

The Journal of mHealth

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Digitising Pharma



INSIGHT

Transforming Clinical Trials with an IoE Approach



DATA SHARING

How Pharma Can Benefit



MOBILE APPS

Transforming the Way Pharma Connects with Patients



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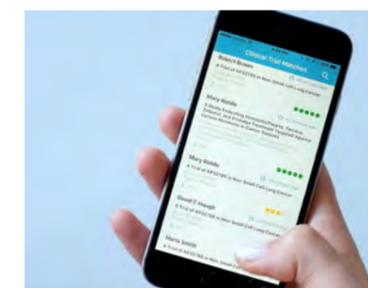
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There is a growing body of evidence demonstrating the promise of mobile technology to boost patient compliance and reduce study dropout rates. Jeff Lee, CEO of mProve Health, a company that develops innovative, mobile patient technologies for life science companies, sat down with The Journal of mHealth to talk about how mobile apps are being used in clinical trials.



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Transforming Clinical Trials with an IoE Approach

Putting Patient Experience First

By Richard Strobbridge, VP Healthcare, CRF Health

Abstract

The Internet of Everything (IoE) developed from Internet of Things (IoT) theory and is based on machine-to-machine (M2M) networks but also encompasses a more complex system including processes and people. The theory was developed by Cisco, defining it as "the intelligent connection of people, process, data and things." For clinical trials, the concept of IoE will allow investigators to capitalise on new opportunities to capture richer, more useful data that better meets the demands of today's clinical trials. The opportunity for end-to-end integration in clinical trials is vast but consideration must be given to implementation and data management to achieve the ultimate benefit: revolutionising patient experience.

A Changing Industry

The advent of mobile, digital, and wearable devices marked a shift in the way technology permeates our everyday lives. The line between clinical trials and digital health is no longer clearly discernable, with clinical technology companies utilising digital health to improve clinical trials. Connecting medical, wellness, wearable and implantable devices, and sensors and applications to a healthcare system via the internet presents vast, new opportunities for clinical trials.

By 2020, experts forecast the global IoT healthcare market to be worth \$117 billion¹, with the number of smart items worldwide projected at around 25 billion.² The IoE has the potential to bring together processes, people and data to make networked connections more pertinent and indispensable. With Gartner research listing the IoE as a top ten strategic technology trend, the IoE campaign is only going to accelerate.

For clinical trials that are adopting digital technologies, an IoE-enabled system is an

innovative way to evolve. The industry is under pressure to make drug development more efficient, increase productivity and reduce costs. Therefore, using the appropriate technology to optimise the process is fundamental. Clinical trials are becoming more expensive and time consuming, with increasing geographical reach, patients and data intensifying the complexities. On-site monitoring and face-to-face visits have become more challenging as the number of global clinical trials has increased. All of this has created a heightened pressure to monitor clinical trials more effectively and use technology more efficiently to optimise processes.

Putting Patients First

A patient-centric approach to clinical research is often a key priority of trial design. For individual patient experience, the IoE brings ease-of-use and increased patient focus. The ability to improve methods of maintaining patient safety and trial integrity could be achieved using a data-led approach to manage patients and respond to adverse events. The ability to constantly monitor patients may also

help subjects to feel safer. At the same time, investigators can gather information in near real-time to intervene at the first sign of potential harm.

The real-time possibilities of an IoE system may enable better participation (in the form of engagement) from trial participants. An obvious benefit of an IoE approach is the potential to redefine patient recruitment by helping to identify patients that are most suited to a trial protocol. New software may also enable investigators to connect with patients in any location, significantly increasing the number of patients enrolled in a trial.

Additional benefits include limiting inconvenience and burden placed on the patient, as informative data can more easily be collected from patients via connected devices, including wearables and sensors, with far-reaching insights. This not only increases patient retention but also patient adherence to trial protocols. For the length of a clinical trial, data can be continually collected, offering a constant approach to proactive patient monitoring and management.



So, what's the catch?

The healthcare market is divided in terms of IoT, based on application: patient monitoring, telehealth, medical/clinical trial operations, medication management, and connected imaging. An IoE strategy appears to offer numerous benefits to the clinical trials industry, however any initiative that includes user-generated communications and interactions associated with global networked devices has its challenges:

- » Concern from sponsors and CROs around patient privacy
- » Obstacles around network and device security
- » Equal access to technology remains a challenge
- » Increased volumes of data present logistical hindrances
- » Ensuring the correct assessment protocol for collected data
- » How to analyse the data
- » Determining clear endpoints

Before integration and the IT boom, data would be collected from a patient once or twice a month in a trial. With new technologies, data has the potential to be continually collected, for instance glucose or blood pressure measurements. While integrating sensors and devices in clinical trials results in more data, the challenge may come in evaluating the sheer volume

of data to identify if a drug is achieving its targets for safety and efficacy.

Despite these challenges, other highly regulated industries, such as banking, are now welcoming the IoE and there are significant learnings from their strategies. Some crucial factors anticipated to propel the market include growing demand for real-time disease management, improved patient care services and effective and efficient treatment outcomes.³

Embracing the IoE

Capturing data in real-time, minimising site visits, and remote patient monitoring have already proved their worth in clinical trials. The IoE takes this to a new level; early adopters will potentially see the biggest rewards and stand to achieve a competitive advantage. However, several critical steps should be considered to ensure successful adoption of an IoE approach in clinical trials:

1. A clear understanding of how to implement the theory
2. Requirements for on-going management
3. Clinical trial sponsors and CROs may need to rely on the experience offered by providers who have established ways of working with an IoE approach
4. Key considerations must be given to evaluating audit requirements, validation issues and data security

5. Utilise remote patient monitoring solutions to take research beyond dedicated investigative sites by using sensors and devices to capture a stream of data from a patient's daily life

In practice, a connected IoE system can monitor continuous data from a wearable device, transmit the information from the patient's home via Wi-Fi or smartphone to a data analysis server and reports can be analysed instantly. An accessible flow of instantaneous information enables those monitoring the trial to act on any risk factors, ensuring compliance in real-time.

The Benefits of Connectivity

From financial and banking services to retail and telecommunications, the IoE is taking center stage across all major industries. According to Cisco, IoE is a \$19 trillion global opportunity over the next decade: private-sector firms can create as much as \$14.4 trillion of value while cities, governments and other public-sector organisations can create \$4.6 trillion.⁴ Benefits from a clinical trial perspective may include:

- » Real-world data for deeper insight into new drug responses, and how they can now be collected due to the digitalisation of clinical data collection and surrounding processes →

- » Better data quality may arise due to more accurate and continuous patient management
- » The use of wireless wearables, medical devices, sensors and mobile applications allows investigators to remotely collect activity information and key biometrics
- » Data can be both collected and analysed automatically, removing the need for any manual input of data
- » Real-time objective data (activity measures, weight, temperature, heart rate) can be combined with subjective data collection (electronic Clinical

Outcomes Assessments (eCOA))

Perhaps the time is right for the clinical trials industry to embrace the new capabilities, experiences and unprecedented economic opportunities that the IoT can bring.

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Data Sharing

How Pharma can Benefit



Katharine Briggs, Research Leader at Lhasa Limited, discusses some of the challenges surrounding the sharing of proprietary data and looks at how an honest broker can help.

Historically, pharmaceutical research and development has been shrouded in mystery. But, as big data continues to transform healthcare, we need to overcome the ongoing reluctance to share data in order to unlock the benefits it can deliver. Katharine Briggs, Research Leader at Lhasa Limited, discusses some of the challenges surrounding the sharing of proprietary data and looks at how an honest broker can help.

We know that one of the challenges the industry faces in medical research is the scarcity of real-world data which is openly available to academic researchers and other parties developing new and improved drugs. This is having an impact on the cost of getting a single drug to the market, with a recent study estimating this to be approximately \$350m. Nonetheless, many companies are sitting on a gold mine of big data and, despite the high costs involved in bringing drugs to the market, many in the industry are still reluctant to collaborate. Ultimately, sharing this analysis could significantly reduce the product development lifecycle.

A rise in collaboration and dissemination of data is not only in the interest of public health, but is also increasingly required by funding organisations and is a vital part of achieving a reduction in animal testing. Aside from the ethical benefits, a reduction in animal testing also delivers other savings in terms of time and money, plus the data and knowledge gained in sharing data could enable more informed decisions about what substances to test and what tests to perform. An initiative led by the NC3Rs and the MHRA involving 32 organisations sharing data for 137 compounds and 259 studies identified that the use of recovery animals could be reduced by up to 66%, saving thousands of animals globally each year.

So, in the face of these obvious benefits, what is holding busi-

nesses back? Regulations to protect the privacy of personal health information are often seen as potential barriers to data sharing due to the risk of accidental, malicious or compelled disclosure. However, data can still be shared as long as privacy safeguards are in place. Redacting data to strip out individual identifiers, statistically altering data in ways which do not compromise secondary analysis and placing restrictions on access to data are all simple steps that can be taken to secure it.

A survey of 1,329 scientists suggested that another concern amongst the pharmaceutical community was the idea that data could be misused. However, creating an End User License where users are required to agree to certain conditions of use, including specific authorisation requirements from the data owner and limiting access to certain users, are measures that can easily be put in place to mitigate risk.

Data being stored in disparate repositories, in different formats and using potentially incompatible data types presents another significant technical challenge but not one that is insurmountable. However, the additional resource needed to convert the data to an agreed format will add to the cost of data sharing. It also makes sense to opt for platform-independent file formats for exporting and importing data such as XML (extensible markup language), CSV (comma separated value) or SDF (structure data file), which can be opened using several software applications. However, using the same format for exporting and importing data does not avoid differences in what data are captured or how those data are captured e.g. as a number, text, etc. Here, data standards such as SEND can ensure that the data being captured are compatible.

Responsibility for deciding if data can be shared is often delegated to legal and IP departments. The disadvantage of this is that they only see the risks and not the benefits of data sharing



and, being risk adverse, say 'no' by default. In addition, the utility of the data can be difficult to demonstrate ahead of the data being donated. In these circumstances, providing a summary about the project which can be shared with upper management and departments involved in granting authorisation, can help to increase publicity and facilitate decision-making.

In the case of confidential data, an honest broker can be utilised in order to protect the security of sensitive data. This organisation needs to be trusted by all partners as they will have access to all the data and be responsible for controlling access for the other partners. A not-for-profit or academic organisation is likely to be preferred over a commercial one for this reason.

The Elemental Impurities project is a collaborative data-sharing project; one of several projects initiated by the pharmaceutical industry in partnership with honest broker and not-for-profit, Lhasa Limited, which enables pre-competitive data sharing.

The collaboration was designed to share analytical data on the levels of trace elements within batches of excipients used in the formulation of pharmaceutical drug products. Its objective is to increase the understanding of the level of risk posed by elemental impurities present in excipients.

Those organisations involved in the data sharing project have been given the opportunity to make use of existing information on Elemental Impurity levels, present in a wide range of pharmaceutical excipients, which is not in the public domain. This collaboration with others has also facilitated more scientifically

driven elemental impurities risk assessments. Ultimately, this will lead to more efficient use of laboratory resources and reduce unnecessary analysis.

Crucially, Lhasa Limited acts as an honest broker and expertly curates the data from participating organisations. This allows a level of anonymity, whereby the submitting companies are known to each other, but who submitted what data and the specific excipient supplier are known only to Lhasa.

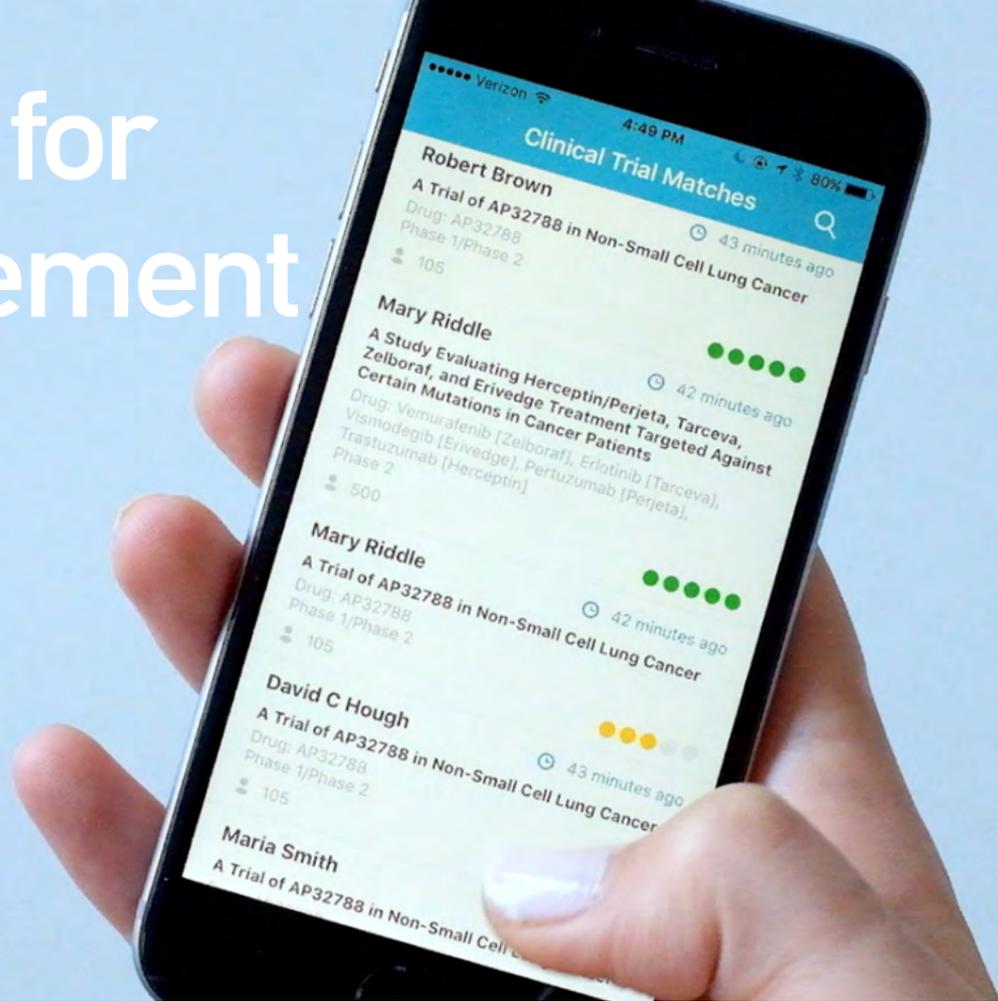
Over the past decade, data sharing within the pharmaceutical industry has evolved from being virtually non-existent to a landscape where most companies will have gained experience through one or more initiatives. However, for the pharmaceutical sector to truly benefit, data collaboration needs to be incorporated into business as usual, rather than remaining the preserve of special projects.

