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Making a Roadmap for Mobile Health

The GSMA mHealth Grand Tour - an epic 2,100 km bike ride from Brussels to Barcelona - demonstrated how mobile health solutions can help people living with diabetes

A GROUNDBREAKING MOBILE HEALTH COLLABORATION

On the GSMA mHealth Grand Tour, more than 100 cyclists participated in a 2,100 kilometers bike ride from Brussels to Barcelona, climbing 22,000 metres on route. The largest one-off research study of endurance exercise and Type 1 diabetes ever undertaken, the Tour enabled industry experts and researchers to closely observe how athletes, both amateur and elite, living with diabetes were able to manage their condition using the latest mobile health technologies (see Clinical Results on page 5). The Tour was orchestrated by the GSMA, in association with the International Diabetes Federation, European Region, under the patronage of the then European Commission Vice President Neelie Kroes.

Riders wore a continuous blood glucose monitor (a Dexcom G5) and heart rate monitor, while their bikes were equipped with sensors to track the distance travelled, height gained, time taken, rest periods and other metrics. These sensors used the ANT+ wireless technology to transmit data to a Sony Xperia smartphone, enabling the tracking of blood glucose levels, heart rate and cycling statistics. NFC-enabled weight scales wirelessly transmitted data to the Sony handsets before and after the day's riding. Crucially, the collection of data required no specific input from the riders, enabling them to ride without stopping frequently.



**Connected
Living**

The sensors also used ANT+ to transmit data to a machine-to-machine (M2M) module, which relayed the data to servers in the Orange Health Cloud via Orange's mobile broadband network (see Figure 1). The Orange Health Cloud enabled families, clinicians and other authorised individuals to view the data on a web portal provided by McCann Health. The ability to see and remotely track blood glucose levels via the web was a world first.

