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Disruptive Innovation in Clinical Trials

Europe

Why clinical trials fail and what we can do about it

The challenges that the pharmaceutical industry faces in launching a drug are plentiful and well documented. From the cost of R&D, high failure rate, ever toughening reimbursement requirements and ever growing competition.

One significant element of getting a product approved is a successful clinical trials. It is an exciting time for the industry as there are signs of change in the way clinical trials are run, with new organisations and partnering models leading the way, innovative approaches to clinical trials and new technologies disrupting the traditional approach.

First and foremost it is really important to understand why clinical trials need overhauling, what elements work, what elements don't, how we engage with the patient and most importantly why clinical trials fail. This will be discussed and debated in detail at Disruptive Innovation in Clinical Trials. In the meantime, I wanted to share my thoughts on what I think are some key stumbling blocks in clinical trials and some of the disruptive innovations that are shaking up the way they are responded too. Take a look at this ebook and share your thoughts also.

Learn more at Disruptive Innovation in Clinical Trials, 4-5 March 2014, London where we will have a dedicated panel discussion also...

Why current clinical trial practice is not working and what can we do about it?

Ben Goldacre, Writer, Broadcaster and Medical Doctor
John Warren, Founder, **Medicines Assessment,** previously **MHRA**
Panellists: Professor George Szmukler, Associate Director, **NIHR MHRN**
Simon Denegri, Chair, INVOLVE, NIHR National Director for Public Participation and Engagement in Research, **NIHR**
Dr Kirsty Wydenbach, Medical Assessor Clinical Trials Unit, **MHRA**

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Problem: **Common clinical trial logistics issues**

The vast size and scope of some clinical trials can lead to complexity and logistical stumbling blocks. The huge amount of data involved in running a clinical trial, as well as the variety of sources being collected and managed can sometimes result in errors. In addition, the multitude of organisations that can contribute to a trial from the sponsor and CRO to the trial site, adds complexities.

So what can we do about it?

The emerging industry collaboration led by TransCelerate has seen some impressive results to date with plenty of important ongoing projects likely to impact the future of clinical trials. Examples that will impact on issues around trial logistics include the ongoing creation of a shared, cross-industry, web-based, **investigator portal** to improve communications between member companies and clinical trial sites. Also Traditional clinical trial practice has resulted in a wide variety of ways that clinical data is collected, presented and managed. Transcelerate's work towards a **Cross industry Data standardisation** is a potential solution that would support the exchange and submission of clinical research and meta-data, while improving patient safety and outcomes

The emergence of new **mobile technologies** and big data capability such as cloud computing offers huge potential in streamlining clinical trials time and cost through its use not only in recruitment and retention as we mentioned before but in data capture and analysing study results. It has the opportunity to put more power in the patients hands and get the data directly from the source, rather than through the interpretation of a clinician.

Problem: **Choosing the right endpoint**

It doesn't matter how well the drug is working on the patient, if the incorrect end point has been chosen this success is hard to measure. Choosing the right characteristic to measure as the endpoint is important whether is a symptom, change is health status, a test result or sign. There a various issues that can influence or alter the endpoint reading, influence from other treatments, complexity of disease, not significant enough change in endpoint.

Problem: **Getting the right patient & keeping them**

A trial is heavily dependent on achieving an appropriate trial population. Recruitment and retention can be a huge stumbling block for sponsors and CROs with the majority of trials significantly under recruited. Deciding the right criteria for your patient selection and relevant therapy is key. So understanding your patient population is key and learning the best way to engage with them is vital in recruiting them and maintaining their commitment to the trial.

So what disruptive solutions are there?

Gamification is the use of game design elements and game design techniques to solve non–game problems**.** In recent years pharma has started implementing games to help engage with patients. Whilst these games have not predominantly been used in clinical trials, their success and acceptance in other aspects of drug discovery and healthcare may well lead to their introduction in the clinical trials environment. Learn about how an example – the NHS clinical trial simulator – has fared.

Social media to learn about your patient population and engage with them better.

Patient led trials such as DevelopAKUre are creating the trial around the patient in a rare disease study along with crowd funding, innovative partnering and utilising social media.

Mobile technologies – Mobile devices have many uses in clinical trials including patient reported clinical outcomes, information source for patients, real time alerts for patients to ensure that they take medication, or report findings on time and the strengthening of the switch from paper records to electronic data capture

Want to learn more? Download this…

The topic of clinic trial failure has been a key focus of past Clinical Outsourcing and Partnering World meetings (which is running alongside this one), with the opening discussion in 2013's meeting focussing on some of the biggest challenges. **Professor Trevor Jones**, Non Executive Director, **Allergan** discussed this in detail. To learn more about what he had to say, **download his presentation**.

Before you do that, here is a taster of what Professor Jones highlighted as his key clinical challenges:

Clinical Trials
- *It's taking too long*
- *It costs too much*
- *It's not efficient*
- *It's unnecessarily complicated*
- *There are too many people*
- *Involved*

Inefficiency in Clinical trials
- *Site recruitment*
- *Site accreditation*
- *Contract !!!*
- *Ethics Committee approval*
- *Patient recruitment*
- *Data verification ……still MOSTLY manual*

Enrolment rates
- *vary by region and range from 75% to 98% of targeted levels, Asia/Pacific and Latin America achieving the highest rates.*
- *11% of sites typically fail to enrol a single patient*
- *37% under-enrol*
- *39% meet their enrolment targets*
- *13% exceed their targets*

Download presentation

Got something to say?

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You're *still* not done with Disruptive Innovation?

There is huge opportunity to transform the way clinical trials are planned and run. Novel technologies and processes offer new ways of working, better outcomes and disruption of current failing practice. We will be delving deeper into this topic at the **Disruptive Innovation in Clinical Trials** conference on 4-5 March 2014.

We'll be discussing:

- How to encourage innovation in clinical development
- How to incorporate new technologies and processes
- How to develop game changing methodologies
- How to get buy in to embrace change

For more information about the event, click here to visit our website

If you are interested in sponsoring this event please contact Philip Bell on +44 (0) 207 608 7035 or pbell@healthnetworkcommunications.com

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