Forget the FDA! Launch Your Medical Device in the UK: Interview with Michael Branagan-Harris, CEO of Device Access UK

Why do many medical device companies struggle when trying to launch their products in the UK? Michael Branagan-Harris has some answers. Before starting Device Access UK Ltd., Michael set up VNUS Medical Technologies UK in 2006, a subsidiary of VNUS Inc. which was acquired by Covidien in 2009. With a small sales team, Michael grew it into a multi-million dollar business. He worked closely with the NHS, National Innovation Centre, and BBC Health correspondents across the country in order to increase patient awareness and drive market penetration. This is what we are going to learn in this interview with Michael:

- How Michael helped VNUS Medical UK become the largest subsidiary of VNUS Medical in the world.
- Why did Michael make the risky move to hire pharma reps for his initial sales team with VNUS Medical UK?
- How VNUS Medical UK used the BBC to help facilitate awareness of the VNUS Closure procedure.
- Overview of Device Access UK Ltd. and how they help companies launch medical devices in the UK.
- The biggest challenges that medical device companies face when trying to launch products in the UK and how Michael believes they can be solved.

Scott Nelson: Hello everyone it's Scott Nelson and welcome to Medsider, home for ambitious medical device upstarts. As you probably know by now this is a program where I interview dynamic people that are doing interesting things in the medtech and medical device arenas.

On today's call, we have Michael Branagan-Harris who is currently the CEO of Device Access UK and on the call, we're going to definitely learn a little bit more about what Michael is doing with Device Access. But upfront anyway we're going to spend some time because he's got a rather interesting story to share with his work with the VNUS Medical Technologies over in the UK. He took a relatively small sales force and grew that business unit into annual revenues of over $5 million. Correct me if I'm wrong Michael but annual revenues of over $5 million in a relatively short amount of time with a relatively small sales force and it eventually became the largest subsidiary for VNUS Medical Technologies. That's what we'll spend a little bit of time with initially. So, without further ado welcome to the call Michael, thanks for coming on.

Michael Harris: Thanks Scott hi. Thanks for involving me in this broadcast.

Scott Nelson: Absolutely, before we get into the story with VNUS Medical and for anyone that's listening when I say VNUS I mean V-N-U-S Medical Technologies. Give us just a brief overview of what you're currently doing with Device Access and then we'll kind of circle back around and dig into some little bit more detail but I kind of want to understand first what you're doing with Device Access.

Michael Harris: Yeah and thanks a lot. Device Access was set up just over a year ago now. I found there was a space in the market for reimbursement for medical devices in the UK and basically we find that within the UK there's a lot of companies that don't have support with market access and reimbursement coding. But the biggest bit of interest that's come my way is the amount of US companies that are interested in or need to involve themselves in our US operations because of the slowness of the FDA.

I set out to help serve companies both in the UK and in the US that want to expand into the market and certainly help to accelerate their market access in the light of restrictive budgets and the need in the US obviously for companies to get their attraction in the markets with new technologies where the FDA have made it very hard and slow for them to really survive at that critical period when they're being funded particularly privately so that's why I set out.

I've been in medical devices for over 20-odd years since 1989 really and I've been involved in bringing in a number of technologies to the UK physicians including the Lap-Band for VCT, Da Vinci Robot, I had a little bit of involvement with that and then lots of other endolaparoscopic devices including the [06:12 inaudible] and lots of new technologies that have now become quite mainstream. It's been exciting to be involved in lots of different technologies in general surgery, gynecology, urology, vascular, cardiac areas that have orthopedics as well.

I love all these technologies so the nice thing is I know a little bit about lots of different technologies and lots of areas of surgery and still having that skill and background of understanding what happens in different parts of the body meant that I could look at a company, look at their idea and think, "Well, actually, yeah, that looks really interesting. I can probably find somebody, a key thought leader in the UK that might be interested in finding out if there's something that could be brought to this market."

That's how it started really, and I found that when I was working in one company I would find that it was almost restricted that I couldn't myself involved in other technologies to a certain extent to help companies get themselves going in the UK. It was a great idea and the other thing I found was that some of the companies I'd worked with that were using external consultants in the US didn't really understand the UK market because they weren't based here and they didn't see the changes and the growing opportunities for innovative medical devices to actually exist here. A lot of companies feel that everything has to go through NICE which is HCA and basically yes they need to look at devices at some stage. If you got something new and innovative, you might find it's easier to move in the European market certainly in the UK market than trying to drive them through the FDA at the moment.