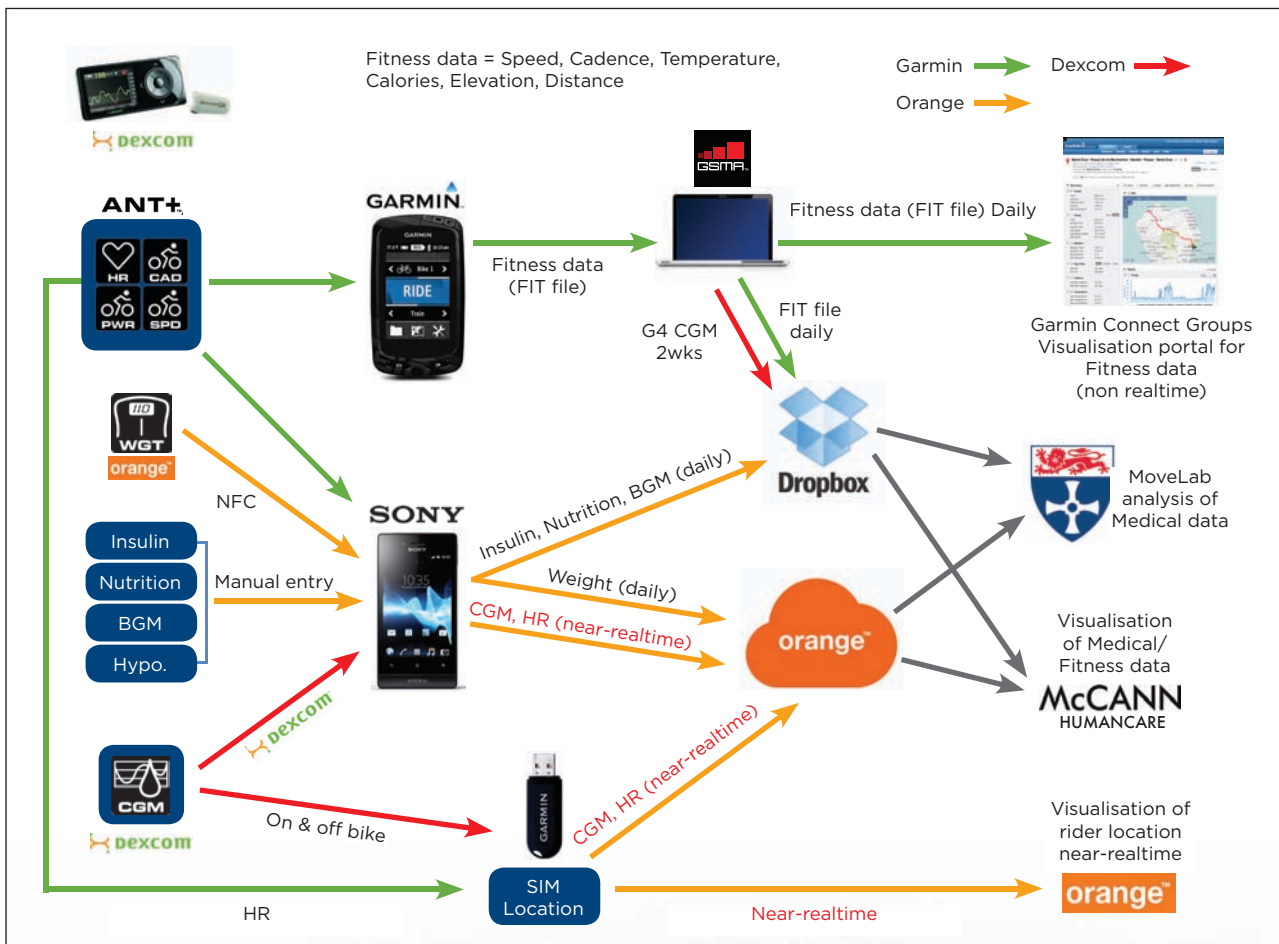


Figure 1

The solution was developed by a partnership of the GSMA, Orange, ANT+, Dexcom, McCann Health, Newcastle University and Sony Mobile using software that complies with the Continua Health Alliance interoperability guidelines.

“The GSMA organised the Grand Tour to showcase how end-to-end mobile health solutions, underpinned by partnerships between mobile companies and healthcare specialists, could bring about a step

change in the way we manage chronic conditions, such as diabetes,” says Jeanine Vos, Executive Director of the GSMA’s Connected Living Programme. “The Tour generated valuable insights that are helping industry players, healthcare professionals and policy makers to better understand the huge socio-economic opportunity and market demand for these solutions, and the importance of appropriate policies that support investment and deployment in the near-term.”



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Lessons learnt from the Tour

Consumers **need and want automated solutions**

Held in September 2013, the Grand Tour showcased how a wireless monitoring solution can help the growing number of people living with diabetes to better manage their condition. In Europe alone, 55 million people have diabetes, according to the International Diabetes Federation.

If not managed effectively, diabetes can lead to severe and costly complications, including cardiovascular disease, renal failure and blindness. The person with diabetes, family members or carers are typically responsible for the management of the condition, which can be very challenging.

People living with diabetes need to monitor their blood glucose levels and then make therapeutic decisions, such as taking insulin or eating, to keep these levels within a normal range. Blood glucose levels can be affected by a range of factors including insulin use, food eaten, exercise, mood and stress. However, exercise can lead to dangerous fluctuations in blood glucose levels, prompting many people living with diabetes to avoid exercise altogether, meaning they miss out on the many health benefits.

The most effective way to mitigate the risks presented by exercise is to monitor blood glucose in real-time or near real-time. On the Grand Tour, alarms on the

continuous glucose monitors alerted riders when their blood glucose levels were dropping. Without these sensors, the diabetic riders would have had to stop frequently and take a traditional lancet and test-strip glucose reading, creating a significant time burden.

“I had never seen continuous glucose monitoring prior to the Tour,” says Nenad Šimunko, an endurance athlete living with diabetes from Croatia who completed the ride. “I was blown away. The Dexcom monitor worked really well – I could see my glucose blood volumes almost in real-time. I have never stopped using it since. I don’t have to think about it. I can’t imagine returning to the old system. To be effective, you would need to take eight to 10 measurements a day, which creates financial stress.” When Mr. Šimunko completed a triple Iron Man event in 2012, he took 60 blood glucose measurements in the 51 hours it took to complete the 7.2 mile swim, 336 mile bike and 78 mile run.

“I have explained the continuous glucose monitoring to my friends with diabetes and, for those who can afford to buy it, it is a new story for them, a new way of living,” adds Mr. Šimunko.

Lessons learnt from the Tour

Remote monitoring provides an **important safety blanket**

Ideally, people living with diabetes should log and share their blood glucose data with healthcare professionals and others with diabetes who could help them interpret the data and turn it into useful information. However, this process has typically required cumbersome equipment and wired connections.

By contrast, in the Grand Tour, the data was transmitted automatically and wirelessly to the Orange Health Cloud, enabling team managers, families and friends to view it online. The data also informed a clinical study designed by Professor Michael Trenell of Newcastle University (see Clinical Results on page 5). Professor Trenell says the remote monitoring system used in the Tour supported riders in four key ways. “We could connect patients to other patients, we could connect patients to care teams, we could connect patients to ideas (new ways of thinking) and we could connect patients to families and important others.”

Rather than just tracking information, the solution enabled the riders to engage with that information. “It enabled us to communicate what is going on,

relieve anxiety and enable people to have informed conversations,” says Professor Trenell.

