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Technology is one thing; enabling it and making it useful for people in their work is quite another

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IBM Watson Health's Director for Global Life Sciences & Go-To Market Leader for Europe & Asia Pacific Christina Busmalis gives her insights into how AI and greater utilisation of real-world evidence is shaping the global biopharmaceutical industry, including the tangible results she has seen so far, and the lengthy path still left to travel.

What is IBM Watson Health today and what are the problems it is trying to solve?

We are focused on addressing the biggest global healthcare challenges. Healthcare systems around the world need to change, and our intention is to help drive that. We are partnering with clients around the world to transform how healthcare is delivered and move beyond "experimentation."

IBM Watson has four key capabilities. Firstly, we have deep industry expertise, both within the company itself and through our partners. Secondly from both the pharma and payer/provider sides, we use raw data to drive our third key capability: unparalleled insights that are generated by an industry tuned platform with analytics and advanced technology (whether AI or not). Finally, all of these capabilities are underpinned by security and trust, leveraging the IBM Corporation proven capabilities in this area.

How does IBM Watson work with patient data?

The nuances of how we work with patient data depend on the rules and regulations of each market, which can vary. What never changes is our emphasis on trust and security, whether the patient data is anonymized or not – these are key strengths of IBM and core to our mission.

The question of who owns what data is a major concern and differs between regions. In Europe, there are consortiums such as the Innovative Medicines Initiative (IMI), the European Federation of Pharmaceutical Industries and Associations (EFPIA), and Horizon 2020, which address the need for data to make better evidence-based decisions. Some countries in Europe are very mature in access to anonymized patient data. In Sweden, for example, you can make a request to do a study and get registry data for that study. However, typically the process to do complete this is many months.

The situation is different in the US. There, IBM itself owns a significant amount of clinical data via the IBM® Explorys solutions, a healthcare intelligence cloud company acquired by IBM in 2015. We de-identify this data to work with pharma companies and biotechs. We can also use it with the hospitals themselves to get population health analytics. We also own financial claims data in the US – when we acquired TRUVEN Health Analytics and added data for 200 million patients.

Handling of patient data, whether anonymized or not, requires trust and security which is a key strength of IBM and core to our mission.

Digital technology, real-world evidence (RWE) and artificial intelligence (AI) are all industry buzzwords but how tangible have results been so far?

We are still in the early stages of a longer journey in terms of technology adoption. 15 years ago, when I started working with life sciences firms, companies' IT departments were primarily concerned with fixing the CEO's email when it went down or running an ERP system. IT was not embedded in pharma processes back then. Now, just as in other industries, pharma companies cannot live without technology.

The difficulty comes with the speed of change. Technology is one thing; enabling it and making it useful for people in their work is quite another. Change management is a huge topic for us which we see across all companies. In the case of AI, for example, how do you augment the human with AI to help them do their job better or faster and really get them to embrace it?

Regulation is another aspect to consider. Especially in relation to pharma, how do the EMA, FDA, or PMDA adopt these technologies? Bringing all of these moving parts together is not an easy task.

Biopharmaceutical companies have science and technology embedded into their missions – therefore is it more straightforward to push these firms to adopt new digital technologies than it would be for other industries? Are these firms listening more to providers like IBM Watson?

Absolutely. The conversations have changed over the last five to six years. Some companies are embedding automatically and want to do it themselves, whereas others are looking much more towards partnerships.

Companies should have the technical skills to do a significant amount of the work themselves, but they should also enable, with partnerships, the ability to be fast. As technology changes rapidly it is difficult to keep up anywhere, but even more difficult within the pharma company itself.

Within IBM Watson Health a big focus is on enabling partnerships with our clients and firms that do a similar thing to us; it’s not something that one company alone can solve.

What key areas is IBM Watson Health focusing on in its work with pharma companies?

We want to help these companies solve their business problems and focus on what matters for them.

Our big focus has been oncology and genomics, especially from a payer/provider perspective; supporting patients and oncologists with evidence-based cancer care. That could be in recommending potential treatment plans or finding the right trials for patients.

Through the use of data and analytics, we aim to utilise machine learning to provide insights into predicting the likelihood of an event. A good example is our work with Roche, where we built an algorithm to help them predict the early risk of kidney failure for diabetics. With 79 percent accuracy, they can now predict whether a diabetic patient will have chronic kidney disease within three years.

