The Ideal Process for Launching Your Medical Device in the UK: Interview with Michael Branagan-Harris, CEO of Device Access UK

Michael Branagan-Harris is the CEO of Device Access UK and has been involved in the marketing of medical devices to the National Health Service (NHS) for the last 27 years. Products he's commercialized range from simple wound dressings to the introduction of the Lap Band for obesity, endovascular graph repair, endo-laparoscopic surgery, and the DaVinci robot.

Since incorporating Device Access UK in 2010, Michael and his team have helped over 180 medical device and diagnostic companies navigate their way into the NHS. Their clients range from small start-ups to large multinationals from across the world.

In 2014, Device Access was granted a commercial license from NHS England to access over 750 million pseudonymous patient health records. This data allows Device Access to examine diagnosis, procedure, and spend data nationally by NHS hospitals, and in turn enables them to do three things:

1. See how their client's technology could affect the current patient pathway.
2. Assist in building a value story with the National Institute for Health and Care Excellence (NICE).
3. Develop a solid business case for local and national NHS Hospital adoption.

In this interview with Mike, here are some of the things we're going to cover:

- What has changed since my last interview with Mike 4-5 years ago, especially as it pertains to the NHS, NICE, and the National Innovation Center (NIC).
- The current and significant need for medtech innovation in the UK.
- The biggest mistakes medtech companies make when commercializing in Europe.
- The ideal process medical device companies should follow when launching their devices in the UK, including Mike's PICO framework and Connect4 Methodology.
- Mike's thoughts on Brexit and what it means for medtech in the UK.

Scott Nelson: Mike, welcome back to Medsider.

Michael Branagan-Harris: Thanks, Scott, it's good to be back. It's been a few years since our last discussion. I hope people are interested in hearing what has happened in the last five years, certainly in our healthcare system.

Scott Nelson: I think they will for sure, especially as it pertains to European commercialization for medtech companies there in the UK. We'll start with our last conversation that we recorded

back in 2011 or 2012. Can you help us understand a little bit about what has changed over the past four or five years, especially as it pertains to NICE?

Michael Branagan-Harris: Absolutely, yes. There are going to be a lot of acronyms in this interview, so I just want to make sure that everybody knows what we are talking about. First, we have the National Health Service, which is our publicly funded healthcare system. It has been around for decades, and it is publicly funded, meaning that we get healthcare provided through paying tax and it is free at the point of care. So it is a nationally funded healthcare system.

You mentioned NICE; the National Institute of Health and Care Excellence (NICE) is a body that is funded by the UK Government that is put there to assess and understand the benefits, the risks, and the economics around new medical technologies and diagnostics. When I am talking to individuals in America, I always describe NICE as being similar to J.D. Power, the consumer report organization that tells you which kinds of Jeep to buy or Chrysler to buy. NICE informs the National Health Service on best practice and best use of technology.

In our last interview a number of years ago, we talked about the National Innovation Center, which is now no longer in place. It was changed and swallowed up by some other organizations within the National Health Service. About five years ago the National Health Service Commissioned NICE to do some new programs around the evaluation of medical technologies and diagnostics, and those two programs were designed to help promote the uptake of new innovative technologies for the benefit of the NHS and patients.

This was quite exciting because before then there were only two programs that were available to look at medical devices. One of them only looked at safety and efficacy of a new invasive procedure, and the other one was an older program, which is still running for pharmacological products, and evaluates technologies around cost effectiveness and qualities.

The approach used by NICE has changed significantly. What we have now is a couple of excellent programs, which can evaluate products and diagnostics and medical technology. Their evaluations can result in an announcement from NICE to the NHS and to others about adopting new technologies encouraging their use. It is very powerful when they mentioned the branded products as well, because they actually evaluate single-name technology through these new programs.

Scott Nelson: That is a great recap. You've got the NHS, which is still the same governing body as before, and then you've got NICE, of course. I think the analogy that you used is a great one in the sense that it serves as the J.D. Power, or consumer report, informing the NHS on what technologies to adopt. But the one major organization that has changed is the National Innovation Center, which is no longer in place. Now you've got new programs that have, in conjunction with NICE, taken its place.

Michael Branagan-Harris: Absolutely. The other thing that has changed, as it has in many healthcare systems, is that we are in a situation where we have a massively growing elderly population. Back in 2014, there was some work commissioned that the NHS needs to build 22 800-bedded hospitals by 2022. That is a lot of hospitals, a lot of beds, a lot of staff, and it's a lot of cost.

