standardisation of labeling is a great way to go. Not only does it make translations easier, it makes quality review easier as well. I've also found that improving our relationships with Quality have opened the door to "Just in Time" labeling and distribution with a quality control person embedded with the clinical supplies warehouse folks.

COMPARATOR SOURCING



The respondents to the Clinical Trial Supply Outlook 2015 Survey placed comparator sourcing as among their main concerns, with controlling cost, quality and availability as their main challenges. In this section we present an article on the difficulties in comparator sourcing, an interview with Boehringer Ingelheim's Peter Orosz, an article on the importance of comparator sourcing and an interview with Helle Aagaard-kirkeby on how to work better with a CRO for better results in comparator sourcing

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THE TRIALS AND TRIBULATIONS OF COMPARATOR SOURCING FOR CLINICAL TRIAL MATERIALS

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The numbers of clinical trials that compare two active drugs, rather than testing a new drug against a placebo, are increasing. Comparator trials are chosen for two main reasons.

Firstly, there may be ethical reasons why using a placebo in place of a genuine treatment is not preferred. For example, if subjects have existing conditions that could worsen if their treatment is stopped for any period of time.

Secondly, there is a general increase in focus on the comparative effectiveness of drugs and therefore there is increasing pressure on drug developers to run clinical trials that will demonstrate the benefits of their products relative to those already available.

Once an appropriate comparator drug has been identified for use in a trial attention turns to how to source it. This may sound like a simple task but increasing globalization of the clinical research sector coupled with the frequent requirement to purchase a competitor's product, make it more complex.

This article reviews the key challenges associated with comparator sourcing of clinical trials materials and ways to reduce the risks associated with this task.

KEY CHALLENGES OF COMPARATOR SOURCING OF CLINICAL TRIAL MATERIALS

A reliable supply of comparator product is required to minimize delays in clinical trials, and to ensure reliability of results throughout, by guaranteeing a consistent drug comparison. Any delay to supply increases the risks for the trial sponsor and can be costly.

Maintaining a short, transparent supply chain

Establishing a compliant, efficient and secure supply chain is key to ensuring reliable supply for your clinical trial. Security of the supply chain is crucial to ensure that no counterfeit comparator is introduced into the trial, which could jeopardize results. However, this is easier said than done in a highly regulated landscape that can cross numerous geographical borders.

Operating in a highly regulated environment

There are many rules and regulations about where you can source drugs from depending on where you are running your clinical trial; US, Europe, ROW. There are also more general trade regulations that govern import and export that must be adhered to.

Maintaining a complete audit trail for every product can be a challenge but is vital to make sure that any special requirements e.g. during handling and distribution are met and recorded to ensure the product stays in specification.

Language barriers

As clinical trials become more global there is a need in many cases for special labeling of comparators to enable clinical staff to understand how to handle and manage the drugs. This can add time, financial cost and increase the risk of error of your clinical trial.

REDUCING THE RISKS ASSOCIATED WITH COMPARATOR SOURCING

As an overall approach, having a full and detailed view of the supply process and putting together a specific strategic approach for each clinical trial is the best route to successfully minimize risk. Here are some more detailed key ways that drug developers can reduce the risks associated with comparator sourcing.

Begin planning early

Early planning gives time for thorough research into the available options for reliable sourcing. The required comparators are often available from multiple

THE TRIALS AND TRIBULATIONS OF COMPARATOR SOURCING FOR CLINICAL TRIAL MATERIALS

sources from across the globe, but each of these sources may have regional differences that are governed by different regulations. It takes time to consider and each source and to decide on the best choice for a specific clinical trial.

Put a clear comparator sourcing and supply strategy in place

Any disruption to supply during the clinical trial could cause delays or jeopardize results. A well researched and thought-out sourcing and supply strategy that includes a complete understanding of global regulations, as well as a detailed approach to demand planning, will reduce the risks associated with any changes to the required quantity of comparator that may arise during the trial – making sure you have what drug developers have what they need, when they need it.

Source directly from the comparator's manufacturer

Sourcing directly from the manufacturer can be the best way to guarantee a reliable quality and quantity of product for a clinical trial. Sourcing directly from a manufacturer means that drug developers can purchase large, single lots of a drug that has a long shelf life. This buys time for things such as relabeling and repackaging that may be required across geographical locations and also minimizes the need for frequent re-supply, which can be costly.

Partner with a sourcing specialist

Of course, a comparator's manufacturer may not want to sell their drug for a comparative trial that may demonstrate superiority over their product. As a purchasing company you may wish to remain anonymous and going directly to the manufacturer reveals identity.

Many drug developers employ specialist companies with a detailed knowledge of the global landscape to remove the burden of sourcing and supply for comparator trials. These organizations deal with the issues associated with comparator sourcing day in, day out and should therefore find it easier to give options that ensure a reliable and reputable supply.

Regardless of the approach you take to comparator supply it is of course crucial that you can trust in the product you are receiving to ensure accuracy in trial safety and results.

First published on Pharma IQ here

COMPARATOR SOURCING AT BOERINGER INGELHEIM

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Peter Orosz
Head of Clinical Supply Chain Management Oncology
Boehringer Ingelheim Pharma GmbH & Co. KG

Pharma IQ:
What should companies know when it comes to investigator-initiated studies?

Peter Orosz:
First of all, the companies should have a clear strategy, whether IIS shall be supported in general or not. With regards to IIS Investigational Medicinal Products (IMPs), the company should be aware of all regulatory and GMP topics, for instance that an IMPD is needed for an IIS also, responsibilities of QP for release of IIS IMPs, regulatory compliance check of IIS IMP, contracts and appropriate quality assurance agreements.

Pharma IQ:
How can companies best deal with clinical trial supply in investigator-initiated trials?

Peter Orosz:
So, for the abovementioned topics, SOPs or working instructions shall be in place and the processes shall be described. In the set-up of these processes it's recommended that all involved interfaces are working on these instructions, primarily colleagues from medical affairs, from legal, QA, Qualified Persons and clinical supplies unit

Pharma IQ:
What are the keys to overcoming the challenges in comparator sourcing?

Peter Orosz:
The major challenges are lead times, reliability, documentation and costs. From my perspective there is one key only and that's a trustful cooperation with a partner, having a good network. A good network of the partner is crucial. Alternatively, direct sourcing from companies or participation in a comparator network as member may be an option.

Pharma IQ:
How has the comparator sourcing landscape changed in recent years?

Peter Orosz:
Yes, indeed, it changed a lot in recent years as the selling companies track the usage of the sold products more intensely. They would like to know who buys the product, whether it is used in a clinical trial and they ask for confirmations that that products are not used for other purposes.

Pharma IQ:
What challenges remain to be tackled in comparator sourcing?

Peter Orosz:
As mentioned above, lead times, reliability of timeline, product availability for resupplies, documentation and costs, are some challenges but in addition regulatory topics get more and more important like use of EU products in the US and vice versa or use of EU products in Asia and vice versa. This is a topic which has to be worked on in the future to get more clarification about the differences in local legal requirements.

Peter Orosz will explore this topic further in his talk "IMPs for investigator initiated studies " at the Clinical Trial Supply Europe Summit.
Find out more by downloading your agenda here

SOURCING COMPARATOR DRUGS FOR GLOBAL CLINICAL TRIALS

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Increasing emphasis on the comparative effectiveness of pharmaceutical treatments has in recent years translated into a growing expectation for developers to prove the relative benefits of their new medicines during the clinical trial process. Under ordinary circumstances, the process of sourcing comparator drugs poses distinct challenges, but when studies are conducted on a global scale the issues are magnified. With pressure mounting for drug developers to carry out comparative effectiveness trials more frequently, sponsors need to have in place a robust strategy to first of all select and appropriate comparator product and then ensure that its supply can be maintained consistently and cost-effectively across all trial sites, wherever in the world they may be.

