Special Report
Disruptive Innovation – The Impact

Perspectives from Senior Pharma Executives

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Disruptive Innovation in the Life Science Industry

At a panel session hosted by ICON early in 2018, senior executives from leading pharma companies shared their views on 'Disruptive Innovation'. The session was chaired by Nuala Murphy (President, Clinical Research Services, ICON) and guest panellists Francesca Wuttke (Managing Director, MSD Global Health Innovation Fund), Dr. William H. Carson (President and CEO of Otsuka Pharmaceutical Development & Commercialization, Inc.) and Badhri Srinivasan (Global Head of Development Operations, Novartis) provided insight into the challenges and barriers to innovation, the likely shape of clinical trials in the future and the important success factors to drive innovation in organisations.

Topics discussed

– The digital explosion and data tsunami

– Direct to patient strategies introducing new players to the industry

– Democratising and destigmatising clinical trials to improve patient recruitment

– Patient privacy and data protection

– Choosing the right innovation and the right partner

– Organisational evolution to deliver innovation

– Resourcing to drive change

– Innovative therapies – pushing the boundaries of current practices

Chair

Nuala Murphy
President, Clinical Research Services, ICON

Panelists/Contributors

William H. Carson, M.D.
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Executive Summary

The industry is experiencing a digital explosion that comes with the challenge of transforming high-volume, complex data into smart data that can be leveraged to advance life sciences. The number of companies working on disruptive innovation has increased substantially over the past few years and investment in this sector is massive. Areas of focus for innovation continue to be around unresolved issues, such as improving patient recruitment and engagement, for which the need to democratise clinical trials will be a key factor in providing a solution. Direct-to-patient strategies are introducing new players to the industry and this may also support democratising clinical trials by making trials more accessible to more patients. As these strategies evolve, patient privacy and data protection will continue to be something that stakeholders need to consider and we are already seeing technologies that may address these issues.

Although pharma companies and CROs are certainly here to stay, they need to change how they look at everything they do across the entire spectrum of drug development. Innovation should be part of their DNA and how they are going to adapt to change. Companies need to become more agile so that they are open to learning. Failure needs to be tolerated because failure – if dealt with in the correct way – is what leads to success.

These concepts are embedded in technology companies so pharma companies and CROs may need to start thinking and acting more like these organisations. Repetitive paper-based processes must be automated and algorithms can support “data crunching” but analysis by skilled data scientists will also be mandatory.

By adopting disruptive innovation, interventions can be made at each stage of the clinical development process to radically change and improve the way clinical trials are designed and conducted, to the benefit of the industry and, most importantly, patients’ lives.

The digital explosion and data tsunami

The current explosion in the digital world is leading to substantial changes in clinical research, such as how patients are recruited and treated, how trials are conducted and how medicines are distributed. At present, with more than 2,000 companies working in the digital sector, some of the biggest challenges are how to identify which are the best companies to work with, which solutions are the most meaningful and how these can be applied to add value to and improve the research process. Ideally, digital solutions should be as broad as possible to be applicable to a number of different processes. To date, many solutions have had too narrow a focus on one particular research area or process to be of general use.

Another major challenge is the amount of data that is now generated in clinical trials and that will continue to increase in the future, described by Otsuka's Dr. Carson as a "data tsunami". He cited as an example, a recent trial involving approximately 500 patients in which data was continuously captured. This one trial generated more data than all the previous studies conducted by Otsuka combined. The sheer volume of the "data tsunami" produced by clinical trials presents numerous challenges including how to analyse it effectively, how to obtain insights from it and how to action those insights. Clearly put, to turn raw data into smart data. The use of algorithms and data visualisation will certainly help with the complexity and quantity of data but is more needed to be ready for the the impact this will bring to the industry?

Direct to patient strategies introducing new players to the industry

A significant development in innovation is the entry of companies that have not previously been involved in clinical research. Dr. Carson cited as an example the partnership between Apple and the American health insurance company Aetna, which is developing health apps for Apple's devices such as the iPhone which will remind users to take their medications, order refills for prescriptions and message or phone their doctor.

'Disintermediation', where a company goes directly to patients for clinical trials rather than going through intermediaries such as CROs or pharma companies, is another important development. For example, the genetic testing company 23andMe® is conducting clinical trials. Genetic profiling, which is now available at a cost of less than $100 per test, will significantly change how clinical trials are conducted because the cost enables every patient participating in a trial to be profiled. "I think this will be transformative…" stated Dr. Carson, "and that really is moving toward having low-cost access to information that just 5 years ago was not even available at any price tag."

Another area of growth is the use of decentralised or 'site-less' trials, a disruptive approach in which a trial is conducted connecting directly with the patient rather than a centralised trial site. Digital developments, such as the availability of a database of patients who are ready to take part in a trial, are set to have a significant impact in clinical trials and are another means by which the time required for patient recruitment can be substantially reduced.