Scott Nelson: Sure. Sure, and there's so much that I want to dig into about what you're doing with Device Access because I think that's phenomenal and there's a lot of media attention right now on the FDA and the problems of the 510(k) approval process, etc. So, I think this is a perfect time to have you on the program to talk about this and how what you're doing can impact medical device companies that are trying to launch their devices over in the UK.

Before I go there, and I think it will set the stage for what you're doing at Device Access. So, before we dig into that in more detail, I want to learn a little bit more about your role with VNUS Medical Technologies and how you, correct me if I'm wrong, but a device that really didn't have any sales in Europe and grew that business unit for VNUS Medical Technologies so quickly. Let's dig into that in a little bit more in detail but before we go further can you give the audience a brief overview of VNUS Medical and the device and maybe the disease state that their device served.

Michael Harris: Yeah basically VNUS was set up in I think 1998 out of the San Jose area and they devised a new way of treating varicose veins, venous reflux disease by shutting down the faulty vein basically. It's like shutting down a highway if you shut it down then all the traffic goes out the other side roads and that's effectively what they were trying to achieve with faulty veins had shut them down. Now the current procedure or the procedure that was being performed previously was actually removing the vein with the surgical approach called stripping and this technique had been around over 100 years at least and it was quite painful because it involved a general anesthetic and a cut in the groin and actually the vein was sort of ripped out using a wire. So, patients typically had quite a lot of pain post-operatively. A cut in the groin and bruising and potential injuries to nerves on the way out.

VNUS cleverly thought of a way to address this by closing the veins using a Radio Frequency Catheter. Absolutely amazing company and so they started it. At the time when it started they had some initial work going on in Europe to get the clinical works so they could get the FDA approval in the US and the device got CE marking well simply quickly and then the company refocused back in the US driving the market there and it got to I think an over 50% market share with the other 50% or so being 10 or so laser companies.

Laser closed the vein in a different way boiling the blood. It was a little bit more painful and required a lot more safety and it was a more complicated way of closing the veins. So, we had lots of competitors saying that VNUS, that's the old system it's slow and we're, and the laser is a great way forward."

All companies did pretty well but in the UK certainly the VNUS was being sold by a distributor and they had 15 or so other products and were focused on lots of different things. VNUS had some initial interest in the private sector but it certainly slowed a lot down, and hence the opportunity for the market of 40-odd thousand varicose vein procedures and the NHS was a good one, which was one that I decided to go after. It was a case of finding a way of getting things moving in the UK, VNUS had a subsidiary in Germany which was doing a pretty good job, but it was a start from scratch in setting the company up. I've recently just come back from a year in Australia working for another company in the area of endolaparoscopic and was delighted to have been given the challenge to really get this company going.

Working on your own with a time difference to head office was challenging. As you can imagine I'd be out all day and then get home and the whole office work would start again till late at night for some period of time because of the time difference to California and the UK. It was a great opportunity but it had to work and I quickly thought, "Well this is only going to succeed if we

think differently if we do this differently," but it was down to getting the right sales team on board which I was lucky if I'll say of any skills, I managed to get a very good team of people together who we went off and did this work of converting this 100-year-old operation to VNUS closure. Whilst they were doing that I could concentrate on removing as many barriers as possible to make it possible for them to be successful and move the business on every day they're on the road so…

Scott Nelson: I'm going to stop you real quick Michael. There is a ton of questions I want to ask you about this because it's really interesting and I think it highlights with your connections and what your knowledge of that market over there in the UK I think it speaks to what you can get accomplished. So, VNUS Medical was working through distributors when you came on board. Do you have any idea, do you remember what the sales looked like before you took over as the Managing Director?

Michael Harris: Yeah I mean I obviously don't want to give numbers away but certainly they had a couple of attempts and very little penetration into the NHS. That actually worked for the distributor that was selling VNUS before I went to Australia and came back but then I decided to go direct but it wasn't anything exceptional put it that way.

Scott Nelson: VNUS, I'm sure the reason they wanted to change from a distributor model to a direct model was they weren't having the impact that they'd like to have. Is that correct?

Michael Harris: They were, and they were just looking at a new modification to a catheter which had been around from scratch which was quite a quantum leap forward in terms of the way it delivered energy into the veins. It was to make sure we need to get better sales. We need to certainly look outside the US to grow our business, and they felt that this product needed the focus from, the people just focusing on that technology.

