

# Laying the Groundwork for Digital Health Solutions, a Conversation with Kal Patel, CEO at BrightInsight

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## Episode Highlights

- Kal's personal experience working at Novartis and Amgen, including founding Amgen's Digital Health unit, one of the early digital technology adopters within big pharma
- Today, most pharma and medical device companies have a digital center of excellence, or even better, embedded digital into their whole organization
- They also spend billions of dollars on direct-to-consumer advertising. Digital solutions can help engagement and adherence, avoiding patient churn and driving clinical and commercial value
- The FDA considers the intended use and risk associated with AI and is moving towards more stringent regulations. Clarity in regulation will lead to faster execution and approval
- Companies like BrightInsight are viewed by pharma and med-tech companies as complements providing the required infrastructure for digital health solutions
- In the current market, BrightInsight is prioritizing expenditures towards R&D, with the goal of gradually increasing investments in sales and marketing to capitalize on this large market opportunity

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## Episode Transcript



**Frederic Laurier (00:06):**

Welcome all to another episode of Crossroads by Alantra. I'm Fred Laurier and I lead the firm's digital health practice. We have the great pleasure of hosting Kal Patel with us today on our podcast. Kal is the Founder of BrightInsight. They're the creator of a platform that helps expedite the application development process for big pharma and medical device manufacturers (MDCs) when it comes to patient-facing applications.

(00:32):

In this episode, Kal will elaborate on how his firm partners with pharma and MDCs to bring to market applications that not only improve drug efficacy and adherence but also ultimately lead to better patient safety. He'll also discuss and touch upon how clearer FDA regulations for the software as a medical device (SaMD) sector has been a boom for his business and other off-the-shelf platforms like his, that need to meet way more stringent security and privacy requirements.

(01:03):

Welcome Kal to our podcast. We're grateful that you accepted our invite. We know that it's a bit of a role reversal for you as you host your own, so thank you again for accepting. Before we jump into the thick of things, let's spend a few seconds on your bio. You initially attended medical school and took an early pivot into the corporate world, initially at consulting firms and then did a couple of stints, fairly long stints, at large pharma. Have you ever practiced medicine by the way?



**Kal Patel (01:34):**

I did not practice medicine. I went to medical school thinking that of course that was the original intent, but I got so enamored around really driving impact at scale and so that desire to drive impact at scale really drove me into pursuing the MBA and ultimately moving into the business.



**Frederic Laurier (01:51):**

To some extent, entrepreneurship was a calling for you, wasn't it?



**Kal Patel (01:55):**

Yeah, it was. Because what I noticed in medical school was just the complete lack of technology getting leveraged appropriately. Actually, on the education side, it was very well leveraged, but once we got into the hospital it was really arcane. So, experiencing that hands-on really had a big impact as well.



**Frederic Laurier (02:15):**

You spent many years at Novartis in sales and marketing and also in account leadership. You then moved to Amgen and two years into your stint at Amgen, you founded their digital health unit. That was about 10 years ago. Fast forward to today where we are seeing a plethora of vendors addressing various pain points, not only pain points for physicians but also for patients and consumers. Back in the day, you didn't see that. What I saw anyways was most of the applications were targeting basic pain points, clinical and operational pain points for the most part, such as EMR and RCM applications. How have your experiences at Novartis and Amgen helped you shape BrightInsight to what it is today?

## Episode Transcript



**Kal Patel (03:00):**

That's right. I did a few different roles at Novartis, and then at Amgen three very different roles: Head of Corporate Strategy and then Global Marketing Lead for one of their main drugs Enbrel. And then as you mentioned, I founded and led what we called Amgen Digital Health, one of the early digital technology focus groups within big pharma/med-tech. And our focus was how do we leverage technology to improve the real-world performance of our drugs. What I saw in my own experience in those roles: it was really not a digital technology gap, it was an application gap. Even 10 years ago, tons of amazing digital technology existed, but we weren't applying it within the context of our therapies. If you could effectively do that, you can drive tremendous improvements in clinical outcomes. To give a couple of examples: most drugs have a major adherence problem, and if you put Bluetooth into a drug delivery device, let's say you have an injectable pen, now with the patient's permission, you can know if, when, where and if appropriate, how much drug the patient's taking.