Smartphone and digital technology is having a substantial impact on clinical trials as it allows easy measurement wherever the patient may be rather than the patient being required to regularly attend a trial site. In 2017, Science 37, one of a number of companies focussing on decentralised clinical trials, completed a phase 2b study for AOBiome in which 372 people with mild-to-moderate acne were enrolled and participated in the study from the comfort of their own homes. This is the first example of a randomised, placebo-controlled study being successfully completed virtually.

Democratising and destigmatising clinical trials to improve patient recruitment

From profiling patients to finding patients in novel ways, significant changes are occurring in how clinical trials are conducted. Historically, only about 3% of patients have participated in trials, however, many more would be interested in taking part if they had a mechanism to find information about the clinical trials for which they could potentially be eligible. Democratising and destigmatising clinical trials by putting patients at the forefront of the process has huge potential. By doing so, the time taken for patient recruitment can be significantly reduced along with the cost to conduct the trials.

As an example of rapid patient recruitment, Dr. Carson cited a clinical trial in depression, conducted jointly by 23andMe® and Lundbeck, in which 25,000 patients were recruited in just one year. A challenge for Contract Research Organisations (CROs) is how to learn from this success and leverage and improve on these results. Approaching patients directly via online channels, using decentralised clinical trial design and partnering with online companies such as Science 37 are just some of the ways that we can change our traditional approaches. "It is really about being at the crest of the curve, as far as the technology and the data are concerned, and trying to understand how we are going to be prepare for what comes next." said Dr. Carson.

Patient privacy and data protection

With the vast amount of data available, an important question is who owns it. In Francesca Wuttke's opinion, the pharma industry is very burdened with data privacy but studies of patients' attitudes indicate that they don't care as much about their data privacy as one might expect. If patients think that sharing their data can improve their clinical condition or that of others, approximately 50-70% of people will be willing to allow their data to be part of a broader data consortium. Although pharma has to be very mindful of data privacy, this need to be balanced with genuine patient concerns. Eliciting change from a policy perspective may need more patient advocacy groups to speak on behalf of democratising data.

In terms of technology, blockchain is an important development for data privacy and protection and increasingly pharmaceutical companies have a position or initiative in this area. Badhri Srinivasan of Novartis stated, "…when there are technology solutions that say – I can take your data but I can keep it safe and secure, nothing will happen to it, it will be under your control but we can use it for the greater good, the argument shifts completely." Blockchain is an excellent example of how patients can have control over their own data, a phenomenon which Dr. Carson believes "could completely transform adverse event reporting and pharmacovigilance so regulatory authorities around the globe will have more information on the drugs than they have ever had before".

In Dr. Carson's opinion, data privacy may be much less of an issue in the future as millennials have no assumption of privacy so they tend to share more personal information. Millennials are also concerned with the greater good so helping people get better is important to them. They recognise the value of their data and the role it can play in advancing healthcare.

Choosing the right innovation and the right partner

Francesca Wuttke researches and makes choices on investment in health innovation so she was asked to provide insight into her experience of what to look for in new evolving innovation. She said there was no easy way to choose but gave the example of Antidote. She looked at how companies found patients. Some were using a digital agency approach, with advertisements online and on social media platforms such as Facebook and then there were companies that interrogate the data from EMRs to identify patients who are potentially eligible but the burden still falls on the study nurse to check if they are eligible and are willing to participate in the study. For her, Antidote really stood out because it identified willing patients and the solution pre-determines that they are interested in a clinical trial. This was a big differentiator. She pointed out that she believes patient advocacy groups, which really drive medical practice in the case of rare diseases, are likely to have a much greater impact in the future for more common chronic conditions. Francesca Wuttke stated, "…we need to really focus on patient-centricity" adding that "patients will be driving their medical choices going forward."

When partnering with technology companies, two aspects are important- first, it has to be a true partnership not just an investment in the company and second, an ecosystem has to be created within the pharma company that fosters innovation and ensures the partnership is successful. In large organisations, it can be difficult for people or departments to adapt to change, to take risks or to adopt innovation. It is important, therefore, that change "…has to come from the top…leaders within the organisations have to mandate digital change". Francesca Wuttke noted. Dr. Carson confirmed that his preference is to pilot an innovation or new solution before rolling it out throughout the whole organisation, an approach that has been taken at Otsuka.

Organisational evolution to deliver innovation

Driving innovation within an organisation can take on different forms either through a stand-alone department or embedding innovation within functions. Badhri Srinivasan pointed out that much research has been done on the subject and broad agreement has emerged that innovation should be separate to the day-to-day operations but to succeed it has to be embedded into the day-to-day business. There needs to be some sort of centre of excellence or an innovation engine at the start that ignites the idea, actively working with operations to help them overcome their hurdles or to help them change their mind-set. The actual process of innovation then has to be embedded in the operating units and the operational functions.

Francesca Wuttke recommended that people be incentivised to drive innovation and a philosophy that failure is okay needs to be established. The paradigm shift of accepting failure and embracing experimentation across an organisation is crucial. Badhri Srinivasan agreed, saying "Let us tolerate failure because failure is what leads to success but it's important to fail fast and fail forward, not make the same mistake again."