At a very basic level, comparator sourcing involves comparing existing pharmaceutical products with those still in development, usually to prove that a new treatment is more effective or works faster than its predecessors. "Most of the time, this is done for best in class, and is usually done during Phase II or III studies," explained Lekishia White, vice president at MultiPharma, in a recent interview with Genetic Engineering & Biotechnology News (GEN). "Comparative trials are prevalent, especially with increasing pressure to get the best drug on the market," she added.

But there is usually a specific set of risks involved with such studies. For instance, most companies would not want rival firms to be aware of the fact that they are comparing the benefits and effectiveness of their medicine to another. However, as Ms White pointed out, such details regularly enter the public domain as clinical trial information usually has to be revealed to the authorities, such as the Food and Drug Administration (FDA) in the US. And even if the new product has not brought any improvement to the treatment of a condition, the firm may still be obligated to share its results.

"This is why drug development is so expensive. There is such a small percentage that makes it through the entire cycle. You could get through trials with a working therapy, but it may not be best in class, so the company decides not to develop it," Ms White went on to say. One of the distinct challenges facing developers when involved with comparator sourcing is getting together all the necessary documentation. Companies will need to obtain a certificate of analysis, or equivalency paperwork, as well as formal approval to use the materials.

"There may be a drug registered and available in Europe, but not in the US. That would require an equivalency statement that ensures it's the same formulation," Ms White told GEN in March 2011. She also explained how different comparator sourcing providers specialise in the areas they service most. "Some of us have better relationships with the innovator companies than others. It's about relationship building." And the best way for companies to know which provider to use is often to attend industry meetings and conferences, she added.

"The clinical trial circle of influence is quite small - word gets around quickly who is reliable and who is best. There are at least ten comparative-sourcing providers - for such a small niche market, that's a lot." In fact, the field is a growing area, with the number of providers having doubled in the past few years. Clinical research organisations (CROs) undoubtedly have a key role to play in the future of global drug development – and in the sourcing of drugs for comparative study.

Decisions over when to rely on in-house resources and where the services of CROs can be strategically beneficial are pivotal in terms of whether or not a new drug is going to make it to market. The latest research suggests that biopharma currently outsources a third of all clinical research. As the need for consistent and cost-effective comparator sourcing grows, this proportion is likely to increase accordingly.

This article was first published here on Pharma IQ

WORKING EFFECTIVELY WITH A CRO

Helle Aagaard-Kirkeby
Primary Clinical Supply Manager, Clinical Supply Development
Lundbeck

Pharma IQ:
What are the key challenges that companies are facing in clinical trial supply?

Helle Aagaard-kirkeby:
The challenges vary. I also think it varies from company to company. From Lundbeck's side and from the studies that I have responsibility we have some challenges in relation to the commercial drug sourcing, since it's a very difficult market. And we use a lot of base treatment, commercial products as a base treatment. We have some situations where it could be very difficult to source some of these, especially in the US.

Also we are not very keen on having manufacturing suppliers in India and China, as we need to ensure the quality of the manufacturing. We have seen some situations where there has been a warning letter issued to these types of manufacturing suppliers either in India or China. So that is why we have to be focused on where we are sourcing the product from.

Pharma IQ:
And how do you overcome those challenges?

Helle Aagaard-kirkeby:
It's very difficult because we need to find a good sourcing partner, a good sourcing specialist on these occasions. And it's always difficult since you have a lot of sourcing specialists in the market. You also need to ensure that they have the right competencies in sourcing of the product. You could end up in a situation where we have some sourcing specialists that have special agreements with manufacturers and they will have a better supply chain than others. And it's very difficult at that point, but we have to be focused on the specialist market and see what specialists fit Lundbeck the best.

Pharma IQ:
How should companies implement forecasting in relation to sourcing in their running of clinical trials?

Helle Aagaard-kirkeby:
I think the best point will be that you, pretty much in advance, try to figure out how the forecast should be, but always when you get the draft protocol and you actually know which product you are going to use try to contact the sourcing specialist. Tell them what you need at that point. I think that would be the best, because sometimes many products take a lot of sourcing lead time and it's better to be in advance that too late, so to speak.

Pharma IQ:
How can companies maintain best working relationship with a CRO?

Helle Aagaard-kirkeby:
The best working relationship depends on how the study team are at the CRO. Sometimes you see that the study teams in the CRO are really not collaborating with each other even though we have different studies at the same CRO, we don't see that in the different study teams that they have a knowledge sharing. So it sometimes is like you're starting up again, even though you use the same CRO.

I think it's very important that the communication is very clear, what we need and what the CRO needs. Sometimes we see a problem where the CRO really does not understand what studies need in relation to clinical supply set up. They need to know the recruitment

WORKING EFFECTIVELY WITH A CRO

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plan in advance, how many patients do they expect in the study, because this is a very important task in relation to setting up the supplies and how much, how quantities should be set in the strategy.

Pharma IQ:
What are the keys to choosing the right CRO to work with?

Helle Aagaard-kirkeby:
It's very difficult, because in Lundbeck we have an outsourcing department, so they outsource the task to a CRO and they have some different standards. Sometimes you really do not what CRO that has been chosen. We have some requirements on my own side for the clinical supply side that we need, of course.

But this year we have competitive staff that know what they are talking about and I also know if they have allocated staff to a study where the staff aren't correct the staff they will change the staff. We need to know that we are able to change the staff, because if one person does not fit our standards and our requirements it will not be a good idea just to move forward with that person. There could be big problems if the person does not really understand the set up and has not the experience in the set up. So sometimes one has to change the staff or the person who has the responsibility for the communication in regards to the supplies at the CRO.

Pharma IQ:
What do you think will be the major changes in the area of clinical trial supply in the coming 18 months?

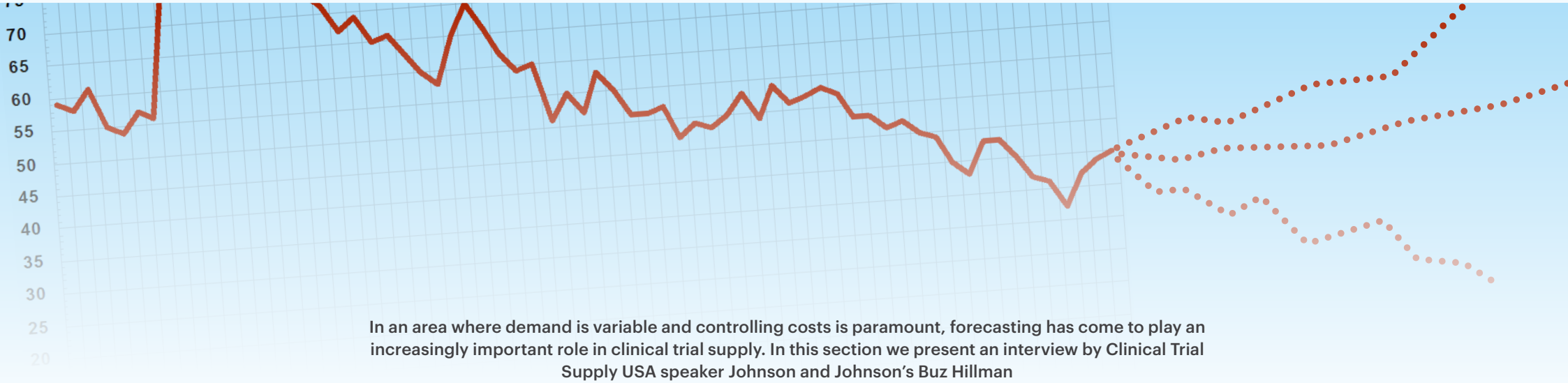
Helle Aagaard-kirkeby:
I think the major changes will be that as it is right now I don't see we have a standard in how you're setting the studies up. I think because of the requirements from the FDA and the EMA about how the studies should be, and how the study set up should be, I think we'll see a lot of different types of studies, more complex types of studies, perhaps more titration studies. I think it's very difficult to see that you have what you call a straightforward study.

Pharma IQ:
And what do you think could be done to advance that cause?