Month on month, year on year, the NHS is under increasing demand, and it either has to build the hospitals, or it has to adopt new technologies. I don't think there is a better time than now for companies considering O-US activities to look at coming to this country to help solve problems with very clever technology designed out in the US. The opportunities have never been better.

Scott Nelson: That's a great point because I think a lot of folks, especially in pure play medtech companies, look at commercializing in Europe for a couple of reasons. One is to establish a regulatory pathway in hopes of potentially commercializing in the US. Or secondarily, something that Ted Lamson the founder of NeoTract mentioned in a recent interview, is they don't have another choice due to the FDA environment at the time. Then as it turned out, it behooved them to commercialize in Europe because it helped them mature in their commercialization strategy and helped them prepare for an eventual launch in the US.

But you are bringing up a third point, which I think is valid, and that there is a huge existing need to fill in the UK to build all of these new hospitals to serve the elderly population. So a lot of medtech companies, if they just viewed commercializing in the UK or in Europe through those lenses to serve that existing need, that would be a good potential business to commence there. Would you agree?

Michael Branagan-Harris: It is, absolutely. I've worked with over 200 companies now, which is a lot of products and lots of therapeutic areas. We have worked extensively in some areas, but I can't think of a single part of the body that we have not worked on in terms of a product. The opportunities are here to come and develop the clinical evidence and to get products established and create value along the way. It is so important when you are a startup company to be able to demonstrate to the investors and others that you are making progress and you have key milestones along the way.

I work with a network of reimbursement consultants from across the world. I've got somebody that has just relocated recently to Los Angeles who's going to be helping me, and I have people in Australia and people in Berlin — literally all over the place. Most medtech companies consider Germany and the UK markets first when they look at making some sort of global progress, and there are benefits. With Germany, there are great places and great places to go, and they have a very clever reimbursement system there.

One of the examples, and I know you just mentioned NeoTract, if you look at the NHS and the UK Healthcare System compared to the German one, one of the benefits of having something like NeoTract done is that you can have it in an ambulatory settings. That means you come in,

you have the under local, and you go out, and you don't take up a bed, you don't take up much OR time. It's quick, it's easy, you avoid the risk of problems in a hospital because you're in and out so quickly.

Whereas in Germany, they actually encourage patients and the system to be in hospital for at least an overnight stay and that doesn't make sense from a productivity perspective. I think you'll agree in the US as well, that the ambulatory office-based procedures are a growing area. Because it means that the doctors are more productive and the drivers are different. So I think that you have to consider that. So what is the benefit to the healthcare system? It might be that the incentives are different in each country. So you need to really work on how to gather the evidence around each of those scenarios to build a value story and a value to your business.

Scott Nelson: Yes, that makes a lot of sense. Mike, you work with a ton of early stage medtech companies in order to help them begin to commercialize in Europe and really, the broader globe from that perspective. You are pretty well known in the space, and a lot of early stage medtech companies come to you, and you see them follow this traditional process that's sort of laden with mistakes. It's not the ideal process to follow, and it ends up looking like they're trying to put a square peg in a round hole, so to speak.

Can you tell us a little bit more about the process that you see a lot of medtech companies following that isn't really the best pathway to go with?

Michael Branagan-Harris: I think the biggest problem is about not considering reimbursement. It's as simple as that. It's almost like saying, put another way, you can go into a country as an illegal immigrant, you can go with a visa, or you can go with a full passport, and the same thing happens as far as reimbursement is concerned. You might be able to think that you can go so far without getting reimbursement and having a clear pathway. You can get limited reimbursement, which is like a visa, or you could go for full reimbursement, which is like a passport. I think it is the same analogy, really.

The biggest mistake is companies manufacturing products, putting prices on them, getting them to markets, and then assuming that these countries are going to be able to buy them within the structure of the reimbursement systems. Certainly, within the NHS or the UK system, most of the time there are ways that you can get things paid for. But you have to consider pricing as well, and how pricing could change considerably between markets. That can have a big difference to a company strategy if the drivers are so different. So there is that to consider as well.

It's like designing a Lamborghini, or something like that. It is like making a very expensive car, but trying to sell it in one of the poorest parts of Africa as opposed to going to Monaco. Where is the money going to be? How easy is it going to be for that country to buy that product? There are so many assumptions made about what the healthcare system needs and how much they will buy. It is really about understanding activity and how to get a product paid for and importantly, what evidence you need to get that product paid for.