As we went on with moving the device into the NHS international health service we realized that yeah one of the things that were required was hands-on support to surgeons and it did require 100%. It's having one product in your bag which is always a bit worrying for some people, but that product had to work, and everybody knew, my team was very knowledgeable on how it worked and how to train surgeons on how to use the technology.

Scott Nelson: Sure okay. You mentioned the sales team how that was a rather big factor in your success over there in the UK. I'd like for you to expound on that a little bit more. Also, what are the other keys to this rather large success that you experienced with VNUS Medical over in the UK?

Michael Harris: Yeah that's two separate questions. I can give you some ideas of what I did with both of them. I think to start with the sales team, I mean, VNUS, we're a relatively small company. They had money but not that deep pockets, and every cent, every pound we spent was watched. The thing for me was typically when companies like this want to go into a market, they like to have experienced salespeople from that background. So, I think it wouldn't have been great if I could have afforded to have had 5 exceptionally well-connected vascular salespeople who had

been working for one of the other big vascular companies to come out. That's not always that easy and most people are always quite difficult to buy and they're expensive.

What I decided to do, which was quite risky, but I decided to look for pharmaceutical reps because I found that a lot of the pharma reps were frustrated. They could always go in and talk about that tablet being blue and the other one being green and then that's the packet and there were very little differences between the two. I think if you can be a success in pharmaceuticals, and when I say success being the sort of the top 5% of the big pharma company, then you obviously have got the intelligence to understand clinical papers and talk at high levels and not be afraid of doctors and physicians and surgeons.

But if you're in the top 5% then you are thinking outside the box and you've got exceptional skills that will help to potentially drive the product forward. The beauty as you know Scott with selling devices that if you can get a good relationship, you have the knowledge, clinical background to better communicate at a high level to a surgeon and be involved in procedures where they see an outcome. They actually see an outcome, the vein has gone and the patient is happy, then they're not going to get that sort of warm and buzzy feeling of achieving something not only the growing relationship with the surgeon and his team but also having treated a patient and actually seeing the result whereas with pharma you'll never see the results.

I've got several people from very wide backgrounds in pharma they can sell anything from antidepressants to contraceptives to all sorts of hormonal things and we've got them on board. They absolutely loved it because they couldn't believe how they could grow relationships and be part of the team and be an important person, somebody that would be called in by the physician or surgeons to come and help with the case which would never happen with a pharmaceutical item.

They really love what they're doing and VNUS had a very fine training team and these guys were put through that in San Jose and came back and hit the road. They knew they had to keep the diaries full, which is important. In the pharmaceutical world, it's all about seeing lots of people and keeping a busy diary and if you can combine that with the skills, their selling skills, and having a great product then there's no doubt VNUS was an astonishing product. It was a recipe for success, and it did actually work pretty well, and they are still out there enjoying it today.

Scott Nelson: You mentioned that move was kind of risky to hire a pharma rep. Is that somewhat uncommon in the UK for device companies to hire pharma reps?

Michael Harris: It sort of is because these people typically stay in the pharma world and I don't think there are that many opportunities. People like to hire people that have been into an OR and seen a procedure. If you're selling an antidepressant or something you never see that side of it, but I think that at the same time to have a good ability to remember clinical information and still extract that into a high-level conversation with the surgeon is equally as important. I think that yes it is unusual but at the moment there are lots of pharma reps and I think the device world is more specialized in terms of people who don't tend to move around so much in that area in the UK.

So, we're in need for some new blood in the industry and it was a big chance, but I think that it was a risk, I wouldn't be working on a startup product if I weren't into taking a few risks here and there. It was a mixture of that and then the ability to get those guys aren't motivated doing their job to be able to do the work I did with getting the product all over the BBC news, talking to the department of health about the system and really driving it through at all angles to remove all the barriers for the guys to be as successful as they could and win business.

Scott Nelson: Yeah okay I think I understand that and that's interesting. I know some people kind of scoff at hiring pharma reps into a more specialized device sale, but it seems it definitely could work and obviously worked for you as long as the foundation is there, from a training standpoint, from a support standpoint within the company. That's interesting that really paid off well for you. So, beyond the sales team and getting those folks engaged in incentivized to go out and sell the device. You mentioned you work not only with the BCC news but also from a regulatory standpoint. Let's talk about that in a bit more detail. You want to start with either the BBC news stuff or the regulatory issues?