Data still exists within silos and the people who could do something useful with that data often don't have access to it. There remains a fear in the sector that sharing data gives away commercial advantages when, in fact, sharing information could significantly reduce overheads and speed up the development of new drugs. With the rising cost of clinical trials and health data, the industry needs to look at collaboration as the way forward. Sharing data is not without its challenges but, with the right partners, the benefits far outweigh the risks.

For further insight on the benefit of data sharing in the pharma industry visit www.lhasalimited.org ■

Calling for Engagement

How Mobile Apps are Transforming the Way Pharma Connects with Patients in Clinical Trials



Patients are the lifeblood of clinical trials. Collecting their data is a necessary step in determining the efficacy and safety of an intervention. However, keeping patients informed and engaged is equally important—and the very essence of the patient-centricity movement. There is an opportunity for mobile apps to make patients feel like “partners” in their clinical trial rather than “generators of data.”

There’s also a growing body of evidence demonstrating the promise of mobile technology to boost patient compliance and reduce study dropout rates. Jeff Lee, CEO of mProve Health, a company that develops innovative, mobile patient technologies for life science companies, sat down with The Journal of mHealth to talk about how mobile apps are being used in clinical trials.

What has driven you to develop mobile apps for clinical trials?

I have been in the mobile field

for more than 20 years, initially developing technologies for non-health related industries. I worked with Fox and AT&T to provide text message voting for American Idol. I delivered mobile solutions for HBO, Disney, Discovery, and National Geographic, as well as working with the 2008 Obama campaign to target and engage with voters. Whether an organization is looking to drive people to vote, to visit stores, or to engage with their ideas, mobile technology can drive connections in many valuable ways.

I became interested in the benefits that mobile technology could bring to health when, over a 30-day period, both of my parents passed away from cancer and my son was born. I spent a lot of time in-and-out of the healthcare system at that point. In 2010, the company I had been working for was sold and I wanted to start something of my own. I became very interested in how technology could be used to influence individuals’ health

choices; how it could motivate them to act; to change their behaviour; to encourage them to have meaningful connections with their healthcare providers.

Denis Curtin, Chief Scientific Officer at mProve Health, was already a good friend, a pharmacologist, and pharmaceutical industry veteran. We got to talking about how we could use mobile in the healthcare space. Back then mobile, technology was relatively uncharted territory for clinical research and presented a huge opportunity.

How can mobile technology change a patients’ clinical trial experience?

Patients generally find themselves as a participant in a clinical research program when existing therapies for their condition are either under-served or non-existent. The unfamiliarity of the process, working with clinicians that they have likely never met before and taking a new medication or exploratory treat-

ment, all serve to raise stress and anxiety. In addition, they are suddenly shouldered with the responsibility of having to deliver data back to the study.

Patients’ participation in a trial isn’t limited to just impacting their own condition, it impacts the entire research field’s understanding of that condition/therapy. Non-adherence in a clinical research study has an impact on every patient that is affected by the same condition and who could benefit from the scientific advances made in that study. When we founded mProve Health, we had the belief that mobile technology could improve the patient experience in a clinical trial, thus improving engagement and making huge strides forward in keeping more patients in the trial.

How can a patient get access to a mobile app if they are participating in a research study?

Apps that can support the classic needs of clinical trials can be easily adapted to any kind of study. They’re typically delivered to the patient via their clinical research site. During their study visits, patients can download the app and enter an activation code (provided by the site) that initialises and sets up their app for their trial, their research site, and all of their study-specific information. The latest technology solutions offer the flexibility to be used on any device, most commonly the patient’s personal smartphone.

What do mobile apps offer patients?

Apps can instantly deliver everything a patient needs to know about the study they’re participating in: their schedule of activities, when their next site visit is, and what will happen at that visit. It can confirm the duration of the appointment, whether meds need to be taken, if there will be blood draws that require fasting, as well as any other eventualities that a patient will need to prepare for in advance. (Patients may wonder, “my eighth visit will be three times as long my sixth visit so how do I plan for it?” “I’m going to be really fatigued after my fourth visit, so I may need to take extra precautions.”) Apps also feature diary

sections, so that information can be collected about their response to medications. Other sections communicate any reference information that would traditionally be provided on paper, giving patients the support and guidance they need to advance throughout the study. Contact sections also make it simpler for patients to get in touch with study researchers.

What value can pharma achieve by implementing patient-centric technology?

Since we started mProve Health in 2010, we’ve seen tremendous growth in the number of studies using mobile apps to engage patients. We’ve seen life science companies make the transition from piloting apps to mainstreaming them as more and more studies that use these technologies get regulatory approval, a “rubber-stamp” of approval for clinical researchers. There’s a growing body of evidence that shows patients who use mobile apps are more likely to comply with the study protocol and less likely to withdraw from the study. Clinical researchers are now tasked with harnessing the value that these solutions promise. For example, if you know that a mobile solution can reduce study dropout rates by 30%, can you reduce the number of patients you need to enroll in the trial? If you know you will have 50% fewer protocol deviations for missed study visits, can you account for that in your study design? It’s these types of decisions that will ultimately reduce the cost of clinical trials.

How do you expect the space to evolve over the next five years?

As mobile apps have come on to the scene over the last seven plus years, and as more technology service providers have started to offer mobile solutions for their previously web-based offerings, there are many apps for clinical trial participants to use. However, too many mobile solutions can be a disadvantage. It forces the patient to access multiple touchpoints in order to fulfil their study commitments—one app to access their study information and documents, another app to receive their study reimbursements and payments, and another app to schedule transportation to get to their study visit. At mProve

Health, we are developing a mobile Patient Engagement Hub that offers patients a single touchpoint to access all of their study services.

To learn more about mProve Health, please visit www.mprove.com ■

Biography Jeff Lee, CEO mProve Health



Jeff Lee is founder and CEO of mProve Health, a leading provider of mobile technologies that connect and engage patients with global clinical research studies. mProve Health, headquartered in Washington, DC, is Jeff’s fourth entrepreneurial technology venture. His prior ventures pioneered the mobile engagement work for the American Idol text-to-vote campaign, Barack Obama’s 2008 campaign, and other high profile projects for Fortune 500 companies including Disney, MasterCard, and Exxon Mobil. He started his career as a corporate strategy consultant at Ernst & Young. Since founding mProve Health in 2010, Jeff has grown the company globally. Today, mProve’s applications are used by 18 of the top 20 pharmaceutical companies, 15,000 clinical research sites in over 60 countries, and they are translated in over 50 languages.

INDUSTRY NEWS

News and Information for Digital Health Professionals



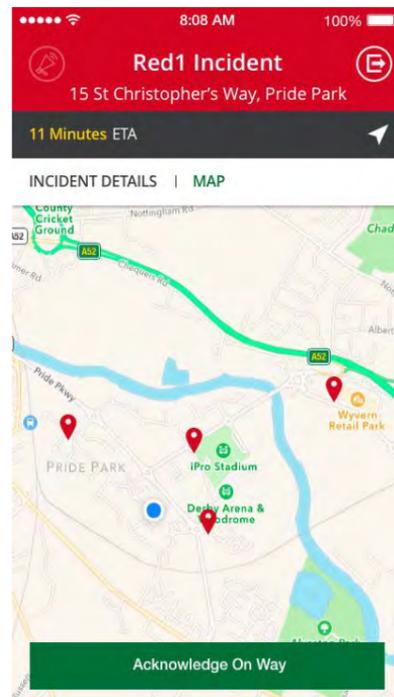
CommonTime Launch First Response App for Lifesavers

CommonTime are pleased to announce the launch of First Response, a mobile application that empowers community lifesavers with real-time data that supports the vital work they do. Available on iOS and Android, the app directly integrates into existing CAD software and staff workflows to reduce response times and administrative work alike.

Andrew Brinkworth, Head of Operations at CommonTime, highlights why First Response will be a game-changer for emergency services, “First Response is a new breed of CFR app that brings together the enterprise resilience expected from CommonTime with the flexibility of a bespoke build – ensuring we are able to meet 100% of the requirements of a tailored emergency system. With a simple, clean user interface and a common data structure we can ensure a tight integration to CAD systems allowing the time of volunteers to be directed where it is most important – with the patient.”

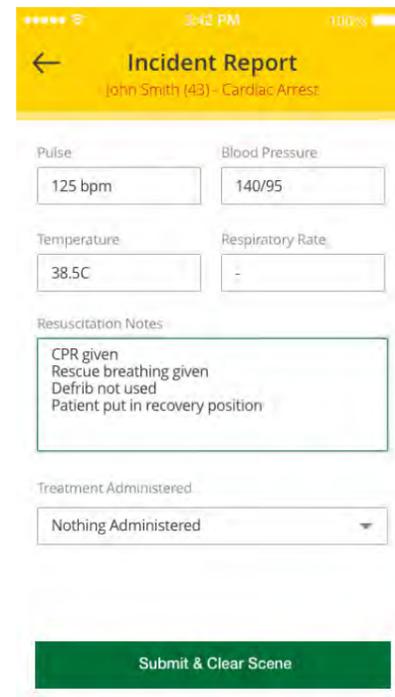
First Responders are provided with a log-in screen, which enables them to sign into the application and become available when ready to start a shift. The closest available volunteer to any incident is notified as soon as dispatch operators are made aware. Because the app offers bi-directional communication, responders are able to confirm to dispatch operators that they are on their way with a single tap.

To speed up response times, turn-by-



turn navigation guides responders to the incident via the shortest possible route. Locations of nearby defibrillators are displayed for collection during the journey. The app also supports a stand down function, emergency police alarm and detailed patient reports.

Ian Knight, CEO of CommonTime said, “We have listened to the needs of both organisations involved in emergency response procedures and the volunteers on the ground. First Response has been designed to meet the needs of both – pro-



viding a simple, non-intrusive platform to equip first responders with all the information they require. CommonTime recognise the value of their tireless work and have taken great care to develop a solution that supports their efforts.”

The First Response app is capable of working offline – as messages attempt to send until a data connection is found, ensuring a continuous dialogue even in areas of poor connectivity. Detailed patient reports can be loaded to devices for completion once. ■

Revolutionary Fingerprint Drug Test Supports Drug Rehabilitation Services

UK-based Intelligent Fingerprinting has announced a non-invasive approach that makes drug testing quick, easy and dignified for drug recovery providers and service users.

The company's revolutionary technology detects drug use by analysing fingerprint sweat, screening for multiple drugs of abuse in less than 10 minutes. Its dignified, non-invasive approach makes it an ideal choice to support drug recovery programmes that currently rely on oral-fluid or urine-based drug tests to track clients' progress.

The new fingerprint-based drug test is portable, offering a convenient drug screening approach for use by drug rehabilitation services in both clinics and community-based centres. The system makes it simple to set up screening sessions, collect samples, administer tests and get results quickly on location. Fingerprint drug testing is also particularly easy to use and non-invasive, sidestepping potential hygiene concerns associated with traditional screening methods that involve the collection and disposal of body fluid samples such as saliva or urine.

“Drug rehabilitation providers need to maintain an open relationship with clients that's based on trust, so it's critical that drug testing is quick, easy and – most importantly – dignified,” commented Dr Jerry Walker, Chief Executive Officer, Intelligent Fingerprinting. “Our new fingerprint drug test can help drug rehabilitation programmes to deliver drug screening directly in communities in a positive way, while also helping measure each client's progress towards recovery.”

The Intelligent Fingerprinting Drug Screening System consists of a sample collection cartridge and the portable Reader 1000, and works by analysing the tiny traces of sweat contained in a fingerprint to detect signs of drug use. Collecting a fingerprint sweat sample onto an Intelligent Fingerprinting cartridge takes just



five seconds, and the Reader 1000 provides a positive or negative result for each drug in the test within just 10 minutes.

Supporting drug rehabilitation programmes

Rehabilitation programmes rely on regular drug screening to measure treatment progress and identify the need for intervention if a relapse occurs. Current drug screening methods are time-consuming, undignified and involve bio-hazardous samples such as urine and saliva which may require specially prepared sample collection areas, gender-specific staff for observed collection of urine samples, bulky storage and clinical waste disposal services.

Change, grow, live (CGL), a national social care and health charity, has been active in trialling the new fingerprint drug test. Dr Prun Bijral, Medical Director at CGL said: “Having visibility of a client's progress – and whether they have used drugs recently – is critical in determining how we tailor our drug rehabilitation programmes to support each individual. During our early tests we've had positive feedback from both our counsellors and service users. The process of collecting fingerprint samples

has been very easy and dignified – especially in comparison with urine samples or using oral swabs. In my view this is the most important benefit; the approach is respectful of our clients, and will help reduce some of the concerns people may have about entering treatment.”