(04:04):

With that knowledge, you can now drive personalized adherence to help somebody be reminded in a way that's appropriate to them at the right time, the right way to help them stay adherent to that therapy. That ability to drive personalization, which we experience in basically every other aspect of our lives was not happening in pharma. And so, that was really the impetus for starting that group or me really pivoting my whole career towards digital health. I think to your point around how the world's changing, fast forward from then to now, and basically every single pharma company and medical device company has some type of digital, either center of excellence or even better I would say has really integrated the digital side into a single organization because they recognize that that's not two separate things, but an integrated view of the world and capability.

(04:55):

Many companies are now moving into looking at how do we improve the real-world performance of our drugs through leveraging digital. And for example, at our company BrightInsight, we look at the portfolio of drugs. We recently estimated this: it's about \$35B of peak sales that represent. My guess is a decade ago that number was probably close to zero. A lot more to be done by the industry for sure, and clearly folks are recognizing and beginning to see the value.



**Frederic Laurier (05:24):**

What is that \$35B made of?



**Kal Patel (05:27):**

The peak sales of those drugs. As an example, with CSL, this is a public one, so we're working with one of their flagship drugs, Hizentra, which helps patients with primary immunodeficiency and has another indication as well. And so, if you add up the sales of that drug for example, and then all the other drugs we're working with, that adds up to about \$30B+ in peak sales.

## Episode Transcript



**Frederic Laurier (05:49):**

Pharma has been leveraging tech or using tech for a long, long time, but mostly to promote and protect their brands using fairly rudimentary CRM applications for brand managers and sales reps. Apps now do much more than that, they help improve drug adherence, as we discussed earlier. Efficacy and also just create a more bespoke experience, a bit like what we find in other parts of our daily lives like banking or for daily purchases. Patient data now that is collected can also help create somewhat of a direct feedback loop between the R&D teams and the patients themselves. To some extent, you and your peers do act as a transmission belt. It is definitely a large opportunity dollar-wise.



**Kal Patel (06:35):**

A hundred percent, and I think that's what the industry's beginning to realize. If you just take one stat as an example: last year in the US, pharma companies spent almost \$7B on direct-to-consumer advertising. That is very ROI-driven spend. They're doing a lot of analytics to support that investment and that's basically helping drive awareness, find patients, get them into the healthcare provider's office, and ask for their therapies. If they're finding that kind of ROI in there, now imagine getting that patient in the doctor's office asking for the prescription. Where we come in is how do you now go from that prescription written to helping that conversion actually happen, and get the person on therapy? And now once you have them on therapy, I don't care what industry you're in, the worst thing you can allow for is your customer to churn. In the case of pharma, you have somebody on expensive therapies, you've spent all this effort and money to get them onto your therapy, and of course, some patients come off of it because it doesn't work or they've effectively been treated, and don't need it anymore.

(07:32):

But for the majority of that churn is avoidable churn, and that's where we come in and work with companies on things like how do you understand key pain points and address those with digital? Just sticking with the Hizentra example, that brand team recognizes that there's a very complex dosing regimen that patients have to follow and track, and that means rotating injection sites on a patient's body. Patients were keeping a paper journal to try to remember where they had last injected and where before that. We've digitized that whole experience, both tracking the recording, et cetera. It's just one pain point that the app solved.

(08:09):

And as a result of that, without really much marketing support, 20% of the user base in the US is using that solution. Something like 89% continues to use it at 12 months. It's clearly delivering value for a huge subset of the journey of those patients. Hizentra (CSL) has since just recently launched that app in Japan, and we're looking to take it more broadly to key markets. To your point, if you have a multi-billion dollar therapy and you can assist the patient, in this case, to have a better experience as a result, be more engaged with therapy, and stay more adherent, that's going to drive better clinical value. But again, tremendous commercial value.



