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# Healthcare in your pocket: the European Commission's approach

**mHealth allows the collection of real time data that can form the basis for evidence-driven care, enabling more accurate diagnosis and better treatment, and supporting better healthcare**

The European Commission is currently shuffling through the responses to its consultation on mHealth, in which it asked for help and advice on finding ways to use mobile devices to enhance health and wellbeing.

This will lead to a proposal from the Commission, due to be published in 2015, on what action – if any – it will take to unlock the potential of mHealth.

The consultation was launched in April 2014, against the backdrop that despite a phenomenal rise in the downloading of health and lifestyle apps, there are significant regulatory and structural barriers standing in the way of extracting the full potential that mHealth holds.

In particular, there is a need to bridge the huge gulf that exists between the rapid consumer uptake of health apps and the unpreparedness

of healthcare system to interact, or to act, on any of the outputs they generate.

Without this integration, mHealth will not fulfil the promise of putting the patient in control, giving greater independence, building self-reliance and helping with the management of disease, whilst at the same time making for more efficient healthcare systems, honed to extract greater value from scarce resources.

The correct structural and regulatory framework is also a prerequisite to enable companies to develop apps and services and to unlock the commercial value of mHealth.

There are around 100,000 mHealth applications, with the top 20 free health, fitness and sports apps having been downloaded more than 230 million times. It's not unusual for technology to run ahead of the regulatory and the legal framework, but given the ultra-high

level of oversight in all other aspects of health, consumer mHealth must represent one of the most run-away markets of all time.

At the same time, lack of clarity in regulation, reimbursement and how mHealth fits into existing care pathways, is keeping mHealth out of mainstream healthcare.

The question for the European Commission is if and how it should wade in with some form of regulation.

Looking across the Atlantic, the FDA has assessed developments and unusually for the agency, taken a laissez-faire view. In guidelines published in September 2013, the FDA said it would only regulate apps that turn smartphones into de facto medical devices. (See article on page 13)

As things stand in the EU, there is no demarcation of the point where life style and wellbeing apps cross over into medical devices. As the monitoring capabilities of smartphones advance, clarity and certainty is needed to protect the safety of individual users.

Paul Timmers, Director of the Sustainable and Secure Society Directorate, says it is not clear as yet, if the EU will need to legislate. (see interview on page 8). In any case, the Commission will need to bear in mind the recently updated Clinical Trials and Medical Devices Directives, and await final agreement on data protection legislation.

As is clear from the Green Paper that formed the foundation of the Commission's consultation, many of the issues around mHealth are not within its jurisdiction – in particular given that healthcare in a member state responsibility. However, the Commission wishes to act as repository of best practice and to help stimulate innovation.

While it draws breath on the legal and regulatory aspects, the Commission is taking mHealth forward with significant funding from the €77 billion Horizon 2020 R&D programme, which runs from 2014 – 2020.

As part of a €306 million programme, 'Personalising Health and Care' the Commission wants to fund pilots that will demonstrate the potential of personalised



medicine to respond to the increasing burden of chronic disease and managing the complexity of co-morbidities, and in so doing, show how personalised medicine contributes to the sustainability of healthcare systems. While mHealth is not mentioned specifically in the description of this topic, it could very obviously make a major contribution to its objectives.

'Promoting mental wellbeing in the ageing population' is another topic on which mHealth could make an impression, for example, in self-medication and compliance, and research to improve prevention and diagnosis of disease.

Similarly, a third topic, 'Understanding disease: Systems medicine', could draw on mHealth in its objective of pulling together biology and medical research data and computational modelling to underpin the development of new evidence-based treatments.

mHealth sits at the heart of a fourth topic 'Self-management of health and disease and decision support systems based on predictive computer modelling used by the patient him- or herself'.

As the topic description says, many medical problems could be prevented or better monitored and managed with the participation of the patient. In order to promote the self-management, predictive personalised models can be combined with personal health systems and other sources of data to raise individual awareness and empower patients to participate in the management of their own health.

# Can mHealth data improve patient outcomes?

Ahead of a workshop at the Gastein Health Forum, Gary Finnegan speaks to Paul Timmers of the European Commission's DG CONNECT



## Paul Timmers

Director of the Sustainable and Secure Society Directorate

It's crunch time for health data in the EU as the European Commission sifts through the mountain of responses received to its Green Paper on Mobile Health (mHealth). As policymakers weigh whether to introduce legislation on mHealth apps in 2015, key voices in the debate will descend on the European Health Forum Gastein to discuss how real world patient data can help to improve outcomes and reboot the drug development system.

One man who knows a thing or two about the nexus of health and technology is Paul Timmers. Having spent years knee-deep in eHealth policy before it was in fashion, Timmers is now Director of the Sustainable & Secure Society Directorate in the European Commission DG CONNECT, at a crucial time in the short history of digital health data.

Depending on your definition, there are literally tens of thousands of health apps, with new products emerging daily. Whether the EU should regulate this fast-moving field – and if so, how – are questions that will occupy the minds of policymakers, patients, academics and industry in the months ahead.

So what's the timeline? 'We will begin analysing the responses to the Green Paper later this year and then see proposals in the course of 2015. We are not saying there is definitely a need [for legislation],' says Timmers.

He added that the European Commission will wait to see the final shape of data protection legislation and the revamped medical devices directives before considering making any proposals to fill gaps.

'Possibly there will be a need [for legislation] but let's see the legal framework that is to come and then decide if we need to clarify how data protection will be applied in the mHealth area.'

The EU's proposed data protection legislation has come under fire from health research bodies, such as the Wellcome Trust, which fear that the new rules would require researchers to secure explicit consent (rather than general consent) from each patient and for every project using patient information. Critics say that general consent is more practical and argue that researchers who draw on large or historic databases will be severely hamstrung.

Timmers says the current proposal would allow medical research provided data protection is respected but acknowledged that the Commission is 'aware of the concerns'. 'It is possible that further clarification will be

required but we must wait and see,' he says, adding that the Commission is open to ideas on how to reconcile data protection and mHealth.

Looking to the positive, Timmers sees considerable promise in the explosion of mHealth apps to help patients and accelerate research, particularly in data-heavy fields like epidemiology.

As a rapidly evolving field, there is much experimentation with feeding mHealth data into electronic health records (EHR) to support chronic disease management, and exploring how real-time patient information impacts on new clinical pathways. 'New clinical pathways are emerging. It's still very much an experimental area that requires validation,' says Timmers.

Regulation aside, there is much that EU policymakers are doing to maximise the potential of mHealth. The new Horizon 2020 research mega-fund earmarks €60 million in

funding for mHealth this year alone and there is considerable effort going into supporting a fledgling digital industry that can be part of Europe's high-tech recovery.

And of course, there is the dull but essential bread-and-butter work of the EU – labelling, certification, standardisation and legal clarification – which can help to build a digital single market.

That the commission sees the potential for data-fuelled healthcare savings of close to €100 billion helps to make health data a win-win, provided it can be delivered in a way that respects consumers.

As the EU contemplates its next move and mHealth apps approach critical mass, the debate on how to make this work for patients is about to move up a gear.



**Green Paper on Mobile Health (mHealth)**

<http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth>

**European Health Forum Gastein**

<http://www.ehfg.org/detailevent.html?eid=79>

**DG CONNECT**

<http://ec.europa.eu/dgs/connect/en/content/dg-connect>

**Wellcome Trust**

<http://www.wellcome.ac.uk/News/Media-office/Press-releases/2014/WTP055581.htm>

**Horizon 2020**

<http://ec.europa.eu/programmes/horizon2020/en/>

## Transcript of interview with Paul Timmers, DG Connect



### What role will mHealth play in providing real-world patient data?

It brings the possibility of having real-time and real-world data – combined – which

is useful for personalised medicine. And on the other hand, it can also very likely bring benefits for epidemiological research, helping to identify patterns of impact.

### How can this be harnessed to develop new clinical pathways?

This is an evolving area. There is a lot of talk about new pathways in our planning around research and development. For example, feeding mhealth data into electronic health records to manage mental health or diabetes. New clinical pathways are emerging. It's still very much an experimental area that requires validation.

### What role can European policymakers play in maximising the potential of mHealth?

We have issued a Green Paper on mHealth and got quite a number of responses that are being analysed. In the call for expression of opinions, we have described a number of potential savings of nearly €100bn in healthcare costs that would be possible; and also the market development potential.