Helle Aagaard-kirkeby:
But you can't do anything about that cause. It's very difficult, because you never know what the specialist decides how the study set up should be. The only thing you can do is that you can try to have some kind of knowledge sharing. Perhaps you can ask other companies or colleagues how we should approach that set up. You need to rethink and need to change the set up. Of course, it's a very good learning process, but actually when you are in the clinical supply area, there is a changing atmosphere all the time and we have a change of study all the time. So I don't think you can foresee that. You just have to go with the flow, so to speak.

Helle Aagaard-kirkeby will explore this topic further in the panel "What are the differences in their CTS approach and what can we learn from each other?" at the Clinical Trial Supply Europe Summit. Find out more by downloading your agenda here

FORECASTING



In an area where demand is variable and controlling costs is paramount, forecasting has come to play an increasingly important role in clinical trial supply. In this section we present an interview by Clinical Trial Supply USA speaker Johnson and Johnson's Buz Hillman

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RESPONDING TO CHANGES IN CLINICAL ENVIRONMENTS BEFORE THEY OCCUR

Buz Hillman
Associate Director - Clinical Supply Systems
Johnson and Johnson

Pharma IQ:
We're now certainly living in the world of big data. How do you think this has affected big pharma in the way it predicts requirements for clinical trials and how can companies improve their reporting to ensure that they have the data they need?

Buz Hillman:
First of all we need to be very specific around how data ought to be assembled and delivered. This data is then pushed out in a very flexible visualisation environment and this environment can be managed in such a way such that it is programmed to produce early warning signs of trouble spots in your clinical trial. You then need to react to early warning signs while there is time to do so.

Pharma IQ:
The upcoming Clinical Trials Supply event in Boston [2013], I see your talk is titled Maintaining an Efficient and Balanced Supply Strategy Through the Use of Clinical Trial Data. In what areas do you think there is the greatest opportunity to maximise efficiency?

Buz Hillman:
SFirst of all I think it's really important to focus on standardisation of data across clinical trials such that there is a standard report regardless of the trial that is being used to report the data. Also delivering the data on a daily basis such that it is immediately available at your fingertips and it eliminates the need to go out to a supplier's website and downloading the data, and then of course finally reacting to your changing clinical environment and environmental factors in a timely manner. It's one thing to be able to have access to this data and for it to be standardised but if you don't act on it in a timely manner than the data serves no purpose.

Pharma IQ:
You've had many successes in your career but what specific change that you have made do you think has made the most impact?

Buz Hillman:
I think standardisation of a great operating model which includes using a great forecasting tool and wrapping it with a great process. You can have the most sophisticated and accurate tools available to you but if you don't wrap good processes around them then the tools are of very little value. And then finally taking best practices into account and implementing them across the board; this brings about consistency and use of best practice portability.

Pharma IQ:
You have led and managed strategic improvement initiatives. What do you think the major challenges are in implementing large strategic changes and how can they be overcome?

Buz Hillman:
Perhaps the most difficult challenge to overcome is getting everyone on-board with the change and in step with a specific timeline. The bigger your organisation is the more complicated change can be and it's very important to have a very senior level sponsor to kick off the endeavour and help clear away obstacles that may be difficult to overcome.

Pharma IQ:
In what ways do you think the clinical trials supply has changed in recent years and what technologies do you see as having the greatest benefit to clinical trial supply in the next five years?

RESPONDING TO CHANGES IN CLINICAL ENVIRONMENTS BEFORE THEY OCCUR

Clinical Trial Supply Europe

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Buz Hillman:
Recent years have brought us remarkable capabilities in drug forecasting as well as IVR/IWR self served products on the market. Those tools have come a long way over the last three to four years. In the future I hope to see better data sharing across environments and better use of this data. We need to be locked in a fast and flexible mode at all times and take advantage of technologies that support this fast and flexible mode of action.

Pharma IQ:
Buz, you're the chairman at the Clinical Trials Supply event in Boston this September [2013]. Why do you think that events like this are important?

Buz Hillman:
First of all it gives you access to critical knowledge in a complicated world from the latest thinkers in the industry. It gives you the ability to learn about industry trends and shape your internal organisation to be able to accommodate those trends and take advantage of those trends. Thirdly, learning about potential changes in the industry from a regulatory perspective; occasionally at these conferences there are regulatory agencies represented or even speaking at conferences and it is very interesting to learn about what's on the horizon from a regulatory perspective. Learning about best practices and services on the market to support clinical trials, another item, influencing the industry to support your future endeavours and then finally I think it is really important to establish external industry contacts, otherwise known as networking, to share best practices, ideas and knowledge about potential product uses or problem resolutions that other folks and firms have encountered and resolved.

This article was first published here on Pharma IQ

EMERGING MARKETS

Looking for areas of opportunity is a common practise in industry and clinical trial supply is no different. The emerging markets can present a less saturated, fertile ground to perform clinical trials, but they can present challenges too. Along with dealing with the more obvious challenges of climate and geography, navigating legislation and staying compliant present a significant test for companies. In this section, we present an interview with Pfizer's Clinical Supply Logistics Director, Adrian Peskett, Pharma IQ's Clinical Trial Supply Heatmap and an article on the difficulties of multinational clinical supply

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FORECASTING A BRIGHTER FUTURE FOR CLINICAL TRIAL SUPPLY IN EMERGING MARKETS

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Adrian Peskett
Clinical Supply Logistics Director
Pfizer

Pharma IQ:
It's almost been a defining trend in recent years in the clinical trial space that people are moving clinical trials increasingly to the emerging markets. What are the main reasons for this, and do you expect this trend to continue?

Adrian Peskett:
From my experience, there are a number of both push and pull factors. One of the pushes is that we are quite saturated in the traditional clinical trial markets, and many companies are looking for alternative countries to do their clinical research in. Another factor is, of course, that there is a huge population in a lot of those other countries, a naïve population at times, and a population where the facilities are now getting better. The regulatory requirements and the Ministry of Health in a lot of these countries, they have put things into place which makes clinical trials possible where sometimes they hadn't been possible before. And I think there is an element, where we're all a business, so there's an element of cost as well. I think generally, people now are looking at global clinical trials, which means including emerging markets, as well as the western traditional clinical markets.

Pharma IQ:
What are the main challenges with working within emerging markets?

Adrian Peskett:
Certainly from the perspective of a lot of the companies that I work with, or have worked for, language is one of the key challenges. So English is typically used as part of the communication – in some of the emerging markets, the level of English, perhaps, is not as strong. So that's one of the challenges, to make sure that you understand what the clinical sites of the investigators are actually requesting from you, or indeed, the customs and the other regulatory authorities. But I think distance is another thing as well – a lot of the strategies are set up so that they are orientated away from the emerging markets, so you need to set up either new depots, or you will ship direct to site, but that distance obviously provides a logistical challenge to consider. And of course, then there's a variety of physical conditions. So I'm talking really about the environment, and the challenges that that can bring, aligned with the infrastructure. So the infrastructure is not always as developed in some of the clinical sites, for getting the materials to the clinical sites. So that can provide an element of challenge as well.

Pharma IQ:
How can companies standardise strategy, while taking into account the needs for individual countries?

Adrian Peskett:
It's difficult, really. I think there are a number of elements, where strategy can be standardised. I think you can look at standardising, perhaps, who you work with as a courier, so that you have an understanding of how they work. You can standardise your labelling by getting a regulatory template in place for a particular country. You can look at perhaps even standardising your brokerage and your distribution strategies. So there are elements of the whole supply chain where you can actually standardise, but I think within that, you need to understand that you always have some variable flexibility that's required. So with the labelling, for instance, depends on the product, as to what information you actually have to have on there. Equally, with the courier process, for instance, you will need different documentation as you come to do the importation. So you can have a more standard, holistic strategy, in how to actually manage your clinical

FORECASTING A BRIGHTER FUTURE FOR CLINICAL TRIAL SUPPLY IN EMERGING MARKETS

trials, that includes the emerging markets, but I think you always have to be aware and cognisant that each individual country actually does have its own regulations, does have its own unique challenges, and that's something that you will need to address on an individual protocol basis, depending on what materials are being used in that protocol

Pharma IQ:
Why do you think that forecasting is so important in these emerging markets, and how can it help the clinical supply process?