One of the mistakes made is the assumption that NICE might necessarily need very long, extensive randomized controlled trials because, in a number of new programs, you actually don't. So people can be put on the wrong journeys, and they can spend a lot of time in areas they don't need to. The best thing to do, and it's open to possibilities for this, is to come and talk to NICE and come and talk to other NHS bodies and ask them what they need, and then deliver what they've asked for, as opposed to assuming what the healthcare system wants in order to get reimbursement.

Scott Nelson: Going back to these assumptions, hearing your Lamborghini analogy and why you wouldn't build a Lamborghini for the poorest parts of Africa, that seems fairly basic, right? It is like business 101. But, to your point, so many medtech companies miss this part. Do you know why that is the case? Or do you have any speculations as to why so many of these medtech companies miss that mark and why they don't take the step back and consider these long term ramifications with respect to reimbursement?

Michael Branagan-Harris: The biggest consideration is that the world has really changed. The days of being able to turn up and sell something without somebody going into the detail of why they would want to buy it and how is it going to be paid for, are no longer. There is a big focus on marketing and on regulatory, but there doesn't ever appear to be that much of a focus on pure market access and reimbursement. Globally, there's a big gap of knowledge here, and although we're an extremely busy consultancy, there are not that many people to go to.

With the US healthcare system, reimbursements involve what the doctor can earn for doing a procedure and how the insurer will pay for it. It's a different system here. The drivers are so different, and I think maybe sometimes there are these assumptions that it's the same sort of thing, but it's not. I often describe a National Health Service doctor and the New York Fireman as being very similar people. Both are paid a salary, and both don't carry a business card.

So if you go to a New York fireman and say to him, "How many fires did you put out yesterday?" "I put ten out." "How many did you put out today?" "I've put 15 out." And say, “Gosh you did really well. You've earned lots of money today," that's not the case. That's exactly what an NHS doctor is as well. So whereas in America, doctors are re-enumerated by doing multiple procedures, multiple diagnoses, multiple treatments and they earn many through that mechanism of activity, it doesn't apply here.

There are so many differences, and I think that is partly why people make mistakes because of these assumptions that you can turn up and go to places and just sell, but it is difficult. At the same time, the difficulty in getting things into the system here really pays off. If you get your device approved, certainly through one of the NICE programs, you have an absolute global impact and they know it because it’s probably the most respected HGA in the world.

I was recently over at AdvaMed in Minneapolis talking to many medical device companies and one of them as far away as Brazil said that they want NICE approval because it's going to help

them get products into the hospitals in Brazil. It is wide and far reaching. So yes, it's difficult now, but it requires a highly specialized area. Reimbursement and market access are brand new recognized skills.

Scott Nelson: This market access function is becoming so important, not just in the UK, but in the US as well. It is a cross between traditional functions, like regulatory, clinical and reimbursement. But market access is almost like a combination or culmination of all three, especially for medtech companies that are in their early stages.

I love your analogy of the New York City Fireman versus the NHS physician. That's a really good way to help us understand for those that aren't familiar with the European or the UK health system. Having said that, let's presume that I am a CEO of an early stage medtech company and we've got early stage investment and the slate is clean, I am not carrying a lot of baggage.

Can you walk me through the process that you would ideally like to see medtech companies follow as it pertains to getting NICE approval within the UK?

Michael Branagan-Harris: We offer a number of different packages to help companies in the space, and the important thing is we spend a lot of time trying to understand, first of all, what problem this medical device is going to solve in our healthcare system. If you can focus on and work on the problem itself and trying to address it with the technology, you run a higher rate of success of getting a product into the system as you would in any healthcare system.

But we have something available in this market, in NHS England for sure, that isn't available to my knowledge in any other healthcare system in the world. That is that we have access to episodes of care from the NHS database. That's when any patient that goes into an NHS hospital in the last four yearsm we have their activity in a database. The activity is split up into several different buckets, but primarily, if you go into a hospital, then your basic information is recorded; your age, sex, how you went into the hospital, was it a general admission of was it an emergency admission? So we know how patients got into the hospital. That's all recorded.

Then we have information about patients age and sex, and the reason for being there, so that primary reason for admission, as well as any comorbidities as well. So for example, you could be in the hospital because you broke your leg, but you could also have high blood pressure and be diabetic. So all of that information is recorded. Then all the treatments a patient has are recorded, where they went regarding care, what treatments they had, and it could be a primary treatment, and it could be all secondary treatments as well.

So we have a laterality, we have levels of spine data, we have open laparoscopic, endo-image guidance. All the information is recorded, and at the end of the episode of care, you have the amount of money that that episode cost also available. So we as a company have access to 750 million episodes of care going back four years, and we're able to look at them to see where a medical device could make a change to a patient pathway. So we can look at patient pathways on an individual patient basis and see what would happen if they have a new therapy, a new

medical device, or a new diagnostic is used. What difference does it make on a local and national basis?