There is clearly a lot of economic activity behind this area and it's interesting for economic development and entrepreneurship. Through the consultation on the green paper we are asking what is the kind of policy development can be done in this field. We are asking what is the real added value in policy at EU level?

A lot of the action at present is on the research and innovation side. mHealth and personal health are part of Horizon 2020 which has a sizeable budget, and at the moment we have had dedicated calls around mhealth. This year's call has a budget of about €60 million. We hope to soon publish results of that call for proposals.

But the Green Paper not just about R&I, it's about labelling, certification and clarification of legislative framework.

The Commission's Green Paper on mHealth states that big data can contribute to 'the reduction of trial periods for medication' and 'the development of innovation business models'. Could you elaborate on what this could mean for how medicines are regulated?

Big data is addressed in a European Commission Communication published in July. Health is an area with big potential for working with big data but so too are other areas such as smart cities. We see economic potential but want to ensure that data are used in a proper way.

Looking more specifically at mHealth and big data, people are experimenting by looking at novel pathways to reduce [the length of] clinical trials. At the same time it's also true that existing clinical legislation is being adapted to provide more flexibility. Having a single set of rules for clinical research should make it simpler to have large scale clinical trials.

So on one side you have big data policy and on the other you have policy on clinical trials in general. In between is a degree of experimentation into clinical trials. All of this is conditioned by other legislation like protection of personal data.



## How might data protection legislation affect the potential of mHealth in this area?

We need to wait for future regulation on data protection to be adopted. Let's see how that moves and that will give a clearer picture. It's an opportunity to clarify guidelines. We have clearly asked in the Green Paper what are issues people see around data protection and mhealth. Possibly there will be a need [for legislation] but let's see the legal framework to come and then decide if we need to clarify how data protection will be applied in the mhealth area.

Have you been monitoring the debate on the impact of data privacy legislation on medical research where the Wellcome Trust, amongst others, expressed concern?

Yes, in terms of data protection and health research we know there is a lot of debate in the field. We think the Commission's current data protection proposal still allows medical research but the matter is still for political discussion. We have received a lot of feedback from the field about balancing and combining personal data protection with health research.

## How does this affect mHealth?

Data protection is highly relevant to mHealth. However, we need to wait and see (the final Data Protection Regulation). It is possible that further clarification will be required. We are aware of the concerns. We have been very open to inviting people to come forward themselves with ideas on how to clarify data protection and mHealth. How do you inform patients, in a simple way, what will happen to their data? We have consistently asked this question of apps providers? There is additional sensitivity in the health area. Consent should be explicitly given by individuals and must fully understand what they are agreeing to.

## How should mHealth apps be regulated?

It's too early to say. The Green Paper has been issued. There is an overview of the current legal framework in the Commission's staff working document. We are not saying there is definitely a need [for regulation]. First we must do the analysis and then any action will follow – but not before 2015.

## In the US, the FDA has taken a somewhat hands-off approach to vetting health apps. How does Europe's position differ and what are the implications of different approaches being taken on each side of the Atlantic?

There are differences but I'm not sure the US is more 'hands off'. If you take an app that replaces the EHR is it a medical device? Not in EU [but it is in the US]. We also have new medical devices directives coming and health apps are referred to in this legislation. It's not necessarily the case that there is a lighter approach in the US than the EU.

## What are the next steps in EU policy on mHealth and what's the timeline?

We've received responses to the mHealth Green paper and will publish these in the 4th quarter of this year. Then there will be debate and analysis on gaps, and a discussion about whether there is a need for additional action. We are focused on investment, support for research, entrepreneurship, guidelines and labelling, legislation – the whole spectrum is open. The analysis will begin later this year and you will then see proposals in the course of 2015.

### Green Paper on mHealth

<http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth>

### European Commission Communication

<https://ec.europa.eu/digital-agenda/en/towards-thriving-data-driven-economy>

### Wellcome Trust

<http://www.wellcome.ac.uk/News/Media-office/Press-releases/2014/WTP055581.htm>

### Commission's staff working document

<http://ec.europa.eu/digital-agenda/en/news/commission-staff-working-document-existing-eu-legal-framework-applicable-lifestyle-and>

# TEMPEST Mobile

## TEMPEST Mobile continues a study on electronic health (eHealth) in 28 EU Member States

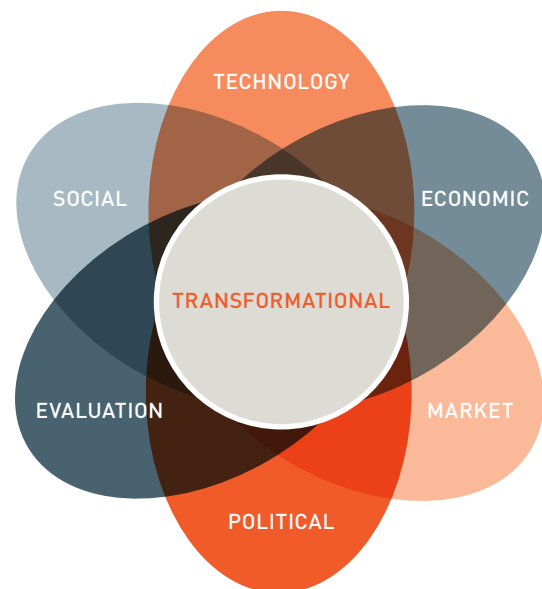


Wendy Currie

Using the TEMPEST database of over 150 quantitative indicators, TEMPEST Mobile uses comparative country data to benchmark mobile health or mHealth performance to allow policy-makers to make better informed decisions about the intersection between health policy and technology.

### Key findings:

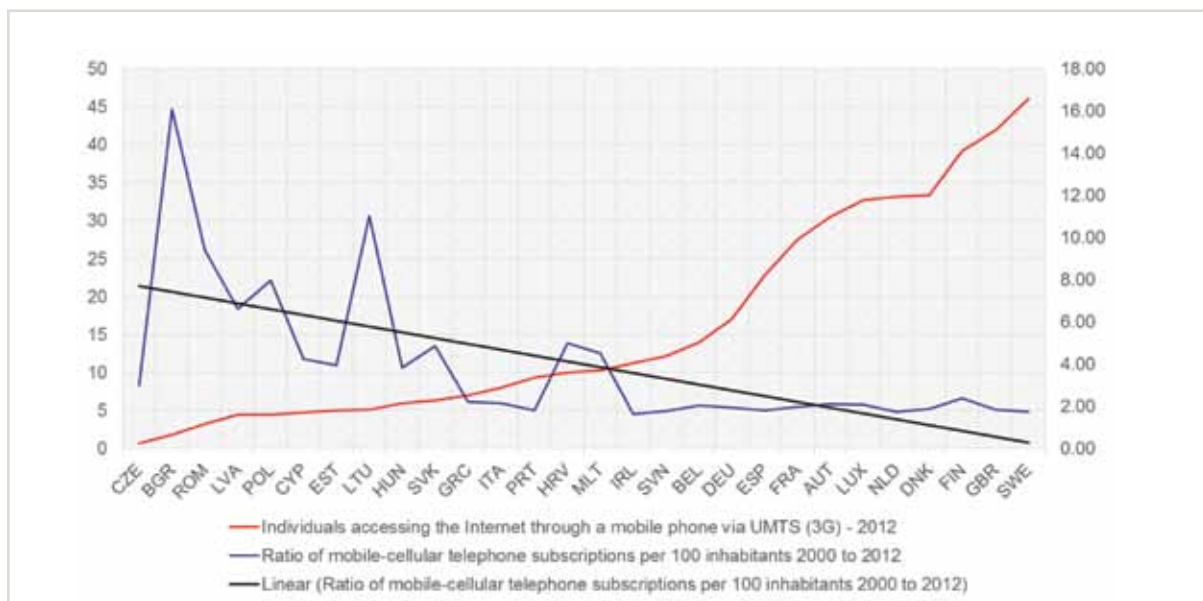
- Despite the large increase in mobile phone subscriptions in all EU Member States, there is a relatively low level of Internet usage among many EU countries
- There is a strong relationship between the growth in e-government and health expenditure which supports the development of mHealth
- EU Member States can be divided into frontrunners, followers, leapfroggers and laggards



- Against the continuing digital divide, there is strong evidence that some EU Member States can leapfrog conventional technology pathways by developing mHealth as a key part of their health system
- Four mHealth scenarios are identified: disruption, integration, commodification and transformation. For transformation to take place, mHealth apps need to improve quality and efficiency of care while also reducing cost.
- Our research suggests that timescales for mHealth to become more embedded into health systems will take longer than predicted, partly due to FDA and other regulatory interventions

The graph below highlights an interesting relationship between mobile phone subscriptions and internet access via mobile devices. The ratio of mobile phone subscriptions between 2000 and 2012 shows that some European countries have significantly increased their subscriptions in this period. However, an inverse relationship exists between the percentage of individuals

accessing the internet through a mobile phone and the number of mobile-cellular telephone subscriptions. As with our previous TEMPEST eHealth study (Currie and Seddon, 2014) where the overall leaders were Denmark, Sweden and the Netherlands, with Finland and the UK close behind, these findings show a digital divide exists in mHealth.