Christopher Strivens is Deputy Service Manager at Norfolk Recovery Partnership, which provides advice and treatment for adults with drug and alcohol problems across Norfolk and is run by a partnership of Norfolk and Suffolk NHS Foundation Trust, The Matthew Project and The Rehabilitation of Addicted Prisoners Trust. He said: “With Intelligent Fingerprinting, there's now a drug screening approach that is non-invasive and undertaken with ease. The Intelligent Fingerprinting drug screening system's portability and non-invasive nature means that our screening sessions don't need to be carried out in a clinical setting, while there is no clinical waste or risk to staff from the collected sample. That makes it much easier to set up sessions, collect samples, administer tests and get results in under 10 minutes. Our service users have found the devices very acceptable and easy to use, and this helps to establish positive relationships with them.” ■

The 10 Startups Joining Startupbootcamp's Digital Health Accelerator

Startupbootcamp Digital Health Berlin the leading program supporting innovative companies combining medical knowledge with smart technologies, has announced the 10 digital health startups invited to join the 90-day long 2017 acceleration program in Berlin starting on September 4th.

These 10 startups from 6 countries are the result of a highly selective funnel which counts more than 3,000 companies scouted from all around the world, 500 direct invitations, 75 skype calls with the top ones and 20 chosen to join the Selection Days, a 3-day event which took place in Berlin on 18-20th of July.

During the event, the top 20 startups went through tens of deep feedback sessions with partners, mentors and industry influencers to advocate their ideas and business models and demonstrate their fit with the scoping areas of the accelerator such as "Awareness and Symptoms", "Therapy Decision", "Treatment, Follow Up and Secondary Prevention", "Behavior Change".

"I don't think I have ever been in the same room at this many doctors at once," said Lars Buch, Managing Director of Startupbootcamp Digital Health Berlin, "We are moving slightly away from direct B2C and moving down the path

towards genuine digital disruption of the health system itself, engaging in all levels from patient-HCP interaction to payers. Amazing teams with life changing solutions this year, I can't wait to see every single company from this batch materialize in the market."

With the support of industry partners such as Arvato Bertelsmann, Deutsche Apotheke und Ärztebank, Munich RE, Philips, Sanofi in Germany, and Dentons, as legal partner, the accelerator will now help the 10 startups providing access to over 100 mentors, €15,000 cash, €450,000 value in partners deal, and 6 months of free office space in Berlin. ■

The companies chosen are:

Torafugu Tech
United Kingdom
Founders: Savvas Neophytou, Constantinos Demetroullas
Torafugu tech is a health-tech business focusing on analytics for health and life insurers to increase product personalisation and improve the health and well-being of their members.

Qolware
Germany
Founders: Cristina Soaz, Therese Tönnies, Aleksandra Patz
Qolware is a smart healthcare & emergency response solution running on regular consumer smartwatches able to identify emergency situations through the detection of abnormal patterns in a person's physiological signals such as movements or pulse.

Cardio Cube
Poland
Founders: Oskar Kiwic, Tom Jadczyk, Przemek Magaczewski
Medical sixth sense empowering hospitals and cardiovascular patients.

BreakBox Aurora
Poland
Founders: Marcin Pitek, Olga Grudniak, Wojciech Gizowski, Jakub Wysocki
Point-of-care diagnostic machine to select precise antibiotic.

InsightMedi
Spain
Founders: Juan Gonzalez, Luis Rodrigues, Gonzalo Mora, Gabriel Piza
A global platform in which healthcare professionals interact around real clinical cases based on medical images and videos.

AISENS
Poland
Founders: Jaroslaw Goslinski, Piotr Owczarek, Adam Wozniak
Our smart sensors allow patients to rehabilitate safely and effectively anywhere.



Hedia
Denmark
Founders: Peter Lucas, Christina Kildentoft, Andreas Jespensgaard, Mads Obdrup
Hedia is a personalised and intelligent diabetes app that helps people with diabetes to live a more normal life.

Beroceutica
Germany
Founders: Jorn Klinger, Marco Schmidt
Clinical datasets are difficult to analyze by reported Machine Learning approaches due to their small samples and many features. Our approach is able to identify significant patterns, which can be used for novel diagnostics and therapies.

Jommi
Germany
Founders: Fabian Oertel, Paul Dziwoki
An interactive e-Health platform to guide and improve our patient's level of care. We increase adherence through analyzing digital data points and showing patients the connections and impacts each lifestyle element (sports, nutrition, medication & well-being) has on their life.

Uvisio
Netherlands
Founders: Larisa Kryuchkova, Vlad Hayrapetyan
Sun protection effective and personal. By utilizing technology and data analysis we give information on optimal sun exposure and personalised sun care and sun protection recommendations, specific to each user.

Scottish Hospitals to Benefit from Access to Crucial Data from New Patient Information System

Ten hospitals across Fife are using real-time information to deliver better co-ordinated care for thousands of patients, following the successful go-live of InterSystems TrakCare®.

Frontline staff in all of NHS Fife's acute and community hospitals are now using the patient information system, which has been positively received by healthcare professionals as a means to support better and safer care, to carry out their work more efficiently, and to replace outdated technology and restrictive paper based ways of working.

The health board confirmed its decision to deploy TrakCare, a unified health information system, last June, as part of its plans to progress towards a single electronic patient record for patients, and to allow authorised clinical staff access to essential patient information needed to inform important decisions at the point of care.

NHS Fife's eHealth staff worked closely with clinicians and embedded InterSystems personnel to deploy TrakCare on schedule. More than 80% of NHS Fife's employees are now trained to use the system, which is making health records, referral and waiting list processes more efficient, and is helping to improve patient experience.

"NHS Fife staff worked tirelessly to ensure an effective go-live of TrakCare," said Mark Palmer, country manager, InterSystems UK & Ireland. "Technology can be a powerful means to connect care and to deliver crucial patient information where it is needed. But for this to happen, it must be accepted and used.

NHS Fife is a powerful example of clinical engagement, collaboration, and determination to ensure that technology addresses hospital needs so that the best is achieved for patient care."

With the go-live of a new patient administration system, phase one of the deployment has now been completed, making NHS Fife the 11th health board of Scotland's total of 14 to use the TrakCare system.

Deployment first commenced in the health board's emergency department, before quickly spreading to other clinical areas. Real-time bed management is providing staff with an accurate bed status across the health board, including acute, mental health and community users, helping to manage capacity and ensure patients are discharged in a timely manner.

The system is also being used to manage patients with specific conditions. For example, electronic questionnaires around stroke and diabetes have been built directly into the system. Benefits are now being realised across the health board, which serves 370,000 people across a large rural area.

Phase two of the project will see the expansion of TrakCare to deliver additional functionality including order communications, which will streamline the flow of important information between diagnostic departments and frontline clinical staff. Mental health administration will also be an important part of phase two. In addition, the health board is working with InterSystems to identify other areas of application in order to achieve the most from its investment. ■

FDA Introduces "Pre-Certification" Pilot Programme for Digital Health Companies

FDA commissioner Scott Gottlieb recently announced a pre-certification pilot programme that aims to speed up the approval process for medical software companies and products that are deemed less risky than traditional medical devices. He stated that through the Pre-Cert for Software Pilot, the FDA seeks to develop "a new and pragmatic approach to digital health technology" that takes into account "the unique characteristics of digital health products and the marketplace for these tools."

The agency acknowledged that its usual approach to moderate- and higher-risk, hardware-based medical devices "is not well suited for the faster and iterative design, development and validation used for software products." The FDA explained that under the voluntary pilot programme, which will initially allow up to nine companies to take part, the regulator will first look at the software or digital health technology developer, "rather than primarily at the product, which is what we currently do for more traditional medical devices." Initial participants will range from small startups to large companies that develop both high- and low-risk software products that are devices.

Gottlieb noted that "historically, healthcare has been slow to implement disruptive technology tools that have transformed other areas of commerce and daily life...but momentum toward a digital future in healthcare is advancing." He added that "for the devices we are asked to evaluate, we know that our policies must continue to empower consumers and facilitate innovation."

According to the FDA, the goals of the programme are to enable



a modernised approach that permits software iterations and changes to occur in "a timely fashion," while also ensuring that the quality of medical product software remains high throughout its lifecycle by allowing firms "to demonstrate their embedded culture of quality and organisation excellence." Further, the agency said the initiative will seek to learn and adapt, as well as adjust its elements and measure based on the programme's effectiveness.

"We have intentionally left the initial [participation] criteria broad because this pilot is purposely designed to be inclusive and flexible," Gottlieb explained, adding "we appreciate that the experience and capabilities of a small company will be different from that of a large company and recognise that we need a pre-certification programme that accommodates both." ■

245M American Lives Managed by PHM Solutions by the end of 2021

Data from Signify Research's report "Population Health Management IT – North America – 2017" shows that the number of lives managed by PHM solutions in North America is projected to increase from 135 million at the end of 2016 to 245 million at the end of 2021.

Over this period, the market in terms of revenues is forecast to grow at a CAGR of 16.6% from \$3.6B in 2016 to \$8.0B in 2021. Solutions will be implemented by a range of organisations such as pro-

viders/ACOs, payers, government organisations and employers. In some cases this will lead to individual lives being managed by more than one entity. The provider/ACO vertical is projected to represent the largest market in terms of both managed lives and platform revenues, with the acute sector driving the lion's share of the provider market.

Factors Driving Growth

The factors driving the uptake of PHM

solutions in North America are focused heavily on US legislation and attempts to modernise health care provision. Although the Trump administration is still attempting to repeal the affordable care care (ACA), creating some uncertainty, it has been assumed that the underlying factors driving PHM growth (such as the move to value-based care) will persist. With most of the dialogue around changes to Obamacare and the Republican alternatives being focused on insurance reform, not care delivery

reform, Signify Research expects the rollout of accountable care organisations (ACOs) and share savings schemes to continue. PHM solutions will be a core tool in their implementation.

Outside of ACO implementation, the targets put in place via MACRA/MIPS are also assumed to survive any future health-care reform. PHM will play a central role for providers implementing strategies to make the transition to value-based care, to hit MIPS targets and to measure performance against these targets.

The Competitive Environment

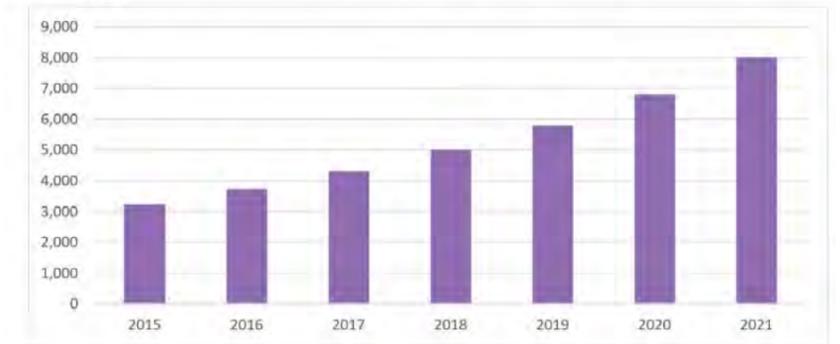
In 2016 55% of the North American PHM market was accounted for by EHR vendors, such as Allscripts, Epic, Cerner and eClinicalWorks and payer/provider-owned vendors, such as Optum, Transcend Insights, Aetna/Healthgen and Conifer Health. The remainder was taken by broad portfolio healthtech/IT vendors such as IBM Watson Health and Philips and best-of-breed specialists such as Orion Health, Health Catalyst, Evolent and Enli.

In terms of overall share, it is estimated that Optum commanded the number one position in 2016, followed by IBM Watson Health, Allscripts and Cerner. However, the supplier base remains extremely fragmented and consolidation is expected to continue over the medium term.

EHR vendors are well positioned to leverage their existing installed base of customers in order to gain share as the

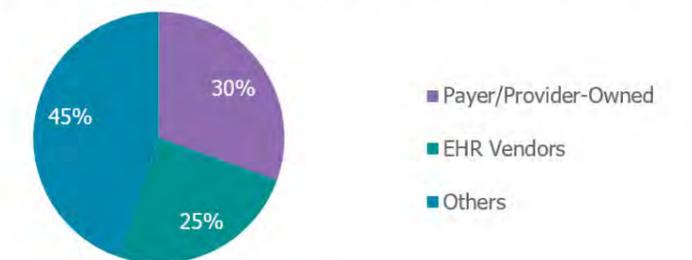
North American Population Health Management Market

Revenues (\$m)



Source: Signify Research

PHM Market Share by Vendor Type - North America 2016



Total Market Size in 2016: \$3.6B

Source: Signify Research

PHM market grows. For many, they are banking on PHM driving a large proportion of future company growth as the EHR market matures. However, historically their PHM solutions have fallen short in terms of functionality and performance compared to the best-of-breed specialists. Through acquisi-

tion and product development the gap has started to close to some extent, but there still remains a significant opportunity for specialists to also enjoy success over the medium term particularly if they can maintain a leadership position in terms of product functionality and performance. ■

MDISS Launches Network of Security Testing Labs for Medical Devices

MDISS, the Medical Device Innovation, Safety and Security Consortium have launched the first of more than a dozen planned device security testing labs and cyber-ranges.

The new MDISS World Health Information Security Testing Lab (WHISTL) facilities will comprise a federated network of medical device security testing labs, independently owned and operated by MDISS-member organizations

including healthcare delivery organisations, medical device manufacturers, universities and technology companies.

Each WHISTL facility will launch and operate under a shared set of standard operating procedures. The goal is to help organizations work together to more effectively address the public health challenges arising from cybersecurity issues emergent in complex, multi-vendor networks of medical devices.

While such security 'proving grounds' aren't new to enterprise IT, WHISTL is the first network of labs specifically designed around the needs of medical device researchers, healthcare IT professionals and hospital clinical engineering leaders. By the end of 2017, MDISS WHISTL facilities will open in New York, Indiana, Tennessee, California as well as in the UK, Israel, Finland and Singapore.

Benjamin G. Esslinger, CBET →

Manager/Clinical Engineer at Eskenazi Health, said “Working with MDISS over the past year on WHISTL has helped us make real progress against some very complex risk scenarios, while keeping the focus on patient safety.”