We use that information to then build a proper strategy to help companies to then engage with the NHS, and particularly NICE, and show them the population data. Now, what we talk about is the language of which we call “PICO”; P for population, I for indication, C for comparator, and O for outcome. So population is the population of patients the product is going to be used for, or the population of patients with the actual diagnosis of a disease or a problem. The population is critical, and I will come back to that in a second.

Indication is what your device does, how it works, and how it solves the problem. C is comparator; so what happens at the moment in our healthcare system, and how are those patients treated? We know all about this patient because we can extract the data from our database and examine how patients are treated in the NHS English hospitals. The O is outcome; what is the difference between the current therapy and your new technology?

We look at this information, critically at this early stage, to try and see whether there is a valid case for a technology that would have a successful entry into the NHS as well as looking at reimbursement analysis to see whether the technology can fit into the current reimbursement programs that are available, that it actually fits into the current coding that’s in existence. Because it’s quite difficult to create new procedure codes at the moment.

So that is the criteria that we use. We spend a lot of time understanding the company's products and working out and being able to see, by looking into this database, how a product could make a difference and what ultimately will be beneficial to the patient. Is it going to reduce the length of stay? Is it going to reduce readmission? Is it going to reduce complications, infections, time in intensive care? We can look at all sorts of pieces of information.

Then we look at the system’s benefit. What would the hospital or the NHS as a whole benefit from a new technology? We talked about varicose veins on the call several years ago; 11 or 12 years ago there was probably in the region of 40 odd thousand bed days associated with varicose vein surgery. Now there are a couple of thousands. This is a technology that's brought this benefit and opened up capacity in our over-crowded hospitals.

So we can go into this information, and we can find how the technology would benefit the hospital in reducing length of stay and freeing up capacity. We can then use that information in those two parts of the story to support the organizations that fund the hospitals for the activity and be able to help them understand the benefits of funding these new products and technology.

Then after we’ve looked at all of that, the other important thing is, is it worth the company coming to the market in the first place? Is there enough money left on the table for a profitable and progressive and value-based company to grow and expand internationally through the hard

work that will be done? I don't know if you know the game called Connect 4, it's a board game that is played at Christmas time.

Scott Nelson: Yes, absolutely.

Michael Branagan-Harris: So you have the four in the rows, the winning strategy of four in a row is patient benefits, hospital benefits for performing the procedure, payer benefits for paying for the procedure, and the last one being the company benefits for all the hard work getting the product to market. So that's the Connect 4 we often talk about when I talk to clients.

A lot of research about the current patient pathway, seeing how patients are treated, and looking at real numbers and being able to apply methodologies to say, "Okay if we put the device into this scenario, what would the benefit be to the system, and to the patient, and to the payer?" I don't know of another healthcare system in the world where you are able to do that. So because of this work we've done, and certainly helping multiple products go through NICE over the last few years, we're very fortunate to be able to work with this incredible database to help companies formulate a strategy around how to get the product into the market here and how to take the products successfully through the NICE programs, or any of the research programs that are available here as well.

Scott Nelson: I love the PICO framework. Is that something that you coined there at Device Access?

Michael Branagan-Harris: No, I am not going to be credited for that one. The Connect 4 is one of mine. But PICO is a methodology that is a nice framework to think about when you're engaging the NHS, and certainly with NICE. It's a language that they use. They're straight to the point; they're not interested in the glossy literature. Who's the population? You need to know if you're coming into the market, what that population is. Coming to the NHS and stating a problem faced by John Hopkins University is not going to apply in our healthcare system.

But if you were to come in and better articulate the real numbers of the cases and number of patients and what those outcomes are like, it is a far more powerful way to introduce a product. This information that we are able to work in has been often presented and published as well. I can give you another example of a situation. We were working with a wound care company, and we wanted to understand pressure ulcers. They are very common in hospitals across the world, but we wanted to try and understand what was the number one reason for admission into an NHS hospital that led to a pressure ulcer?

So we extracted every single episode of pressure ulcers, which is recorded in the patient's notes. It isn't necessarily recorded when they come in because they don't have pressure ulcers when they come into the hospitals. They might just come in with something else and while they are recovering, developed pressure ulcers. So we extracted all the information, and we reversed it to find out what was the number one cause of a pressure ulcer, and it's actually

pneumonia. If you come into a hospital with pneumonia and you don't have a pressure ulcer, you're in a hospital for 11 days. If you come into a hospital and you develop a pressure ulcer, you're in for about 23 days.

