NEIL WILLIAMS, MEDICOM INNOVATION PARTNER

Neil Williams is Director of Front-End Innovation and Head of Connected Health at Medicom Innovation Partner, which he joined in 2015 and where one of his key roles is to evolve the company's third-generation connected health software platform. Having started his career in the clinical setting, working in the critical care faculty with a leading NHS University Hospital, Williams moved into industry where he has focused for many years on healthcare IT including medical devices, clinical decisions support, health analytics and care pathway design.

In this interview with ONdrugDelivery Magazine, Williams discusses the crucial role connectivity is taking in the drug delivery device industry, describes some of the challenges associated with patient privacy and how Medicom understands and overcomes these, and also explains how, as part of the Phillips-Medisize / Molex businesses, Medicom is well positioned to deliver connected delivery systems to clients, for small scale manufacture right up to very high volumes. He also introduces the third-generation connect health cloud platform that Medicom will be releasing in 2018.

Q Thinking of all the stakeholders – patients, clinicians, pharma industry, etc – what do you see as the most significant trends and most pressing demands driving the connectivity of drug delivery systems at present?

A For more than ten years the digital health world has been talking about the cost of care doubling, due in part to pressures on the healthcare system. There is pressure on the provider and care networks due to an ageing population: the diseases that occur as people age, the comorbidities and the cost of managing those conditions. Then we see a very significant increase in the payment-by-results agenda which puts a lot of pressure on the pharma industry to really demonstrate that they are getting the results they claim. That needs to be answered if pharma companies want to maintain price points.

There is, definitely, a big directional change in the biopharma world to realise this. I think, ultimately, the pressure is coming from the payers who are saying that if a treatment really meets its claimed p-value then they will pay, but if it doesn't meet that then the stipend that the payers arrange at the end-of-year contract isn't awarded.

I think, in almost every other aspect of our lives, technology has improved things for us. It could be argued perhaps that too many emails, for example, make life more complex, but overall things have improved thanks to connectivity. You can now turn your lights, heating and oven at home on and off from anywhere in the world using your smartphone, you can set your house alarm, book travel, rearrange car insurance. Yet for tracking your medication adherence, only a very few companies have really adopted connected technology early.

> "We are now creating the third generation of our connected health platform using world-leading technology that includes the most commonly used health integration engine and a very rich analytics tool … I've been involved in healthcare IT for 22 years now and this cloud platform that we're building out is far more advanced than anything we've seen on the market."

There is a big challenge with adherence. Only 50-60% of patients, even with chronic diseases, are adherent to their drug delivery. Non-adherence results in a huge burden – such as emergency department admissions – and ultimately death in many instances. The death of 125,000 Americans per annum is associated to medication non-adherance.

You have to look at who are the risk-bearing entities in this process. It's not so much the payers or insurers, it's the pharma companies … and obviously the patients themselves, who make lifestyle choices based on the information they get. More engagement, more connected drug delivery, should push up life expectancy for patients.

Patients live in a more connected world so they find it quite unusual, for example if they are using a prefilled syringe, that they have document their doses manually. It's another burden and one that in most other aspects of their lives they just don't see because things are increasingly done electronically, often automatically.

The accelerating migration of care from hospital facilities to the home is evident in all advanced care systems around the world. We need to be able to capture data in the home just as well as we would if the patient had come to the clinic for treatment. All of these things are accelerating towards a more connected ecosystem outside the hospital.

Q Please could you give us an overview of Medicom's offering in this field?

A The broad offering presented by Medicom is that we work with clients to manage product lifecycle right from Phase II or early Phase III to prepare for launch, to prolonging their opportunity with a drug when it comes off patent. We do that by creating a very specific user experience, directly related to the medication, to the patient and to the disease they have, and a strong engagement with the patient, using drug delivery device design.

There are various companies who you can go to and buy, for example, a ready-made autoinjector "off the shelf". We don't do this. We have more than 1000 technology accelerators that we can apply to designing a device for drug delivery. So the first point of contact is to create a great drug delivery device for particular patient groups that addresses specific needs, rather than trying to apply one system universally to different patient groups with different diseases and different lifestyles. We can get a device designed and developed often in a shorter time than it takes to get an "off-the-shelf" device through the applications and approvals process.

