CLINICAL OUTSOURCING & PARTNERING WORLD Europe 2014

A-Z of Clinical Trials

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Clinical trials are not working well enough. Change is beginning to happen in the pharma industry, where time and resources are being invested to develop and discover how to run clinical trials more efficiently and to create a better experience for the patient.

In light of the ongoing change and new developments, we have pulled together a list that represents what's happening in the clinical sector. This is our A-Z of clinical trials, a complete look into the key components of a clinical trial, the best and brightest technologies and processes and key examples of the companies trialling exciting new clinical approaches.

Does it match your list? If not, tell us what we have missed out. Leave your comments in our LinkedIn group or tweet them to us @totalbiopharma #clinical14

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A

Adaptive Clinical Trials – one of the biggest innovations in the clinical trial environment is the implementation of Adaptive Clinical Trials. These trials allow a degree of flexibility during implementation. This could be mean dropping a treatment arm that is not effective, altering dose levels, or increasing the trial size if a drug is proving less responsive than had been predictive. By allowing researchers to analyse preliminary results it can be determined which of several potential options the study should follow in order to increase overall efficiency.

B

Big Data –The amount of data available to life sciences organisations has expanded hugely over the last few years and the switch from paper to electronic recording will only increase the availability of data. Big data techniques can help address the high failure rate of clinical trials by streamlining processes and matching patients to trials more effectively.

Recent initiatives include:

GSK and SAS's anonymised clinical data cloud

Merck Maccabis anonymised medical data partnership

A partnership between GNS Healthcare and Covance focused on developing predictive models of clinical trials through analysis of clinical data. The NIHs creation of several "Big Data to Knowledge Centers of Excellence".

C

Clinical Outsourcing and Partnering World Europe 2014 – Clinical Outsourcing and Partnering World Europe 2014 is now in its 7th year, and continues to bring together experts and key influencers at the heart of the pharma outsourcing.

D

Disruptive Innovation – A disruptive innovation is one that helps to create a new market, through the displacement of an earlier technology, all at the expense of an already existing market. Due to falling outputs, many pharmaceutical companies are implementing Disruptive Innovation techniques in their clinical trials, and elsewhere, in order to increase productivity.

With so many potentially disruptive technologies and techniques being implemented in the clinical environment at the moment it can be difficult to keep up. Fortunately, the inaugural Disruptive Innovation in Clinical Trials conference is dedicated to showcasing the most important upcoming innovations in the clinical trial environment.

E

Electronic Data Capture – Recording all your clinical trial data in electronic format can increase the data accuracy of the recording as well as decreasing the time to collect data. Electronic data capture can also facilitate data transfer between partner organisations such as CROs and sponsors with vastly improved ease hwne compared to traditional paper systems.

F

Functional Service Provider (FSP) – The FSP model of clinical outsourcing allows a company to separate core and non–core capabilities, and then to outsource anything which is not part of their core capabilities. This allows the company to outsource to specialised providers within the industry (e.g. clinical monitoring, biostatistics, oncology etc) rather than funding a non-core capacity of the company. This model can facilitate increased patient retention, lower costs and allow for greater flexibility.

G

Gamification – 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.

H

Hired Help – Hiring Clinical Research Organisations (CROs) to run clinical trials is now very much an established part of the clinical environment. The reduction of R&D budgets and in–house resource means that the amount of studies run by vendors has increased astronomically over the past decade.

Integrating Data – Data integration is an essential element of modern clinical trials during which decisions need to be made quickly, accurately, and based on high quality data. Data is now generated from electronic patient diaries, EDC tools, central laboratories and other sources. With all this data there is a need for it to be organised and standardised in order to give an accurate picture of the clinical trial.

J

Joint Ventures – With more and more companies focusing on their core competencies and accepting their lack of expertise in certain areas, many are forming joint ventures, including:

InClinition and MedFocus have joined together to allow Indian based Incliniton to benefit from MedFocus' European experience.

Indian CROs TCG lifesciences, Panorama and AlfaGene Bioscience have joined forces to create Axcellerate which will focus on US clinical service requests.

ReSearch Pharmaceutical Services and Japan's Asklep are creating a joint venture company that will aim to deliver leading–edge R&D outsourcing solutions in Japan to the biopharmaceutical and medical device industries

Wuxi Pharmatech and PRA are to begin to provide trial phase I–IV services in China
Catalent and China based Shang Pharma are to provide end–to–end solutions for clinical trial supplies: including comparator sourcing, primary and secondary packaging and labelling, and storage and distribution.

K

Key Players – There are many players involved in clinical trials, but the four main ones are: the drug regulatory authority, the trial sponsor, the clinical researcher and the patients.

L

Logistics – With fewer and fewer trials having positive outcomes it's incredibly important to ensure that study implementation is carried out correctly and is able to ensure the best possible chances of success. Clinical trial logistics cover transportation, storage, packaging, labelling and recruitment.

M

Mobile technologies – Mobile devices have many uses in clinical trials including:

•Patients reporting clinical outcomes
•Patients learning about diseases, trials and being able to identify clinical trials of interest to themselves
•Physicians identifying likely study participants in their medical units
•Enabling real time alerts for patients to ensure that they take medication, or report findings on time
•Enabling the switch from paper records to electronic data capture

N

Numbers – Achieving and sustaining patient numbers is a sore spot for the industry. Enrolling a patient can cost tens of thousands of dollars and it is currently estimated that the 52% of patients drop out. To try and mitigate these costs many companies are recruiting patients through social media and mobile applications. Other recruitment techniques involve tools such as gamification, and mobile reminders to keep patients engaged.