This can be used to understand the types of patient cohorts that a treatment relates to. More real-world evidence is being utilized in marketing, as well as in drug development, with the growing

awareness that the real world needs to be considered when developing treatments.

How big an impact can AI and better utilisation of RWE realistically have on the drug R&D process? Where will the biggest impact be?

Clarivate Analytics recently produced a paper which found that the cost of bringing a drug to market has dropped below USD two billion. This was due not to the advent of new technology, but to the fact that last year 40 percent of the drugs that went to market were for orphan drugs for rare diseases. Furthermore, 76 percent of the drugs that went to market were from companies that had an R&D spend of less than USD two billion. This shows that Big Pharma – which is spending the most on R&D – is not bringing drugs to market as quickly as smaller biotechs.

Companies are therefore able to reduce the costs of bringing a drug to market; now the question is: “imagine how can technology improve this even further?” From a technology perspective, in drug discovery, there are over 150 start-up companies looking at AI in drug discovery, which is an overwhelming amount. Most will not survive, but some are already adding value. For example, a company called FDNA looks at phenotypic and genomic data to understand precision medicine. Another, Insilico Medicine, looks at identifying new biomarkers around ageing-associated diseases.

How does IBM Watson Health fit into this?

At IBM our focus is on clinical development. We see great opportunities to shorten timelines and reduce costs in the clinical space. Our IBM Clinical Development product is an electronic data capture (EDC) system and acts as a platform to help get trials up and running quickly and manage all the data generated throughout that trial. It is a very flexible technical solution upon which we can build increasing functionality. We recently introduced AI for Medical Coding within our IBM Clinical Development solution. The service is designed to be an assistant for the Medical Coder with Adverse Event and Medical History coding against the MedDRA dictionary. It suggests up to 5 possible codes for those challenging free text verbatim that would require manual coding. This will reduce coding time and most importantly improve coding accuracy and consistency.

Over 80 percent of trials are delayed. Over 50 percent of sites never recruit a patient. An amendment costs USD 40,000 a day and up to eight million in potential revenue. All statistics show that the clinical trial process is flawed. We hope to make an impact at the design of the protocol. One area we are focusing on now, to be launched later this year, is advising and helping companies

build the right protocol.

We do not build the protocol ourselves, rather we help our clients, including clinical research organizations (CROs), to build their own. When you start to build trial protocols, one of the biggest problems is the inclusion/exclusion criteria and determining who the right patients are for a particular trial. If you can use real world data (RWD) to help determine that, you can build a better protocol. Our first focus is on optimising that protocol with the goal of reducing amendments, cost and time. Beyond protocol optimization we are focused on site selection, patient recruitment levering advanced analytics and AI as well as e-Consent with Blockchain.

At what stage of AI adoption in pharma do we currently stand?

As an industry, we are still at an early phase of a long journey. AI has been around since 1956 but did not become mainstream until less than 15 years ago, thanks to the computing power to be able to use it becoming more affordable and faster.

> Revolutionary AI – where AI is completely autonomous – is far in the future

We see three areas of AI: ‘narrow,’ ‘broad,’ and ‘revolutionary.’

Over the last 10 years or so, we focused on Narrow AI, whereby you take a slice of data and do something with it quickly – single task in a single domain. The RWE project with Roche that I shared earlier, predicting the likelihood of an event, is a good example of that.

As with any technology, you have to be able to scale up and take it mainstream to become more economical. That is where Broad AI comes in. Broad AI is the focus area for IBM Research and bringing our capabilities into Watson Health.

Broad AI is able to take in many different data types – for example, not just clinical data but genomic financial, and imaging data – and focus on broad business processes. It changes how you do AI underneath, and allows you to combine reasoning and learning. It is faster and can use less data. It provides the required lineages for recommendations within the AI system – also knowns as “Explainable AI”. Broad AI models and algorithms adapt to the data available. You are no longer having to redo an algorithm for a specific data type, which starts to drive economics and scalability.

The pharmaceutical industry represents an interesting test case for Narrow and Broad AI. AI adoption is growing and accelerating in the sector: the use of “Narrow AI” is increasing in drug discovery, clinical operations, commercial effectiveness, market access, and back-office areas. However, the pharmaceutical industry is very earlier in its journey to “Broad AI.”