Michael Harris: Yeah I mean, I guess there were just different things that I did in trying to drive patient awareness because I had a sales team out talking to surgeons and you know what it's like. Some people are happy to change their stuff using the technology and others will only look at it 5, 6 years down the line. VNUS has been around for a few years by then. I mean certainly been in the UK for about 5 years with one of the previous technologies but certainly what I wanted to do is really get the surgeons interested, the patients interested, and the salespeople motivated.

One of the first things I did was get some very good key opinion leaders on board, they were happy to talk to the BBC cameras or BBC about this breakthrough technology which really had been quite widely used by then in the States but was generally unknown in the UK. I got to know a surgeon near here in the South of England who happily worked with me to get the product onto a new story about this new walk-in, walk-out treatment for Venous Reflux Disease Varicose Veins using that technology. I remember the morning we had a lot of interest on the internet from that and people ringing up wanting to find out where they can have the procedure done because the procedure was being offered under the State Health System, so it was paid for by the Government.

That was one thing that sort of started off and then like a lot of people, I was spinning lots of plates at the time so to speak. I mean, I was running a company, doing payroll, helping with the accounts, the books. One minute I was buying a water cooler for the office or buying photocopiers. It was basically here's an office, find it and get the staff and get the administration, get some furniture in it. It was everything to set up an office.

One day I had a phone call from a company trying to sell me quite expensive advertising space in a congress magazine for a big vascular show and I thought, well this looks very good but this is only going to be read once and then it's going to be thrown in the bin, and I sort of thought about whether to spend this money on this advert for the procedure and decided there are other ways of doing this that I could get surgeons and patients interested. I had been on a flight that day so

what if I put an advert into an inflight magazine which you've got your SkyMall magazine which is very, very thick.

We've got an airline here that doesn't do any television at all and all you have to entertain yourself is just this inflight magazine. So, I spoke to them because I knew that this particular airline was going to be used a lot for flying a lot of the surgeons to a show in the middle of the UK and decided to put a full-page advert on the procedure in there aimed at the patients. This particular airline flew 12 million people a year and I thought, well if I can have put an advert for the technique or this new treatment in the magazine, not only will we be getting queries from people wanting to find out more but would also on that flight, during that congress we'd have a lot of surgeons reading as well. I just thought it was a more powerful way of thinking around that to get both sides interested. It actually worked because we had a number of surgeons coming to the booth at that meeting saying, "I've read about this on the airplane, I need to get involved. I'm going to have patients wanting this so when can I start?" It was a great way of driving the actual desire for the surgeons to offer a new technique to keep up with the times.

Scott Nelson: That's a great story so that actually paid off. You actually had physicians that came up at your booth there and said, "Hey, I read this on the inflight magazine," because my initial doubt would be that's a great idea but how many physicians were actually going to read this, but it sounds like they actually did.

Michael Harris: Well yeah we did a mixture of that and the sales team said, "Oh we're advertising that in Fly V," which was the airline and we have read a few copies on the booths and said, "Look we're now advertising this and we've got patient interested," which we had. We had a lot of inquiries. We had set up a text system where a patient could text their number to somebody who would reply with the website and details and ring them and ask them if they want a leaflet sent or a patient information leaflet.

It's just a way of creating awareness and it really didn't cost a lot of money. It was like $1,600 a month to advertise to potentially a million patients a month. It was just one other thing, one other activity combined with BBC news stories. It then started growing over the UK as we got KOLs in each region. We got in on about seven or eight BBC news channels and we'd bumped it up with a Google campaign so we captured the patients in each area that would see the Venous story, and so it was great.

We would then go to the areas that weren't offering it and say, look we've got interest in this technique from patients, are you interested in offering the technology?" This thing grew the market across the country, so it was fascinating seeing that happen. I put that down to again a great sales team and the ability to think outside the box, restrictions, and think of ways of growing awareness for this incredible technology. So, yes it worked, and the competition was interested as well because they hadn't thought like that. It was just trying to do things differently and that's what I did, took a few chances and it worked.

Scott Nelson: I'm sure with some of these unique ideas that you implemented. I'm sure you had some copycats out there, right, or no?

Michael Harris: A little bit. We used to run stories on other angles like we had an Olympic rower who had a Venous Reflux Disease Varicose Veins that if she'd have the typical vein stripping procedure then she would have missed that one so much training would have made it impossible for her to compete and train. I think we had that run as a story and we try and look at it from different angles. So, yeah I did and the competition they just didn't… maybe with bigger, bigger companies they never had the ability to make these decisions. It was down to the fact that I was left to get on with it and luckily as I said I had a good team going out there and bringing the sales in, so it worked pretty well.