So you are looking at a much longer length of stay and a much longer capacity issue for a hospital. To be able to then develop a value story around a new technology which would alleviate pressures is a much easier conversation when you know what the impact of these things are to a healthcare system. That is probably one of the more interesting ones we did for that client, but it's getting into the nitty gritty of activity and outcomes.

Scott Nelson: That's a great example. I know when you first told me about this database that you have access to, anyone would walk away feeling pretty impressed with that sort of data or that sort of culmination of data points. Going back to the PICO framework and your Connect 4 analogy that you described before, in hearing you describe that, the Connect 4 example applies anywhere. If the US is the ultimate goal, making sure that you nail each of those buckets — the patient benefit, the hospital benefit, the payee benefit, the company benefit — everyone wins. Investors win, patients win, healthcare providers win. It's a really solid methodology, or lens to view things through, regardless of where you're commercializing.

The other thing that really rings true for me in hearing you describe this ideal process is by taking all of these numbers, the database that you have access to is real data. It's real numbers. They are not assumptions, and that then allows the medtech company to effectively engage in a really good dialogue with NICE because you are using their language. So instead of a sales process, it turns into more of a win-win type of conversation. Those are kind of my thoughts in hearing you describe that. Is that ringing true for you, Mike?

Michael Branagan-Harris: Yes, it is. We work a lot on a national basis. We have a limited bandwidth to start running around the country on an individual hospital basis. But ultimately, by being able to go into a healthcare system on a national basis and understand what value your technology is going to bring, by having the right level of information you can go in on a local hospital basis as well.

We talk about carpeted areas and non-carpeted areas. The carpeted areas are where people make the big decisions and write the checks and pay for things. What we talk about is to be able to provide information as to what to talk to in the financial parts of the hospital and you can only do that if you understand what they're spending, what they're spending it on, and what problems they've got.

Do they have a waiting list of 700 patients that are waiting for orthopedic surgery, and do we look in the system and realize that their length of stay data for certain procedures is very long and they may be using an old piece of technology? By having the information to be able to go and talk on a local basis into these carpeted areas and have a proper strategic and consultative conversation around solving a problem, and not just a medical device with a nice bit of glossy literature, is what we're increasingly doing as well.

So we're supporting a lot of companies in this way to be able to engage better. Certainly, it's knowledge of understanding the reimbursement system. With each healthcare system in the world, every year there are changes to policies and changes to amounts. You've got to be kept up to date, and we're fortunate we work with a great network of people that work locally because one person can't learn each healthcare system in the world. It's so complex that you need to have help on the ground on a local basis to do this properly.

Scott Nelson: Couldn't agree with you more, Mike. I just want to thank you again for coming on the program twice now, and describing not only the changes that are going on in the UK with respect to NICE and NHS, but also detailing out an ideal process that you prefer medtech companies to follow in order to see the results that I think everyone wants to see realized.

For the last question, since you're in the UK and right in the heart of Brexit, I wanted to get your take on Brexit and what that means for healthcare, or medtech specifically?

Michael Branagan-Harris: I am very positive about the future for us as a country. I think that we've been in this area of the world which hasn't been growing as much as other countries like America and India and China and the Asia Pacific areas. I am excited about the future for us a country going forward and being able to trade with who we want to, when we want to, and how we want to. Then at the same time, attract businesses into this country with a very fair tax regime and be able to offer, certainly the US medtech industry, a fantastic place to start on their OUS strategy.

We're in a great position of having this single healthcare system, called the NHS, that many other countries look up to and to how they get people in the system, how it's funded, and the credibility of NICE. Also, and I haven't touched on it much, is the opportunity for research is outstanding in the country with some of the leading universities. So my view is that I am excited about the future. We have a massive opportunity and a real desire to adopt new technologies. So I would definitely encourage people to have a look at this market in Europe.

Scott Nelson: That's great. It seems like anytime you read pieces of information online, it is how the Brexit is going to lead to massive failure and disruption. So I think it is really valuable to get your take on it, considering you are local and you work with a lot of these big name organizations and institutions like the NHS and NICE and other medtech companies that are trying to navigate through the system. It is refreshing to hear your take on Brexit and the fact that there is a ton of opportunity and it could be really beneficial for everyone.

So Mike, thanks again for your time and walking us through best practices as it applies to working with the NHS, NICE, and the ideal process or framework to use when trying to make some headway in Europe.

Michael Branagan-Harris: Great, thanks, Scott. It was really great to be interviewed again. I appreciate it.