Revolutionary AI – where AI is completely autonomous – is far in the future.

Your role oversees both Europe and APAC – two similarly-sized pharma markets but with very different dynamics. What are some of your key markets within these two regions?

Japan remains a very important market in the pharma industry and to drive successful technical innovation.

I see Japan as a very different market from the rest of Asia. It is very mature but also innovative, with strong data and privacy laws. The country is also very keen to experiment with new technologies across many industries. As a result, we have had a lot of success in innovating there.

Additionally, the country has a tight, collaborative community that shares experiences – if you can show value with a few of the key companies, the rest follow.

What are some of the opportunities and challenges for IBM Watson Health in China?

China is *the* place to be to grow and scale business in a very large market. There is USD two billion being spent on clinical trials annually there, which is going to grow to USD 4.5 billion. We also see great potential in the Chinese clinical trial space: trial costs there are less than half those of the US and yet, still just seven percent of global trials are conducted there.

IBM has been there for decades. I was there in 2007/8 as a subject matter expert for one of our global pharma clients to develop a strategy, vision, and roadmap to support their “HyperGrowth” Business Strategy in China; it was exciting then and it is still exciting now.

Although there are more than 3,000 pharma companies in China (counting both multi-national companies (MNCs) and locals) and a lot of growth, doing business there is a challenge. For example, recently passed regulations mean that data must stay in China. On top of that, there are certain license requirements for software vendors which require more investment or local Chinese partnerships.

The final concern is around intellectual property (IP) protection. Because of these concerns – particularly that what companies run locally in China is accessible to the Chinese government – foreign companies need to be very careful about what data and technologies are brought into the Chinese market.

We make those decisions on a case-by-case basis. For example, IBM Research works mainly with open source technology in China because the IP holder grants users the rights to study, change, and distribute the software to anyone and for any purpose. This reduces the risk to the company.

What about Europe? Does the market still hold potential, even compared to the megamarkets of the US and a rapidly developing Asia?

The US is still the biggest market in the industry. But I see compelling areas of growth in Europe.

The two most important topics in Europe are data and collaboration. With more European data and greater collaboration between stakeholders, there will still be a lot of opportunity on the continent. It bears repeating that Big Pharma is still in Europe and still innovative. Roche, Novartis and Sanofi still make key decisions from their European headquarters. Europe is a hotbed for skills; there are hotspots in Cambridge England, Switzerland, and Belgium.

One of the solutions we have developed globally (and which is highly relevant to data and collaboration) is around stakeholder management, infused with AI. The solution uses AI to sift through the millions of records of public data to find and work with the right key opinion leaders (KOLs) in a country to transmit the right key messages. This process is particularly helpful in predicting and identifying rising stars in specific therapeutic areas in which companies need to work. This is very relevant in Europe where companies have to be at the local market for KOL influence.

The European market for biotechs is also promising. A recent McKinsey study analysed 1,000 European biotechs and found that the top areas of focus – accounting for 40 percent of firms – were immunotherapy and CNS. In the US, advanced therapies account for only 25 percent of companies. The fact that these European biotechs are operating in different therapeutic areas to their US counterparts can be a key differentiator and drive progress.

What kinds of questions should a biopharma CEO be asking about digitalization and AI?

CEOs need to talk basics. They don’t necessarily need to understand the technology itself. But they need to explain how it brings value to their organization in layman’s terms, how they can take action to remain high performing, and how they can leapfrog their competitors.

CEOs need to understand that technology is no longer a cost-centre, but an enabler to get to faster decisions and better security.

The IBM Institute for Business Value (IBV) conducts an annual C-suite study, where we interview 4,000 C-level executives across the world. In 2018, the top external impact that CEOs across all industries were most concerned about was technology – above markets, people, globalisation, or regulatory issues. Technology is, therefore, clearly a hot topic in the minds of CEOs.

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My last 14 years have been exclusively focused on the life sciences. It has been fascinating to see how far behind pharma has been in applying and enabling technology compared to other industries. Consequently, there is huge potential for greater adoption of technology in this industry and digital transformation.

In ten years, it will be interesting to see whether pharma has internalised this knowledge or whether pharma still needs to bring it in from outside. I greatly hope it’s the former.

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