Scott Nelson: Yeah that's interesting. You mentioned the Google AdWords campaign, I think everyone understands the premise behind Google AdWords but the text system that's interesting I never heard of that. So, patients can send a text to a certain number then you would mail them out like an informational brochure or something like that?

Michael Harris: That's right I mean, whether it happens over in the US a lot but certainly you can see a lot of adverts to different things and you just text the number so typically people would be on a plane and they would write a number down or put it in their phone as they switch their phone off the in-flight mode then they'd send a text and we'd better ring them back or send them a reply text with the information on the website. Maybe it's a service that's only available in Europe or the UK. It seemed to work.

Scott Nelson: Okay and then with your work with BBC, the stories that you ran, was it on a local level with local physicians that were doing the procedure, or did you just work with KOLs and BBC? Give me a little bit better idea of what that looked like.

Michael Harris: Yeah no it was a mixture of really I mean, it was a nice story. It was the technology that was being offered by the NHS, by the State Health Service so it wasn't plotting in a group of private hospitals for example because you know we've got a different health service here but how it works was typically we'd have BBC Health Correspondents trying to find stories in their regions of new things that were going on. Normally they were only looking for negative stories because they always get a lot of interest but here is a new technique that is going to save a lot of pain and bruising and discomfort for patients.

Ultimately we start ringing them up and say, look I've got a story, I've got a KOL surgeon offering this, so I'd be quite happy to go and do some filming. Well, they'd come in, normally it's a Friday afternoon it will take them 20 minutes to run the story they'd interview the patient, see a bit of the procedure. We'd have some nice animation, and yeah those stories are still on the BBC site. It worked really well, and they were happy with it, they learned a bit about something different and it was a nice, positive story for a change about the NHS.

Once we got one area sewn up a lot of health correspondents know each other. It was a case of, well they've run it in this area, would you like to run it in your area, we've got somebody interested? Sometimes it's periods of time in the year when the BBC News people find that they need to have stories for when it's quiet or they're on holiday for example Christmas time or

during the summer holiday vacation period they would leave the stories to run when they were away. These ran and worked pretty well so there was quite a collection of them actually.

Scott Nelson: That's great stuff, fascinating. Fascinating ways that I'm kind of a big believer that the medical device industry, a lot of companies could do themselves a favor by adopting some of these more progressive marketing avenues and you speak to that, you obviously speak to that because of what you accomplished with the VNUS Medical over in the UK.

At that point, I think it kind of sets the stage, if you're okay with moving on. I'd kind of like to talk about what you're doing with Device Access and dig into that a little bit more in a little more detail because we can obviously tell that you accomplished quite a bit with VNUS Medical UK and I'm sure there's probably even more stories to tell but for lack of time I should say I'd like to find out a little bit more about Device Access. Are you okay with moving on at this point?

Michael Harris: Absolutely yes, thank you, Scott.

Scott Nelson: You gave us an overview of kind of the premise of Device Access and what's you're doing and the fact that you're helping companies. Real layman's overview, you're helping companies launch their devices in the UK but give me an understanding. Are you mostly working with emerging technologies?

Michael Harris: A lot of the time, yes, I mean typically the US-based companies with some very, very good ideas that are before the FDA approval process need to get some clinical work done in Europe and have a CE marked product. So, with the CE marking you're mostly green light to selling in the UK and other European markets. Obviously, the nice thing about the UK is we all sort of speak the same language. What I typically do is I open up, give them the knowledge really, and support them in terms of helping them to meet with the right people to show the technology.

There are parts of the NHS that like to look at new technologies. There is also a horizon scanning section of the NHS that looks out for emerging technologies. So, some companies may be approached by these agencies that look at emerging technologies and on the horizon scanning to find out what's new out there. That's really encouraging. I started working with the National Innovation Centre which is based in London in the Department of Health and they look at new technologies and evaluate them in terms of what benefits could they bring to the NHS and that's where I took the VNUS Closure procedure through.