**Frederic Laurier (08:47):**

However, they don't have to be mutually exclusive, do they? What we've found out through our own deal-making activities is that pharma and MDCs want to control patient interactions. But regardless, those insights need to be digitized one way or another.

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Those same pharma and MDCs that build their own software development and data sciences teams, how do those groups or teams feel about you and your peers potentially competing with them?



**Kal Patel (09:14):**

First, before I directly answer that question, just to your broader point. What we're finally seeing is the shift where the pharma and medical device industries are going from... I used to talk about this on panels and stuff where it's hard to find an industry that didn't try harder to know less about their end customer. Like pharma literally did not want to know who's the person using my therapy? How's it working for them? How's their experience? Is it working? is it not working? It's been a slow journey and it's still not complete, but to your point, they're beginning to be like: "Well actually, there's a tremendous amount of clinical and business insight to actually know the end user and their experience and we shouldn't be afraid of that, but we should figure out how to embrace that." And that's where we come into your question directly.

(09:59):

We're a complete complement to those teams because we, at BrightInsight, are the global infrastructure that helps pharma and med-tech companies build regulated digital health solutions. What does that mean? That means you want to build a digital solution or you want to take a device, you want to digitize it, you want to bring this data back into your environment so you can see the data, you can crunch the data, you can get insights, you can build algorithms, you can figure out ways to drive more clinical and business impact. Then you want to deploy that back out. Well, you need compliant infrastructure to do that. That's meeting all the regulatory requirements, meeting all the privacy requirements, all the security requirements, et cetera, right? At BrightInsight, we provide that out of the box.

(10:38):

All of these teams, they really are going to leverage us as partners. They don't want to be home growing this kind of infrastructure, that would be like somebody saying: "Yeah, I don't really want to use AWS or Azure or Google Cloud. I'm going to build my own cloud infrastructure." That makes no sense. Keep in mind, a decade ago that's what the industry was doing. Literally big pharma was building and running their own private clouds. Now, it's a question of, okay, which cloud are we going to use or which ones we're going to have strategic partnerships with? Why? Because you can't do security. Thousands of Google Cloud security people are working all day long. How many can you hire and do to keep your cloud secure or AI or whatever tools? And it's the same thing with what we do. Building infrastructure that can really scale across products, across geographies, and can keep up with constantly changing security, privacy and regulatory laws. We don't have a partner to do that, and that's really the role we play. We're really enabling infrastructure for them.

**Frederic Laurier (11:32):**



This applies not only to pharma, but really to any industry. We see buyers all the time facing the same dilemma. Shall we buy? Shall we build? Some capabilities are core and need to be internal, but some probably would gain in terms of efficiency by being outsourced. There's also the question of speed to market and cost, that comes into the equation. Are you seeing less pushback now than you were earlier on from pharma, in terms of partnering with you?

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**Kal Patel (12:00):**

Yeah, for sure. The kinds of other partners that a pharma company or med-tech company was looking at four years ago were the likes of systems integrators: the Accentures, the Deloittes, or the Cognizants of the world. We basically never come across them. I can't think of the last time any of those names came across, certainly in the pharma context. Medical device companies frankly still have a bend towards wanting to home-grow. That will pass because mark my words, they will fail at that because every industry has proven over and over and over again - if you try to build your own end-to-end infrastructure, unless you've successfully built an entire ecosystem around that, you're not going to be successful at it. Med-tech companies will still turn occasionally towards partners to try to home-grow this type of infrastructure. But yeah, over the last four years, totally different mindset.



**Frederic Laurier (12:48):**

That's fairly consistent with what other people in the industry are telling us, especially clients. So, really no surprise here. On your website, you mentioned that some partners using your platform have accelerated time-to-market by up to two years. That's very, very significant. Can you elaborate on some?



