Clinical Trial Supply

An Inside Look Into Site Centricity

Clinical Trial Supply: Site Centricity

With the expanding global spread of clinical trials, the trial supply arena has shifted in focus towards the advantages of site centricity. Here, the enhancement of clinical trial supply is propelled by the sites' perspective., Closer collaboration and feedback from sites assists with overcoming various operational challenges in clinical trials.

Some have advanced to test site centric models. The rise of telemedicine has opened the horizons for teams to run with these 'hub and spoke models' 1 This set-up involves trained physicians engaging with patients in local community health clinics, monitoring them remotely and collecting data using telemedicine technology.. This strategy reduces the amount of specialists needed and has numerous cost and efficiency benefits in comparison to deploying a range of medical centers.

Pharma IQ speaks to Dr Samantha Carmichael, Lead Pharmacist Clinical Trials of NHS Greater Glasgow & Clyde and Mandy Wan, Lead Paediatric Research Pharmacist, Evelina London Children's Hospital in regards to the growing general culture of site centricity in today's clinical trials.

Mandy is a clinical trial pharmacist at the Evelina London Children's Hospital. Her experience is mainly with paediatric clinical trials , working on both commercial clinical trials as well as non-commercial sponsored clinical trials, and have over the years worked with many vendors. With a different hat on, Mandy works with different clinical trials units on setting up multicenter paediatric non-commercial studies and provides advice on their clinical trial supplies. While there has been increasing focus on site centricity in delivering clinical trials, Mandy feels that In practice there is still a lack of acknowledgement of on-site challenges with clinical trial supply. She would like to see greater emphasis given to practical issues such as storage capacity, clear labelling and patient handling when vendors are planning the clinical trial supply chain.

Samantha is the lead pharmacist for clinical trials within NHS Greater Glasgow and Clyde where she manages two teams; one being the pharmacists and technicians who run all the trials that hosted on behalf of both commercial and non-commercial sponsors. The other team works on behalf of the sponsor – NHS GGC an academic sponsor. There is a dedicated pharmacy team who deals with everything around IMP management for those studies.

Thinking about site centricity from the hosted site, Samantha has much the same experience as Mandy. Her team covers all therapeutic areas across seven hospitals. Samantha feels that site centricity and patient centricity are quoted a lot by sponsors as a focus, however it is still not filtering through to the actual supplies at the user end. As an academic sponsor NHS GGC are also end users and take that opportunity to try and make clinical supplies that are suitable for patients and the sites. For example, close consideration of what size supplies are and what volume patients have to take home, transport

and store. One of the key things is still space at sites and the amount of refrigerated space required.

Partnership Management To Enhance Vendors' Supply

Mandy shares the opinion that there is significant room for improvement in regards to clinical trial supply chains and that there is often negotiation struggles when setting up clinical trials. There is often a lack of appreciation from the sponsor in regards to activities at site level. The obvious discussion issue is cost, especially the cost of having frequent deliveries to site versus the storage capacity at sites. Mandy said: "Getting that balance right seems to be quite difficult. I totally appreciate that from a sponsor perspective that you have a limited budget, but at the same time with increasing number of clinical trials, many UK sites are struggling with finding appropriate storage space to store clinical trial supply. Direct to patient delivery is an exciting opportunity but this model of distribution is still very much in its infancy"

There have been a small handful of occasions where Samantha has had the opportunity to provide feedback on pharmacy manuals which has then been taken on-board. One particular vendor actioned some collaboration feedback to produce an innovated label allowing sites to place kit numbers on different sides of the primary or secondary packaging, to aid with easy referencing in storage.

Enhancements Higher Up The Supply Chain To Simplify The Lives Of Site Managers And Patients

Individuals higher up in the supply chain need to visualise and experience products rather than just a written explanation.