I had some established contacts there, but a lot of people haven't heard of the National Innovation Centre, that's the NIC. So, what I typically do, and this is slightly different from a lot of consultants is like to be out and about talking to people and I have a good network and I'm not somebody that sort of sits and writes power points. I'm actually not very good at that, I like to actually meet people typically at Heathrow Airport, spend a week with them meeting with potential key opinion leaders, and going into the Department of Health with their products to find out and judge this level of interest of their technology.

It's really opened up my mind to learning lots more things. I mean I've been working on ophthalmic projects which have been astonishing. This technique could potentially save the National Health Service millions upon millions of dollars. They're particularly interested in things that will save money as well as improve patient outcomes. So that was a good one for me, and I'm still involved in that project. But I've done things from macular degenerative disease to actual regenerative medicine technologies. So, some quite high-end things.

I've been involved in other things around gynecology, some sort of straightforward but clever new technologies for addressing problems, and the thing about the NHS is at the moment, they're actually actively looking for new technologies under an initiative called QIPP which is Q-I-P-P which is Quality Innovation Productivity and Prevention. It's a challenge to save the NHS a lot of money between now and 2014. The program is open for manufacturers to go into the NHS and say, actually we've got something here we think we can save 5,000, 6,000, 10,000 bed days if they were to adopt this new technology for example, or to save a lot of time or to improve with innovation in hospitals.

A lot of people don't know these things exist. I've got a group on LinkedIn which is UK NHS Medical Device Market Access for Innovative Medical Devices. A bit of a long name but I post a lot of news about what the NHS is up to, opportunities for sure, and updates on what's going on. Just recently there was an opportunity for companies both within the UK and overseas to approach an agency in the North of England. We're asking manufacturers, what have you got that can help us with these challenges? We've got a growing elderly population. The usual thing that you're dealing with over your side of the lake and what have you got? Before it was, we're not interested, or we like doing the same old thing. They actually have to now start looking at new technologies and the Government is already enthusiastic about this.

There are really good opportunities there but a lot of people or some people just don't understand where to start and that's the thing. I'm happy to meet people and to spend a week with them. I've just spent an incredible week with a company with a device that goes in the mouth to stop people from eating so much. Now, these can be treated in lots of different ways, but this technology is fascinating, and we spent that week meeting with the Department of Health to [36:39 inaudible] the impact of this technology and what it could do to reduce the growing burden of obesity cost in Type 2 diabetes. Met with KOLs, they haven't seen anything quite like this before but that's what I like, I like things that are different.

Then we met with some private hospitals and we actually did some work in Holland as well to find out what the market was like for this particular company based out of Atlanta. This guy has gone back. He has gone back and he's really going to drive his market initially into Europe because again it was difficult and slow and with pressure with the FDA. That's one example of five days and changing the company's direction so to speak into where they're going to go to survive really.

Scott Nelson: Okay, real quick you mentioned several different organizations there that you work with, I think that's fascinating. I guess if I'm looking at it from my standpoint, if I'm a company that wants to gain some traction over in the UK that's almost overwhelming and the idea that you almost serve as a connector of sorts for companies that want to gain some traction in the UK

we can probably do a whole separate interview just on that. One organization mentioned was the NIC. I am unfamiliar with that organization. How do they play with the NIH then?

Michael Harris: The NHS.

Scott Nelson: The NHS I'm sorry.

Michael Harris: Yeah. That's fine. Basically, the National Innovation Centre was set up. It does two things which are fascinating. One half of it is about asking surgeons or doctors in the NHS about their ideas under a program called WIBGI which is Wouldn't It Be Great If, WIBGI and they ask the people within the NHS, wouldn't it be great if we could have X," and they'd answer and there were fascinating ideas from inside the NHS. There are so many great talented people in our health service that responded and there've been lots of technologies that have been brought out of that. The National Innovation Centre would then go to industry and say, we have this idea, would somebody please make this for us, and we could help drive it into the National Health Service.

That's one side and the other side is that they have looked at new technologies, early-stage technologies. Some of them are people that have got this idea and out of the shed. In the backyard, they've dreamt of an idea of technology, but they have to screen them. There was one that's quite funny I will share with you about a guy that had a way of helping women deliver babies or have babies quicker in the latter stages of pregnancy by putting them in a revolving chair and spinning it around and thinking that the centrifugal force would increase the speed of the delivery of the baby. So, from ideas from that.

The other thing I believe had gone through the National Innovation Centre was some spectacles, some glasses that you could put on and adjust a prescription by injecting water between the space between the glass of the lens and so you could increase or decrease the prescription for a patient for people in the Third World. A lot of very clever thought ideas have gone through the National Innovation Centre that has helped people not only within the UK but also in places like Africa where they're now dumping these spectacles, glasses across areas where there are no opticians.