Adrian Peskett:
Forecasting is important from all perspectives, to be honest, with any parts of our business. Without a true forecast, then you're always being reactive to whatever you're doing, and as a result, inevitably, there'll be unforeseen challenges, which will lead to delays, and if you haven't forecast reasonably accurately, then that's going to lead to potential problems further down the line. I think for the emerging markets, forecasting is just as important, if not more important, given the fact that, as I've already mentioned, that there are longer logistics challenges potentially in place, and certainly, importation, for instance, into certain countries, can take months to get those supplies in. And without effective forecasting about how that protocol's going to run, then you will find that you will be short of supplies, and either having to manage them in a site to site basis, or even, going without supplies for patients.

Pharma IQ:
In what ways do you think that clinical trials supplies changed in recent years, and what technologies do you see as having the greatest benefit to CTS in the next five years?

Adrian Peskett:
FI think we've definitely seen a change, obviously, in the geographical spread of where the clinical trials are taking place. And I think that will continue as mentioned. I think it will continue to move to a more global basis. The technologies, as a result, have had to improve, in alignment with that, so I now see a lot more IRT protocols, rather than manual protocols that are in place. I see that we're continuing to improve the inventory systems, within companies, and also to improve the information flows within the systems that we're using. So over the next five years, I'd expect to see a lot more linkage between the CRO systems, the IRT systems, and between the courier systems, so we can get real visibility of where those supplies are, be they in a depot, be they in transit, or be they at a clinical site. And I can see that this will be pretty much the trend as we move forward – it's to improve that visibility, so that we can actually have global visibility of where all the material is, how it's being managed, and look at that across all of the countries that are involved.

Pharma IQ:
You're speaking at the Clinical Trial Supply Europe event in Frankfurt this January [2014] – why do you think events like this are important?

Adrian Peskett:
I think, really, because it builds a good platform of knowledge; importantly, it shares experiences to show people that you're not alone in this process. I think it also offers the opportunity to network, and to establish some go-to people for help, and for queries if you're facing a particular challenge. You know, are there other companies facing those same, similar sort of challenges? I think really, where we are with this part of the organisation within pharma, we are all focussed on ensuring that our patients receive those supplies, and I think that's probably the most important thing that we do, is ensuring the patients get those supplies. And we can help each other in that. We're not impacting any of our companies' IPs, or any of the other aspects where we might be getting a competitive advantage. So this is an area where we can share information, where we can share learnings, where we really can use our network, and we can ensure the patients get that drug.

THE GLOBAL CLINICAL TRIAL HEAT MAP:

The **Top 20** Countries for Clinical Trial Activity

www.pharma-iq.com

Rising drug development costs and globalisation have lead to an increase in clinical trial outsourcing, but where are the hottest areas for clinical trial activity? This Pharma IQ infographic highlights key areas for clinical trial activity, including the top 20 countries and their respective trials.

Density of Clinical Trials Worldwide

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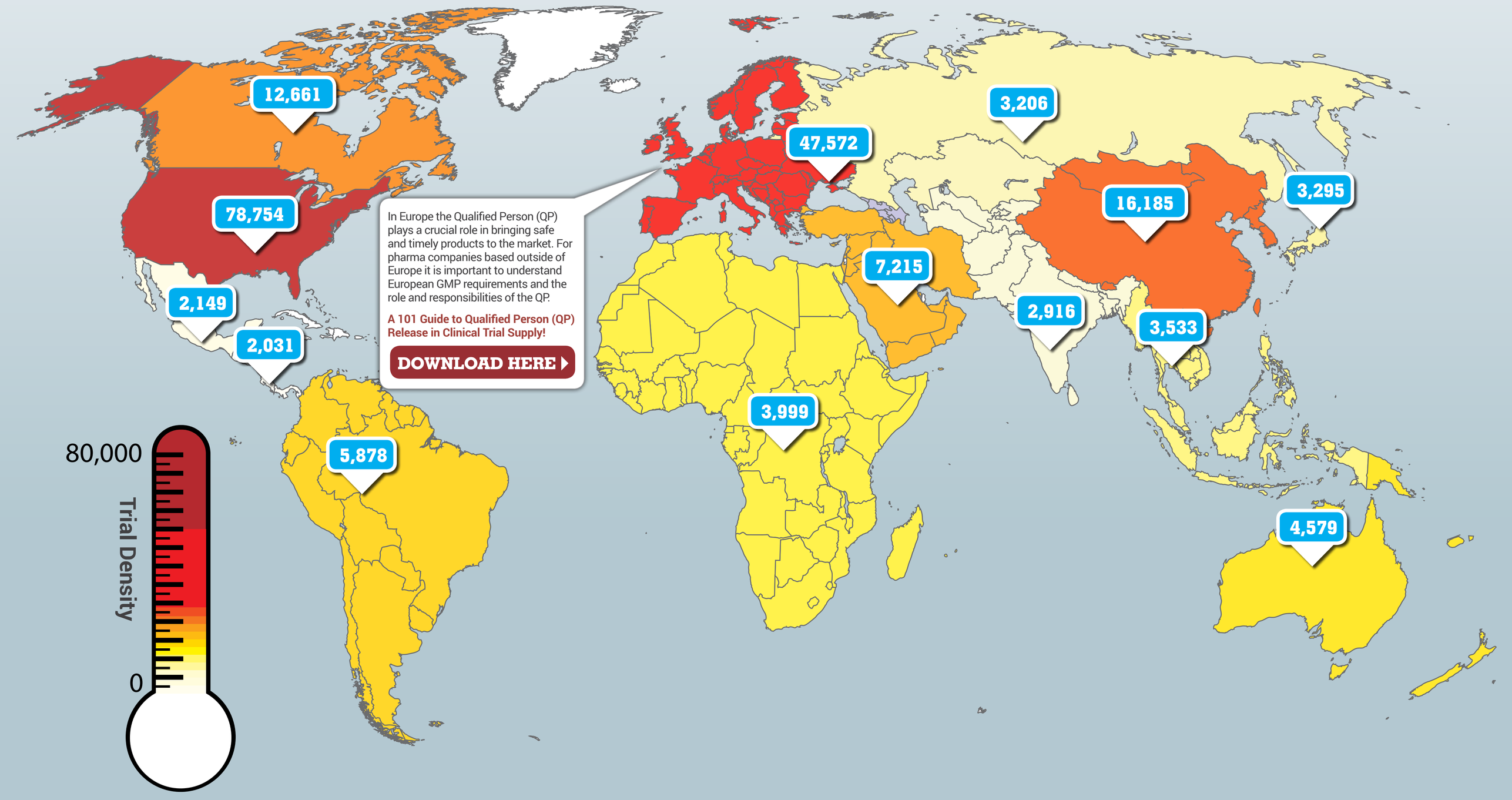

In Europe the Qualified Person (QP) plays a crucial role in bringing safe and timely products to the market. For pharma companies based outside of Europe it is important to understand European GMP requirements and the role and responsibilities of the QP.

A 101 Guide to Qualified Person (QP) Release in Clinical Trial Supply!

DOWNLOAD HERE

171,347
STUDIES WORLDWIDE

18,000
CLINICAL TRIALS ARE REGISTERED EVERY YEAR

45.9%
OF CLINICAL TRIALS REGISTERED ARE IN THE US

(Sources: ClinicalTrials.gov, Clinical Trial Supply: Top 10 Statistics – Pharma IQ)

The Top 3 priorities for clinical trial supply managers

- **Emerging Market Supply Chains**
- **Outsourcing Distribution & Logistics**
- **Cool Chain Logistics**

Information taken from Pharma IQ's The Global Clinical Trial Heat Map

DIFFICULTIES IN MULTINATIONAL CLINICAL TRIAL SUPPLY

Clinical Trial Supply Europe

ALMAC

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Clinical trials are a vital part of the research and development of new drugs and, as one of the final stages in the process, the speed at which they are undertaken and the prevention of unnecessary delays could get drugs to market quicker, potentially saving lives.