Additionally, we are now creating the third generation of our connected health platform using world-leading technology that includes the most commonly used health integration engine and a very rich analytics tool that allows our clients to assess data from patients globally. It complies with all of the privacy laws. It creates a highly structured, codified database so our clients can do global comparators, look at different behaviours in different markets, do some behavioural science. It provides the means to compile data that is solid enough to be used for publishing research, for reporting Phase III studies etc, with the aim of really improving adherence. It supports US 510(k), combination product submissions, the medical device data system (MDDS). It uses the same technology that underpins some of the world's most successful hospital electronic medical record systems and is used by health systems around the world to empower integration.

I've been involved in healthcare IT for 22 years now and this cloud platform that we're building out is far more advanced than anything we've seen on the market. It will be fully released during 2018 but it's being made available to some clients now; we're already working with organisations that are adopting it.

Figure 1: Medicom is evolving enterprise-wide technology platforms that support healthcare.

A big problem with many of the connected medical technology platforms available on the market right now is that they are monolithic solutions, created around a drug, which are expensive and cannot be repurposed. Medicom too has taken this approach in the past. What we are creating now is an enterprise-wide connected health solution that allows patient identifiable information and device data all to be integrated into a common platform. It functions across a client's entire business, so it's not franchise by franchise.

Other systems that are out there are either monoliths, pure device data repositories or offer limited regulatory flexibility, don't support enterprise wide "multi franchise" data management and lack the powerful analytics needed for population health. You need to then create a separate clinical database, and to get meaningful data you need to connect the two, and the device data becomes patient identifiable. This all just sounds very old-hat compared to what the latest technology makes possible in connected health. What we see a demand for, and will bring to market, is something that really specifically addresses the biopharma need for an enterprise-wide connected health solution.

> "Privacy is a really important issue, and trust is an equally important issue. In the end, the patient needs to be in full control of what they share and with whom. That's the only ethical position to take."

We have deep understanding of privacy laws, and extensive experience too, having taken connected solutions to market in more than 30 countries already. We'll deliver our cloud platform uniquely to clients so that you will never have data belonging to pharma company one located in the same place as data belonging to pharma company two – they will always have separate environments.

To summarise Medicom's offering, it goes from enterprise-wide connected health, covering all franchises with one common platform, to delivering unique patient experiences by franchise and designing unique drug delivery devices by franchise based on our extensive technology accelerator portfolio.

Q Why did Medicom opt for parenteral and pulmonary devices in the first instance?

A I think it's because we saw these routes of delivery as the highest revenue risks to biopharma companies. About six or seven years ago, Medicom realised that particularly injectables were going to become a challenge, especially as the biosimilars world was developing very rapidly. A lot of those drugs were being developed for rare diseases, as orphan drugs, and of course a lot of CMOs weren't really geared for dealing with low volumes. We focused on that niche of rare diseases, complex delivery, etc. We also have extensive experience in the inhalation segment and, additionally, have done a lot of work in smart pill packets.

Q A strength of Medicom now, through its parent company Phillips-Medisize, is industrialisation know-how. How does this know-how add to the mix when it comes to connected devices?

A Since June last year Medicom has been part of Phillips-Medisize. Historically, Medicom was geared towards low-volume manufacturing, rare diseases for example. Now we're extremely well integrated with Phillips-Medisize and of course Molex, a global electronics leader. In our projects now we include all aspects of the entire business and we can now engage with projects that go to volume. We've got clients that require more than 100 million units a year. So we go from small scale, which we produce at Medicom's own facilities in Denmark, through to full global production at facilities around the world.

The challenge we had historically is that, whilst we have a very talented resource in Denmark and Cambridge, UK, with which we'd have gone through a great design process with a planned manufacturer, we would have had to have done a technology transfer and there is always a bit of pain in doing that tech transfer. Whereas nowadays we have Phillips-Medisize as part of the team right from the beginning. It really works as one company. And if we need electronics insight, who better than Molex to have as a go-to partner! So we can handle everything – full board design, full-scale manufacture and all the interconnects. We have great experience in Medicom around wireless connectivity and app design. We're building the truly differentiated cloud platform as I mentioned just now.