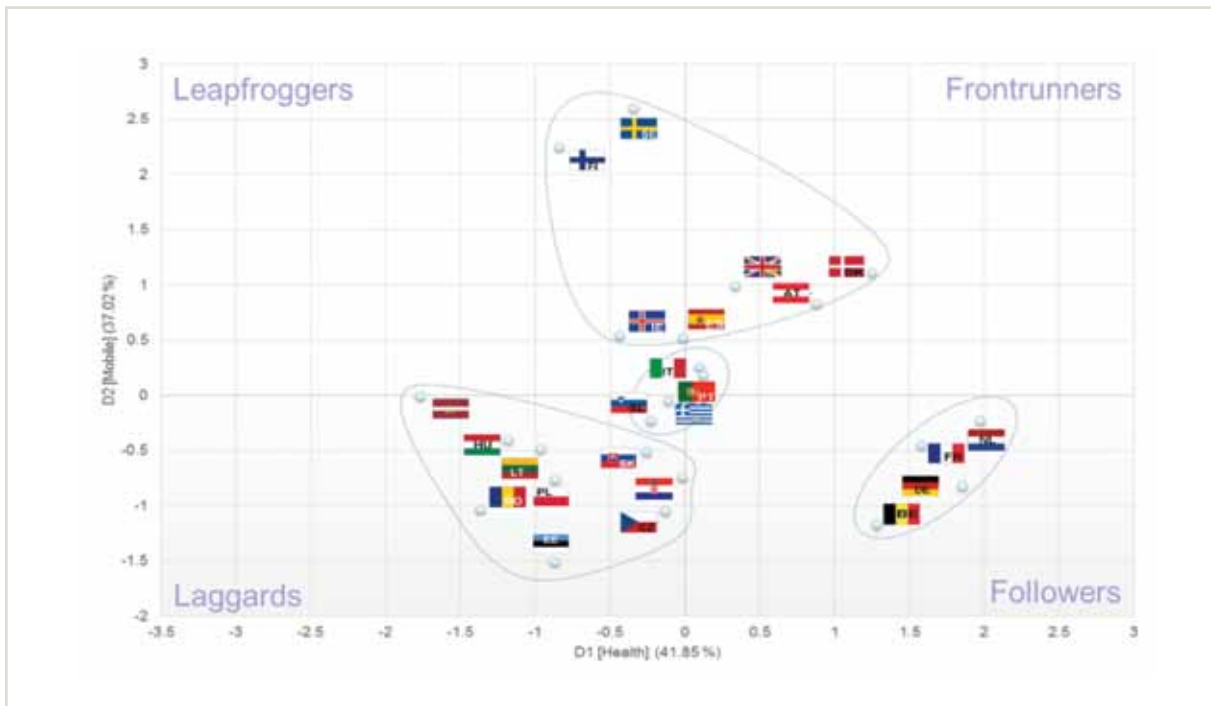
Source: Adapted from Eurostat 2012

## Frontrunners, Followers, Leapfroggers and Laggards

mHealth readiness is measured across 10 quantitative indicators capturing mobile and health data. This identifies the how the EU Member States can be divided into frontrunners, followers, leapfroggers and laggards. Frontrunners are strong in mobile and health measures, whilst laggards need to catch up. The followers tend to have strong health systems, which may be a disincentive to move to mobile. The interesting group is the leapfroggers. Our findings suggest that leapfroggers can bypass traditional technology pathways by developing and using mobile apps in everyday healthcare.

Mobile Health or mHealth covers “medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other devices”

Source: European Commission, Green Paper on mobile Health, 2014. p.3.

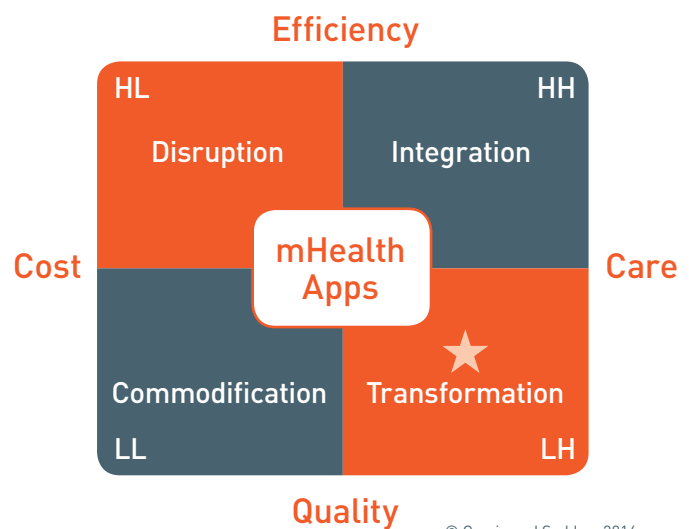


## mHealth Scenarios

So far, mobile health IT falls in three categories: 1) administrative health IT functions, 2) health management IT functions, and 3) medical device health IT functions (FDASIA, 2014). For administrative functionalities, such as billing, inventory management and scheduling, there is no external agency oversight. For health management functionalities, such as health information and data exchange, there is likely to be agency oversight if a product meets the statutory definition of a medical device. For medical device functionality, where mobile devices and monitoring technology poses a greater risk to patient safety, more stringent oversight will follow.

We identify four scenarios which will facilitate or inhibit mHealth adoption and diffusion. They include, disruption, integration, commodification and transformation. For transformation to take place, mHealth apps need to improve quality and efficiency of care while also reducing cost. This is the optimal scenario. However, most of the

100,000 plus mobile apps are currently focused around commodification which are low cost and offer citizens few benefits. Where mHealth apps offer higher quality, this needs to be weighed against other factors such as data privacy and security, as regulatory oversight needs to increase to protect citizens. mHealth further offers opportunities for integration of health and social systems, but this may also need to be balanced around cost implications.



© Currie and Seddon, 2014

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- FDASIA Health IT Report (2014) [www.fda.gov/MedicalDevices](http://www.fda.gov/MedicalDevices).
- Seddon, J.J.M. and Currie, W.L. (2013) Cloud computing and trans-border health data: Unpacking U.S. and E.U. healthcare regulation and compliance. *Health Policy and Technology*, December, Volume 2, Issue 4, December 2013, Pages 229–241.

# FDA sums up on mHealth: smartphone + health app = medical device

**The US Food and Drug Administration wants to encourage the development of mHealth, but is stepping in to regulate apps it considers make phones and tablets function as medical devices. To avoid harm, these must work as intended and not impair the performance of other devices**

It's not unusual for technology to run ahead of regulation, but in the case of mobile health (mHealth) the gap is remarkable. When the US Food and Drug Administration (FDA) set out guidelines on how it will oversee the market in September 2013, it noted there was already widespread adoption and quoted industry forecasts that 500 million smartphone users worldwide would be using a healthcare app by 2015.

This is considerable penetration in what is still an immature market, with half of a forecast 3.4 billion smartphone and handheld tablet users, including patients, healthcare professionals and consumers, expected to have downloaded a health app by 2018, according to the market analysts Research2Guidance.

The FDA has not taken responsibility for oversight of all mHealth apps in the US, but of software applications that in effect turn handheld wireless devices into medical devices. Its *Mobile Medical Applications Guidance for Industry* puts the focus on apps that "present a greater risk to patients if they don't work as intended" and apps that could cause smartphones or tablet to interfere with the functioning of other traditional devices that someone may be using.