**Kal Patel (13:06):**

Yeah, that's exactly right. Again, to your earlier point, when you are talking about a pharma drug or medical device. Ultimately there's an area under the curve, right? Your patent life is going to drive that and the competitive landscape's going to drive that. So, you have a period of time where you want to maximize sales and drive value. And so, if you are going to drive a digital solution that's going to drive more market share or keep patients on therapy longer, etc. Why would you want to take two years to bring that innovation to market if you can cut off 18 months working with our platform and our products? And so, that value story becomes very compelling, especially when a typical drug is multi-billion in sales. Lockless drugs are multi-billion in sales. And so, to your point, you start moving the needle faster, you're going to create way more value than taking that extra time. So, just a top line and profit value is so big, forget about that it'll obviously cost you more to build something for two years versus work with us and move faster.



**Frederic Laurier (14:04):**

Switching gears a bit, let's talk about the FDA and the role they're playing. They have been very active over the last few years trying to put safeguards around ML and AI. There's even an action plan that was published by the FDA in 2021 around SaMD. Can you please put in layman's terms what it means for the industry and for folks like you?



**Kal Patel (14:27):**

Yeah, so let's start at a higher level and then come into a little bit more of the specifics, right? The FDA, they're regulating medical drugs and devices. It's very safety oriented to ensure that there's a very clear understanding of potential harm. In the case of this category of software, it's medical devices, they really come in when there's a medical or clinical intent of the software, right? Let's say someone's wearing, as an example, a glucose monitor, a continuous glucose monitor on their arm or on their body, and that's sending that glucose reading to a phone. It goes to the backend cloud and then it displays for the patient. It says: "Oh, your glucose reading..." FDA doesn't care about that because they're going to look at that and say really what you're doing is you're digitizing a paper journaling exercise. But now you take that same data flow of glucose

## Episode Transcript



readings and let's say you have an algorithm in the cloud and that algorithm is looking at that and it's saying: "Oh, based on this data and potentially other data, I'm going to recommend now to the patient how much insulin they should take."

(15:29):

"Hey, Mrs. Smith, you should take 20 units of insulin." Now you go from FDA: "Does not care." To being at the highest level of regulation requirements. My example I would imagine is a Class III, which means the highest level of risk, software as a medical device algorithm. Why? Because if anything in that algorithm, but really that entire system fails, the patient could end up in a diabetic coma in the ICU. That's kind of how the FDA thinks about software is like: "What's the intended use of the software?" "What's the associated risk of that software?" "Clearly a benefit, right?" Helping somebody personalize drug dosing their insulin is a massive clinical benefit. And I'll look at the benefit side, but also the risk side. These are relatively new categories of course. And so just like the industry, the FDA's trying to evolve and be responsive to enabling this innovation, while at the same time trying to ensure safety. What we're seeing from the FDA in general is they're trying to move towards clarity.

(16:27):

For example, the final guidance that came out in October is that it's more stringent compared to the previous one. Meaning that more of these clinical decision software tools will fall under the category of medical device versus sitting outside of regulatory purview. So, for our customers, that certainly means that they're happy they're working with us and treating these as medical devices because otherwise they could be outside of compliance requirements. To the FDA's credit, they're actually also investing time and effort to want to learn directly from the industry. It'll be an iterative progression. And I think not just FDA has a role here, but the industry has a very important role including companies like ours because we have to have a bidirectional communication pathway, which we do. That sort of informs what are we trying to achieve and helping our customers achieve. And for them to say: "Okay, well how do we help try to ensure patient safety while enabling this very valuable innovation?"



**Frederic Laurier (17:21):**

What's the impact that this may have on approval timelines? Do you feel that standardized platforms like yours will actually expedite that process?



**Kal Patel (17:29):**

I think what it'll mean is more clarity. And clarity leads to faster execution and approval. Because faster approval can be interpreted as: "How does the FDA just give more freedom to operate and people can do what they want to do and get approved faster." I don't think that's the right way to think about it. I think the way to think about it is: "Let's do what's right for the patient, but let's translate that into clarity." And then, clarity is what enables decisions and speed. And when there's a lack of clarity, that's when people are kind of churning: "Do we need to do this?" "Do we don't need to do this?" "Should we do it this way?" "Should we do it that way?" And that sort of is what sucks up the time. Let's say a more liberal view. But it's the clarity of the view that then enables it. Because we can, and we already do, support customers to build highly complex, highly regulated software and do that quickly and compliantly. I'm not afraid of the FDA setting a high bar. It's just the lack of clarity that then is what slows things down.