We're still the only company with a combination product connected auto-injector, the BETACONNECT™ (Figure 2), that's launched in both the US and the EU. We have other technologies that will reach the market with other clients during 2018.

Since the acquisition, our capability to do things on a global basis and set up manufacturing facilities around the world puts us in a completely different space to where we were in say early 2016.

Q In today's drug delivery business, whilst the drug formulation, the pharma company, regulation and numerous other factors are naturally all critical considerations during device design, the patient is always front and centre. Can you talk about what benefits Medicom's technology and expertise bring specifically to the patient?

A There are a couple of points I'd make here. First, from Medicom's perspective, no experience is "generic". We create unique experiences by disease, by drug and we can even tailor that further by, for example, age group. The requirements that a six year old girl has of her treatment are different from those of a sixty year old man. Their experiences are different, the education and training during their treatment are different, the way they are encouraged during the course of their treatment is different. We tailor that specifically.

We engage with patients right at the beginning of the process and we do a huge amount of usability work. Typically we get that done quickly – in about three to six months, and before we go into design controls.

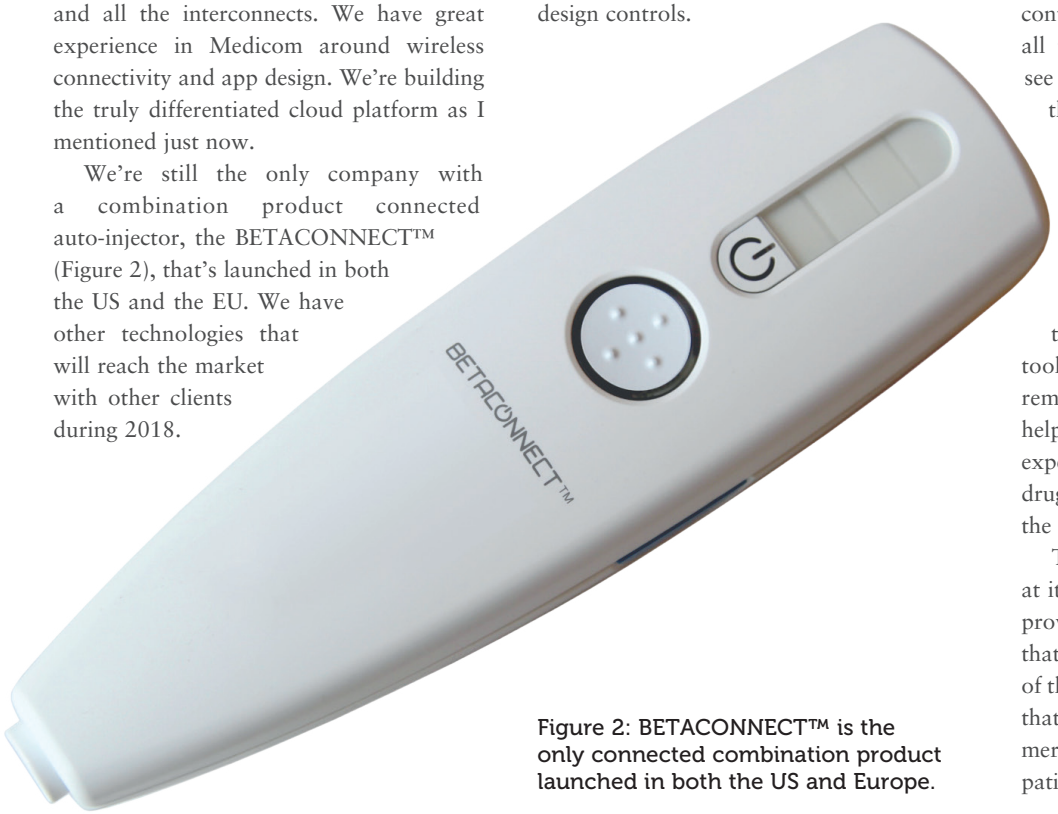

Figure 2: BETACONNECT™ is the only connected combination product launched in both the US and Europe.