"Some mobile apps carry minimal risks to consumers or patients, but others can carry significant risks if they do not operate correctly. The FDA's tailored policy protects patients



while encouraging innovation," said Jeffrey Shuren, Director of the FDA's Center for Devices and Radiological Health said when the guidelines were released.

In the guidance document, the FDA provides examples of mHealth apps that are not considered medical devices, those where it will exercise discretion and reserve the right to regulate, and those apps over which it will definitely have oversight. It refers to this third subset as mobile medical apps.



The FDA said when issuing the guidance a year ago, that the majority of apps fall into the first two categories. However, the increasing processing power of mobile devices, the growing bandwidth of WiFi networks and increasing maturity of the market could change this.

## The FDA definition of a mobile medical app

In the FDA's view, a health app becomes a mobile medical app when it turns a smartphone into a device that functions as an instrument for use in the diagnosis of disease, in the cure, mitigation, treatment or prevention of disease, or is intended to alter the structure, or any function of the body.

### This includes:

- 1 Mobile apps that connect to existing medical devices to display, store or analyse data, for example, providing mobile access to bedside monitors, or mobile apps that directly control a device, such as by activating an insulin pump to deliver insulin.

If a mobile app merely displays or stores data from a medical device but does not allow any manipulation, it is classed as a medical device data system and will be regulated as a class 1 device (Class 1 covers the lowest risk devices with the fewest regulatory requirements).

- 2 Mobile apps that control attachments, display screens or sensors, such as a blood glucose strip reader or electrocardiograph electrodes or a motion sensor for monitoring sleep apnoea, attached to a smartphone or other handheld mobile device.

- 3 Mobile apps that perform patient-specific diagnoses, or provide treatment recommendations, for example, image processing applications or radiation therapy planning.

In the middle ground, the FDA reserves the right to regulate – but says it intends to “exercise enforcement discretion” over mobile health apps that:

- Help patients self-manage diseases
- Help individual users in organising and tracking their health information

- Provide access to health information
- Help patients communicate potential medical conditions to healthcare professionals
- Automate simple tasks for healthcare professionals
- Allow patients and healthcare providers to access personal health records.

Mobile apps that can be used in healthcare or patient management, but which the FDA does not consider to be mobile medical apps and which it will not regulate include:

- 1 Apps that provide access to text, for example, medical text books, reference materials, medical definitions or translations of medical terms into other languages
- 2 mHealth apps for use as educational tools or to reinforce previous training of healthcare professionals. While they may have functionality in addition to reference material, they are not devices because they are education aids and not for use in diagnosis and treatment
- 3 Mobile apps for automating administrative tasks in healthcare, such as scheduling appointments, managing human resources and financial accounting
- 4 Apps that perform generic functions such as note-taking or allowing patients and healthcare professionals to communicate through email or other web-based protocols.

The FDA has set up a website listing medical apps it has approved and those for which it intends to exercise enforcement discretion.

The FDA has set up a website listing  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm368784.htm>



# Real World Evidence in Adaptive Clinical Trial Design

Report of a Policy Conference, Brussels, 17 September 2014



**John Crawford**

Healthcare Industry Leader, IBM Europe

Real world data hold the potential to improve drug discovery and development, speed access to market, improve patient care and make for more responsive and sustainable healthcare systems.

But while a number of projects and live implementations are pointing the way, there is much to be done at a policy and at a practical level, to pull the strands together and harness real world data to boost health.

The European Forum of Pharmaceutical Industries and Associations (EFPIA), represents pharma companies that invest a combined total of €30 billion per annum in R&D Europe. The Association wants to promote the use of real world data, to boost the productivity of this drug discovery and development machine, and also to increase the value its products deliver to healthcare systems and to patients.

To launch a broad debate on the topic, EFPIA brought together some of the leading experts, including regulators, clinicians, drug development specialists, eHealth entrepreneurs, members of health technology assessment bodies and policy makers, at a conference in Brussels. They discussed how real life evidence can be applied to improve clinical trial design, showcased best practice in capturing and utilising real life data, and considered how real time monitoring could enhance the patient/practitioner relationship.

## Real World Data: impact on research and policy

One of the most powerful drivers of real world data is the rise of mobile health apps. These allow the collection of data that can form the basis for evidence-driven care, but they also raise significant issues, including those of data protection, patient safety, liability, validation and the need for international standardisation.

The European Commission is currently considering how best to unlock the potential of eHealth, and **Peteris Zilgalvis, Head of Unit, eHealth and Well Being, DG Connect**, updated delegates on the latest thinking, as the work of analysing responses to a consultation on the matter progresses (See an overview on page 6 and read an interview with Paul Timmers, Director of the Sustainable and Secure Society Directorate, on page 8).

There are great opportunities to develop new creative products and services, and the Commission wants to create the correct framework, by encouraging cross-border coordination, improving the technical infrastructure, filling the skills gaps and helping to foster the trust that is needed to drive the market forward.



“We are keeping the possibility of legislation in the background. We may use it, but we want to allow the maximum leverage for innovation, whilst ensuring patient safety is not compromised” Zilgalvis said. “We want the same rules across the piece,” he added.

mHealth is mainly a bottom-up phenomenon and currently there is a gulf between the data that individuals collect on their own behalf and their official medical records. This raises the issue of how, and if, to make electronic health records and mHealth interoperate. Ideally, there could be access to electronic patient records to get feedback, for example to assess the benefits of a change in diet or lifestyle. “The question is, how to open up healthcare databases to these kinds of interactions?” said Zilgalvis.

Any regulation must be innovation-friendly, and ideally, the European Commission would like to see a system of self-regulation built around EU-wide guidelines.

Given that health is a member state responsibility, EU-wide guidelines would

still leave companies to deal with different national rules. It is hoped that the new EU Data Protection Regulation, currently in the legislative works, will mean harmonisation of issues such as where data is hosted.

The EU also has a memorandum of understanding with the US to work together on interoperability standards for mHealth, and Zilgalvis said any inputs to this effort would be welcome.

There are concerns that moving from a position where health records are held in one geographical location, to holding them in the cloud, will introduce vulnerabilities. However, the reverse may hold. Estonia’s national electronic health record system enables people to see who has access their data and when, and to complain if there has been inappropriate access.

This gives patients a greater level of assurance than is the case now, when they have no knowledge of who might have looked at records held in a general practitioner’s surgery, for example.



If there are challenges in changing the culture at a doctor/patient level, to allow for the integrated use of mHealth, there is a bigger problem in opening up the way for secondary use, to allow pharmaceutical companies, public health agencies and academic researchers to work with this data.

Giving people personal control of health data undoubtedly looks like the way forward. This is already evident in patient registries that have been set up by rare diseases patients' groups, to increase understanding of the natural history of a disease and make it easier to set up clinical trials.

In a recent study by the US based social media company Patients Like Me, 94 per cent say they are willing to share their health data. Whilst in the past that might have been too onerous, it should be possible to get consent electronically from pre-registered subjects. The process need take only five minutes.

## Culture and practice

While there is a way forward in terms of data protection requirements, consent and the transmission of data, there remain significant issues in terms of standardising content at an EU level, as **Hans-Peter Dauben, Head of the German Agency for Health Technology Assessment (DAHTA)**, reminded delegates. "There is not even a consensus on particular diseases, for example, the definition and treatment of hypertension varies from France to Germany," he said.

Even if everyone worked in English, this problem would still not be solved. "If you talk in English to doctors in the US, there is a complete mismatch, and it takes time to understand the differences," said Dauben. Meanwhile, a local attempt to set up a health technology assessment glossary stumbled because a word had the opposite meaning in Switzerland to its meaning in Austria.

"In other words, IT is not the solution: for me standardisation is not a technical issue, it is about culture and procedures," Dauben said.

Increasing understanding of the quality and content of data is one of the objectives of the Innovative Medicines Initiative 2's GetReal project, which has the aim of factoring real world data in drug development, as **Chris Chinn, VP and Head of Health Investment Evidence at GlaxoSmithKline and GetReal project coordinator** explained.

"For example, in discovery, when you are trying to understand a disease, and you think you have a mechanism of action and a drug profile, you can use real world data to understand how the disease is manifest and what the outcomes are with the current treatments," Chinn said.