However, many in the industry are calling for the process to be shortened as some drugs can take up to two decades or longer in development, and, with many diseases like malaria, TB and dengue fever, reducing this progression by even a few years could literally mean the difference between life and death for millions.

Regulatory restrictions to supply

Writing for the Atlantic, Amanda Glassman, the director of Global Health Policy at the Center for Global Development, said that currently clinical trials are a mess, a "tangled process", which urgently needs overhauling so that pharmaceutical companies can capitalise on promising new medicines, vaccines, and diagnostic techniques and the global population can benefit from their use. She explained that there are currently 90 drugs or processes in the pipeline for malaria and 59 for TB, with just a fraction of those getting through to the final stages of clinical development.

"The many other drug and vaccine candidates for neglected diseases waiting in the pipeline for late stages of clinical development must face lengthy, inefficient review processes or non-existent regulatory capacity in the poorest, least developed countries before these technologies can reach the millions in need," Ms Glassman explained, adding that many trials, particularly those spanning many different countries, face delays of a year and upwards while approval is sought from authorities in those nations involved. This can then be subject to even more postponement if approvals need to be sought in sequence rather than concurrently.

The bottlenecks in regulations dramatically extend the length of the clinical trial process and can count for as much as half of the end cost of conducting the research, however, she suggested that introducing a regional approach to regulation would provide a more sustainable platform for supply and oversight, dramatically reducing costs.

"Clinical trials produce goods that span entire regions and, as such, they need a system of regulations to match. Reducing inhibitory costs and bureaucratic hold-ups would benefit the estimated one billion people that suffer from neglected diseases - be it malaria, TB, or other lesser known diseases - every year," Ms Glassman insisted.

Distribution costs

However, it is not just regulations that can drive up the cost of drug development and, eventually, distribution, some practitioners are calling for even more testing prior to approval, to ensure that drugs are actually cost effective to use – particularly with rare drugs and in countries with no public health care system.

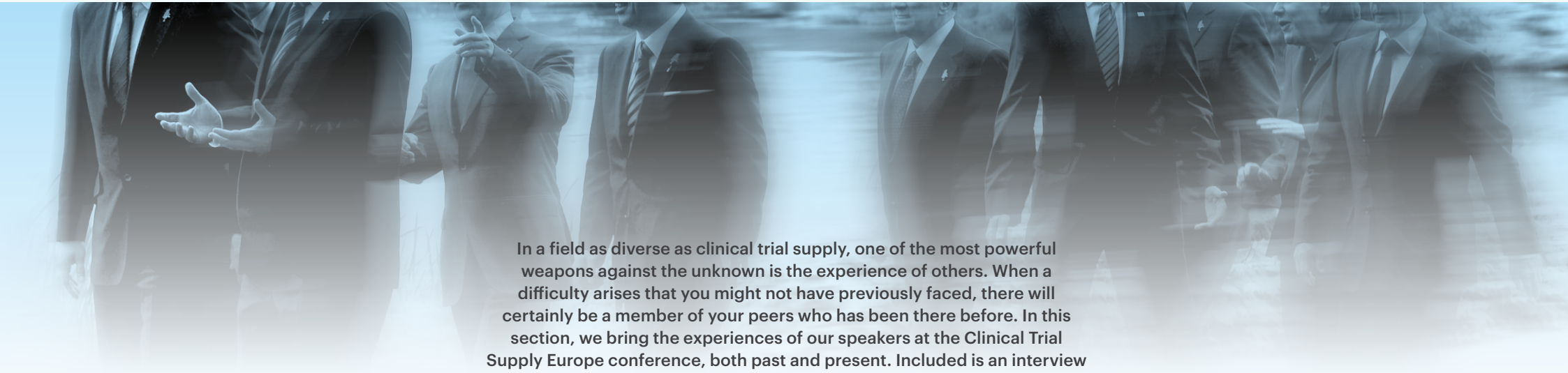
Speaking to AZ Central, Michelle Ruha, a Banner Good Samaritan Medical Center Poison and Drug Information Center physician, who took part in the US clinical trials for a scorpion sting anti-venom which is particularly rare, said that more research needs to be done during clinical trials to ensure the new drugs on the market are actually affordable. Her comments were prompted by the revelation that a single vial of the anti-venom costs over $7,900 (£4,967), sometimes up to $15,120, however John C Lincoln hospital has only recouped $10,047 of the $68,040 it has spent on the treatments as patients cannot afford it.

"You don't want to look at a parent who has a very sick child in the emergency department and say we can give you one treatment and it will cost you this, or we can give you another treatment and it will cost you that," Ruha said. "It's not just the cost that's important. If you use the anti-venom, children will be able to go home in most cases."

Given the increasing costs of drug development and research, both in regulation and in delivery costs, it is little wonder that many pharmaceutical firms are looking at their supply chains to see if they can recover any costs.

This article was first published here on Pharma IQ

INDUSTRY INSIGHTS



In a field as diverse as clinical trial supply, one of the most powerful weapons against the unknown is the experience of others. When a difficulty arises that you might not have previously faced, there will certainly be a member of your peers who has been there before. In this section, we bring the experiences of our speakers at the Clinical Trial Supply Europe conference, both past and present. Included is an interview with Eef Verhaegen on insights from CROs and Justine Swinney on distribution plans. Also included is video interviews with Ricardo Lima, Kim Tang Hvistendal, Sherri Wilson, Samantha Carmichael and out chairman, Steve Jacobs

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Client Case Study

Clinical Supply Chain Management

Biotech company running a pivotal phase III study utilized the expertise of Almac's Supply Chain Management team to supplement their limited internal resources. Their oversight ensured continuity of drug supply when patient recruitment was x 3 times faster than anticipated.

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BACKGROUND

A small, US-based biotech company was planning a 5 year, phase III, randomized, double-blinded, placebo-controlled study. The study was conducted across multiple sites in the US involving 10,600 patients. This was a pivotal study for the client who initially contacted Almac for a better understanding of clinical trial supply management and to leverage our expertise to determine how much drug they would require. Following discussions with our Supply Chain Management (SCM) team, they felt they lacked the resources and expertise internally and contracted Almac to provide core supply chain management services. The Almac SCM team assisted with devising optimal and cost effective packaging, distribution and drug accountability strategies throughout the life of the study.

CHALLENGES FACED

The SCM overseeing the study faced a number of challenges:-

The sponsor originally anticipated that the initial enrollment phase would be completed in 18-months, but due to an aggressive patient recruitment effort, patient enrollment greatly exceeded this expectation and was 3 x times faster than originally expected. This resulted in a significant increase in demand on bulk drug product manufacturing as well as primary and secondary kit production. The increase also meant more frequent shipping and a higher volume of supply movement given the large number of sites involved (~300).

The trial design, duration and higher risk patient population meant a higher degree of uncertainty in patient response. While the sponsor had some clinical study experience with the product and an anticipated drop-out rate, the different patient population presented an unknown.

Kit Design Considerations

Upon review of the clinical protocol, the SCM team realized that a common pack design would be key to meeting the high volume of supply that this study was going to require. However, the varied duration of visit lengths throughout the run-in, randomization and maintenance phases presented some challenges to developing the kit strategy. After thorough consideration, the SCM team proposed the following supply strategies:

1) For the Lead-in phase, which consisted of 14 days of dosing (7 days on active and 7 days on placebo), the patient supply was packaged in 7-ct bottles. Due to the uncertainty in the pace of enrollment and a high number of sites, a 100% overage of the 7-ct lead-in bottles were prepared. This provided assurance that ample supply would be available, but because of the low bottle count this came at little cost to overall supply.