Second, privacy is a really important issue, and trust is an equally important issue. In the end, the patient needs to be in full control of what they share, and with whom. That's the only ethical position to take. There's no need to restrict somebody from using a tool if they're anxious about where the data goes, so in all scenarios we give the patient the opportunity to choose whether they share their data back to the pharma company, whether it is anonymised or identifiable. If they want to be considered for research projects then by default they will have to identify who they are.

Patients can also decide who else they want to share their data with. They may have a loved one or a carer who they want to give access to their data. There's also alerting. For example for emergency medication or something unusually episodic you might share data on that but no information about your background dosing. Results can also be shared. We integrate with testing technology and patients can put their results into various tools. Also connected technology can be used to help create what are known as "legitimate relationships" with healthcare providers so patients may wish to share their data with their provider network.

Increasingly we see providers setting contracts with patients to share the data if they want to continue to use smart devices, but the ultimate result is that it must be really and totally in the individual patient's control. They have the option to switch all these things on and off. They should see the pharma company as a sponsor for them to use their technology, whether or not they share the data. If they don't share their data they can still use the connectivity between their device and their smartphone.

It's not a philanthropic venture on the part of the pharma company though. Biopharma are providing a tool that offers education, engagement, reminders for adherence etc, which all helps make sure the patient has a good experience while being treated using their drug. But the patient does not need to share the data at all.

Today, when a pharma business is looking at its patient population, the product that's provided is not just the drug, it's the services that are provided around it, and certainly all of the organisations we work with recognise that patient engagement is more than a mere marketing tool. It's about making sure patients adhere and that they get the best

results possible from the medication that's been prescribed to them.

From our perspective, because of our third-generation connected health platform, data can potentially go straight back into the care provider network, almost bypassing the pharma business and going straight to the clinician.

Privacy is a big challenge. Obviously the EU GDPR [General Data Protection Regulation] will be in effect from May 2018 which creates an additional burden on the pharma companies. There are massive differences between North American privacy laws and those in the EU. The EU is more stringent. For example, under CFR21, in the US patients shouldn't be able to fully delete their data in case there's a legal challenge later in life. They can suspend access to their data but they cannot delete it. In the EU though, you have the right to have the data removed. Even different markets in Europe have a different view on privacy. The GDPR regulation is trying to harmonise this but our experience is that there was an EU-wide standard beforehand but implementation in each market changed – sometimes because of privacy and sometimes because of clinical practice. As a business, Medicom understands this complex area well and we know how to create regional variations of a configuration.

Q How does Medicom fit with the wider Phillips-Medisize and Molex organisational structures and strategies?

A For legacy Medicom projects already underway at the time of the acquisition, Phillips-Medisize and Molex have added substantial additional insight. A number of projects started almost immediately after the acquisition because the deal really caught the industry's attention. On these we have teams of people across all of the business units but we all work as one. A decision is made early on for each project as to where is the best place to lead it from. But the businesses work together. So if we need electronics insight we bring Molex in early.

Molex have fantastic technologies – flexible boards (they can even print circuit boards on paper that you can wrap inside drug delivery devices like pens), tiny interconnects, great power management – things that are beyond what Medicom alone would have been able to deliver in-house. Phillips-Medisize is well-known for being accomplished at producing at volume. They really understand design for volume. And so everyone is involved right from the beginning.

One of the key things we offer to clients is something we call "Jump Start". We simply run a workshop for a couple of days with them. There are usually two weeks' work ahead of that during which we learn as much as we can about the client's needs from the information they provide to us. But during the workshop with them we really assimilate all of that, capture all their needs and by the end of a couple of days we've reached a point where we're visualising what their device and software solution could be. This approach saves a lot of time and money for the clients. They are very quickly in to working out the art of the possible, not trying to be on bleeding-edge technology but on the leading edge. All of the value-add components across the Medicom, Phillips-Medisize and Molex business units are applied to the client when they need to be.

Looking at how it works commercially, there are things that come to Medicom because clients see a need for a complex design and technology solution. There are things that go to Phillips-Medisize where, for example, clients are quite advanced in their design concept and are asking questions around going to volume. Each of us pulls bits of the business in as needed.

