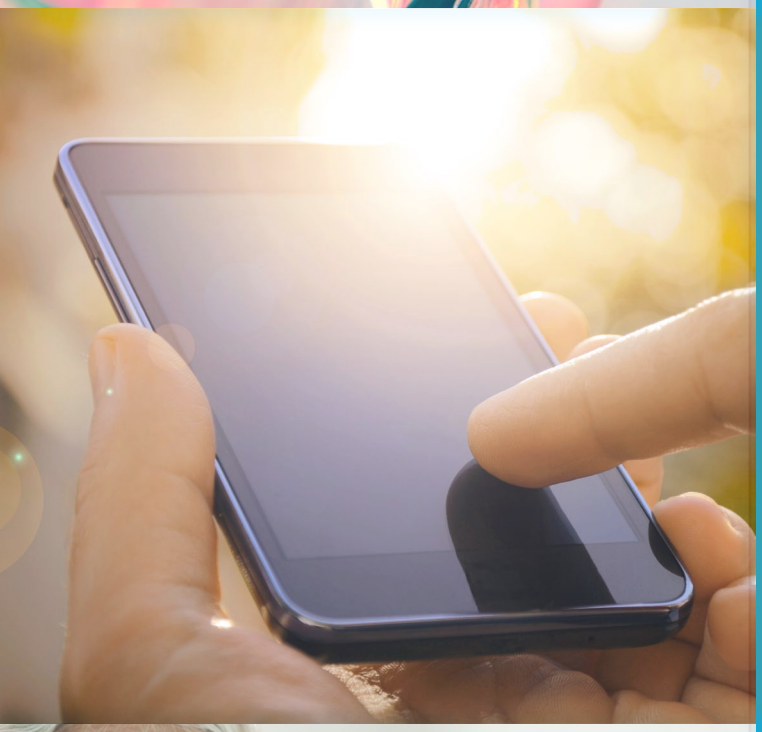

Innovation in Clinical Trial Supply

Pharma iQ
a division of IQPC

Pharma iQ
a division of IQPC

Clinical Trial Supply Europe

Innovation In Clinical Trial Supply

Innovation is thought to be a keystone in the process of being competitive in any market. Within clinical trial supply, a lack of innovation can be costly in regards to a range of variables.

With this in mind, Pharma IQ discusses the latest trailblazing techniques in the arena with a panel of Clinical Trial Supply specialists.

Panel

Dr. Andrea Zobel
Global Senior Portfolio Director Clinical Logistics, Parexel.

Due to feature in Clinical Trial Supply Europe 2016:
- Expert Panel: Tracking Returns, Reconciliation & Destruction to Manage Costs
- Ideas Market: Exploring the Numerous Supply Chain Arms of Direct to Patient Shipments Session

Steve Jacobs
Board Chairman Global Clinical Supplies Group

Due to feature in Clinical Trial Supply Europe 2016 *As conference Chairman*

Bernard Jaucot
Associate Director Global Clinical Supplies PPD

Due to feature in Clinical Trial Supply Europe 2016:
- Expert Panel: Tracking Returns, Reconciliation & Destruction to Manage Costs
- Ideas Market: Exploring the Numerous Supply Chain Arms of Direct to Patient Shipments

Cedric Druck
Director, Belenox SPRL

Due to feature in Clinical Trial Supply Europe 2016:
Catch Cedric at the event in January for insightful discussion and networking.

The Consequences Of No Innovation

While contemplating the consequences of not innovating within clinical trial supply, the main factor highlighted was the loss of time.

Bernard noted: "We're at the end of the supply chain. We need to get those drugs as soon as possible on the market. So the more we win time, the more money they will win. For some blockbusters it's $1 mllion dollars a day, so you can understand the impact."

He adds that the ideal aim is to innovate so the industry can function faster while remaining compliant. He emphasises the need to interact with authorities so R&D firms can make smart adaptations and compliantly innovate.

"At the end of the day, a sick patient is waiting for this novel drug to make them healthier. If we don't do [things] correctly, he or she might die because of us …. So, yes, compliance is very important."

Andrea noted that a lack of innovation could cause focus on patient centricity to slip especially in regards to having the right patient recruitments. She indicated that the competitive environment will often provide the answer on whether initiative has slipped in this area.

Cedric noted: "Well, supposing that no innovation would take place, that would be an increasing challenge in the coming years for the pharma [industry] because drug development [has been] evolving in the past few years and the trend is continuing. So, more and more biotechnology, cell therapies and genome specific treatments are being utilized."

New research strategies such as adaptive trials, umbrella and bucket trials alongside the trend to obtain heightened analysis in less time both are placing pressure on the clinical supply industry.