While this can guide decision-making, the same clinical trials are required as before. At the same time, it is hoped that factoring in real world data will increase understanding of the effectiveness of a drug and provide information for health technology assessment bodies. The aim in GetReal is to understand to what extent real world data can inform relative effectiveness and comparative effectiveness, to deliver real time improvements. (For more on the GetReal project, see page 24).

GetReal brings together a consortium of 29 partners in pharma companies, academe and health technology assessment, including the UK National Institute for Health and Care Excellence (NICE). **Sarah Garner, Associate Director for R&D at NICE** and also project director for the CASMI (Centre for the Advancement of Sustainable Medical Innovation) Adaptive Licensing project, pointed to the "extreme difficulty" of translating research evidence from traditional randomised trials into recommendations for how a drug should be used (or not) in clinical practice.

"A lot of the time, clinical trial protocols exclude relevant groups, for example, the over 60s, those taking other drugs, people with co-morbidities," Garner said. "You are left to infer what will happen when you are in the real world."

<http://news.patientslikeme.com/press-release/patientslikeme-survey-shows-vast-majority-people-health-conditions-are-willing-share-t>

Factoring real world data into clinical trial design and interpretation may provide illumination, but only if it is correctly applied. In particular, with real world data you lose randomisation. For example, in clinical practice doctors are likely to give the newest drugs to the sickest patients. “This results in lots of noise and you can make the wrong choices,” said Garner.

Adaptive licensing is an approach to try to overcome this, by licensing drugs that are shown to be safe and to be effective in a limited patient group, and then using real time feedback to find out how the drug performs in practice, and expanding usage, if appropriate.

In the first phase, under Framework Programme 7, the Innovative Medicines Initiative 1 focussed on developing tools to make drug discovery more efficient. GetReal and other projects that are being set up under IMI 2 are more focussed on the whole life span of products.

“It’s not only a case of the data, but also the methodology and the tools IMI 2 aims to develop to make the most of real world data,” said **Nathalie Seigneuret, Senior Scientific project manager at IMI**.

IMI 2 is also widening its scope to involve mobile phone companies and other industries, and will concentrate on implementation. “We won’t finance projects that result in a [scientific journal] paper, and that’s it. We want implementation, and projects have to be aligned across discovery and development,” Seigneuret said.

## Showcasing the best practice in data capture and usage

The EU confronts its usual patchwork of regulatory systems, lack of standardisation and cultural diversity as it moves to adopt real world data. However, there are beacons of best practice and here-and-now data capture that can prove some signposts.

One example is the Clinical Practice Research Datalink (CPRD), which provides access to a vast volume of data held in electronic patient records by general practitioners in the UK. The anonymised data can be used for observational



**Sarah Garner**

Associate Director for R&D at NICE

studies and assessing feasibility, and tools are under development that will open up its use in interventional randomised trials.

The aim, as **Tim Williams, Head of Research at CPRD** explained, is to supplement clinical trial data with real world data. “You can get data on patients in your trial from before the trial, during the trial and in longer term follow-up, and they can be tracked,” Williams said. (For more information see the article on page 25).

Another impressive example of the power of real time data comes from Vanderbilt University Medical Center’s VigiVU, in which a desktop computer application for monitoring patients in the operating room has been ported to a smartphone and tablet platform, increasing the usefulness and flexibility of what was already acknowledged to be an important tool in protecting patient safety.

As **Brian Rothman, Medical Director of Informatics at Vanderbilt** told delegates, VigiVU provides anaesthesiologists with the full ‘situational awareness’ that they lack unless they are face-to-face with a patient. VigiVU delivers real life data on vital signs of patients under anaesthesia. It also streams a live video of the operating room. “You can be in the moment and define the next steps,” Rothman said. “I’m in one operating room now, which operating room am I required in next?” (For more on VigiVU, see page 26).



### Joel Haspel

Director Strategy and Business Development  
EMEA at Oracle Health Sciences

The goal is to improve outcomes by the proactive identification of any emerging problems, providing the opportunity to mitigate or eliminate an emerging deleterious event. This is not changing the standard of care or the level of direct human supervision.

If health information is sensitive, then so too is financial data. But while it is possible to get access to personal financial information from anywhere in the world, health information is all too often stuck in paper records that patients cannot access at all.

**Joel Haspel, Director Strategy and Business Development EMEA at Oracle Health Sciences,** gave delegates some sense of the difficulties of bringing the flexibility that is taken for granted in personal banking into healthcare, and of standardising health data for analysis.

It is like entering a darkened room he said. "You don't know how dirty it is, and even if you turn on the overhead lights, you can't see into the corners. It's only when you switch on the spotlights that you can see what needs to be done to clean up the data," Haspel said.

In the US, Oracle is not focussing on information silos, but rather taking a holistic view that integrates primary, secondary and tertiary level healthcare. The information could be used to identify patients that fit a clinical trial protocol. "You can see exactly which provider can give you access to which patients and you know when you are recruiting for a trial that you have the most up to date information," Haspel said.

Currently, Oracle's database gives access to six million patients, by the end of the year it will be ten million. "We are hoping to grow the number and make the system global," said Haspel. The company is in talks to extend data collection to Europe. "The clinical need is that the data is real time. We want to get people as they are diagnosed," he added.

A recent clear-out of the cellars at IBM uncovered a 1964 black and white film in which doctors at a hospital that had installed a (very) early IBM mainframe were asked for their thoughts on how it should be used.

“All the ideas we are discussing now – improving patient safety, decision support, clinical trial recruitment – were there then,” said **John Crawford, Healthcare Industry Leader, IBM Europe**. Since 1964, the volume of patient data has grown astronomically, and many countries now realise they have a fantastic resource which they are not exploiting. “Given this data exists, we should be obliged to use it to improve healthcare,” Crawford said.

As yet, no country is systematically re-using data in electronic health records. Meanwhile, the arrival of mHealth and web-based platforms means citizens can create and manage their own health data, and personal information of this type has become a new asset class.

In dealing with all of this data, analytics will be critical, especially in interpreting unstructured text records, which even if in an electronic format, are not machine readable.

IBM’s Watson system has the capability to digest and interpret vast amounts of unstructured data. It can, for example, read scientific journals, using the information to create and then test hypotheses, learning as it goes. Watson is currently under test in a number of healthcare settings. Commercialisation of the systems awaits the findings of these studies. “The feedback we are getting is that it augments the experience of doctors,” Crawford said.

Data protection and data security is rightly at the forefront of considerations when contemplating opening up individual access to electronic health records. It is possible to maintain confidentiality, as the national health information system in Estonia demonstrates. Patients and healthcare organisations use smartcards to access the system, and in ten years of operation there have been no major data leaks, said **Peeter Ross, Project Expert, Regional Telemedicine Forum, Estonia**.

Setting up the health information system was one element of a government move to computerise all its services. “Rather than installing an IT system for every ministry and agency, the government came up with the concept of installing a secure data exchange layer that connects different databases,” Ross said.

Data cannot be duplicated, but it is possible to check if someone has medical insurance, for example, by making a query from a hospital information system to the population register. This means that although there are silos of data such as health records, gene banks and e-prescriptions, it is possible to access them all simultaneously to create services.

Currently, the health information system contains more than 30 million documents, including diagnostic images, e-prescriptions and ambulance records. There have been some notable successes, for instance, only 2 – 3 per cent of prescriptions are still written on paper.

In terms of R&D, anonymised data is available for research and the environment for creating new services around the data is good. Ross said the engagement of citizens with their data is interesting in that there was a peak at the beginning when the system was launched, but now only around 4 per cent of the population regularly access their records. “It is not the data they are interested in, it is the personalised services that have been created,” said Ross. An example is the ability to get a medical certificate for a driving licence online.

For the future, Ross believes the data could be used to conduct online clinical trials that are both retrospective and prospective. It will be possible to do online monitoring of patients.

## Real time monitoring and enhancing the patient-practitioner relationship

Real world data is of interest to the pharmaceutical industry because of the potential it offers to make the recruitment and running of trials more effective, to move to adaptive licensing and to take a different, value-based approach, to the pricing of pharmaceuticals.