On the level of the people the integration has been really smooth. We're all on first name terms across the business units, we genuinely work together closely and you'll often see people from across all three divisions attending conferences together as one team. I've been through M&As before elsewhere and there's typically a struggle and some pain and, often after acquisitions on this scale, you'll naturally see a human impact on the business evidenced by quite a number of people leaving. This just hasn't happened in the case of Medicom, Phillips-Medisize and Molex because everything has been additive.

The acquisitions are a really good story. Medicom strengthens the organisations in the connected drug delivery space. Medicom have advanced connected drug delivery insights, Philips-Medisize bring advanced, global, volume manufacturing and additional device design capability, Molex are a leading design and manufacturing electronics business.

Q Finally, please could you tell our readers a little about yourself, your career, and what it is about Medicom in particular that, for you, makes it an attractive organisation to be a part of?

A I've always worked in healthcare. I used to work in Critical Care and was often engaged in medical education by the Department of Resuscitation Science at Leicester University Hospitals. I left there 22 years ago to work in medical devices, clinical decisions support, healthcare IT, health analytics and care pathway design. I joined Medicom Innovation Partner two years ago to evolve their connected health offering that will emerge next year as our third-generation connected health platform. I'm based in Cambridge in the UK but have worked all around the world.

I have been involved in drug delivery previously – I used to run marketing for devices for Hospira in the EMEA. I also have experience working in patient engagement, having worked for Microsoft for some time looking after their HealthVault platform across EMEA.

I saw Medicom as a really interesting business that was growing well, had really good leadership and a good vision of where it wanted to be. To me, Medicom just presented an opportunity to solve many of the problems that pharma was facing.

I remember the first pharma conference I attended after joining the company and listening to all the fear, uncertainty and doubt in the room about privacy, liability, pharmacovigilance, all of those challenges. I thought to myself, we fixed all of this in healthcare IT years ago. No-one expects their MRI to turn up on YouTube! There are lots of rules, processes and standards already in place that you can take from the care delivery network and use because it's well proven, well developed and tested over many years. You can apply it to what is in effect an expanded care delivery network, moving medication delivery from the clinical facility into the home. We've discussed the benefits of this move already, but for the patient it is simply better to resort to hospital treatment only when it is really needed, because people who stay in hospital longer than necessary are more like to get sicker. If patients who can be treated at home are treated at home they are more likely to recover.

For me, looking at Medicom I saw that this was a great company because it was

pushing the boundaries in that space. They had already created great technology, they had a good foundation, and I thought, this is somewhere we can really make some impact and create value for stakeholders. The acquisitions just enhance that. Molex is itself part of Koch Industries and so the reach and capabilities, and the level of investment we're now making, were never possible in the Medicom only days. It's an even stronger business than the one I joined two years ago – and the level of interest and the pipeline of work has expanded dramatically. It always was an exceptional business with talented people and these days there are more than 500 talented engineers that we have access to around the world, all focused on drug delivery. It's a great place!

ABOUT THE COMPANY

Medicom Innovation Partner (a Phillips-Medisize Company) is a leading global innovation, development and low-volume production provider focused on drug delivery devices and connected health solutions. Medicom Innovation Partner was established as a technology venture of Bang & Olufsen A/S in 1989 and the company has been a dominant player within the drug device world for more than 25 years. Medicom holds a dedicated staff of more than 90 high-calibre innovation specialists, mechanical, hardware, software, quality assurance, regulatory and production engineers based in Struer, Denmark, and Cambridge, UK. Medicom has experienced considerable growth over the last five years.

As of May 31, 2016, Medicom became part of Phillips-Medisize Corporation. Phillips-Medisize is a leading global outsource provider of design and manufacturing services to the drug delivery and combination products, consumable diagnostics and medical device, and speciality commercial markets. The company has annual sales of over US$700 million with 80% of the total revenue coming from drug delivery, medical device, primary pharmaceutical packaging and diagnostic products, such as disposable insulin pens, glucose meters, speciality inhalation drug delivery devices, single-use surgical devices and consumable diagnostic components.