The Tour also highlighted the commercial demand for remote monitoring. Jacob Leach, Vice President of Research and Development at Dexcom, says: “In something as rigorous as the Tour, the diabetes sufferer is concentrating on riding the bike and isn’t necessarily thinking about their glucose levels, so we had the web system watching over them and it could contact the care giver, if need be. Most of the riders commented that they couldn’t have done the Tour without the glucose monitors. It acted as a safety blanket for the riders.”

In time, endurance athletes with diabetes are likely to make routine use of remote monitoring so that trainers, team managers and physicians can see their health data in real-time, enabling them to advise the athlete or provide instructions. “With continuous glucose readings you can predict where the athlete blood glucose is going,” says Mr. Leach. “So a physician can warn a rider: In 10-20 minutes, you’ll need to eat some carbohydrate. Professional riders don’t have remote monitoring yet, but they will have it soon.”



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Lessons learnt from the Tour

Clinical results: Learning from elite athletes with diabetes

During the 2013 Grand Tour, 28 of the riders participated in a clinical study of the effects of multi-day endurance exercise on blood glucose levels designed by Professor Michael Trenell, NIHR Senior Research Fellow & Director, MoveLab, Newcastle University. Eight of these 28 participants were professional athletes with Type 1 diabetes, 10 were sub-elite athletes with Type 1 diabetes and 10 were amateur athletes without diabetes. All 28 cyclists wore wireless continuous glucose monitors two weeks prior to the ride and during the ride.

The study found that the methods that high performance athletes with Type 1 diabetes use to manage their diabetes may provide real life examples of how to perform exercise and optimise diabetes control. The recreational athletes with Type 1 diabetes had higher interstitial glucose levels during exercise, in recovery from exercise and during sleep; and experienced more hypoglycaemic events than elite athletes with Type 1 diabetes. Elite athletes with Type 1 diabetes had interstitial levels of glucose comparable or better than people without diabetes during exercise, in recovery from exercise and during sleep. The study concluded that the stability of interstitial glucose levels in elite athletes with Type 1 diabetes provides valuable practical insights on how to optimise glycaemic control during exercise in non-elite patients.

Collaboration and partnerships across sectors are essential for success

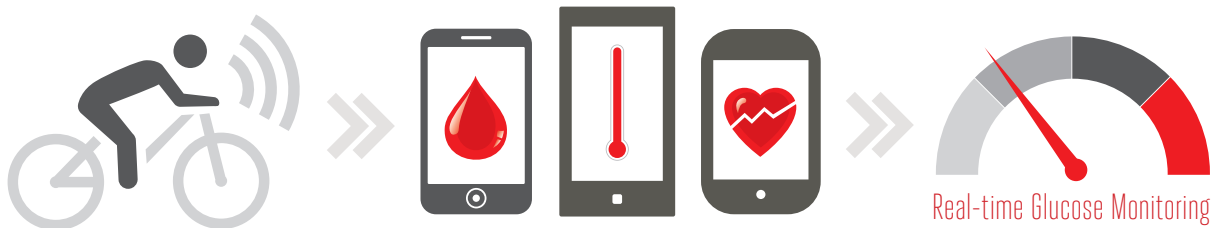
A pioneering cross-sector partnership, the 2013 Grand Tour provided a live test bed in which multiple companies and clinical specialists could work together to refine a wireless monitoring solution. For example, healthcare equipment maker Dexcom worked in partnership with mobile operator Orange to create an app that pulled in data from Dexcom's sensor, enabling the riders to monitor their blood glucose levels on their smartphones or on a web portal.

"When working with telecoms companies, we saw the different skill sets different companies can bring to the table," says Jacob Leach at Dexcom. "Whereas we are experts in glucose monitoring, we didn't know necessarily how best to collect and post the data on the Internet."



Since the 2013 Tour, Dexcom has further refined the app, before launching a commercial version for Apple's iOS operating system at the end of 2014. An Android version is set to follow. As well as enabling the user to monitor their own blood glucose levels, the app can be configured to send a notification to a care giver if certain parameters are met.

Although Dexcom had already been developing the app, the lessons learnt from the Tour and Orange's input played a key role in determining the ultimate shape of the solution. "The Tour helped us solidify some of the decisions we had made," notes Mr. Leach.



For Orange, the Tour also provided important information, insights and contacts. “It got us in touch with a lot of stakeholders in the diabetes sector,” says Benjamin Sarda, Head of Marketing at Orange Healthcare. “We have created very good relationships with the International Diabetes Federation, med tech manufacturers and pharmaceutical players. We were able to test all the pieces together. While each technology is great on its own, integration is the challenge – you can get a lot of technical issues,” he adds. “The Tour was an open innovation platform providing honest and real-time feedback.”

The Tour helped Orange to hone its Connected Health Centre - a secure data exchange and aggregation platform for hosting telemedicine services in compliance with local regulations.