2) While there was variation in visit lengths in the randomization and maintenance phases, spanning 8 weeks to 26 weeks, the SCM team identified the potential to employ a common pack design of 140-ct bottles and use the IRT to assign the appropriate number of bottles based on the visit length. In addition, to assist with site and patient compliance, 3x kits of 140-ct bottles were packed and labeled to better facilitate the dispensation of kits required for the longest duration visits. The use of a common bulk drug supply (140ct bottles) simplified primary and secondary production planning and lowered production costs.

Clinical Supply Forecasting

The original enrollment expectation was 18-months, but as the study start grew closer, the sponsor became concerned with that estimate based on recruitment efforts. Utilizing Almac's proprietary clinical supply forecasting solution – SupplyWise™, the Supply Chain Manager prepared multiple forecast scenarios by altering variables such as patient enrollment, site start-up, patient drop-out rates, site seeding levels and overage factors. The reporting features available in SupplyWise™ allowed for a side-by-side assessment of the forecasted demand for each scenario. The creation of multiple scenarios with varied patient enrollment completion periods ranging from 6 to 18 months allowed for a robust assessment of the impact on demand and after evaluation of the reports, the sponsor settled on the 8-month forecast as the baseline scenario and planning around that model was initiated.

ALMAC APPROACH

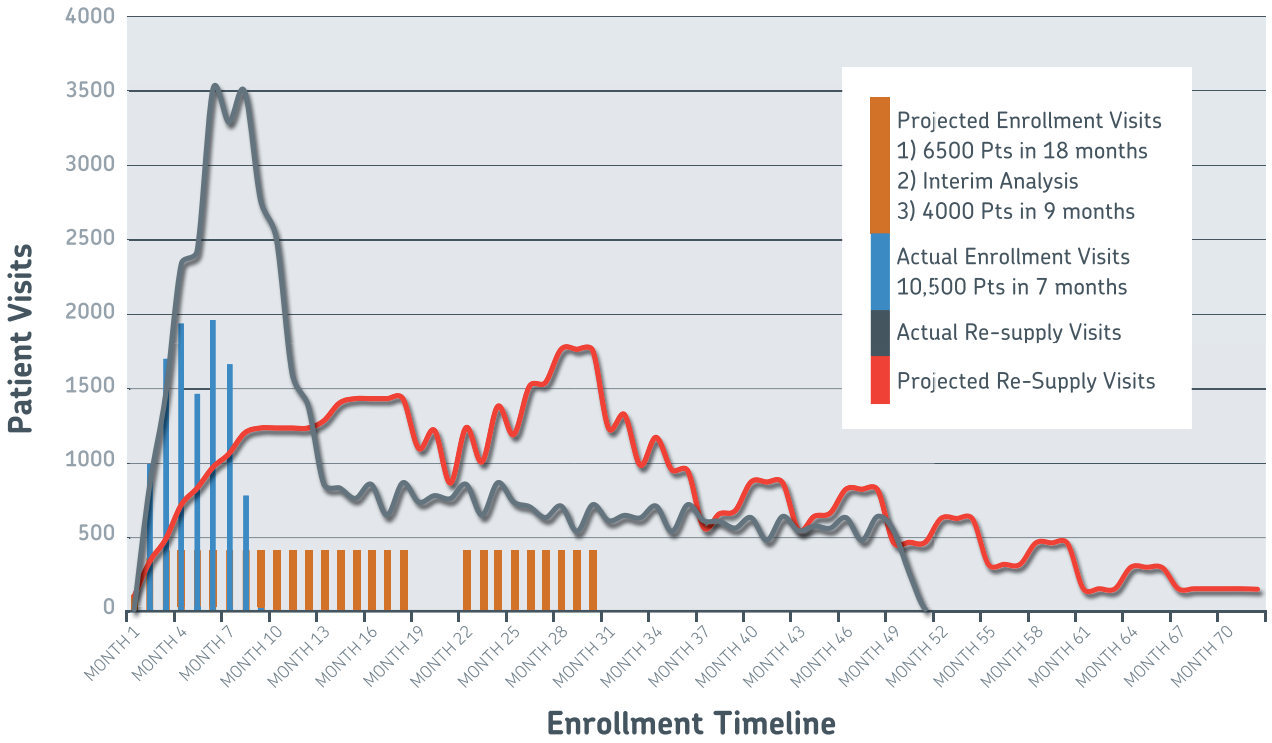
SCM Oversight – monitoring of actual events vs. projected

As anticipated, enrollment got off to a very quick start. The SCM maintained close oversight of the enrollment and tracked the actual supply use to the projected demand. After the first couple of months, it was evident that enrollment and supply use was outpacing the 8-month projection scenario and was more aligned with the 6-month forecast scenario. Fortunately, adjusting the supply strategy to this scenario in response to the actual recruitment rate was not a significant challenge because this scenario was evaluated early on and the sponsor had already planned for that contingency with their drug product manufacturer.

Once the sponsor decided to update the active forecast to the 6-month demand scenario, the SCM continued to monitor actual

Patient Visit Projections – Scenario Comparison

The SCM utilized SupplyWise™ - Almac's clinical forecasting solution to enable a side-by side assessment of the forecasted demand for each scenario.



vs. forecasted supply use and updated forecast projections with actual enrollment data on a monthly basis. Implementing the clinical forecast into the overall supply plan enabled the Almac SCM and sponsor team to see that the projected demand stayed in line with expectations to ensure the bulk production schedule was still in alignment with the customers desire to never fall below 3-months of on-hand inventory.

Another key to the forecast maintenance was ensuring the drop-out rate was in line with the projections originally predicted by the sponsor. A lower than expected drop out rate could have had significant downstream impact on demand in the maintenance phase. When there was a variance in the initial projected drop-out rate, the close oversight of the SCM ensured they were able to modify the forecast accordingly which reduced the supplies needed by 23%.

Due to the large number of sites and rapid enrollment rate, the sponsor was also concerned about the frequency of shipments and especially sensitive to the possibility of stock outs. To address this concern, the Almac SCM developed 4 different supply strategies that were designed to satisfy 4 different screening and lead enrollment levels. The screening and lead enrollment levels at the sites were then monitored on a weekly basis and when site activity reached the pre-defined level, the sites were adjusted to a higher supply strategy. Likewise, when site activity declined and screening and lead-in levels fell, the strategy would be downgraded to reduce on-hand quantity. These adjustments to the IRT system ensured adequate supply levels were maintained while also reducing the frequency of shipments.

RESULTS

- The kit design recommendations that Almac made for the lead-in, randomization and maintenance phases coupled with the development and assessment of multiple clinical supply forecasts enabled planning for the sponsor's desired forecast scenario and also assured that adequate supply would be available to meet the projected demand for each of these phases of the study.
- Monitoring actual patient enrollment and supply demand and comparing to the original projection based on the 8-month forecast scenario allowed for confirmation that the 6-month forecast scenario was more appropriate and facilitated a quick decision by the sponsor to adjust their strategy to fit the 6-month enrollment projection. At the same time, long term monitoring of patient retention rates and adjusting the forecast to account for the differences resulted in a 23% reduction of the long term maintenance kits that would need to be produced.
- Development of site stocking strategies based on screening and enrollment levels and weekly monitoring of site activity provided a means for ensuring sites were assigned to the appropriate supply strategy based on their patient levels. The strategy proved highly effective at both reducing the frequency of shipping and at avoiding site stock out events due to inadequate supply levels.

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THE VIEW FROM BOTH SIDES – PHARMA AND CRO INSIGHTS

Eef Verhaegen
Associate Director Global Clinical Supplies
PPD International

Pharma IQ:
What are the major challenges currently being faced in clinical trials supply?