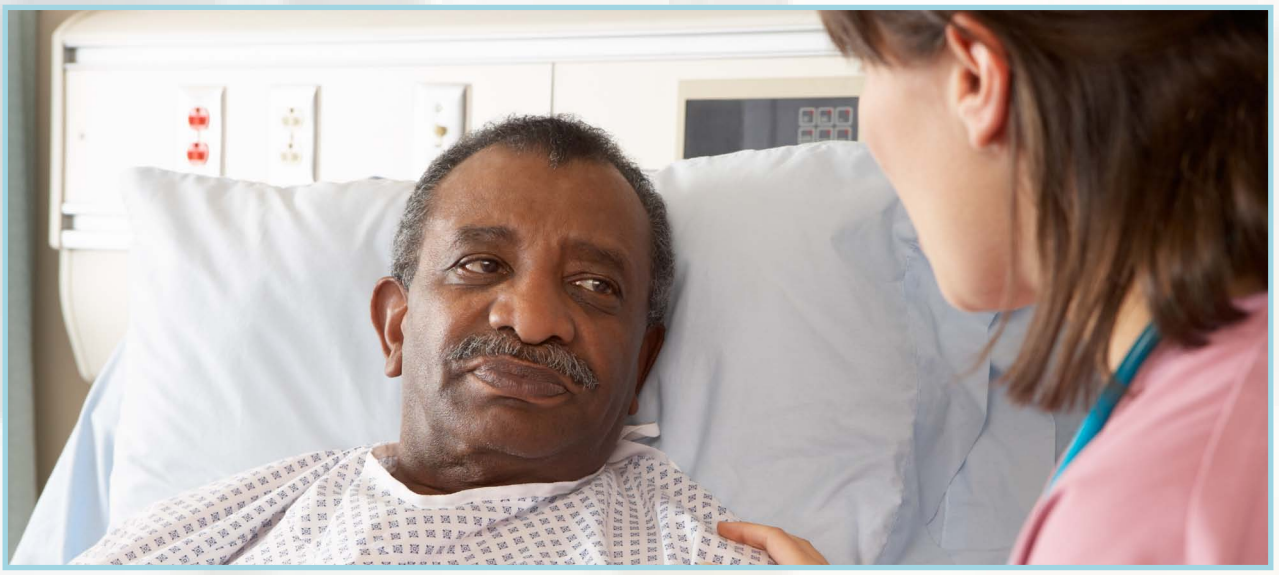
Mandy noted that when focusing on dimension size, labelling text and shipment documentation, visual aids really help with the discussion and then professionals can start to realise the sorts of problems the end user is experiencing. Further, information from higher up the supply chain is often not being filtered down to those who are conducting site visits, creating uncertainties and a negative image of the sponsor.

Mandy added: "I have actually just had one study where they were able to send us demo patient kits that we can actually look at before the study opened and that was very useful. More often then not, practical issues with supply only become apparent when the actual supply arrive on site and the patient is waiting. On this occasion, we were able to test whether our syringes and bottle adaptor were compatible with the bottle in advance."

The Importance Of Feedback To The Progression Of Clinical Trial Supply

A two way conversation established during set up is vital to allow for extra time in planning and decision making to meet both sponsor and site priorities. Samantha continues that this is important as constant pressure is applied around setup times from both sponsors and national metrics set within the UK for opening research studies. Protocols are sometimes received to review earlier before the formal application process for approval in the UK to run studies has been started. This gives the sites extra time to ask questions about the supplies before the timeline to opening is critical.

Samantha: "You are probably aware that with the HRA in England and Scotland we are basically driven by Government metrics to get studies approved, open and



patients into them as quick as possible. A two-way conversation before that process starts is useful. The sponsors do speak to investigators early on but they don't always necessarily speak to the people who deliver the supplies (pharmacy departments in the UK). The opportunity to be ahead of the game before the clock starts is really valuable in terms of getting that first patient's visit right the first time."

Common Mistakes In Clinical Trial Supply

In setting up a clinical trial most companies are aware that there are a lot of simultaneous studies, but there is an inevitable bias towards their own study in terms of their priorities. It can be a challenge to obtain recognition of the fact that the site is managing over 100 studies and the site may need to balance their portfolio.

The Future Of Site Centricity For Clinical Trial Supply

There is undoubtedly a lot of talk around site centricity however the action is seemingly yet to follow. One point being that the sponsors' internal metrics tends to supersede focus on site centricity. Moving forward, Mandy is keen to see a progression in this area to explore opportunities for direct delivery to patients' homes to simplify participants' involvement. Samantha notes that there are case studies in the industry illustrating that communication is the key tool to achieving focus on site centricity within the timeframes wanted.

Interested in continuing the discussion or hearing more from Samantha and Mandy consider attending the 2017 Clinical Trial Supply conference.

Resources

1. http://www.appliedclinicaltrialsonline.com/clinical-trial-site-centricity-vs-patient-centricity-what-s-more-compatible-model

Clinical Trial Supply Europe

23-25 JANUARY, 2017
LONDON,

Pharma-IQ is delighted to announce the return of the MOST interactive and the MOST senior Clinical Trial Supply event, attracting senior clinical supply chain professionals from across the pharmaceutical and biotech industry.

This year's event will continue to look at in an interactive manner how we can effectively manage the supply chain and reduce wastage, with topics of discussion to include: improvements in temperature controlled logistics; forecasting and investigator initiator studies.

New Sessions for 2017

- Applying monitoring technology to minimize temperature excursion
- IRT use for expiry date allocation
- Effectiveness of predictive modelling
- Clinical Trials Supply forecasting and simulation in-house
- Adopting JIT labelling for clinical studies to overcome planning issues for clinical supply
- Challenges faced in complying with GMP when repackaging

Download Agenda

www.clinicalsupplyeurope.com

Call: +44 (0)207 036 1300 **Email: enquire@iqpc.co.uk**