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**Frederic Laurier (18:30):**

Understood. One last question and then we'll let you go Kal. Markets are not as good as they were when you raised your round with Insight Partners. What has been the impact of those market conditions on your short-term decision-making and longer-term planning?



**Kal Patel (18:47):**

Let me highlight kind of where you finish, which is our approach is all about the long-term. How do we navigate the short-term within that context of the long-term, right? BrightInsight's objective is to be the de facto platform, a regulated platform for biopharma and med-tech, right? If you're a biopharma or med-tech company anywhere in the world, we want you to be building your regulated digital health solutions on top of BrightInsight. That's how we see accomplishing our mission of leveraging digital to improve clinical outcomes globally. We're playing for that long game. That means that the majority of every dollar we're spending, our largest category of spend is actually R&D. Last year, let's just sort of keep it slightly round, we put 40% to 50% of every dollar we spend, including our cog spend into R&D, into our platform, into the in vitro diagnostic and disease management solution that we're building on top of our platform.

(19:40):

That's our focus. Why? Because we want to have the most robust platform, and we believe that's how we become the de facto for the industry, and we look out 3 years, 5 years, 10 years. Now with that said, to your point around the economic environment that we're in right now, of course, capital is harder to get and more expensive to get, so, we're just very prudent about that. So, we're very thoughtful about every dollar we spend. Would we do more R&D if money was easier to get? Yes, we're tightly managing our expenses, and so, we stretch out some things like some of our product development pipelines. And that's I think just a prudent and very reasonable way to operate. It doesn't take our eye off the long-term objective. We're incredibly well-capitalized, and we have multiple years of runway, constantly being pinged by investors that are wanting to learn more about what we're doing.

(20:27):

And so, as CEO, one of my main jobs is to ensure that as a company, we control our destiny. And a big part of this is to have the financial balance sheet to go do that. That's always top of mind as we're making choices on our investment. When we look at benchmarks, we're way above on R&D spend for a company of our size. We're way under on sales and marketing spend because that's a very conscious decision. We have a handful of, for example, frontline sales folks. Why? Because again, we're playing for that long game, and so, we don't believe that what we want to do is just take what we have and then sell the heck out of it. We don't think that's the right answer for the industry and certainly for patients.

(21:07):

We want to keep skewing towards R&D investment, having more of a methodical, compounding ability to grow the business, and then we'll dial up sales and marketing over time in a much more gradual way as the business grows. But if we can keep growing with a very lean sales and marketing organization, that's the best way to do it.



## Episode Transcript



**Frederic Laurier (21:25):**

Hey Kal, as always, it was very insightful talking with you. It was a great discussion. Probably my key takeaway from today's discussion is how pharma has become more receptive to platforms like yours. Sounds like it was not always the case. Initially, they intended to build their own private clouds to some extent, or private cloud infrastructures. They kind of pivoted away from that, and I understand why. Now they can turn to third-party platforms like yours that provide a much more affordable and efficient way to build applications. End result is patients have a more enjoyable experience, which ultimately leads to better outcomes for the patients themselves. Thank you so much again for taking the time. Looking forward to our next discussion Kal. Enjoy your day!