Esslinger is the current 2017 Trustee and past President of the Indiana Biomedical Society. He works with Matthew S. Dimino, an Imaging Engineer at Eskenazi Health and educator at Indiana University -Purdue University Indianapolis. Esslinger continued, “Remember, medical devices are still on the frontier of cybersecurity, and security best practices for devices are still maturing. Our new WHISTL facility enables us to run medical devices through tougher, more realistic test regimes. Hidden vulnerabilities surface more quickly, and that helps us build more responsive standard operating procedures.”

WHISTL facilities focus on identifying and mitigating medical device vulnerabilities, sharing solutions and best practices, and device security education and awareness. Newly uncovered vulnerabili-

ties will be responsibly reported to device manufacturers and to the NHISAC-MDISS Medical Device Vulnerability Program for Evaluation and Response, or ‘MDVIPER’ at <https://mdviper.org/>.

“WHISTL will provide much-needed insight from actual developers and users of medical devices, which will result in increased relevant and actionable information sharing and situational awareness for all stakeholders in healthcare”, said Denise Anderson, president of NH-ISAC, “NH-ISAC looks forward to partnering with MDISS on this important effort for the community.”

MDISS, under a \$1.8M contract from the Department of Homeland Security (Science and Technology Directorate, Cyber Security Division) built the medical device cyber risk assessment platform, or ‘MDRAP’. The platform helps health systems, device manufacturers, and technology firms collaborate to produce and share device risk assessments. The fast-growing and standards-based MDRAP platform features moderated crowd-

sourcing and facilitates timely, responsible sharing of risk assessments and threat indicators, while helping automate critical device inventory, audit, oversight and vulnerability tracking tasks for hospitals.

Dr. Nordenberg, MD, Executive Director of MDISS, and former CIO at the National Centers for Disease Control’s National Center for Infectious Diseases, stated, “MDISS WHISTL facilities will dramatically improve access to device security know-how while protecting patient privacy and stakeholder intellectual property. Solid cyber-lab governance will support an international-scale network of research and training centres of excellence, designed especially for medical device designers, hospital IT, and clinical engineering professionals.”

WHISTL’s device testing protocols will have their foundation in the UL Cybersecurity Assurance Program specifications (UL CAP; at www.industries.ul.com/cybersecurity), especially with regards to fuzz testing, static binary analysis and structured penetration testing. ■

Pioneering Diagnostic Device Offers Increased Detection of Cervical Cancer

A pioneering diagnostic device identifies more abnormal cells on the cervix than standard colposcopy, according to data published in two European clinical papers.

ZedScan is a portable, handheld device which uses Electrical Impedance Spectroscopy (EIS) technology to detect dysplasia and cancer of the cervix. It can measure and detect tissue changes in women identified with an abnormal smear test.

UK research published in the European Journal of Gynaecological Oncology (EJGO) shows ZedScan, an adjunct to colposcopy, increases the detection of high-grade CIN in women referred with both low-grade and high-grade abnormal cytology.

The combination of ZedScan and colposcopy improved the outcome of women who were treated at first visit with over 95% having high-grade CIN on histology.

The second paper published in the European Journal of Obstetrics and Gynaecology (EJOG), examines the influence of HPV genotypes on colposcopic performance. It also reveals by using



ZedScan, more high-grade CIN is detected irrespective of HPV genotype.

Speaking about the results lead researcher and colposcopist, Prof John Tidy, Professor of Gynaecological Oncology, said: “Colpos-

copy as a clinical examination has remained mainly unchanged for 90 years and relies on visual indicators. This means it is a subjective interpretation and in some cases patients can be over-treated or disease can be overlooked. Using ZedScan as an adjunct to colposcopy however increases detection and enables clinicians to make better informed decisions at a patient's first visit.”

The increased detection of high-grade CIN means the combined examination is more sensitive when compared to colposcopy alone. A negative colposcopic impression and ZedScan is very effective at excluding the presence of high-grade CIN so permitting discharge to community based cervical screening. The combined examination also allows more timely and appropriate management of women referred to colposcopy.

“The reason why this data is so important is it will help us with the forthcoming changes to screening programmes in the UK. From 2020 women aged 25 will have been vaccinated against HPV16 & HPV18 and will enter the UK cervical screening programmes,” said Prof Tidy

“The proportion of women referred to colposcopy with HPV16 infection will be fewer, however women with HPV O (other high risk) genotypes will continue to be referred. Any high-grade CIN associated with HPV O infections will be more difficult to detect because of the lack of aceto-white change associated with these lesions. The addition of ZedScan, a non-visual diagnostic, will help to improve the detection of high-grade CIN in the women referred to colposcopy as we move into a post HPV vaccinated screening population.”

The ZedScan system was developed by UK company, Zilico Ltd, following a collaboration between the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust. It consists of a portable handset, docking station, a single use sensor and software application.

The non-invasive device takes 10–12 readings around the cervix, which takes approximately 2 to 3 minutes. It analyses the underlying tissue structure that identifies disease giving clinicians additional information which helps them better manage the patient at the initial examination. ■

Mixed Reality Offers Glimpse of Medical Future

A group of University of Dundee students have won prestigious studentships with world-leading medical technology company Medtronic after developing new learning tools in augmented reality.

Seven students from a range of disciplines have been offered studentships with the company, after completing a three month project which saw more than 50 students design and build new medical software and teaching tools through the Microsoft HoloLens. The HoloLens is the first self-contained, holographic computer, which allows users to interact with holograms in mixed reality.

Professor Tracey Wilkinson, joint programme lead with Nicolas Denervaud from Medtronic, said, “The aim of the project was to design and create innovative augmented reality apps for medical education and training, using the HoloLens device as a training tool.

“We have a large number of active, fertile, creative minds in our university who are very comfortable with modern technology. Allowing our students to develop their ideas with support from Medtronic has led to immersive and fascinating learning.”



Nicolas said, “The Medtronic team were really impressed with what had been achieved in a very short period, and one of the prototypes is going to be demonstrated at the European ENT congress in October.

“The company are now sponsoring seven summer internships, giving several of the students an opportunity to develop their ideas further. This is an important project for us, in our effort to develop new teaching modalities, with the aim to help

Health professionals deliver improved patient outcomes.

“Our interns will be tasked with bringing an educational app in anatomy and ENT surgery to completion, so that it is ready for use by trainee health professionals.”

The company has also agreed to run the project again next year, this time over six months to allow more time for development. ■

Digital Health Platform Actively Engages Patients in the Home

HAP Innovations have announced results from a pilot program of its Spencer® digital health platform. Spencer, the company's new FDA-registered health hub, shows promising early results, including driving patient engagement rates as high as 80 per cent, leading to substantial changes in underlying behaviours affecting medication non-adherence.

"Finally, we have a technology that aging patients will use – not because they have to, or because they're told to, but because it helps solve the complexities of their health care and allows them to remain independent longer," said Tom Rhoads, founder and CEO of HAP Innovations, LLC. "

The Spencer digital platform includes a countertop in-home medication dispensing and engagement device, the SpencerAssist™ mobile app for family caregivers, and the SpencerCare™ clinical site for pharmacists and care providers. Pharmacists monitor patient medication and input, and with those insights, care providers can call or schedule a video appointment using spencer.

Patient use of Spencer to answer questions or to ask care providers for support is averaging greater than 60 per cent, and has reached 80 per cent. In addition to consistent engagement on two levels – taking a package of pills from Spencer and answering questions – preliminary data shows a 90 per cent rate of taking medication as directed, much higher than the 40 per cent to 70 per cent that has been reported in recent studies

"These early results give us great hope for a breakthrough in increasing medication compliance and patient interactivity through the everyday use of game-changing technology," said Alan Menius, Chief Data Scientist, HAP Innovations. "We're excited at the prospect of sharing formal study results in the near-term."

We know that individuals managing more than one chronic condition and taking multiple prescription medications are at an increased risk of hospitalisation. Studies have shown that increasing adherence reduces hospitalizations and decreases cost. A national network of pharmacists specialising in the treatment of patients with multiple chronic conditions monitor patient input using the SpencerCare™ clinical portal. This enables personalised health coaching.

"Engagement driven by spencer creates a habit where taking medications becomes part of a daily health routine,"



said Rhoads. "That's what sets Spencer apart from simple medication reminders focused solely on adherence – it's a new breed of technology that takes on the complexity of behaviour change."

The Spencer-certified pharmacy network currently offers coverage in 32 states as HAP Innovations delivers against orders in multiple markets, including accountable care organisations (ACOs). The company is set for rapid expansion through its distributor agreement with a major healthcare solutions company, and spencer will enter the life sciences market later this year as part of a clinical trial protocol. ■

SoleraONE Mobile App to Support Medicare Diabetes Prevention Program

Solera Health, a preventive care benefits manager, today announced the integration of the SoleraONE mobile app into Solera's technology platform to support community-based Diabetes Prevention Program (DPP) providers with digital make-up sessions. This functionality will be critical to successfully delivering DPP to the Medicare population under recently proposed rules from Centers for Medicare and Medicaid Services (CMS). DPP seeks to impact the growing incidence of type 2 diabetes with evidence-based, affordable, and high-quality lifestyle change programs. In March 2016 CMS announced that the DPP would be a new preventive benefit to all Medicare beneficiaries based on actuarial analysis that demonstrated a \$2,650 return on investment over 14 months.

As a covered preventive benefit, eligible Medicare participants will have no cost access to community-based, in-person DPP to lower their risk of developing type 2 diabetes. CMS further clarified the new Medicare Diabetes Prevention Program (MDPP) benefit in the 2018 Physician Fee Schedule published on July 14th, 2017. The Medicare DPP benefit, available to all Medicare members beginning April 1, 2018, is limited to in-person community DPP providers. Although virtual and digital providers are excluded from providing the program to Medicare members, the Medicare DPP benefit will allow up to four digital DPP make-up sessions to support sustained program engagement for in-person DPPs throughout the 12-month program.

Solera actively manages a national network of community organizations and digital solutions delivering the DPP as a covered medical ben-



efit. The SoleraONE app is designed to strengthen coach and group DPP interactions while simplifying nutrition and physical activity tracking for DPP participants. The SoleraONE app is uniquely positioned to fill the gap for community-based in-person DPP program providers to give participants the opportunity to make-up sessions remotely through engaging video content in English and Spanish. With the SoleraONE app, DPP providers in the Solera network can now offer their participants the benefits of an in-person program coupled with digital capabilities.

The app also includes an integrated lifestyle coach portal that significantly reduces or eliminates the time required by DPP lifestyle coaches to review participant nutrition logs and provide real-time participant feedback. Community in-person DPP providers benefit from streamlined data tracking and provider workflow management to improve efficiency and lower associated program delivery costs.

The SoleraONE app is fully integrated into the Solera Health technology platform, which is used by Solera's in-network community DPP providers to support Medicare's administrative and regulatory requirements for

compliance, data privacy and security, reporting and program integrity.

"One of the challenges of combined in-person and digital DPP delivery is the ability to seamlessly incorporate all member data into a single patient record for reporting and claims submission," said Brenda Schmidt, CEO, Solera Health. "We also recognized the importance of supporting our in-person DPP providers and actively worked to meet their need to offer Medicare participants make-up sessions with our mobile app, SoleraONE, for sustained patient engagement to support program outcomes."

Solera's technology makes chronic disease prevention programs affordable, accessible and efficient by connecting at-risk individuals with a diverse range of lifestyle modification programs as a covered medical benefit. The company's national scalable model was designed to consolidate highly fragmented programs and services into one integrated network, allowing health plans and medical providers to increase consumer access and participation while lowering associated costs. ■

Partnership Expands Insurance Health Coverage for US Consumers

DarioHealth, a leading global digital health company with mobile health and big data solutions, today announced that it is expanding its insurance coverage provider network by entering into a strategic agreement with New York-based Byram Healthcare (Byram).

Recently, DarioHealth expanded its 3rd party insurance coverage option for U.S. consumers who want their DarioHealth products reimbursed by insurance. The addition of Byram to the DarioHealth provider network will further accelerate market penetration in the insurance reimbursable market for DarioHealth's U.S. consumers.

In operation since 1968, Byram is a market-leading distributor of reimbursable medical supplies to home patients

and home health agencies in the United States. Byram has strong positions in its principal product lines of ostomy, wound care, urology, diabetes, and incontinence supplies, which are sold nationwide. Byram has built a portfolio of over 600 payor contracts covering more than 200 million lives, along with a dedicated revenue cycle management infrastructure to support claims filing and collection processes. With more than 900 teammates, Byram has national reach in the direct-to-patient market in the U.S., which it serves with an experienced management team and a sizable customer-facing sales and service team.

Perry Bernocchi, CEO of Byram Healthcare, commented, "We are excited about this new partnership with DarioHealth and look forward to strong mutual growth

as a result of this expanded access."

Erez Raphael, Chairman and CEO of DarioHealth, commented, "DarioHealth initiated the provider network approach earlier in the year and it has been met with much success. By partnering with only the most reputable 3rd party providers, our team is fully committed to help consumers take control of their self-diabetes management."