“It would be possible to make sure that those drugs that add the most value are the most-rewarded. This is not a new idea, but it is hard to make practical,” said **Richard Torbett, Chief Economist at EFPIA**. The prospect real world data opens up of being able capture outcomes data is very appealing. It will make it possible to replace existing price/volume agreements and open the way to new commercial arrangements, in which innovation is rewarded.



Through the Innovative Medicines Initiative, EFPIA's members are involved in projects, such as GetReal, that are relevant to this objective. Torbett said that in parallel it is necessary to draw up a roadmap for the next 10 – 20 years. The pharmaceutical industry spends €30 billion per annum on research in Europe and there needs to be a plan of action to get better leverage out of this investment, to help deal with the rising incidence of chronic disease and the illnesses of old age. "We are really interested in this area for the long-term and really interested in partnerships and hearing ideas," said Torbett.

As one particular example, he appealed for ideas on how EFPIA can extract further value from the European Medicines Verification System, currently being installed, which will verify each pack of medicines all the way across the supply chain, from manufacture to dispensing, with the aim of reducing theft and counterfeiting.

"This system is a huge investment, and it will generate an enormous package of information, opening up the potential for secondary use," Torbett said. One thought is that it could underpin new ways of promoting adherence, he suggested.

**Jack Bowman, founder and CEO of Handle My Health**, said that one way to improve adherence is to give patients ownership of their data. This grass roots engagement can be used to link adherence to outcome and to the patient experience. "You can get a true view of how they are responding to a treatment," Bowman said.

Once all of a person's data is aggregated in one place, it becomes actionable. In addition, it is possible for a doctor to fill in the gaps of

what has happened to a patient in the weeks or months since the last consultation. (For more on Handle My Health see page 27). At the same time, patients are empowered by being guardians of their data and information governance issues are overcome.

Similarly, Patients Know Best provides a tool putting patients in control of their health record and for information to be passed from patient to doctor in a secure environment. "This puts patients at the centre, with health and well-being under their control," said **Mohammad Al-Ubaydli, founder and CEO of Patients Know Best**. He added, "What people care about are the services; they aren't interested in the medical record, but in getting information out of it."

**Simon Gabe, Consultant Gastroenterologist at St Marks' Hospital, Harrow, UK**, who uses the Patients Know Best system as part of caring for patients with the rare disorder Intestinal Failure, agreed the crucial element of personal health records are the services that can be provided to help patients with self-management of disease and to enable them to ask questions easily if they have a concern. "It has to be usable at the front end," Gabe said. (For more on Patients Know Best see page 29).

Patients Know Best and Handle My Health provide important examples of how putting patients in control of their own health data can address information governance issues, give patients tools to manage their own disease and underpin a more collaborative relationship with doctors.

But the problem for **Leo Exter, Director of WeStartup**, is that they remain isolated examples. Things are not progressing quickly enough because there are not enough start-ups, people are not creating services that can be layered on top of electronic health records. "We want to enable more health start-ups," Exter said.

WeStartup has set up [healthstart.eu](http://healthstart.eu) as a forum to involve pharma companies, doctors and patients. Patients can express their needs and business models can be tested, Exter said, inviting delegates to visit and contribute ideas via the website, [www.healthstart.eu](http://www.healthstart.eu).

# Standardisation for real world data must focus on culture, not technology

**The hurdle in making real world data available for research and for use in drug development is not dealing with the technical complexities but with the information content. And who is responsible if the data are wrong? asks Hans-Peter Dauben**



## Hans-Peter Dauben

Head of the German Agency for Health Technology Assessment (DAHTA)

The hardest part of attempts to strengthen the links between drug development and health technology assessment, is not in how data is transmitted, but in its content.

“There is not even a consensus on diseases, for example, the definition and treatment of hypertension varies from Germany to France,” said Hans-Peter Dauben, Head of the German Agency for Health Technology Assessment (DAHTA).

As the pioneer of health technology assessment in Germany, setting up DAHTA in 2000, within the German Institute of Medical Documentation and Information (DIMDI) and having worked at an EU level for the past decade to scope information system principles with regulators and pharma companies, Dauben points to a need to improve knowledge management in evidence-based healthcare systems.

But in health, the compilation of common descriptions, metadata and ontologies, is made very complex by the information content. One project to draw up a health technology assessment glossary encountered a word in Switzerland that had the opposite meaning in Austria.

Even if everyone used English the problem would not be solved, as the different disease descriptions used in the US illustrate. “We have many cultures and the question of how

to handle this is difficult,” Dauben said. “For me, standardisation is not a technical issue, it is about cultures and procedures.”

In Germany, work on harmonisation to allow access to health insurance data had to take account of differences between the country’s 16 Lander (states), and was also influenced by the discussion taking place at an EU level.

The project began in 2010, taking two years to collect information from the insurers, check it and overcome any errors, before then moving on to deal with standardisation. “Before we could offer the data as a resource for science it was 2014. We want to improve on this,” Dauben said.

Even given rules for standardising content, there will inevitably be times when errors or inconsistencies in making records mean real world medical data are incorrect. “Who is responsible if the data are wrong? How can you be sure the correct data are entered?” Dauben asked. “When people see it coming out of a computer, they assume it is correct.”

For example, using automatic blood pressure monitoring devices, rather than the traditional manual cuff, can create an experience gap. Trusting the device may lead to a lack of insight on the part of young doctors.

In broad terms, the technical aspect of using real world data in clinical development and marketing authorisation is the easy part. “But you have to have behind it cultural understanding and intelligence tools,” Dauben concluded.

# GetReal to improve decision-making in discovery and development and speed market access



## Chris Chinn

VP and Head of Health Investment Evidence at GlaxoSmithKline and GetReal project coordinator

The €16.3 million, three year Innovative Medicines Initiative project GetReal represents a concerted effort by the pharmaceutical industry to develop new approaches to incorporating real life data into drug discovery and development. It is hoped this will not only inform decision-making in development, helping to reduce attrition, but also provide information for health technology assessment bodies and commissioners, to speed market access following regulatory approval.

“In discovery the aim is to use real world data to get a better understanding of the disease, how it is manifest and what the outcomes are with the current treatments,” says Chris Chinn, Vice President and Head of Health Investment Evidence at GlaxoSmithKline. “When you think you have a mechanism of action and a drug profile, real world data will give you enough information of sufficient quality to guide internal decision-making. But you still have to do the critical experiments,” says Chinn, who is the coordinator of the GetReal Consortium.

Using real world data may improve the chances of demonstrating efficacy in a set of clinical endpoints in controlled circumstances and getting regulatory approval. It is also hoped that factoring real world data into development will provide insights into how effective a drug will be in clinical practice, when it is subject to the preferences of doctors, the guidelines of different healthcare systems, and at the mercy of patient compliance.

It could be that the relative effectiveness of drug is greater in clinical practice than in the controlled trial – or it could be less. The gap

opens up or closes because of the way in which patients and physicians behave, and because of random events.

“What healthcare decision makers get before launch is efficacy, but what they want is effectiveness: How will the drug do in my healthcare system?” Chinn says.

GetReal aims to bring the effectiveness “mindset” into drug development. The project is analysing existing HTA methodologies and processes to inform the development of a decision-making framework to assist in designing trials that capture real world effectiveness data – including relative effectiveness – during clinical development, rather than once a drug is on the market.

Factoring real life data into clinical development is not something pharma companies can do unilaterally, and GetReal plans to develop relative effectiveness decision support for other stakeholders. The project involves HTAs as partners, with the R&D team at the UK’s National Institute for Health and Care Excellence, for example, co-leading one of the work packages and contributing to four others. NICE is one of the 29 partners involved in the public/private consortium.

GetReal will also establish a forum for industry, academics, regulators, HTA bodies and patient groups to share insights and build a consensus. It is recognised that to break new ground in applying real world data to provide pre-market understanding of relative effectiveness, all the stakeholders must agree on the methodology and have the skills and expertise to apply the tools. Given this, the projects will put significant effort into training.

“All the pharma companies involved on the GetReal project are interested in understanding how real world data can help us understand effectiveness,” Chinn said.



# Capturing the value of the real world data held in medical records



## Tim Williams

Head of Research, Clinical Practice Research Datalink, MHRA

While there is widespread recognition that electronic health records represent an important source of real world data, it is far from straightforward to marshal and organise this information and make it accessible for research.