Eef Verhaegen:
I think currently that the major challenges are definitely linked to ancillary supplies, especially with the Sunshine Act coming into place, into the US, as well as the new GDP guidelines that are being brought into place at the start of last year. There's more aim for a central supply, which is in a lot of clinical trials for ancillary suppliers not really something that has been done over the years. In a lot of cases it has been bought locally and provided locally to sites, however due to all these changes in regulation and guidelines it is important now that ancillary supplies also are being labelled, that we know exactly where they are coming from and where they are touching all the ground. That all changes strategy, bringing that to a more central approach seems to give several companies several hiccoughs; it shouldn't be that difficult as they actually follow exactly the same as what you normally do for an investigation of products; however it does seem to have caused several challenges globally for a lot of studies. And then the other challenge I would say is definitely the upcoming use of bio-similars; these products are very expensive and so of course the waste challenge there is a big challenge, you need to ensure that you run with actually a very tiny amount of overage to ensure that the cost for the client is not becoming too over-excessive, which then of course brings challenges from a forecasting perspective as well as keeping continuity of supplies coming for all the patients.

Pharma IQ:
How can companies work better with CROs?

Eef Verhaegen:
I think definitely the main point there is communication at the start, and communication much more early on in the project phase. I think in a lot of instances everybody is focusing on the clinical trial aspects and on the regulatory aspects, everybody is focusing on when can countries be ready to start, when can we have our first patients in, but nobody is really looking at okay, we are trying to make sure that all these timelines are getting shortened and shortened and shortened but nobody really fits in if that is feasible from a supply perspective, yes or no. So that really early on communication is still very important. What we also see with smaller bio-pharmas where there might not be an experienced clinical supply team, that it then falls back on the clinical trial lead to also have the clinical supply discussions, which is also a challenge. It's not always very straightforward, you know, it's difficult to explain why some of the processes can't be shortened because of course we can't hamper the compliance. So that's definitely, yes, the communication being still something that really needs to be sorted from day one onwards.

Pharma IQ:
What can pharma companies learn from CROs, and vice versa, with respect to clinical trials?

Eef Verhaegen:
That's the most difficult question out of all of them to be honest with you; I worked at both sides, I worked for large pharma and clinical supplies, I worked for biotech companies in clinical supplies, I now work at the CRO side for clinical supplies, and there's not really from how clinical supplies are treated, or how we are managing it, between CROs, pharma, small or large, there's not really a large difference. I think however what the main difference is is that within larger pharma companies the development plan is already going on for a long, long time and so the clinical supplies people there know exactly

THE VIEW FROM BOTH SIDES – PHARMA AND CRO INSIGHTS

what is going on with that product, how it is being manufactured, and all that knowledge, if that could be transferred to the CROs, for example, again early on in the process so we could help them better to develop the strategy for the clinical trials, then that would definitely be something that I would urge for pharma companies to do. However, in regards to how the supply chain is managed, I don't particularly see a big difference between pharma or CRO side.

Pharma IQ:
How can companies engender a compliance culture in clinical trial supply? Obviously you mentioned the GDP regulations there.

Eef Verhaegen:
Yes, there's definitely the GDP regulation but there's also the GMP regulations; I think it's important to have the quality team involved also early on, and make sure that the strategies that are being put in place are acceptable from a quality perspective. In regards of the new GDP guidelines, yes there are some changes but it's also nothing that can't be overcome. I think the main items are definitely make sure that from a counterfeit perspective, make sure that all your standards that you are using have been ordered well in advance, that you keep that order thing going over a regular cycle. Make sure that all these contracts are in place so that you at least already know that you are buying from a respectable vendor, or reputable vendor. Do the same with all the other vendors down the line, if you are using vendors, to ensure that compliance in regards of temperature control, even for ambient products, I think what we are mainly doing is ensuring that now, in every single shipment we are actually bringing temperature recorders to ensure we know exactly what is happening with the products from start to finish.

Pharma IQ:
What trends will shape the area of clinical trials supply over the next 18 months?

Eef Verhaegen:
I think that the main one is going to be what we said in question number one, the ancillary supplies; I think that's going to be a big trend there, we are going to move more towards centrally supplying that and seeing that throughout clinical trials instead of having the local approach. And then definitely also barcoding; there are several competitors that I'm aware of in the industry that already are forcing barcoding on kits, and that will actually charge extra in case you're not having a barcode on your kit. Although barcoding is already very embedded into the commercial supply it's still something that's not really that embedded in the clinical supply end but that's definitely something, a trend that we will see changing over the next 18 months.

Eef Verhaegen will explore this topic further in the panel "What are the differences in their CTS approach and what can we learn from each other?" at the Clinical Trial Supply Europe Summit. Find out more by downloading your agenda here

COMPLIANCE IN YOUR DISTRIBUTION PLAN

Clinical Trial Supply Europe

ALMAC

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Justine Swinney
Managing Partner
Brizzey LLC

Pharma IQ:
What are the major challenges currently being faced in clinical trials supply?

Justine Swinney:
For me it's the increasing pressure to spend less money, coupled with increased requirement for those trials. The number of trials and how long they take and how much money they cost. And there are obvious cost implications of that, which is a challenge, but I think part of the knock-on effect is on the people side of things.

You've got that situation of poor morale, where people feel like they're having to do so much more with less, and perhaps that they're also spending time on the things that aren't necessarily why they got into this business in the first place. They're doing a lot of bean counting, a lot of justification of why they need people or resources etc.

What that's leading to is really a loss of good people from the industry, and I think that is going to continue and I think it has an effect on the people who are left. Not everybody's in a position where they can leave, or they have reasons that they want to stay, even if they're not happy. You have people with poor morale staying. And then you have people who are leaving who you really wouldn't want to leave. To me, that's the knock-on effect.

Pharma IQ:
What is up front distribution planning, and why is it important?

Justine Swinney:
Obviously this is the topic of my roundtable [at Clinical Trial Supply Europe], and it's a topic that's very close to my heart. Something that I've been involved in for most of my career in clinical supplies, and so I could probably list a million and one reasons why this is important, but I try to think about how to boil that down into one big reason, and I think it's basically the same reasons that all planning is important.

We're working in an environment where what we produce is very expensive. The time criticality is paramount. And what we're doing is important and we have patients waiting for what we're shipping, at the end of the day. We can't afford to get anything wrong, really, and so distribution is important to minimise those risks, just as any other kind of planning is.

I think one of the additional reasons why specifically distribution planning is important is that there are a lot of people who are working in clinical trials for whom this isn't an area of expertise. You get into customs regulations, which is outside of health authority, in addition to the health authority restrictions on distribution. So if you don't focus on it, I think there's probably a greater risk that it will not naturally just happen automatically in parts of other planning, and so it needs to be called out and focused on.

I think there's also that whole: 'Amazon can do it' kind of mentality that has led to a lot of misconceptions out there about the complexity of distribution when you are dealing with clinical trials, and so there is an obvious risk that we can oversimplify it if we don't really focus on it and have people dealing with planning around those very specific complexities.

Pharma IQ:
What are the key elements of a distribution plan?

COMPLIANCE IN YOUR DISTRIBUTION PLAN

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Justine Swinney:
I think there's a compliance element, particularly the trade compliance. So how do we make sure that we comply with the customs laws and the importation laws that we're going to have to deal with as we move these clinical supplies about? I think there's a documentation requirement which does link to the trade compliance. Which documents do we need for each country and how do we fill them out correctly so that we are compliant and that we move the material where it needs to be as smoothly and quickly as we can?

There's a product handling aspect to it, so there's how do we make sure that we really understand what this product needs by way of temperature control, temperature monitoring etc., while it's in transit. How do we set up that lane to protect it in whatever way it needs protecting? I think one of the biggest things is: How do we make sure that distribution planning is then linked to the rest of the planning?

One of the biggest things with that is to look at a country's specific requirements that are broader than just distribution and making sure that we factor all of that in to the overall plan. So in other words: How do we make sure that we plan our timing for distribution to factor in not just the timelines that it takes to get an import license to ship goods, to get them through customs, but also to make sure that that initial ship date is right based on when we'll have regulatory approval. When we'll have ethics committee approval.