With the addition of Byram Healthcare, DarioHealth expects to cover 30% of consumers in the U.S. diabetes market. In just a few months since launching the insurance health coverage initiative, DarioHealth has received tremendous feedback, and covered major insurance plans, such as Aetna, United HealthCare, and various Blue Cross Blue Shield programs. ■

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Oct 2017

3-5

IoT Solutions World Congress

Barcelona, Spain
For more information visit www.iotsworldcongress.com/visit/passes-and-prices/

September 2017

12-13

Internet of Health

Amsterdam, Netherlands
For more information visit <https://internetofbusiness.com/events/internet-of-health-emea/register/>

14-15

International Diabetes and Degenerative Diseases Conference

San Diego, CA, USA
For more information visit <https://www.clytoaccess.com/international-diabetes-and-degenerative-diseases-conference>

18-19

Artificial Intelligence Innovation Summit

San Francisco, CA, USA
For more information visit <http://exlevents.com/artificial-intelligence/#JournalmHealth>. Get 15% off registration with discount code C932JMH

27-28

Artificial Intelligence in Drug Development Congress

London, UK
For more information visit <http://www.artificialintelligence-congress.com/>

27-28

15th Annual Pharmaceutical IT Congress

London, UK
For more information visit <http://www.pharmatechnology-summit.com/>

November 2017

8-10

4th European Congress on eCardiology & eHealth

Berlin, Germany
For more information visit www.e-cardiohealth.com/call-abstracts

22-23

Diabetes Professional Care

London, UK
For more information visit www.diabetesprofessionalcare.com/

28-30

Giant Health Event

London, UK
For more information visit www.giantthealthevent.com

The Rise of Artificial Intelligence in Healthcare

The adoption of artificial intelligence in healthcare is rising rapidly, as the industry recognises the opportunities to apply these technologies across the continuum of care. Here, Jeroen Tas, Chief Innovation & Strategy Officer at Philips, discusses how AI-enabled systems are helping to drive improvements in the way in which care is organised and delivered, as it becomes an integral feature across Philips' portfolio of products.



Jeroen Tas has over 30 years of global experience as an entrepreneur and senior executive in the healthcare, information technology and financial services industries. He was appointed to the role of Chief Innovation & Strategy Officer for Philips, in February 2017, driving innovations in smart systems, software and services to improve people's health.

How is Philips utilising AI and what do you see as the significant opportunities for AI in healthcare?

We are already applying AI in many of our solutions and we believe that ultimately the majority of our products will become AI enabled.

A large part of our business is involved with imaging and this is an area where we are increasingly applying AI in order to more effectively analyse those images. Whether it is an image of a foetus, or an image of the heart, we are essentially using AI to, firstly, quantify what we see on the image, to compare it to normal, and then to generate a visualisation from that. Where we automatically find deviations from normal, or identify markers on an image, we can then combine this with patient information that we already have, in order to provide something that we call 'anatomical intelligence'.

We recently launched an AI software product called Illumeo, which can extract relevant information from a patient's investigations and automatically highlight any issues that would be relevant to the clinician. It can also be used to compare different imaging scans to allow a clinician to determine whether treatment regimens have been effective. Something that is extremely difficult to identify with the human eye, owing to the subtle differences between images.

This type of solution is even allowing us

to see whether it might be possible to identify a condition like Alzheimer's prior to any onset of symptoms. To do this, the solution can look at imagery from multiple studies to determine the rate of brain atrophy, and determine whether the shrinkage of the brain is actually faster than normal. Similarly, we can analyse the images to check for tiny dots that would indicate plaque developing in the brain. These form very gradually, and ultimately lead to the symptoms of Alzheimer's.

This can also be done on images from pathology. What would have previously been analysed under a microscope, can now be digitised, and we can use artificial intelligence to identify the right tissue, then process the tissue and ultimately identify specific biomarkers within that tissue.

AI can also be used to process genome sequences that are produced from a sequencer and actually bring these three aspects together so that we have a much more precise view of a patient's condition. This means that in an oncology setting, for example, we can look at the anatomy of the cancer, we can look at how the cell structure evolves and we can actually look at the DNA that drives that cancer!

All of that is enabled through artificial intelligence. This means that we are moving to a much more precise diagnosis. We can then again apply AI to identify the right therapy choices, by linking them to a specific diagnosis profile of a patient. This brings us to another use case for AI,

whereby if we are trying to get an effective profile of a patient then it is useful for us to be able to analyse all the earlier investigations, tests and reports that have been conducted on that patient. However, the difficulty with healthcare is that more than 75% of all this information is unstructured, for example, these might be reports written by a radiologist or specialist. This is where we can begin to use natural language processing, specifically linked to medical anthologies, so that we can start to interpret what is in a written report and what is actually relevant for this specific patient's care. We therefore use AI to extract the relevant information and make it interoperable.

Another application is where, instead of looking at an individual patient and their medical history and their profile so that we can make a better diagnosis, we begin to actually look at the entire population of patients. For example, we could analyse a million patients within a certain area to see how many of these patients have specific diseases, what are their risk profiles, what are the costs to the system? We can then use AI to start stratifying patients groups in order to begin interpreting complex information that can give us insights into the specific needs of those patient groups.

This type of analysis can also be used to automatically monitor particular patient groups. For example, if we want to monitor elderly patients, with particular chronic conditions, who are living at

home, we can stream real-time information that will help us to perform that task.

[At Philips] we have a fall detection monitor that provides this type of information for if a patient has fallen, but the data collected by that device means that we can also use AI as a means of predicting potential falls. If someone is wearing the device and the solution identifies that in the past couple of days they are getting up more slowly, or their gait has changed, or we have monitored them stumbling, then these factors will suggest an increase in the probability that they will fall. By identifying this it means that an intervention can be taken at the right time, to help prevent a fall from occurring.

This is a use case that we can use for people at home but also for people in the hospital. If people are in an intensive care unit and they're connected to monitors we can get a really good insight into the health of that person, and from that we can identify deterioration in that patient. Like the onset of sepsis, or cardiac arrest, and if we see those things happening then it provides a window to intervene and try to avoid those acute situations.

As you can see, we are applying AI in many of our propositions, some of them are concerned with interpreting images and some of them are involved with interpreting patterns and complex information. Many of the solutions that I have described, we already have in the market, with the AI working behind the scenes.

How do you view the role of AI in healthcare?

I think that the first focus is to improve clinical decision making. Supporting clinicians by streaming data, interpreting data, providing effective visualisations, detecting deviations from normal, providing early warnings – these are all areas where we can use AI to focus on supporting the clinicians to make the right decision at the right time.

But, there are of course processes that can be automated as well. For instance, radiologists used to have to look at an image and if they wanted to compare that image to an earlier investigation then they would have to manually retrieve prior studies and then measure and compare those images. This is now all automated, the software can do it for them and identify any differences and highlight any deviations from normal. As a result I think that this type of technology doesn't automate a job, but it will automate aspects of a job, in this case.

Conversely, when you take a solution like our Lifeline fall detection device and use that to start predicting falls ahead of time, then you are doing something that could never have been done before.

When it comes to other solutions, we have thousands of imaging devices in the field, we have hundreds of thousands of monitors and defibrillators in the field, and of course we want to connect these devices,

we want to start automating preventative support and maintenance and we want to help people optimise the workflows, and asset management, around these devices. We recently launched a product called Performance Bridge which does exactly that. It uses AI to help optimise those assets and optimise the workflows around those assets. That also allows you to proactively manage and maintain hardware and software in the field.

What are the challenges of applying AI in healthcare?

We all know that the quality of your AI is only as good as the quality of the data that you feed into it. The quality of the data, ensuring that it is interoperable and then making sure that it is handled with the right privacy and security regulation, which is definitely non-trivial in healthcare, is essential.

I think that there are still some challenges around the regulatory landscape in dealing with these types of algorithms, specifically if these algorithms are not just doing decision support but they are actually applying clinical decision making. The healthcare industry only allows you to deploy this type of technology if you can provide the clinical evidence to support it. This means that the regulators have to find a way to continue to allow you to evolve the different algorithms that you develop, without having to constantly stop and then revalidate. ■

Transforming Trials

Why Data-driven Drug Development is Critical to Gaining Competitive Advantage



By Pamela Brankin

Modernising clinical trials using collaborative cloud technologies is key to engaging the right patient population, improving efficiency and productivity, and accelerating the development of targeted solutions

It is well known that the drug development process is lengthy, expensive and prone to failure. A 2016 study¹ of clinical development success rates by the Biotechnology Innovation Organisation showed that only 30.7% of developmental candidates make it to Phase III trials, with only 9.6% making it to market. The cost of failure is high. Company stock prices can plummet, jobs are lost and research sites can be closed to protect the core business. Both employees and stakeholders are impacted, and ultimately patients directly suffer the consequences of lost research opportunities.

But why are so many clinical trials failing? Significant data, infrastructure and organisational challenges face the pharmaceutical industry today. In an era where patients increasingly demand a personalised approach, and new data streams from wearable devices, genomic medicine, mobile apps and clinical systems converge, the storage, sharing and analysis of this data becomes increasingly non-trivial.

No other industry is more awash with data, or more dependent on it for success. From drug development to clinical therapies, the entire pharma R&D pipeline is increasingly becoming an exercise in collaborative data science, which can only be driven by cloud technologies.

Barriers to collaborative innovation

This is a difficult time for global pharmaceutical companies. Their traditional business models are being challenged as healthcare efficiency drives are stepped up, millions of consumers turn to health apps and wearable technologies, and data-intensive fields such as personalised medicine start to become more established in government policy, if not yet in clinical practice. And while connectivity, communication and collaboration are increasingly recognised as vitally important for healthcare transformation across the entire innovation lifecycle, from early stage R&D to patient participation, none of it is possible without investment

in IT capable of powering new business models and promoting patient-centric drug development.

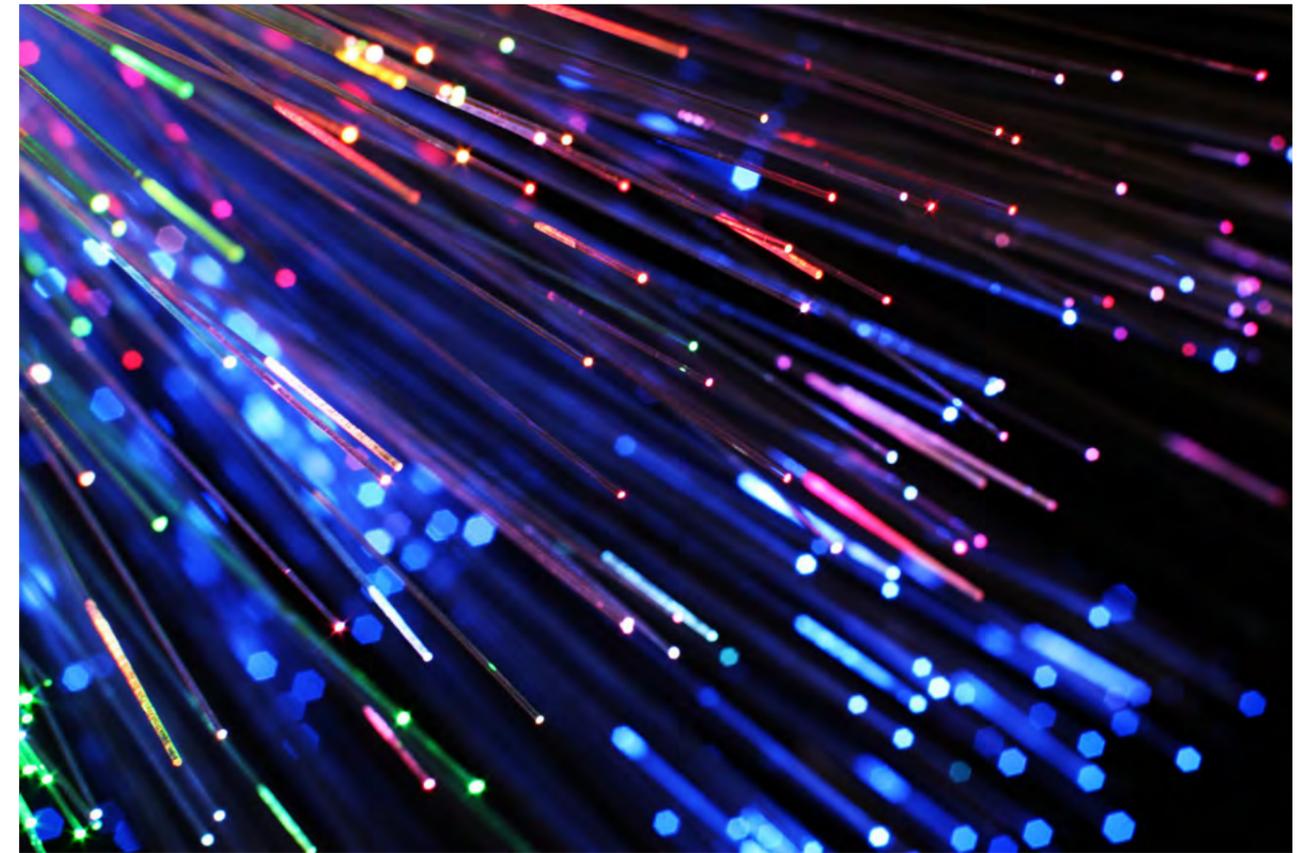
Against this backdrop, becoming a data-driven business is no longer a choice, it's a necessity. Legacy systems that are unable to adapt to the demands for this type of multi-channel, multi-user interaction, or scale to the level needed to support the complex, data-driven R&D projects of today simply cannot function as required - pivotal elements translating IT solutions into competitive advantage.

Unfortunately, many pharma companies continue to conduct trials using traditional methodologies and legacy computational systems known for separating information into silos. Interoperability suffers, it's expensive to maintain multiple systems and licences, and it takes longer to conclude results. Add to this the siloed organisational structure which pharma companies are often subject to, and it's clear that facilitating cross-functional collaboration and encouraging innovation is hampered by limitations in both technological and operational strategies.

Transformative technologies, empowered patients

As the pharmaceutical industry becomes increasingly challenged by both internal and external factors, individual organisations will find it difficult to compete on growth alone and must turn to technology in search of other competitive advantages.

With so many trials proving ineffectual for the patients and resulting in failure due to poor study average performances, pharma companies are struggling to develop the innovative treatments they seek and failing to gain competitive advantage. A technical and cultural revolution must take place across the clinical research ecosystem to improve efficiency and productivity, and accelerate the development of targeted solutions. Investment in cloud platforms and mobile technologies alongside an increased uptake of adaptive trials is key.