In regards to these advances in trial design complexity, Cedric notes that the clinical supply chain needs to field these increasing levels of diversity via adopting new processes and methods. "….the fact of not innovating would really, I think, be a major hurdle in the coming years if pharma don't adapt their supply chain in advance."

Market Culture

As highlighted previously, the need for strict regulations has bred a what some dub as a conservative attitude towards innovation in clinical supply.

Bernard explained: "We have to work with standard, sturdy and robust, qualified processes, so that makes it, for me, a bit slower to really innovate." He added that he uses the term smart adaptation instead of innovation due to the idea that the market has to innovate in the open space that regulation has left available.

Steve said that due to the gradual approach to innovation or change, the industry's main issues have largely stayed the same. As the industry is risk averse by nature, a really clear return on investment must be evident for any new methods or techniques to be adopted.

Andrea noted that there is a tendency for the market to have rigid viewpoints – seeing each trial standing as a silo. She added: "They have a lot of potential to interconnect different trials by using technology and adapt this only with the client specifics... instead of having for each individual trial a complete new."

However, Cedric notes that innovation is one prevalent trend he has spotted within big pharma at the moment. Especially, in regards to making the supply chain more efficient and streamlined.

Recent innovative trends spotted within clinical trial supply include, interactive response technologies, planning and forecasting systems being connected to manufacturing and to the commercial supply chain and labelling strategies such as the decentralised just in time labelling,eLabelling.

eLabelling

One area of focus as of late is the concept of e-labelling - when the patent can access the labels virtually, so the physical box only holds a minimal aspect like a barcode that is linked to the e-label. However, specialists have highlighted that a recent potential directive has specified directions that go against the vision of e-labelling, by stating that all information including expiry dates must be shown on all labelling including on primary packaging.

In regards to these possible rules, Steve notes that this could produce hurdles for the market and enhance the reliance on methods such as just-in time labelling and on-demand shipping:"… versus where we were able to go ahead and … feed the site and put drugs there and then have all the other automation lines, the IRTs and some of the planning and forecasting go ahead and work for us."

He adds that some are hoping there will be a partial reversal upon the ruling on the clinical trial regulations on removing expiry dates.

Patient Centricity

Additionally, the shift towards patient centricity has triggered the existence of a range of fresh methods, including direct-to-patient

shipments, medical wearables connecting with smart phones and eDiaries

Bernard mentioned the possibility of using smartphones and tablet technology towards drug accountability and traceability. He added that that the potential from smart phones and tablets in the hands of investigators and patients could be: "Incredibly powerful for our business."

Pooling

Cedric mentioned the development of pooling and adding several layers to the manufacturing in regards to transit. "An idea [being] to have some layers of intermediate products between drug product and secondary kits that can be pooled amongst trials and enable just-in-time labelling, just-in-time packaging."

Gaps in the Market

Andrea notes that the world of clinical supply could learn from the advances made in neighboring industries. "So when you are talking about tracking and tracing [for] pharma authentication, the pharma industry itself is far behind, for example, automotive or consumer goods, where they have such types of unique identifiers and theories. So, there is a lot of innovation potential by simply using what's already used in other industries."

When contemplating what needs to be on the horizon for clinical supplies, some in the industry feel that the market should play a more active role in sculpting policy and regulations with clinical development authorities. Others stressed a need to lobby to align the clinical trial supply industry with more commercial notions.

Clinical Trial Supply Europe's entirely interactive, discussion based agenda is due to address the burning issues today's industry faces.

Clinical Trial Supply Europe

19 - 21 JANUARY, 2016
Brussels, Belgium

Maximise Efficiency & Reduce Costs by Implementing a Patient Centric Clinical Supply Strategy

7 Reasons to Attend

- Overcome the complexities of supplying to blind studies by participating in preparing the supply chain for a **live blind study** with **Opko Biologics.**
- The **first and only event** that **Johnson & Johnson** will be sharing their innovation in **JIT labelling.**
- Tackle **comparator drug management** by joining in with the fast paced ignite session with **Boehringer Ingleheim**.
- Put your burning questions to the exclusive panel on **harmonising GCP Standards** with **PRA International & Takeda.**
- Reduce costs by embedding modulation and simulation in the clinical supply chain with key insight from **UCB.**
- Understand and apply the **benefits of outsourcing** your clinical supply chain with **Merck Serono's** breakout session.
- Apply knowledge on **outsourcing destruction** with unique insight from key CROs: **PPD & PARAXEL**.

Download the Agenda

www.clinicalsupplyeurope.com

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