Apart from the technical challenges of IT systems and standards, and the costs involved, there are the significant data privacy issues to be overcome.

The UK Clinical Practice Research Datalink (CPRD) provides an active a model of best practice in data capture and usage that can help inform efforts to unlock the potential value of health records.

To give one example, the single point of access that the CPRD provides to electronic health records made it possible to pinpoint all the patients fitting the inclusion criteria for a particular clinical trial in two hours.

That's not the same as recruiting them of course, but the CPRD also has a relationship with a recruitment broker who interacts with general practitioners to identify patients and invite them for pre-screening and possible recruitment.

The CPRD was officially launched as an eHealth research service in March 2012, as part of the government's Plan for Growth, to give researchers better access to National Health Service data and to attract more clinical trials to the UK. All the data are anonymised and patients can opt out if they choose.

However, as Tim Williams, Head of Research at CPRD explains, the service traces its roots back

to 1995. In total, it now has access to more than three billion records and a database of 12 million current patients. "The CPRD has a lot of experience in large health databases," Williams said.

In observational studies, this makes it possible to overcome any discrepancies and inconsistencies in how data were recorded. "For example, doing a study using observational data in diabetes, the data may not be perfect, but if you can look at 200,000 cases, it becomes an effective tool. You know the data may be wrong in a few cases, but you can deal with this statistically," said Williams.

The CPRD also represents a gateway between electronic health records and investigational trials, with the potential to allow real world data to be factored into drug development. "The whole point is being able to supplement clinical trials data. We can get the data on patients in a trial, from before the trial, during the trial and in longer-term follow-up, and we can track them," Williams said.

Although there is no operational connection, the CPRD is co-located with the Medicines and Healthcare products Agency. This gives CPRD access to the expertise of the UK drugs regulator, whilst at the same time enabling the MHRA to develop new surveillance methodologies for monitoring real world safety, effectiveness and benefit-risk relationships.

Since the launch in 2012, CPRD has been working to enhance its services. It is soon to make available a new tool, TrialViz, which will open up the data to enable trial sponsors to find out if there are enough subjects in a given area to make a trial feasible. "This is in response to the question 'Can you use the data for feasibility studies' that we keep getting asked by pharma companies," said Williams.

# Showcasing the best practice in data capture and usage – anaesthesiology

**No one can be in four places at once. But the VigiVU smartphone app provides ‘situational awareness’ that enables supervising anaesthesiologists at Vanderbilt University Medical Center to be in the right operating room at the right time**



## Brian Rothman

Medical Director Informatics,  
Vanderbilt University

As Medical Director of Perioperative Informatics at Vanderbilt University Medical Center, Dr Brian Rothman has to move between different four operating theatres, assessing patients and advising colleagues before, during and after surgery.

A smartphone app VigiVU™, developed at Vanderbilt, not only delivers real time information on the status of each patient – both in terms of their vital signs and the stage of an operation – but also a live video feed of the operating room. This keeps anaesthesiologists up to date with exactly what is happening where, building ‘situational awareness’ and allowing a more proactive response to any change in circumstances.

The VigiVU™ app is a mobile version of an earlier system, Vigilance™, also developed at Vanderbilt, which delivers data to a fixed workstation. “It’s obviously more convenient to get information on a smartphone, rather than referring to a computer on a desktop,” Dr Rothman says. Transferring the functionality of Vigilance to the VigiVU™ mobile app, gives me more flexibility and freedom of movement.”

The instant access to patient data increases the ability to fully oversee their care. If a problem looms, the supervising anaesthesiologist can immediately communicate with staff in the operating room, to put in place corrective measures whilst on the way to give hands-on care.

## Prescience

Complementing the access to patient data and updates from colleagues in the operating room, the video pictures of the procedure further increase awareness of exactly what is happening. “When I look and see a dressing being applied, I know the patient will soon be ready to be brought round,” says Dr Rothman. “This helps me to be there before anyone needs to call me.”

Colleagues compliment Dr Rothman on his prescience, remarking on his tendency to turn up just before they page him. While VigiVU™ is not replacing any staff or functions, it does make for greater efficiency and best use of his time, Dr Rothman believes. “My care providers know what they are doing, but I can keep an extra eye on things.” VigiVU™ helps in managing workflow and letting anaesthesiologists know where and when they need to be physically present.

## Patient safety

The anaesthetic complication rate during surgical procedures at Vanderbilt University Medical Center is too low to power a clinical study to quantify VigiVU™’s contribution to improving patient safety.

However, Dr Rothman cites one example, where a patient who had been stable for hours suddenly developed low blood pressure after a carotid rupture (which was unrelated to the procedure). “I looked at the video and from all the activity I knew something was wrong and should go down there. Sometimes with critical events, staff don’t have time to notify anyone,

they have to attend to the patient,” Dr Rothman says.

To date the VigiVU™ app has been available to anaesthesiologists only, but it is about to be released to all Vanderbilt’s surgeons. “They have been asking for it. Anaesthesiologists mostly worry about what is happening in the operating room. Surgeons on the other hand, need information about how patients are both before and after performing a procedure in the operating room,” says Dr Rothman.

While – as yet – there may be little solid evidence, his experience using VigiVU™ has convinced Dr Rothman that real time data makes it possible to enhance care.

“The best way to improve outcomes is to be proactive, identifying conditions and opportunities to prevent or mitigate problems. With VigiVU™, I have a better chance of knowing about something being wrong as it happens, instead of reacting after the event,” Dr Rothman concludes.

## Real Time monitoring and enhancing the patient practitioner relationship – Handle My Health

**People are handling much of their day-to-day business and many of their social interactions through smartphones and tablets. Now these covetable consumer items and must-have apps are set to become an important tool for managing chronic diseases**



### Jack Bowman

Founder and CEO of Handle My Health

In addition to significant computing power, smartphones and tablet pcs are always on, providing the necessary communications channels, the convenience and the user familiarity to turn this technology to a new purpose, in helping people to manage long-term conditions, such as diabetes, cystic fibrosis and HIV.

Handle My Health was set up in 2012 to develop a mobile health technology platform, Handle My Health: MIAMI, around which other providers are creating apps that support one-to-one personalised healthcare across a range of chronic disorders. “The model is for Handle

My Health: MIAMI to adopt the Facebook approach for healthcare, where the patient owns and controls their data,” says Jack Bowman, the company’s founder and CEO.

These services help with treatment adherence, including compliance in taking medication that can be so important in managing a long-term condition.

In addition, Handle My Health users can make personal observations of how their illness affects them from day-to-day, creating a detailed longitudinal record.

“Beyond improved self-management, Handle My Health: MIAMI plugs the data gap that exists in all healthcare systems,” Bowman says. Normally, patients share information with their doctors in an episodic manner, seeing them every 6 – 8 weeks,

say. Care is based on how a patient presents on the day. “There’s a lack of real world, real time data and the doctor doesn’t really know how you’ve been between visits,” Bowman notes.

## Long-term view

For example, a patient with cardiovascular disease may have high blood pressure because of the stress of having to get to an appointment. Their doctor can look at the longer-term trend as recorded, stored and uploaded from the Handle My Health: MIAMI platform, and see that over time blood pressure is under control.

This promises not only to improve patient care and patient safety at an individual level, but also to bolster the sustainability of healthcare systems. The pressure health systems face as a result of the rising tide of long-term conditions are replicated world wide. “People are living longer and being diagnosed earlier, which will put a massive strain on healthcare services. Preventative models of care need to be put in place and the must be better management of patients with chronic disease,” says Bowman.

As currently structured, health care systems are in “firefighting” mode. Patients get treated when they have an exacerbation. “With mobile health patients can be in control, it gives them more self-confidence,” Bowman says. As a result, their condition is better controlled and they stay healthier for longer.

Although mobile technology and the power of real time data present a compelling proposition, the uptake in health has been slow. In part this is due to rigidities in health systems, which are slow to adapt and incorporate mHealth applications into their care pathways. In Europe, most healthcare is paid for through statutory services or public insurance schemes, and providing patients with desirable consumer apps is incompatible with this.

## Fragmented consumer markets

From the consumer end sales are being driven by a large catalogue of health, fitness and life style-related smart phone apps, but to date the market has been very fragmented. That is about to change, with companies such as Google, Apple and Microsoft making a coherent pitch for the mobile health market.