Transformation of this scale is not about tweaking around the edges – it is wholesale digital modernisation of clinical trials aimed at tackling the increasing financial, operational and data challenges facing pharmaceutical R&D, and which will ultimately impact on healthcare provision.

Flexible, successful, data-driven

Looked at from this perspective, the case for using adaptive trials as a research methodology is strong. Trials that evolve as they progress are known to improve efficiency, increase the probability of success and decrease development time, adding value to all phases of development. In exploratory phases, adaptive trials can combine development phases and improve resource allocation. In confirmatory trials they enable early stopping, change of allocation rates and reassessment of the sample size, patient subgroups or specific treatment arms.

By testing candidate compounds in parallel during the adaptive trials process, a greater number of candidates could benefit from a suitable active treatment. New drugs can be trialed and stopped if found ineffective or harmful, reducing waste. Both individual and combinations of developmental candidates can be tested, allowing participants to experience the best options available to them while also increasing efficiency by reusing protocols, staff and infrastructure across multiple compounds.

Trials can also be adapted in response to initial results, offering more successful treatments to a wider group to test findings if certain traits shared by groups are discovered. This exposes trends and similarities amongst candidates who respond better

to different therapies, which in turn will allow healthcare professionals to offer a more tailored treatment to individuals with similar clinical characteristics.

The use of adaptive trials, while beneficial, introduces complexities to the trial process. Successful planning and data management supported by platforms which enable advanced analysis and multidisciplinary collaboration becomes increasingly invaluable.

A project that exemplifies these benefits is the European Prevention of Alzheimer's Dementia (EPAD) project. This European public-private collaboration between 38 organisations will use an adaptive trial design to test Alzheimer's Dementia prevention treatments while the disease is in its pre-symptomatic phase. The group has created its own register, identifying 24,000 people across Europe who already participate in national and regional research studies, long-term cohorts or clinical registers. From this register, people with varying likelihoods of developing Alzheimer's dementia will undergo standardised tests, and will be considered to take part in EPAD's proof of concept trials.

It is hoped that this trialling process will lead to significant discovery and subsequent understanding of the illness and how it can be managed.

Real-time and patient-focused

Currently research participants can provide broad or blanket consent to a range of different future research purposes. ➔

However, if research activities change, they cannot update their preferences. In such cases consent must be re-requested from the participant, who must re-read lengthy forms containing complex terminology, which can affect retention. It isn't abnormal for clinical trials to require costly extensions and the inability to effectively engage participants and obtain consent is detrimental. As consumers increasingly simplify their lives - and health self-management - using mobile technologies, so ongoing, patient-centric partnerships between participants and researchers become increasingly desirable and achievable.

Dynamic consent is a technology-led approach to patient consent utilising personalised online platforms to secure and manage informed consent and allow open dialogue between researchers and participants; a key characteristic of adaptive trials, which rely on rapid responses to manage mid-trial variations.

Bolstered by the dynamic consent model, adaptive trials allow important research to be undertaken quickly, efficiently and, crucially, in partnership with a greater number of the right patients at the earliest opportunity. Combining these two techniques can be powerful, but requires the use of scalable cloud data platforms that span public, corporate and healthcare networks.

Stratification and drug development

One reason behind trial failures is the lack of patient stratification prior to clinical trial design and enrolment. Many drugs fail because their efficacy varies widely across the patient population. A lack of appropriate stratification means that non-responding patients are being included in inappropriate trials. In order to move away from "all-comers" trials, the early identification of factors - including genetic, environmental and lifestyle - influencing efficacy in patient subpopulations is key.

To ensure further investment and development in a drug, evidence in the form of near real-time data must be presented, demonstrating safety and efficacy in human volunteers. If we are to routinely apply an adaptive methodology to proof of concept studies, all outcomes must be captured and reported in near real-time, and transferred to a central hub for analysis, necessitating the use of a flexible and responsive analytical environment.

This will involve the use of cloud-based data analysis platforms, such as Aridhia's AnalytiXagility, capable of integrating and enabling the collaborative analysis of streams of data from multiple sources in real-time. This not only supports critical decisions to be implemented in optimal timeframes, but also allows researchers to respond rapidly to emerging results.

ReproCELL, a pioneer in preclinical stratification, recently led a research collaboration through the Stratified Medicine Scotland Innovation Centre - Scotland's national centre for precision medicine.

In the first project of its kind, the collaboration combined the data from fresh tissue assays with genomics to demonstrate a new model for the early preclinical prediction of efficacy and patient stratification. Diseased tissue from two chronic inflam-

matory diseases was used to investigate inter-patient variability in drug efficacy using ex vivo organocultures of fresh intact tissue. In the presence of standard of care drugs, the reduction in inflammatory cytokines was used as a measure of drug efficacy. The individual patient responses were matched against genotype and microRNA profiles in an attempt to identify predictors of responsiveness.

This project demonstrated that by testing drug effectiveness in fresh disease-relevant tissue samples and relating these responses to genomic data, drug developers can seek to link genotype to patient variation in drug responses at a much earlier stage than has previously been possible.

R&D in the cloud

There is no doubt that data-driven technologies are having, and will continue to have, a positive impact on drug development in terms of securing patient engagement, harnessing the flexibility and efficiency offered by adaptive trials, and forging new paths for preclinical stratification. Ensuring that people, data, knowledge and tools can combine seamlessly across the entire drug discovery to development lifecycle is made possible only by properly managing the convergence of the cloud, analytical software and mobile devices.

By advancing the use of technologies which allow multiple participants to collaborate around the increasing availability of data from electronic health records, mobile health applications, sensors, and so on, we can better enable pre-clinical stratification, identify the most effective drug candidates, improve clinical trials success rates, and accelerate the availability of effective medications to affected populations - with less risky and more profitable research and development.

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Full EPAD acknowledgement

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About the author

Pamela joined Aridhia in 2011, taking on the role of Head of Marketing and Communications in 2015. With responsibility for the strategic development, implementation and management of an integrated marketing and communications strategy, as well as the commercialisation and dissemination of strategic initiatives and clinical research programmes, she occupies a pivotal role in the organisation's ongoing development. ■



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Coordinate My Care

Enabling Patient Choice when it Matters Most

Sharing patient's wishes with health and care providers across London through Coordinate My Care's personalised urgent care plan is delivering care quality and operational benefits with a system that is better addressing patients' needs.

Over 500,000 people die in England and Wales every year¹, and almost half of those die in hospital² – despite the fact that under 3% of people say³ that is where they want to spend their final days.

Statistics such as these highlight why the Coordinate My Care service is so important, beginning in London's Royal Marsden hospital as a way of recording an individual's end of life care wishes. Now, the service not only captures patient wishes, it is sharing this information between the capital's multiple health and care providers especially when urgent care is required, for all patients not only those who are terminally ill.

Working with London's 32 clinical commissioning groups, GPs, out of hours, 111 service providers, the London Ambulance Service, and based on InterSystems' health information sharing platform HealthShare®, Coordinate My Care has developed into an intuitive, personalised urgent care plan that is putting patient choice at the heart of healthcare.

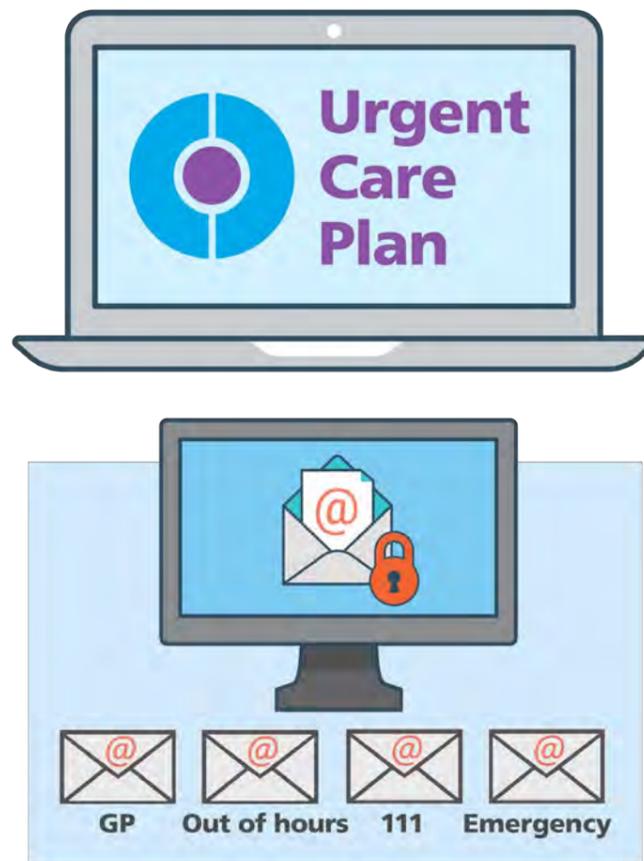
By sharing patient wishes at times of most need, the programme is helping people receive care in the place they would like, most usually the home. And at a time of financial pressures, the programme is also saving tens of millions of pounds across the capital, and could save England's NHS over £500m if it was implemented across the country.

Respecting patients' wishes

Coordinate My Care enables patients to work with their care providers – usually their GP – to discuss and record their wishes and enable those plans to be shared with the urgent care providers, during the 'out of hours' period, when urgent care may be required. It does this through a web-based interface that asks essential questions about their care, including their medical needs, as well as their preferences for any social, nursing, spiritual, and cultural needs. At all times the patient can review their plans on their smart phones.

Immediately as a CMC urgent care plan is created, care providers, such as their GP's out of hours' provider, 111 or the ambulance service are automatically alerted that the patient has an urgent care plan, and can treat accordingly.

Coordinate My Care worked with InterSystems to develop an electronic urgent care plan using InterSystems HealthShare which harnesses information from a number of systems, and feeds it into the system's urgent care management application, which is used to access and edit the care plan.



Additional information is added by the patient's GP or nurse, in discussion with the patient. This information is then shared with care providers, with the appropriate consent. Patients can access the plans, which are reviewed when appropriate to ensure that a patient's wishes are current. To support this review process, reminders are sent to the person's GP, and escalated to others involved in the patient's care if no action is taken.

Updated care plans are notified to all urgent care providers, so that they know that they are viewing the latest care plan. Users of EMIS, the largest IT supplier to GPs in London, can see directly from their screens when such a plan is in place.

Impact on patients and professionals

The results for Coordinate My Care are impressive. It is in use in over 1,000 GP practices across London; over 35,000 plans have been created, up by more than 10,000 in 2016 alone, thanks in part to its strong ability to share information across vital care providers, and its simple user interface.

Records show that for those Coordinate My Care patients who have passed away, 78% died in their preferred place. One in five are dying in hospital, rather than almost 50% doing so at a national level. Families can be confident that their loved one's wishes are known and will be respected, without having to repeat the same information at times of distress.

Care providers are seeing a similar transformative impact. Paramedics have information available via mobile devices, enabling them to make crucial decisions that reflect the patient's choice.

As David Whitmore, senior clinical advisor at the London Ambulance Service says: "Coordinate My Care plans have radically changed the way patients are treated. Beforehand, we were not sure what the care plan was and may have taken people to hospital when it was not the best thing for them. This system has changed that, so patients can receive the care they want. Now, he says, treatment can take place in the home, which is preferable.

Out of hours and 111 operators have access to a much more rounded view of the patient, meaning that they can determine the best course of action suited to a patient's wishes, which helps them provide better care and reduce the number of unnecessary hospital admissions.

Whilst the care benefits are considerable, the financial benefits are equally impressive. Coordinate My Care is, on average, saving the NHS £2,100 per patient, equating to an annual saving of over £16.8m in London alone. If implemented throughout England, projections for annual savings would be over £556m⁴.

A Clinical Solution to address NHS Urgent Care Crisis?

Professor Julia Riley, consultant in palliative medicine and clinical lead for Coordinate My Care, shares how the service is improving patient outcomes and enabling a paradigm shift in how the NHS approaches unscheduled care.

When a member of my family was dying of metastatic malignant melanoma, she wanted to remain at home with her four children, all under the age of five. Yet, time and again, when she

needed help in the out-of-hours period, a well-meaning GP or paramedic would arrive, not knowing anything about her or her wishes, and she would be taken to hospital.

For myself and many others, this lack of information sharing made an already painful situation much worse.

There is also the additional impact on the NHS. Twenty per cent of those in the last year of life have five or more unplanned admissions, creating an often unwanted burden for both the patient and the NHS. For many, this is the last thing they want.

It was for these situations that Coordinate My Care (CMC) was created.

CMC offers one standard, digital urgent care plan making sure that the patient's wishes are taken into account by everyone who will be responsible for their care. It includes important information about the patient's illness and medication, how and where the patient would like to be cared for, and people to contact in an emergency. It shares this information with all the health professionals who might be involved in treatment: from paramedics and emergency services to hospital doctors and specialist nurses.

Though it is underpinned by an IT platform, CMC has been developed as a clinical service that changes the culture of how urgent care is conceived and delivered, from one that is reactive, to one that is proactive and patient-centred.

Transformation has to come first, so technology supports new ways of working. By providing trusted information to care providers at times of urgent need, and as part of their clinical workflow, we have been able to support that transformation. That has meant ensuring that care plans are created with the patient and a trusted clinician, and that information is audited regularly and shared appropriately at the point of care. To further encourage trust in the data, and support robust information governance, over 1,000 information sharing agreements are in place with organisations across London.

Culture change is crucial, and to support this we have trained over 20,000 individuals on how the service operates. This extensive training covers how to identify vulnerable patients, how to have difficult conversations around care choices and how to operate in a 'virtual multi-disciplinary care team'. Online learning and real-time support is also provided.

CMC has been in existence for nine years, since the publication of the 2008 end of life care strategy. In that time, it has seen multiple iterations so that it can integrate into numerous NHS pathways, including those for out-of-hours' GPs, 111 and ambulance services. Thousands of hours of professional time have informed developments, with contributions from those involved in the clinical, enterprise architecture, design, patient safety, pharmacy, communications and testing aspects of the service. Patients have provided feedback on the development of the service at every important stage.