They look at developing ideas and concepts within and also talk to companies about their ideas and try or help to demonstrate if their technology were adopted what the impact on the NHS would be in terms of the costs and improvements in efficiency, effectiveness of the technology, and social care cost, etc. So, you come out with a number. They did this with VNUS and worked out that it would save the NHS 17 million Pound sterling. You can then drive that marketing story across the NHS and say, well look we have this technology looked at and assessed by the Government, by the National Innovation Centre and they're realized that it has its impact. It's only helped a fair bit to drive the adoption of the procedure into the health service for me. There are lots of other sections to talk to. I mean anybody considering all-US activities, I can't speak highly enough of the United Kingdom Trade & Investment.

The UKTI has offices across the US and they encourage typically US companies to do business outside of the US and into the UK and can help work very closely with them, help the companies to set up and understand not only how to do business in the NHS but also pointing them in the right direction. Where do I start? Where do I set my office up? Who's there to help me? What are the tax and accounting issues? The shipping and distribution issues of getting products from the US to the UK. The UKTI is free and may help US-based companies do business in the UK and is actively out there.

Scott Nelson: Yeah okay. Just out of curiosity there are those US companies that want to do business au US in the UK for example. Are you finding that most of them already have a PMA or a 510K in the US and are wanting the CE mark or are they trying to get a CE mark first and then use that as sort of leverage or maybe use that sort of as some traction to get a US approval?

Michael Harris: I'd say the latter, help them to get traction and get some good clinical work is done but typically I think the FDA likes to have their data and their clinical work is done in the US. But typically, these companies come over with their devices and get them moving here fast. A lot of them have to because financially they can't survive long enough to be able to help get the money in to pay for the operations. So, that's sort of what I'm finding.

Scott Nelson: Okay and then also as kind of a follow-up question to that. Is it the National Innovation Centre is that what it is? Is that NIC?

Michael Harris: Yeah.

Scott Nelson: There's not an equivalent organization in the US because that sounds fairly unique.

Michael Harris: I don't think there is I mean I have done some work in at the markets with my work when VNUS was bought in 2009 by Covidien. I went into the rolling EMEA Market Access and Reimbursement and there are sections, there are other ways of getting traction and it's only Germany and Holland for sure with innovative products. They're all a bit different. I think that ultimately having good data in the NHS and getting the approval of technologies in the NHS here in England means a lot in other markets. They understand that it's a public health service and they're going to look at everything and the reasons for choosing certain technologies or adopting certain technologies based around certainly cost, but also offer a good service that works for everyone. I think that it does mean a lot when these companies do gain approvals and certainly nice for their technologies to kind of help in other markets are well.

Scott Nelson: Okay and some of these companies that you're working with to gain some market traction over in the UK, are you finding like two or three main areas or challenges that most of these companies are facing? I mean is there a couple that you can think of and how you typically help to solve those issues?

Michael Harris: Yeah that's a good question. A lot of the time what sort of happens is US companies will put somebody into Europe, typically the UK, and ask them to sort of go out and sell the product and I think that the chances are that its understanding that reimbursement is

different in each country but it's getting them to understand that there are ways of really accelerating market access if they knew who to talk to. Within the US, reimbursement is typically based around surgeons getting paid for doing different procedures. The more procedures they do or the way it's done has an effect on their income.

In the UK, surgeons and physicians get paid a salary by the hospital for performing the procedure, so the whole emphasis behind reimbursement is slightly different. It's based around making sure that the Government has a Code or a HIG to cover the intervention. If they don't, then you have to think of creative ways on how can you get this technology paid for where there isn't a code, where there isn't a HIG or DRG.

The earlier the work is done, the better and a lot of companies decide on a price for their device. They think well we sell this for $2,000 in the US so therefore we can sell it for $2,000 in the UK. It might be that they could sell it for $5,000 in the UK if they knew a bit about the pricing and the structure over here. That can work in two ways, I've worked with companies that have device design products in the US market and tried to move into the UK and have been unsuccessful because the whole pricing structure is so different around the technology that it's not going to win and people have wasted a lot of time and money and resources in doing that.