“This is fantastic from an awareness point of view. The marketing power of these companies will make people aware you can address health issues through smartphone apps,” Bowman says. It’s not clear as yet how this will play out, because it will still be necessary to bridge the gap and integrate personal mHealth applications into healthcare systems to get the full benefits.

Another major – and growing – obstacle is the continuing concern about data protection, privacy, integrity and security. Handle My Health addresses these issues with the highest level of security for storage and transmission of data, and by giving users ownership of their own data and complete control of with whom it is shared.

The Handle My Health: MIAMI platform remains in pilot mode. However, there are 150,000 users who have downloaded a range of apps that are relevant to the management of chronic obstructive pulmonary disorder, Type I diabetes, mild cognitive impairment (dementias), HIV, epilepsy, asthma and depression. The company is working with a number of academic and clinical partners running randomised trials to gather evidence of the benefits, both in terms of helping strained healthcare budgets stretch further, and improving care and outcomes.

“The key is personalisation,” Bowman says. “This empowers patients, helps them understand their conditions and gives them better control over time. And the real time data that is collected means the doctor can treat the patient not the disease.”

Rather than perceiving an illness as a barrier to any progress, patients can collect detailed data of what they can do, and set their own targets for improvements, incentivising self-management.

Regulatory pathways and reimbursement also present hurdles to the mainstream deployment and scaling up of mobile apps, and are an issue across Europe as a whole. However, health care providers are well-aware of the need to move to more preventative care. “It may take longer than elsewhere in the world, but this model will become mainstream in Europe,” Bowman concludes.

# Real world data puts your health in your hands

**Clinicians may have the medical knowledge, but patients have the practical experience. Patients Know Best puts individuals in control of personal medical records, helping to improve day-to-day management of their disease and enabling health systems to provide integrated care**



## Mohammad Al-Ubaydli

Founder and CEO of Patients Know Best®

## Simon Gabe

Consultant Gastroenterologist at St Marks' Hospital, Harrow, UK

The way healthcare is organised currently, an individual's information is spread around different record systems – with the general practitioner, in files at Accident and Emergency, the X-ray Department, the Pathology Lab, or in any one of the information silos in individual outpatient clinics.

"The data is all over the place and often the patient is the last to know the result of a test or consultation," says Mohammad Al-Ubaydli, founder and CEO of Patients Know Best, a social enterprise which provides a web-based system enabling people to take control of personal health records. "This places patients at the centre and puts health and well-being under patient control."

Patients Know Best was born of the fruit of personal experience. Al-Ubaydli himself has a long-term illness and the need to make appointments with different clinicians, manage his medication, and coordinate his care, led to the insight that patients do indeed know best, in the sense that they have all the personal experience.

Over years of receiving treatment, Al-Ubaydli noticed clinicians were relying on him to know important information. "This was not because I trained as a doctor myself, but because I was the only one who turned up to all the appointments," Al-Ubaydli said.

That led him to set up Patients Know Best in 2007, providing a highly secure medical version of

Facebook, where all records can be centralised and kept up to date and patients can decide who gets access to what data.

Evidence is accumulating that putting patients in control in this way improves the quality of care of patients with chronic and rare diseases. In one example, giving inflammatory bowel disease patients the ability to track their symptoms using Patients Know Best has reduced the number of flares, resulting in fewer visits to Luton and Dunstable National Health Service Foundation Trust's Accident and Emergency Department.

Although some in the medical profession may be resistant to giving individuals control over their records, in fact it improves the level of interaction clinicians have with their patients, says Simon Gabe, Consultant Gastroenterologist at St Mark's Hospital, Harrow, UK, who runs a clinic treating people with Intestinal Failure.

This is a rare condition for which there are only two specialist centres in the UK. "We look after 300 patients, who live around the country and in other countries. Patients Know Best enables us to interact with them in a fantastic way," Gabe said.

Patients get direct access to test results, often before their GPs will have had time to process them, and can pose questions directly to their specialist. "They can interact as easily and as often as necessary; patients also find it useful to have access to other healthcare professionals, such as dieticians and nurses," said Gabe.

For patients, the crucial element is not the health record per se, but the services that are layered on top. "What patients care about are the tools that help them manage their condition. They want to get on with their lives, not be obsessed with health data," Gabe said.

# A pocket diagnostic for Parkinson's Disease

**With smartphones now able to record movement, activity, location and voice they can become diagnostic devices in their own right. Researchers in the UK have started a 2,500-subject trial in which mobiles will test for Parkinson's disease**



## Dr Max Little

Aston University's Nonlinearity and Complexity Research Group

There's an arresting example of the power of real life data in the work of mathematician Dr Max Little, who is developing a novel diagnostic for Parkinson's and other neurodegenerative diseases, based on voice, gait and reaction analysis of data collected by smartphone.

Smartphones are capable of making digital voice recordings of such high quality that the recordings can be analysed to pinpoint minute changes in speech patterns that are indicative of Parkinson's disease.

At the same time, the accelerometer in a smartphone that tells the device which way up it is, can be used to pick up abnormalities in gait that are one of the hallmarks of the disease. A smartphone can also be used to record reaction times, which again can be slowed by Parkinson's disease.

Dr Little of Aston University's Nonlinearity and Complexity Research Group has developed algorithms for analysing this type data as the basis of a Parkinson's disease diagnostic.

The development is important because of the difficulties of making a definitive diagnosis of Parkinson's disease in its earlier stages. Even once diagnosed, it is difficult to make objective measurements of the symptoms of the disease, meaning there is no quantitative information around which to base treatment decisions.

"The questions this leads to both from a technical point of view and the challenge of getting quantitative data, are, is there a technique to get objective measurements and if so can you get them more cheaply than having an MRI (magnetic resonance imaging) scan at a big centre?" Dr Little said.

Little was first drawn to look at voice analysis after getting access to a large database of recordings of people who had been diagnosed with Parkinson's disease. The initial algorithm he wrote in 2006 to analyse this data had 86 per cent accuracy in diagnosing Parkinson's disease versus healthy controls.

This inspired further effort to improve the method and Dr Little now claims 99 per cent accuracy.

At the same time, Dr Little has developed a way of assessing gait. The accelerometer in a smartphone works by detecting the force of gravity enabling the device to sense which way up it is. "So it can also measure the forces acting on me when it is my pocket," Dr Little said. Recording and analysing data from a 20 paces walk test gives 98 per cent accuracy in distinguishing people with Parkinson's disease from healthy controls.

The technologies that are out there in terms of hardware, algorithms and machine learning techniques are now sophisticated enough to diagnose Parkinson's disease before overt symptoms are manifest, Dr Little said, presenting his work at the British Science Festival at Birmingham University in September. The diagnosis could be performed on the smartphone or the data downloaded to a central server for analysis.

It also becomes practicable to score symptoms on standardised clinical scales. This will inform the development of new treatments for Parkinson's disease and is a prime example of how real life data can improve clinical development. In addition, the information can be used to objectively assess the extent to which the disease is progressing, and in prescribing treatment.

The smartphone diagnostic is very accurate in separating sufferers from healthy controls. Now Dr Little is embarking on a 2,500 patient trial to see if it can distinguish Parkinson's disease from other pathologies that cause similar symptoms, and if it can pick up early, subtle, symptoms of Parkinson's disease.

The trial at Oxford University, will involve people diagnosed with Parkinson's disease, people who are known to have a genetic predisposition to Parkinson's but are not suffering from the disease, and a third group of people that are exhibiting symptoms, such as sleep disturbances, that are possible indicators of Parkinson's disease.

"We want to see if the technology can detect the disease before it is diagnosable by standard techniques," Dr Little said.



# BETTER SCIENCE, BETTER HEALTH

New Trial Pathways and  
Better Patient Data



Royal College of Physicians, London, October 21st, 2014  
(VIP dinner October 20th - **by invitation only**)

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- How can Europe proceed in the implementation of new development pathways and evidence generation to improve the access of needed new therapies to patients?
- What are the current best practices, successes, and opportunities for the integration of patient data and analytics to improve patient outcomes and identify new medicines?
- How can IMI2's efforts and programmes under Horizon 2020 help European patients and healthcare providers?

#### KEYNOTE SPEAKER:



**George Freeman**  
Parliamentary Under Secretary  
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