Coordinating this approach to care also requires robust interoperability. CMC is currently a pan-London service, commissioned by the capital's 32 clinical commissioning groups to ensure that patients can benefit from the service wherever needed. This ➔

has meant we have designed and delivered an interoperable solution, based on InterSystems' HealthShare information platform, that can be seen by any legitimate and authorised user through multiple systems, and that draws in centrally managed data services such as the Spine.

The result is a system that is delivering benefits now, and can benefit the wider NHS. The system has been designed to be scalable. Both the platform and the contractual arrangements have been positioned so that they can be adopted by other areas across the NHS, not only for urgent care, but other services such as cancer treatment.

The impact of the system, which has been awarded National Innovator Accelerator (NIA) status after rigorous peer review, is clear. Around 50% of all deaths occur in hospital nationally. Among patients who have created a CMC urgent care plan, just 18% die in hospital, with more spending their final days in their preferred place of care.

The results for the patient are also compelling. As Mary, a patient with renal cell cancer who set up a CMC plan in 2016, said:

"Now I have a plan, I feel so much happier. Because I've got some control over things. I will probably need urgent care in the middle of the night again – that's how cancer goes. But, this time, everyone will know what to do with me. They'll know exactly what I have, and how it's being treated. I won't have to explain it all and repeat myself to different people. I'll get the right painkillers, at the right time. And I'll be in my own home, instead of sitting in pain in A&E. I'll get the care I need, the way I want it. Sitting here, feeling strong today, I can't tell you how reassuring that is."

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Achieving Digital Transformation in Healthcare with Device Management



Dave Alampi,
CMO, Jamf

Ten years ago, Apple launched the first-of-its-kind iPhone and three years later introduced the iPad. The iPhone totally revolutionised the standard for mobile phones, while the iPad set a new standard in mobile computing. Both devices have transformed industries such as education, retail and hospitality, and are now starting to leave a significant impact on healthcare in particular.

iPads and iPhones have allowed healthcare organisations to wholly transform the delivery of healthcare. By deploying Apple's technologies, hospitals and GPs have increased productivity and enhanced the patient experience, allowing them to digitalise their healthcare services. Today's hospitals have tapped into Apple's iOS healthcare capabilities, and have utilised CareKit and ResearchKit to develop custom patient care and medical research apps. In addition,

the NHS has recognised the potential for apps to empower patients to take a greater role in managing their care, and has recently re-launched its own app library. It is also becoming increasingly common for caregivers to use iPads and iPhones to communicate with staff and patients, monitor patients' vitals and access medical records while on-the-move.

The government too has recognised the potential for mobile technology to transform the NHS. It recently announced a new £6 million Pathway Transformation Fund to allow for the intake and application of new technologies to improve the delivery of healthcare. However, before the NHS purchases and integrates new devices into the service, it needs to implement a focused strategy to enable a smooth technology roll out. This will enable the service to set itself up for digital success. A new technology roll-out programme that includes mobile device management and education for end-users should be one of the key tenets of the transformation strategy. If the NHS does not prioritise

a robust transformation programme, it will never be able to realise its digital goals -- regardless of how much money is allocated for healthcare technology.

Meanwhile, with cybersecurity dominating the headlines after the recent WannaCry ransomware attack, which rendered outdated NHS systems unusable, it is important for the NHS to make device security a top priority – to ensure the service runs smoothly and maintains its reputation as a trusted public entity.

Jamf recently commissioned an independent survey with Vanson Bourne to learn more about the biggest challenges that healthcare IT decision makers face when managing mobile devices. Out of the 550 IT decision makers polled from healthcare organisations in the UK, France, Germany, US and Australia, the survey revealed that confidence is low in current device management solutions, as more than one-quarter (27%) are not fully confident. Other top concerns when managing staff mobile devices includes security (83%), data pri-



vacancy (77%), inappropriate employee use (49%) and software updates (48%).

Organisations can look to a robust mobile device management (MDM) solution to optimise both the iPad and iPhone's capabilities to address the challenges facing healthcare IT decision makers. Such a solution would secure patient data, keep devices compliant with industry regulations, minimise the organisational burden of managing devices and encourage employee engagement. It is a key component of digital transformation, and can help healthcare organisations, including the NHS, achieve its digital transformation goals by setting up its current and future device programmes for success.

Protect confidential patient data and records

As security is understandably a top priority, healthcare organisations can be confident that staff and patient data are secure on managed iPhone and iPads. With MDM, hospitals, GPs and surgeries can take a greater part in developing and deploying custom device security settings across an entire inventory of managed devices. Organisations can implement specific passcode parameters, enforce secure device connectivity to VPN and Wi-Fi networks, maintain consistent user profiles and set up supervision capabilities. By deploying similar settings across a library of devices, it's easier for the devices to be managed with greater efficiency.

A key element of MDM is that patient data is not stored remotely on a server, but on managed, secure devices. There-

fore if an iPad or iPhone is lost or stolen, it's easy for an administrator to remotely wipe a device, meaning that confidential data is always kept under lock and key.

Together with Apple's native security capabilities, including Touch ID, which only allows access to authorised users via their unique fingerprint and hardware-based encryption that safeguards confidential data, organisations can be confident that patient data, clinical communications and medical records are secure with an MDM solution in place.

Keep devices compliant in a dynamic regulatory landscape

As healthcare regulations continue to evolve, organisations need to be certain that they have the right tools to ensure devices adhere to new regulatory mandates. MDM's remote management capabilities play a critical role here – it allows organisations to keep devices compliant with new legislation, such as the upcoming General Data Protection Regulation (GDPR). With MDM, healthcare organisations can easily identify non-compliant devices and quickly issue patches or updates to bring all devices in line. As MDM security settings can be changed and quickly issued to an entire inventory of devices, healthcare organisations can enjoy the flexibility in adjusting the settings as regulations change.

Lessen the IT burden of device management

An MDM solution minimises the burden of device management for non-IT staff. Healthcare organisations can easily configure and deploy new devices

remotely with MDM's "zero-touch" capabilities. Once iPads or iPhones have been rolled out, organisations may easily issue any software patches and over-the-air (OTA) updates via MDM software, thereby ensuring devices can be quickly updated without disrupting staff.

Improve staff engagement and work satisfaction

One of the major benefits of MDM is that staff can begin using managed Apple devices as soon as the device is powered on. Staff are unhindered to immediately update patient records on their iPad or iPhone, monitor patient progress and communicate with one another. Unlocking Apple's unparalleled user experience with an MDM solution will boost staff's productivity and also result in higher levels of staff engagement and satisfaction.

Realise digital transformation with MDM

Healthcare organisations that tap into the capabilities of an MDM solution can enjoy the multitude of benefits that devices such as the iPad and iPhone provide with both staff and patients. Managing devices with a robust MDM solution can assist organisations on their digital transformation journey by digitalising their healthcare offerings in a scalable way. MDM allows organisations to protect confidential staff and patient data, ensure compliance with regulatory mandates, reduce the IT burden and provide an exceptional mobile experience to engage with employees. As the application of Apple devices in healthcare continue to expand, organisations can be confident in their cutting edge devices managed by an MDM solution. ■

Digitalising Bed Management

How Touch Screen Technology can Reduce Hospital Bed Waiting Times

Anybody who has spent time in a GP's waiting room understands how frustrating healthcare waiting times can be. These inconvenient waits are bad enough when nervously awaiting routine appointments, but are significantly more stressful when urgent care is required. Here, Adrian Swindells, a director of touchscreen computing specialist Distec, explains how using touchscreen PCs for bed management can help medical practitioners improve availability.

The state of the NHS is undoubtedly one of the UK's most discussed topics in recent years. Whether on a political or social level, there are all manner of discussions and debates spurred from the challenges facing the organisation and what the future may hold for it.

One of the most prominent challenges is that of bed management and waiting times. According to bed availability figures from the NHS, on average 89 per cent of all available overnight beds were occupied in the first quarter of 2017. This accounts for approximately 116,643 beds across the UK and is above the 85 per cent considered to be the maximum occupancy rate.

The reason for specifying an upper limit for occupancy is to allow hospital staff time to not only clean beds but also to ensure that enough are free for patients that need them. Managing this process is becoming increasingly difficult, particularly in light of the hospital closures and ward downgrades that have either occurred recently or been announced for coming years.

There are a couple of reasons why this is happening. According to Matt Schuchardt, a director of HIMSS Analytics, "few hospitals know how their beds are used and where they're in use." In effect, many hospitals are not equipped with the tools to effectively manage patient flow in a growing population that overwhelms existing systems.

Schuchardt identifies a solution to this, which is to use newer software that can make managing

bed-availability data easier. Yet while this is indefinitely a critical component, it is only a partial solution. To truly make headway in improving bed management, hospitals must adjust how this information is accessed.

For example, investment in bedside touchscreen PCs and ward digital signage not only allows doctors to access up-to-date patient records faster, it also gives them access to the hospital's bed management system. This means that, in the case of an emergency admission, hospital staff can quickly and easily access the system and identify what beds are free and clean.

This provides a small step towards better healthcare. Without spending valuable time finding an available desktop PC and accessing the bed management system, doctors can spend more time treating and caring for patients. This will gradually ease the strain on bed availability by minimising the time each patient spends waiting for care.

As UK health secretary Jeremy Hunt stated in January 2016, "proper investment in IT can save time for doctors and nurses and means they can spend more time with patients." By reconsidering the digital systems and how they are physically accessed, healthcare managers can alleviate the frustration of long waiting times for patients and practitioners alike. ■



DISTECLTD Adrian Swindells, a director of touchscreen computing specialist Distec, explains how using touchscreen PCs for bed management can help medical practitioners improve availability.

REF:DIS048

The Internet of Things is Driving the 'Consumerisation' of Healthcare

The arrival of the IoT in the healthcare sector means that consumers will now have the power to take control of their own health in a much more personalised way through technology.

There is absolutely no doubt that the Internet of Things (IoT) is completely transforming the healthcare sector by redefining the procedures that use applications, devices and people when it comes to interacting and connecting between them, with the aim of providing solutions geared towards medical services.

In the healthcare sector, the IoT ecosystem places new tools and efficiencies at the disposal of healthcare professionals, forming a comprehensive system of medical care with the goal of providing patients with substantially improved care, significantly reducing costs and improving the treatments used. In addition, the IoT represents a conglomerate of numerous opportunities that can be used by the managers of health centres, hospitals and clinics while at the same time optimising resources through the automation of workflows and process excellence. Today, the vast majority of hospitals use the IoT for asset management and for controlling the humidity and temperature of operating rooms.

Kevin Patel, an analyst with consultancy firm Xangati and one of the most active contributors to IBM's blog on the IoT, lists the key benefits that healthcare companies get when they integrate the IoT in their infrastructures. 'Healthcare providers are realising the advantages that come with the connectivity of IoT solutions, providing real-time patient monitoring and dramatically reducing unnecessary visits to the doctor. At the same time, the most advanced healthcare systems guarantee a dramatic reduction in hospital stays and readmissions,' contends Patel.

Improved treatments, another benefit of the IoT in the healthcare sector

Connectivity applied to medical solutions through the cloud or other virtual

infrastructures provides healthcare professionals with the ability to access real-time information that gives them new tools when it comes to decision-making and offering evidence-based treatments. This capacity development ensures the provision of healthcare services. "With patients being monitored continuously, and caregivers having access to real-time information, diseases are treated more promptly, minimising the margin of error, by receiving accurate data through automated workflows that are combined with decisions supported by the data received. All of this is an excellent way of cutting expenditure by reducing the costs involved in these systems," says Patel.

Connectivity in the healthcare system through the Internet of Things puts an emphasis on the patients' needs, such as: proactive treatments, greater diagnostic precision, performing surgical procedures at earlier stages, and improving recovery treatments. Improving the management and administration of drugs by pharmacies to optimise public expenditure on medicines is another aspect that benefits from IoT processes and devices, given the effectiveness of the technology when it comes to optimising costs.

The consumerisation of healthcare with the arrival of the IoT

In an article that assesses the transformations that the IoT is wielding in the healthcare sector, Jeroen Tas, CEO of the Philips Healthcare Informatics Solutions and Services Business Group, highlights the process of consumerisation taking place in the field of healthcare. 'Companies that have never before exerted influence in this sector are swiftly becoming its major power-brokers. The business models of many clinics and health centres are being redesigned to adapt to the growing influence of data-fuelled customers. Unique partnerships are being forged between agile start-ups and established brands to capitalise on this new digital-first world.'

For experts like Tas at Philips, the most

important change taking place in the healthcare industry with the arrival of the IoT is the outcome of the data revolution, which empowers people to live healthier lives through the use of their own tablets, wearables and other devices. The arrival of the IoT in the healthcare sector means that consumers now have the power to take control of their own health in a much more personalised way. Jeroen Tas also referred to the advances achieved in cloud-based technology. 'This year, a unique strategic partnership between Philips and Salesforce has created a platform that enables medical devices to operate in conjunction with deep sets of data.'

The analysis of this type of data – amassed from electronic medical records, diagnostic information gathered through imaging equipment, monitors and hand-held personal devices – enhances the decision-making powers of healthcare professionals and lets patients take a more active role in managing their personal health. These innovations are not only transforming the care of chronically ill patients but are also suitable for people who simply want to maintain their good health.

According to the Philips expert, the journey of the IoT through the health sector entails the consumer taking control in this first digital world. 'Consequently, the business model of the health industry needs to evolve, taking into account the fact that any company can now become a healthcare provider, as long as their technology is meaningful to the customer.'