Together Phillips-Medisize and Medicom are becoming one of the leading players within the growing drug delivery device and connected health market.

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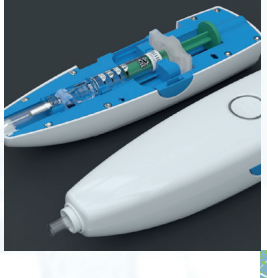

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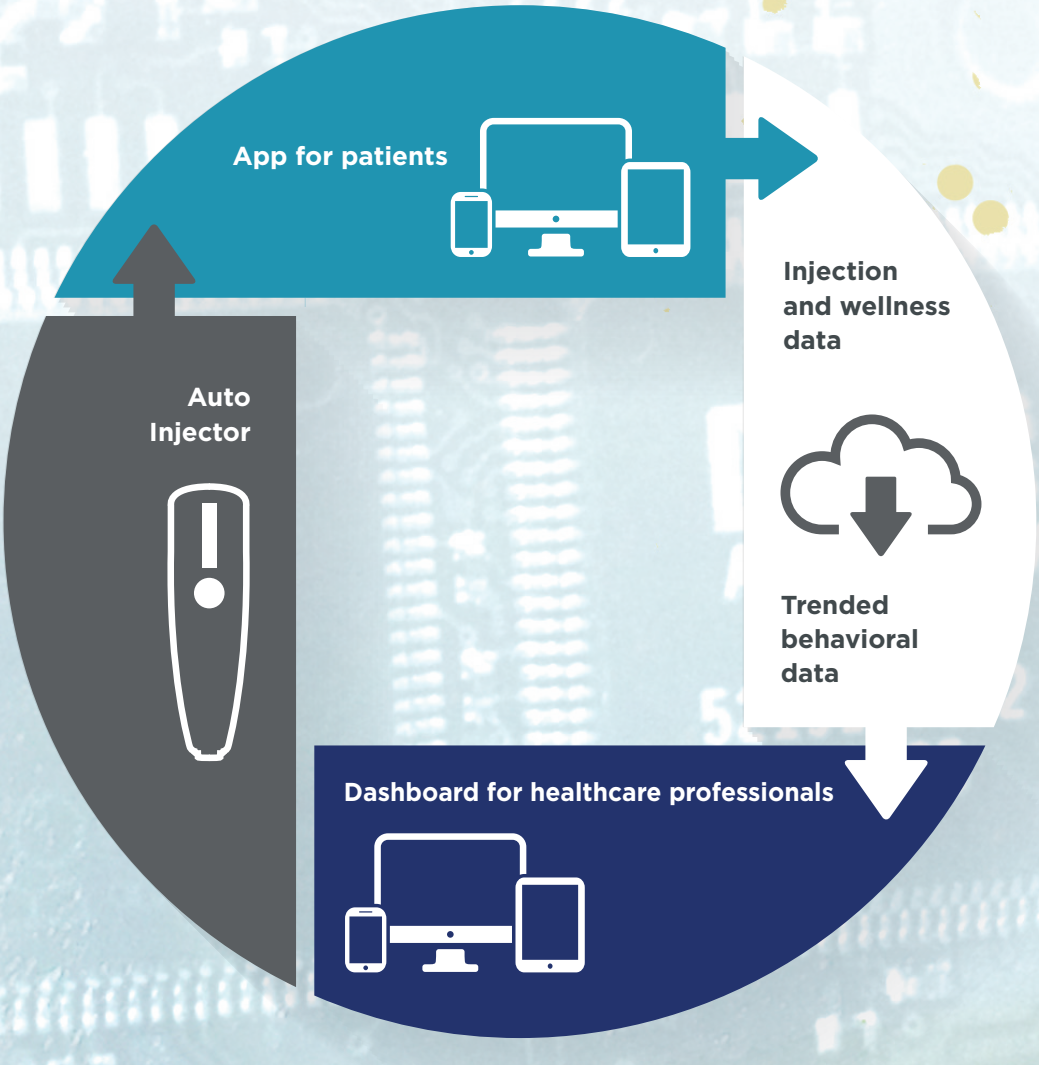

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