Importance of interoperability and common standards

Although many existing mobile health solutions are standalone and proprietary propositions, an interoperable, standards-based ecosystem of personal connected health devices is beginning to emerge, which will enable people to choose the solution that is right for them, without being restricted to equipment from a single vendor.

In the Grand Tour, the use of the Continua Health Alliance standards enabled the seamless connection of devices from different manufacturers and the subsequent transfer of data directly to the cloud. The use of standardised interfaces and data formats in the Tour significantly reduced the required development time to weeks, rather than months, according to Orange. Standardisation can also help generate economies of scale as they have done in the mobile industry. Some healthcare systems, such as those in Denmark and Norway, have adopted the Continua standards.





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Progress since the Grand Tour

A high profile event supported by Neelie Kroes, then Vice President of the European Commission, Xavier Trias, the Mayor of Barcelona, and Eddy Merckx, five times Tour de France winner, the 2013 Grand Tour generated considerable publicity for mobile health solutions.

The Tour was featured in 496 unique articles, as well as being the subject of coverage on the BBC, Tele2 and Catalan TV. The media coverage has helped fuel both supply and demand for mobile health solutions for managing diabetes, in particular, and chronic conditions, in general.

For the participating companies, the Tour served as a marketing

platform, as well as a technical test-bed. "The Tour helped to

position Orange as an end-to-end solution provider – an integrator," says Mr. Sarda. "We hadn't been perceived to have been providing an end-to-end solution, but providing SIMs/cloud/hosting is less than 20% of what we do in this space."

Building on the positive impact of the 2013 Tour, Orange will again be partnering with the GSMA for the

2015 edition of the mHealth Grand Tour, which will run from Brussels to Geneva via Paris in September 2015.

The mHealth Grand Tours provide valuable insights into how people with different levels of experience respond to real-time data, notes Adam Denton, Director of Hydron Events and organiser of the 2013 Tour. "As the riders learnt to use the technology, they got much better at managing their condition," he says. "They become better at keeping themselves in the sweet-spot. Initially, people can over-react to a reading, making major adjustments to what they are eating or their insulin intake – they start chasing it,

so their readings start to go all over the place. The more experienced people make minor adjustments, eating one jelly baby, rather than a whole packet, or taking one unit of insulin, rather than three."

"As the riders learnt to use the technology, they got much better at managing their condition."

Mr. Denton said the people who rode in 2013 learnt a great deal about how to manage their diabetes, further enhancing their athletic performance.

How policy makers and regulators can help

The Tour highlighted how mobile health technologies could help clinicians to cost-effectively monitor chronic diseases, such as diabetes, moving healthcare systems on to a more sustainable footing. As well as giving patients more control and reducing stress, mobile health solutions can help healthcare providers to capture valuable data that can be used to refine future treatments.

Professor Trenell of Newcastle University says the Tour demonstrated how mobile health solutions can give patients the information they need to make decisions themselves. "We will see great improvements in the quality and efficiency of patient care through the use of mobile technologies," he predicts. "There is a tremendously rosy future ahead of us. We are on the cusp of a step change in healthcare in which we will be empowering patients in the way they should be empowered."

However, that rosy future depends on the mobile health sector overcoming a number of regulatory barriers. "You are spanning multiple regulatory authorities that are not all aligned and so you have multiple hoops to jump through," says Professor Trenell. "The regulatory environment is not really moving at the pace we need it to. It is wrapped in cotton wool and although there is a need for that to protect people's data, we also need innovation."

Whereas the mobile industry is accustomed to launching new products and services and then refining them over time, the medical technology industry doesn't work that way. New devices, services and solutions can take years to gain regulatory approval.

There are a number of measures governments and multinational bodies, such as the EU, can

take to enable their citizens to benefit from mobile health. In addition to increasing clarity and legal certainty in the areas of data protection and the application of medical device regulation, these include developing policies that support integrated patient-centred chronic disease care, supported by appropriate reimbursement policies based on health outcomes.

Tour organiser Adam Denton says regulatory constraints meant the riders and their support teams in the 2013 event couldn't make use of the full functionality of the wireless monitoring solution. "European regulation meant we had to blind the data to the phone, so the delivery to the Internet was delayed," he says. "We were intentionally making the solution worse."

However, experts say there is an ongoing cultural shift in the medical and clinical care community. "They are increasingly acknowledging the role that mobile health services can play in managing chronic diseases," says Professor Trenell. "That means regulators are having to think about it – they are consulting the community on the way forward."

Mr. Denton says the planned 2015 event is likely to gain regulatory approval for near real-time uploading of riders' blood glucose levels, suggesting European regulators are increasingly keen to see mobile health solutions progress.

If you would like to join the 2015 edition of the mHealth Grand Tour as a partner, supporter, supplier or team, please contact Jeanine Vos at jvos@gsma.com

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