IoT in healthcare: a market that will account for between \$117 and \$163 billion by 2020

According to a report published by MarketResearch.com, the Internet of Things segment geared towards the health industry will amount to some \$117 billion dollars by 2020. Depending on the company using the term, we might be talking about the Internet of Things (IoT for most companies), the Internet of Everything (IoE in the case of Cisco), ↗

or the Industrial Internet, when GE is doing the talking. However, this analyst notes that the combined IoT market is much bigger than the figure reflects.

The 'Accenture 2017 Internet of Health Things Survey' notes that by 2020 the IoT industry in the healthcare sector will move in the order of \$163 billion, with year-on-year growth of 40% between 2015 and 2020. At the same time, the Accenture report notes that 73% of executives in the healthcare industry agree with the statement that the IoT will act as a disruptive element in the sector within the next three years; though only 49% of this group acknowledges that their organisation understands what the IoT can do to optimise their workflow.

With regard to the budgets that health sector organisations devote to investing in IoT technologies, the Accenture report notes that firms whose annual IT budgets are below \$26 million earmark 6% of it to the Internet of Things, while companies whose budgets range between 26 and 50 million dollars devote 9.7%. Companies whose budgets range between 51 and 100 million dollars earmark 10.5% of their budgets to the IoT;

while budgets of between 100 and 200 million dollars devote 12.6% and those with IT budgets in excess of 200 million dollars assign 13.7% to the IoT.

'Ignoring the potential of IoT in the health sector means that executives in this market risk losing a number of advantages they have already achieved; for example, exercising the most appropriate management to attract and retain patient-customers, and achieving substantial savings in administrative and medical costs,' notes the Accenture report, while at the same time stressing that: 'The Internet of Health Things (IoHT) already provides quantifiable savings, but it is essential to continue investing in order to advance the digital economy and ensure long-term business survival.'

About IoTSWC

Organised by Fira de Barcelona, the IoT Solutions World Congress, IoTSWC 2017, is the biggest event of its kind and the only one to combine an exhibition area, knowledge transfer, test benches and networking at the highest level. It also enjoys the support of the main international associations in the sector – the

Industrial Internet Consortium, Industrie 4.0, and the Industrial Valuechain Initiative.

Now in its third edition, IoTSWC 2017 will bring together more than 220 companies and 250 speakers on 3-5 October at Fira de Barcelona's Gran Via exhibition centre. The congress programme will be based on eight main themes: Manufacturing, Utilities, Connected Transport, Healthcare, Buildings & Infrastructures, Open Industry, Blockchain and Quantum Computing, and will address the main challenges that companies are facing in an increasingly digitised universe to enable them to take advantage of all the potential and benefits of IoT solutions.

Further information:

<http://www.iotsworldcongress.com/>

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interested in and confident of early stage device innovation³.

In the UK alone University spin-offs accounting for 34% of new life science start-ups each year⁴. This finding highlights that start-ups in life sciences are very often composed and set up by visionary academics who, unfortunately, would probably not hesitate to describe themselves as inexperienced with the practicalities of setting up a business such as composing a robust business plan, sourcing a reliable supply chain, managing partners, tax and staffing issues. Yet all these key business activities need to be fleshed out and accounted for if early stage companies wish to impress investors and secure funding. A recent report by Mind-Metre Research confirms that a lack of key skills is a turn-off⁵.

This environment, which sees early-stage, often academic, start-ups struggling to get funding, translates into a Catch-22 situation, where the only people knowledgeable enough to innovate are denied access to funding because they lack business experience and only firms that have already received funding are able to access more. Such an environment is damaging to the whole life science sector as it stifles innovation, discourages entrepreneurial initiative and ultimately suppresses important developments that could improve patient health.

Life science early-stage start-ups should, therefore, consider wisely what type of support is offered by different types of investors, being careful not to underestimate the importance of access to mentors and advisors that can show them the ropes when it comes to the practicalities of setting up a business. So, while the initial draw to a particular accelerator programme might be the availability of funding, not all programmes are set up to provide structured growth opportunities and counsel.

You should also consider the overall regulatory and entrepreneurial environment of the country your accelerator programme is based

in specifically: are start-ups being offered incentives such as tax incentives or credits for R&D? How accessible are bank loans? What is the regulation on the transferral of fiscal losses? Is incorporation procedure seamless and easy? Italy for example has recently passed a pioneering 'Italian Start-up Act' placing it second in the 2016 European 'Start-up Nation Scoreboard' for adoption rate.

Data shows that 90% of all start-ups fail within the first year⁶ and raising money also relies on a person's ability to relate their vision and network, but securing the right exposure- being in front of the right people at the right time- is no easy task with many businesses crashing at this stage. Choosing an accelerator that operates in the right sector can help connect with advisors and peers that understand your business, its processes and can help map out a future roadmap that avoids many of the obstacles and pitfalls that are common to your type of business. Similarly, the right type of accelerator will expose your business to investors that are a good fit to your business. Joining an accelerator programme that provides counselling and practical training as well as introducing you to truly relevant and experienced mentors can also be critical to building up the business to a stage where it becomes even more valuable and when finding funding is less fraught with obstacles.

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Finding the Perfect Match in Funding

What should researchers be looking for when seeking funding?



By Giovanni Rizzo, PhD MBA
Chief of Innovation Division,
Z-Cube S.r.l.

The global life science sector is buoyant with commentators reporting that it is set to grow to the value of \$447.5 billion by 2020¹. The outlook for early-stage life science start-ups,

however, is slightly less rosy as they are often largely cut-out of this bounty with large-scale M&A activity accounting for most investment. The European life science start-up panorama is in fact blighted by a critical inconsistency: businesses typically tend to get funding when they have reached relative maturity, and yet they are unable to reach maturity without significant funding. To solve this many businesses are going public too early by commentators' standards at the risk of undervaluing their business.

Traditionally, large pharma has been the source of funds for life-science businesses, but alternative funding initiatives are now gaining ground especially for early stage start-ups. So for example Liquidia Technologies received a \$10 million equity investment from the Bill & Melinda Gates Foundation in support of their development and commercialisation of safe and more effective vaccines, while hedge funds in Boston and San Francisco recently backed Intarcia Therapeutics, which is developing a potential treatment for type-2 diabetes².

Medical Device start-ups were seen to be securing an even smaller share of venture capital in 2016, however, here too the scenario is not all negative as early stage acquisitions for companies with just a CE mark or no regulatory approval is increasing. This result indicates that there may be an important shift in confidence among funders as medical device acquisitions typically happen at a much later stage than their biopharma counterparts. This shift suggests that strategic acquirers are becoming more



The Benefits of Data Analytics in Healthcare



Organisations of all sizes and across all sectors are using data analytics to gain a clearer insight into their own processes, enabling them to make more informed business decisions, reduce operational costs and improve customer and partner relationships. The NHS is no different, says Steve Clarke, Healthcare Solutions Manager, Kodak Alaris Information Management.

Healthcare providers in the UK that leverage data driven from clinical and business analytics are discovering new opportunities to lower costs, provide better care for patients and establish health programmes.

In fact, according to P&S Market Research, the market for data analytics in the healthcare market is projected to grow at 23.3 per cent annually to reach \$43 million globally by 2023.

The ongoing challenge, however, is in being able to effectively compile all forms of structured and unstructured health data into an analytics database.

In its Fit for 2020 Capability Review, NHS Digital, the national information and technology partner for the health and care system says: "We want to empower the health and care system to be intelligent in the way it uses data and information to drive improvements in health and care, by delivering world class data and analytics services through the highest level of skills, expertise, tools, techniques and technology."

However, the report finds NHS Digital's work on the frontline of healthcare provision is being hampered by not working collaboratively enough or effectively gathering and analysing data.

This is a common problem. Data chaos is most rampant at the threshold between physical and digital documents, which makes effective information capture, via a combination of scanners, software and services, vital.

Though clinical and business analytics can lead to dramatic improvements in patient care and business operations, it can be challenging to extract comprehensive information from healthcare data in unstructured formats such as email, faxes, text messages and paper, which can limit analytical outcome accuracy and usability.

In order to take the complexity out of information capture, organisations have to work out how to seamlessly connect the physical and digital data worlds to create a joined up information management system that enables them to extract maximum value from all of their data.

The goal for any healthcare provider is to use data classification, extraction and management software to tap into previously siloed, unstructured data, to realise a 360-degree patient view from all existing health data.

Having access to health analytics has the following benefits:

Identify health risks in real-time

Clinical analysis allows healthcare practices to generate reports based on aggregated data at individual and group levels to identify illness trends, proactively treat patients and offer focused preventative wellness programmes or advice.

Clinical analysis also helps reduce hospital re-admissions by helping clinicians provide comprehensive, proactive care and discharge at the right time. It can highlight complications that are commonly linked to primary illnesses so healthcare providers know what symptoms to watch for. This early warning can help care providers treat patients at the first sign of an exacerbated or secondary illness, thus avoiding re-admission reimbursement penalties.

Plus, real-time analytics can help predict disease outbreaks, enabling preventative measures such as offering vaccinations for illnesses like the flu and pneumonia, which traditionally have high costs of treatment. These measures not only reduce costs, but they can also improve the overall health of the community.

Make decisions based on foresight

In the past, clinicians had to make deci-

sions based on personal experience or data manually aggregated from databases and spreadsheets. Making decisions based on spreadsheets introduces unnecessary risk because spreadsheets are notoriously error-prone and labour intensive. Data management software is exponentially faster, more powerful and more reliable than manual legacy tools such as Excel, which were originally designed for finance.

For healthcare providers like the NHS, this real- or near-real-time data analysis can improve patient care and quality of life, because it is based on data gathered from silos across the entire organisation, and is free of human intervention (therefore reducing error). Clinical and business analytics allow administrators and care providers to make decisions based on data offering supported foresight instead of guesswork.

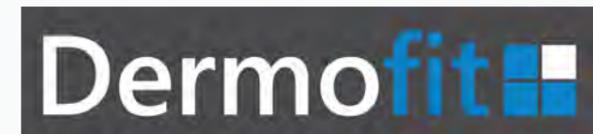
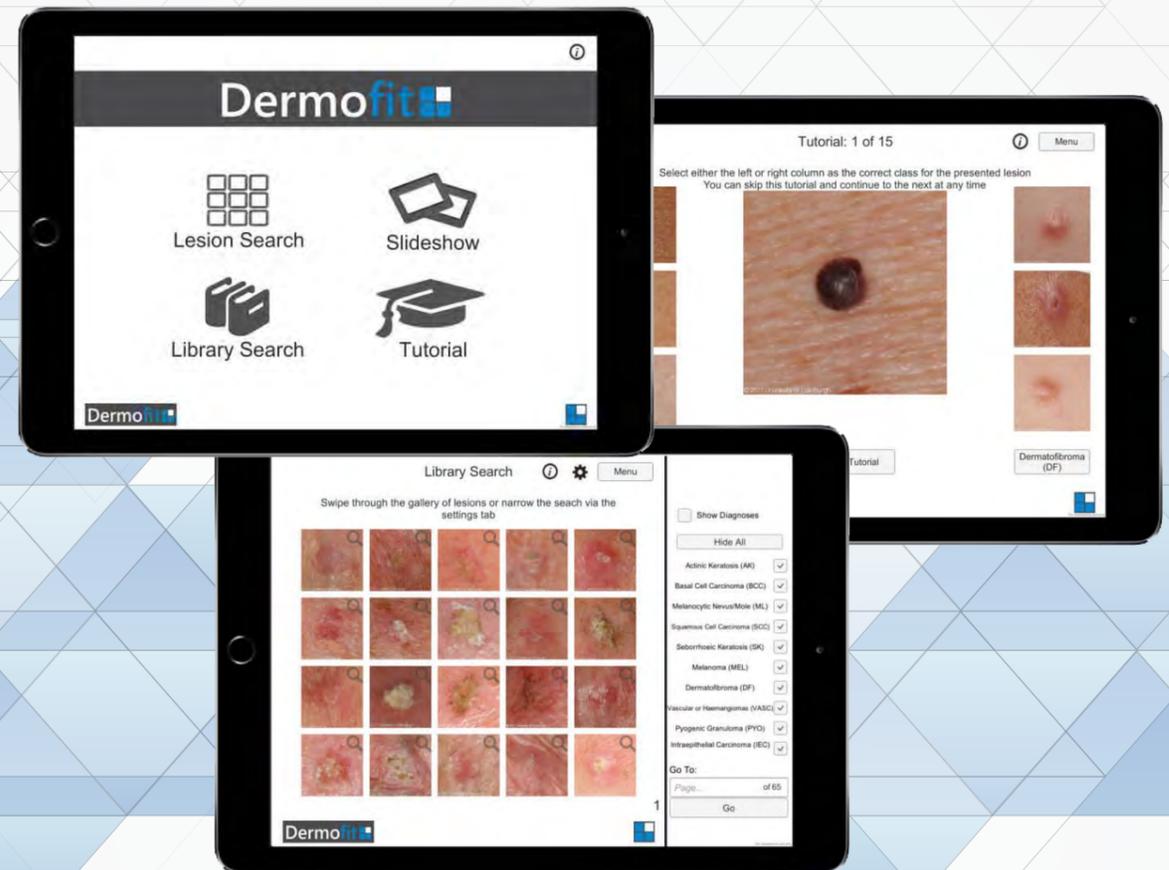
Understand if treatments are effective

Clinical analysis allows healthcare providers to monitor the effect of treatments over time with individuals or groups. This real-time data can help medical staff change an ineffective course of treatment earlier in the patient care cycle, in contrast to the traditional 'watch and wait' scenario.

In conclusion, new health data analysis tools provide expanded opportunities for healthcare providers to streamline operations, improve patient care and outcomes, as well as reduce costs.

The NHS still has a long way to go to reach the Government's ambitious target of making £22bn of efficiency savings by 2020, while at the same time modernising its IT systems. But, by gathering critical data trapped in silos and systems across the organisation, applying predictive analysis and making results available; clinicians, administrators, key decision-makers and healthcare practices can begin to lower costs and improve quality of life for everyone. ■

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