Dr. Carson said that an organisation needs systems in place so that innovation comes from the top down but also needs to have a 'bottom up' approach and both of these have to happen simultaneously. In addition, it is important that the organisation is not too bureaucratic because bureaucracy can easily obstruct the flow and pace of change.

The companies that are going to emerge six months or two years from now will be vastly different from the companies that are here today because of the rapid pace at which data and technology are evolving and how they are being used. Organisations are going to have to move faster in the procurement process and will not be able to sustain an 18-month cycle to complete the procurement process. In the future, procurement groups will have to work much more quickly so that when a promising novel agent becomes available it can be adopted quickly and progressed to clinical trials.

Resourcing to drive change

There was agreement that the demand for Data Science is expected to grow, whether this is as an in-house function or outsourced. Given the large amount of data produced by a trial, most of the 'data crunching' will likely be done by computers but there will still be a need for humans to move from 'data crunching' to interpretation and validation of the data to the provision of insight. Machine learning and artificial intelligence are rapidly growing with the prevalence of middleware technologies but human intervention will still be needed interrogate, understand and interpret the data.

Badhri Srinivasan commented, "…we don't just want an answer, we want to understand the path to that answer as well." An example he gave to illustrate this is someone who has back pain could say 'you know this back pain is killing me.' A computer algorithm analysing this data could interpret 'killing' as meaning the person has a high probability of either committing murder or suicide. Therefore it is important to understand the context and how the computer interprets the data. "A complex algorithm that does magic is much less useful than a simple algorithm that can actually trace back and say how you actually got to the answer".

Another example is where there might be information in the data that is not quite a trend but could have a major impact, such as the emergence of adverse events. All the trial data can be captured but potentially useful or significant information could be missed if the data is not analysed correctly.

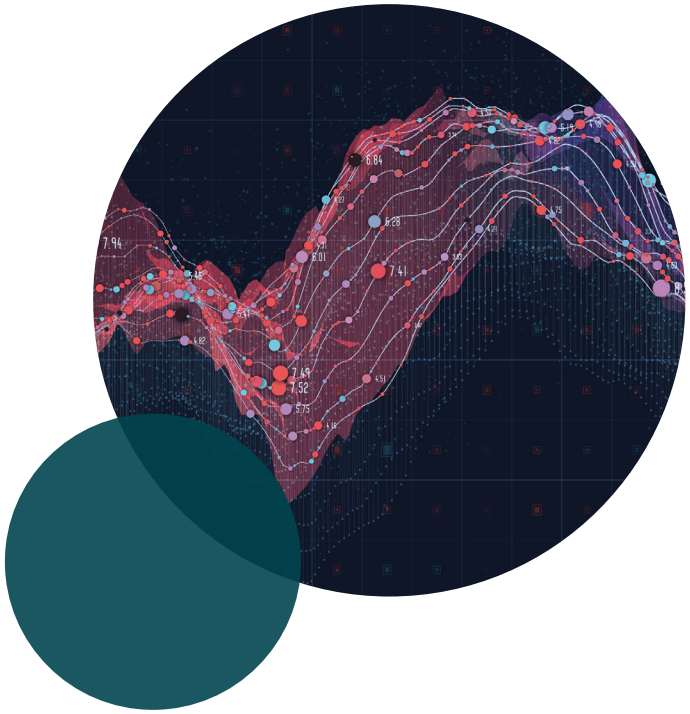
Innovative therapies – pushing the boundaries of current practices

Recently developed therapeutic approaches such as CAR-T (chimeric antigen receptor T-cell) therapy and CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) gene editing are niche and complex research areas. They do however have the potential to play a meaningful role in bringing down the high costs of development and increase the availability of life saving drugs for patients. This area in particular is ripe for digitisation and for novel approaches because the therapies themselves are novel. To really make a difference in this promising area the panel suggested that stakeholders keep communication channels open to the study teams, discuss where they are experiencing the biggest pain points and come to it with fresh eyes of how difficulties can be overcome, as previous processes and practices will not necessarily work.

With Novartis receiving the first ever FDA approval for a CAR-T cell therapy, Kymriah™ (CTL019) and ICON's recent work on CAR-T* it was expected that this topic would come up for discussion. Badhri Srinivasan was invited to discuss the challenges facing the study teams in this new therapeutic approach and how disruptive innovation might play a part. He outlined one particular difficulty in transporting blood to the manufacturing unit and then getting it delivered back quickly. Logistical challenges have the potential to be overcome either through innovation in the supply chain, robotic processes or through mathematical models.

Advice on coping with the impact

Badhri Srinivasan counselled on the need to double down on innovation, become more agile and continue to learn as one entity without the constraints of hierarchy. Francesca Wuttke recommended that organisations start to look at the most basic aspects through the entire spectrum of drug development and really think about making innovation part of their DNA. Dr. Carson's closing words of advice related to a simple yet significant process change: everything should be digital rather than paper-based, anything that can be automated should be automated, and more importantly to remember that automation is not innovation.



*The challenges of manufacturing and distributing CAR-T therapies" Pharmafocus November 2017

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