O

Outsourcing – With companies reducing the sale of in-house R&D facilities, the outsourcing of clinical trials is now an established aspect of most clinical development programmes. The number of trials run by CROs is increasing year on year and the value of the CRO market reached $13.6 billion in 2012.

P

Partnering (strategically) – The increasing capabilities of the large CROs is allowing them to form long term partnerships covering a full range of services. Merck Serono recently announced a 5 year agreement with Quintiles who will “collaborate in strategic decision–making processes affecting the development of the Merck Serono portfolio.” This shows that in at least some instances CRO’s are being seen as partners rather than resources.

Q

Quality by Design – The quality by design concept is that quality can be planned, and that most quality crises relate to the way in which quality was (or was not) planned. Thus by introducing the concept of quality to the process, quality results should occur. In 2013 Pfizer developed a Quality by Design management tool to facilitate its ability to process reams of data from clinical trials. The tool looks to raise the quality of trial submissions, improve regulatory compliance and avoid a costly rework.

R

Risk–based Monitoring – Unlike traditional trials, where source document verification has to be done on 100% of data points, Risk–based Monitoring allows monitoring to be targeted to where it will deliver the greatest benefit to the study, whilst reducing costs and saving time. A risk assessment is carried out at the beginning of the study to identify various aspects of the study that may warrant monitoring.

S

Social Media – Social media has impacted almost every aspect of modern life, and clinical trials are no exception. Whether its recruiting patients to trials, designing the trials themselves, or indeed designing a clinical trial via crowd sourcing, social media is having a direct effect on the design and implementation of trials.

T

Transcelerate – the Transcelerate Biopharma initiative is one of the best examples of multipharma collaboration. Its purpose is to develop shared industry research and development solutions to simplify and accelerate the delivery of innovative products to patients. Transcelerate currently has 8 initiatives:

- Development of risk–based site monitoring approach and standards
- Development of a shared user interface for investigator site portals
- Mutual recognition of study site qualification and training
- Development of clinical data standards
- Establishing a comparator drug supply model
- Creation of common clinical trial protocol templates
- Development of clinical trial networks for pediatric and minority populations
- Establishment of a global investigator registry

U

Universal Problems – Whilst there will always be problems specific to individual clinical trial, there are many problems universal across the industry. Such issues include: difficulties in patient identification, recruitment and retention, missing clinical trial data, poorly designed studies, miscalculated timelines, and reduced R&D budgets. Whilst no one company has the answers, greater collaboration and cross–company communication will enable companies to tackle these problems.

V

Virtual Studies – Virtual clinical trials are where patients participate remotely without having to physically visit trial sites. Through the use of mobile devices, virtual clinical trials have the potential to widen the available trial population, speed up clinical development, improve patient compliance, and deliver high quality real time data. Pfizer attempted the first virtual study (Entitled REMOTE) back in 2011 which was terminated early due to a lack of patient uptake. However, the long term cost-benefits, alongside the increasing prevalence and familiarity with mobile devices will likely mean that virtual trials will return in some fashion.

W

Worldwide Environment – With increasing competition over patients and resources, the cost of clinical trials has skyrocketed in the traditional R&D zones of the EU and US. In a bid to access greater and cheaper resources, research sites have found themselves spread across the globe. The shifting of trial locations to developing countries (in particular the BRIC group) has had many effects on the cost, quality, patient type, and duration of clinical trials. From an outsourcing perspective China is still very much a hotspot with many CROs growing their infrastructure there.

X

G**X**P – G**X**P covers Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP): the best practice guidelines for quality for their individual areas. The purpose of GXP guidelines is to ensure a product is safe and meets its intended use.

Y

Year 2014 and Beyond – The clinical trials of the future will no doubt be carried out in a far different manner than to those of today. Some of the predicted innovations are:

- Remote patient participation in trials
- Cloud based IT systems that are a one stop shop for all clinical needs
- Trials designed and implemented using social media
- Trials designed using big data techniques
- Increased gamification to help engage and educate patients
- Patient led and designing clinical trials
- Increased use of mobile technologies by all participants in the trial

Z

Phase **Z**ero – Phase 0 studies are exploratory studies that often use only a few small doses of a new drug in each patient. The biggest difference between phase 0 and later phases of clinical trials is that there's no chance the volunteer will be helped by taking part in a phase 0 trial. Because drug doses are low, there's little risk to the patient in phase 0 studies compared to phase I studies.

We'd love to meet you…

We're hosting Clinical Outsourcing & Partnering World Europe 2014 in London and would love to see you there.

The 7th annual Clinical Outsourcing & Partnering World will address the key strategic and operational considerations vital in making the right decisions when entering into and during a clinical partnership.

We'll be discussing:

- Clinical trial efficiency enhancement
- Clinical trial data optimisation, management and standardisation
- Vendor/sponsor relationship development to help drive partnership outcomes
- Novel partnership models

For more information, go to www.healthnetworkcommunications.com/cow

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