If you look at all of those different elements, and the team has worked together beforehand to really understand for each country what's a realistic timeline and planned around it, then I think we have the maximum chance for success, of everybody hitting the dates that they want to hit.

Pharma IQ:
How can companies engender a compliance culture in clinical trials supply?

Justine Swinney:
I think it's about building it into the overall activities, as opposed to it being something standalone. In other words, for example the trade compliance is part of a distribution plan. It's built into that so that your compliance with valuation requirements for example is built into that plan up front, and you can see it in the context of the documentation that you're going to have to send which is going to get it through customs and not only mean that you are compliant and don't get into trouble, but because you're compliant that you actually get through that clearance process more quickly and the drug gets to where you want it to.

It's in the context of your overall goal as well as the separate compliance goal. It's linked back together. I also think it's important to make sure they understand why this is, that you truly are looking at this pragmatically. In other words there is a balance between pragmatism and compliance. That it's brought back to what's sensible, what meets the regulations, but is only restrictive to the level that it needs to be restrictive.

In other words that you're not telling people they have to put a high valuation on there because you're being super conservative. It's because there are these rules in place and they're very specific about what that should look like, and therefore this is the methodology that's been applied to meet those regulations. I think it's about making sure that people really understand why you need to be compliant and how you've reached your approach to that compliance

Justine Swinney will explore this topic further in her roundtable "The importance of robust up-front distribution planning for clinical supplies " at the Clinical Trial Supply Europe Summit.
Find out more by downloading your agenda here

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What are the major challenges when it comes to comparators in clinical trial supply?

In this Pharma IQ interview Ricardo Lima, Head of Pharmaceutical Development, Bial Research & Development, shares his insights on major challenges when it comes to comparators in clinical trial supply and what he thinks will be the major trends in clinical trial supply in the coming 18 months.

To find out more about the latest developments in clinical trial supply go to: www.clinicalsupplyeurope.com

What are they keys to a good working relationship with a CRO?

In this interview with Pharma IQ Kim Tang Hvistendal, Director of Clinical Supply at Veloxis Pharmaceutical, speaks about the outsourcing decision-making process and addressing the major challenges in working with a CRO and maintaining a good working relationship in clinical trial supply.

To find out more about the latest developments in clinical trial supply go to: www.clinicalsupplyeurope.com

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How can you control risk in shipping?

In this Pharma IQ interview Sherri Wilson, Director of Clinical Supply Chain, Pfizer talks about how product data fits into the planning of shipment strategy and how one can control risk in shipping.

To find out more about the latest developments in clinical trial supply go to: www.clinicalsupplyeurope.com

What can pharmaceutical companies learn from those working on site in a trial?

In this Pharma IQ interview Samantha Carmichael, Lead Pharmacist Clinical Trials for NHS Scotland, shares her insights on what pharmaceutical companies can learn from professionals working on site in a trial and recent major trends in clinical trial supply.

To find out more about the latest developments in clinical trial supply go to: www.clinicalsupplyeurope.com

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What do you think will be the major trends in clinical trial supply in the next 18 months?

In this interview with Pharma IQ Steve Jacobs, Chair, Global Clinical Supplies Group, shares his insights on the major challenges and trends impacting clinical trial supply professionals.

To find out more about the latest developments in clinical trial supply go to: www.clinicalsupplyeurope.com

CONCLUSION & THANKS

Clinical trial supply can be a hectic field to be involved in and at times it often feels like it can be at the whim of things like weather, volcanoes and the demeanour of customs agents. The effects of these unknown elements can be minimised by ensuring the rest of the system is optimised. This is one of the reasons that topics like forecasting are coming to the forefront and why having the best information (hence labelling) and information gathering methods are becoming essential. The bottom line in any industry will be cost and reducing unnecessary cost by methods like forecasting will always be popular. Equally taking advantage of cost savings by looking for new markets will bring new opportunities and challenges in equal measure.

Often the best way to overcome these challenges is to understand how peers have solved similar problems. We hope that by bringing together the thoughts and opinions of leaders in the field in this report has been useful for you

Pharma IQ would like to thank all of those who took part in the **Clinical Trial Supply 2015 Survey,** along with the Pharma IQ community for supporting and publicising the survey. We would also like to thank our expert panellists whose invaluable insights made this report possible. A final thanks to you for reading.

Clinical Trial Supply Europe

REDUCING WASTE, MAXIMISING EFFICIENCY AND EMBEDDING FLEXIBILITY INTO YOUR GLOBAL CLINICAL SUPPLY CHAIN

Join us celebrate Clinical Trial Supply Europe Summit's 5th Anniversary in Frankfurt, Germany from 21st - 23rd January 2015!

Being the first European Clinical Trial Supply event in the year, Pharma IQ together with executive panel of speakers evaluates the achievements of 2014 and sets a direction for 2015 allowing you to stay ahead of the game.

After five years of analysing the field of Clinical Trial Supply, we realise and understand the huge progress the industry has made. However, what does the future hold and why should we continue talking about GDP standards, labelling practice, forecasting and comparator sourcing?

By bringing together regulatory experts, industry leaders and innovative services, Pharma IQ's Clinical Trial Supply Summit faces the challenges of clinical supply head on and provides you with essential knowledge that can bring you quicker results and make critical decisions easier to solve.

KEY HIGHLIGHTS OF CTS EUROPE SUMMIT 2015:

In January 2015, join Pharma IQ and 120+ clinical trial supply experts to learn about...

- **Effectively sourcing comparators** and shipping for clinical trials
- **Reducing costs and improving cost** efficiency in clinical trial supply
- **Forecasting and simulating** clinical trial supply
- Regulatory updates on **labelling and repackaging** for clinical trial supply
- Reviewing the procedure for **recalling the product back from the clinical trial**
- Educating your site staff about the **storage and preparing for audit**

SO WHAT'S NEW FOR 2015?

- **Head-to-head sessions:** CRO vs. Pharma - What are the differences in their CTS approach and what can we learn from one another?
- **Consultancy roundtable game:** work in small groups to identify 5 challenges that you face on a day to day basis and then pass them on to the next team to become a consultant and help another team to solve their challenges
- **Cost saving panel:** How to reduce costs by looking at refining 4 key areas of your supply chain?
- **On-stage interview with regulators:** it's your chance to find out about the future of CTS

And much more... To see a full list of topics and find out about this years highlights take a look at the draft agenda here.

For further information go to www.clinicalsupplyeurope.com

About Pharma IQ

Pharma IQ
a division of IQPC

Pharma IQ, a division of IQPC, is an international online community focusing on providing pharmaceutical professionals with knowledge, information and articles. We are dedicated to creating a learning environment for sharing ideas, best practices and solutions within the pharmaceutical community Through Pharma IQ, you will be able to access pharmaceutical information resources such as presentations and podcasts, as well as events such as webinars, seminars and conferences. By signing up to the Pharma IQ membership, you will gain access to our growing database of multimedia presentations from leading pharma practitioners, weekly newsletters to keep you updated on latest pharmaceutical content and Pharma IQ members-exclusive discounts on pharma events that offer solutions to your everyday business problems. Pharma IQ and IQPC provide useful training courses, conference and expositions for pharmaceutical executives to network and learn the latest pharma business development and trends occurring in organizations today. Pharma IQ focuses on establishing an interactive experience featuring practical, objective and up-to-date insight from pharma industry leaders.

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ALMAC COMPANY PROFILE

Almac – your trusted partner in clinical supply chain management

The Almac Group is an established contract development and manufacturing organisation that provides an extensive range of integrated services to over 600 companies globally within the pharmaceutical and biotech sectors. The services range from R&D, biomarker discovery and development, API manufacture, formulation development, clinical trial supply, IXRS® technology (IVRS/IWRS) through to commercial-scale manufacture.

The international company is a privately owned organisation that has organically grown over 40 years and now employs in excess of 3,500 highly skilled personnel. Almac is headquartered in Craigavon, Northern Ireland with operations across the US (Pennsylvania, North Carolina and California) and in Asia (Singapore and Tokyo).

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