The earlier you can think of reimbursement in the UK or in Europe whilst you're designing the product and think of the outcome as opposed to thinking, "Well, it cost me $100 let's sell it for $200 and be really greedy," when you can potentially sell it for a lot more if you knew the end price. It's really that that's important and having that sort of thought process about pricing as early on in the production or concept of the idea as possible.

Scott Nelson: Okay and just hearing you talk about this subject, what is it about a company that wouldn't want to consult with you if they're trying to launch a device in the UK because it seems rather obvious. Not only are you a connector in a network or you know the right people to talk to, but you also know the space. You've been there and done that. Why is it that companies don't go that route, they just haphazardly pay someone over in the UK and say, well go sell this?

Michael Harris: Well that's a really good question, Scott. I think that the thing is there's not a lot of people doing what I do. I mean market access and reimbursement people are typically working for big companies like J&J, Medtronic, Boston. They're the guys that work full-time in those organizations, these huge organizations and they're employed just to look after that product. Now independent people with my sort of background are quite rare and it's sort of knowing about them really and there are companies in the US that can help and can understand the coding but being on the ground, based over here to be able to go out and talk and network at the right levels is what it's about really.

It's just not many people doing this. I think that's the thing and certainly, in the pharmaceutical world there're lots of people doing reimbursement and market access but that's a whole different game as you know. So, I guess it's lack of people, lack of knowledge, and unfortunately, some people spend months and even years trying to work this thing out and it's wasted time

when you can really if it's a good idea, you could really accelerate growth in this great market here.

Scott Nelson: Sure, okay and I know we're kind of getting short on time here. I'd like to wrap things up. Michael when you look back at your 20 plus odd years in medical device sales and now what you're doing with Device Access, which is fascinating work. Is there a couple of pieces of advice or things that you know now that you wish you knew back when you started?

Michael Harris: That's a really good one Scott. I just think that anybody who's in this market if they really look around at what they're doing. I mean it's fascinating, it's a great industry this, a bit like you. So, you make the most of it and be willing to take a few chances here and there. I think you can be stuck in companies and not see the other opportunities around and I see some amazing new medical devices that are coming through now and so yeah just keep an open mind.

I guess ultimately my bit of advice would be to really care for those customers. I mean, I've gone through looking after general surgeons out doing calls with them and supporting them with cases. A gynecologist, vascular, cardiac, you name it, and I can now pick up the phone five, six, seven years on and I've got their mobile or cell phone number and I can normally ring them up and say, remember me, I've got this new product, and that's nice. Do a good job when you're out there and who knows where it might take down the line with new and emerging technologies. So, really care for those customers would be my thing and it certainly helped me in what I'm doing now.

Scott Nelson: So, ultimately what you're saying is from the get-go in your case you work for Michael Branagan Harris Incorporated in a sense where, as you maybe move on from one company to the next ultimately it's your reputation that's lasting with these various customers.

Michael Harris: Yeah it is I mean I've just realized that I had to become the product. After the whole VNUS thing, it was a great experience and a great thing to be involved in and I sort of decided to become the product as opposed to selling the product. Nobody can take me away from me really so that is what I decided to do and it's good, I'm enjoying myself.

Scott Nelson: Yeah very good stuff. Well, this has been a fascinating conversation, Michael. I really appreciate it and for those that are listening, where can they go to learn more about Device Access and what you're doing?

Michael Harris: Its deviceaccess.co.uk is probably the easiest website to go to or intonhs.com is another one. I've got several but they all link into my website which actually is a little bit out of date now, but you've got a general idea of how to contact me and find out more about what I do with VNUS.

Scott Nelson: Okay and that's deviceaccess.co.uk and you've got a tab on there where you post the news of what some of those various organizations in the UK are doing. You referenced that before I think.

Michael Harris: I have yeah and they're changing a little bit at the time but no that's on there as well. So, it gives you a bit of an idea as to what they're looking out for in terms of innovation at the moment.

Scott Nelson: Okay and I'll make sure I link to it when I post this interview here, I'll make sure I link to you on LinkedIn as well and people can find you… Why don't you say the name of your LinkedIn group one more time?

Michael Harris: It's something like the UK NHS Medical Device Market Access for Innovative Medical Devices. That's really typically what I'm looking at but I'm on LinkedIn so connect with me there. I do send out lots of updates as to opportunities and things that are going on.

Scott Nelson: Very good, very good well I can't thank you enough Michael. It's been a great conversation and everyone I encourage you to check out Michael's website and find him on LinkedIn. Thanks, everyone for listening, I appreciate it.