# Alantra – Digital Health Coverage




# Alantra – Selected Recent Healthcare Transactions


<p>2023 </p> <p><b>Blackford</b></p> <p>Sell-side advisory</p> 	<p>2022 </p> <p><b>STADA</b></p> <p>Sell-side advisory</p> 	<p>2022 </p> <p><b>YPSOMED</b> SELF-CARE SOLUTIONS</p> <p><b>DiaExpert</b> Diabetes bewegen</p> <p>Sell-side advisory</p>  	<p>2022 </p> <p> NeoHealthHub.</p> <p>Sell-side advisory</p> 	<p>2022 </p> <p> Accent Equity</p> <p>Sell-side advisory</p> 
<p>2022 </p> <p> Aakamp Pharmazeutische Lohnherstellung</p> <p>Sell-side advisory</p> 	<p>2022 </p> <p><b>WOOM</b></p> <p>Sell-side advisory</p> 	<p>2022 </p> <p><b>republic</b>.m</p> <p>Sell-side advisory</p> 	<p>2022 </p> <p> Balhousie Care Group</p> <p>Sell-side advisory</p> 	<p>2022 </p> <p><b>STRATEGIC NORTH</b></p> <p>Sell-side advisory</p> 
<p>2022 </p> <p><b>Childs Farm</b></p> <p>Sell-side advisory</p> 	<p>2022 </p> <p> ANALYTICAL WIZARDS</p> <p>Sell-side advisory</p> 	<p>2022 </p> <p> Riffyn.</p> <p>Sell-side advisory</p> 	<p>2022 </p> <p> TARA</p> <p>Sell-side advisory</p> 	<p>2021 </p> <p> Baird Capital</p> <p> Prescient</p> <p>Sell-side advisory</p> 
<p>2021 </p> <p> HELIOS MEDICAL COMMUNICATIONS</p> <p>Sell-side advisory</p> 	<p>2021 </p> <p><b>BEE HEALTH</b></p> <p>Sell-side advisory</p>  	<p>2021 </p> <p><b>CareCloud</b></p> <p>Buy-side advisory</p> 	<p>2021 </p> <p> MOBILE VASCULAR PHYSICIANS</p> <p>Sell-side advisory</p> 	<p>2020 </p> <p> gsk Pfizer</p> <p>Sell-side advisory</p> 

# Alantra – Selected Recent Technology Transactions

2022 



Sell-side advisory



2022 



Sell-side advisory



2022 



Sell-side advisory



2022 



Buy-side advisory



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Buy-side advisory



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Sell-side advisory



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Alantra benefits from a global senior Healthcare team with deep local presence, able to reach global strategics and investors

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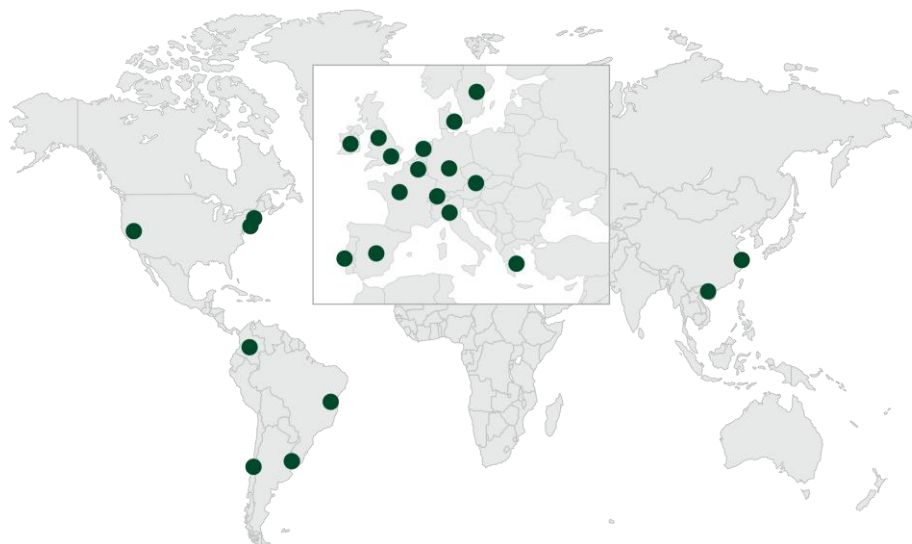
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25

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555+

Financial Professionals<sup>1</sup>

100+

Partners<sup>1</sup>

\$265bn+

Deal Volume<sup>2</sup>

1,420+

Completed Transactions<sup>2</sup>

1,065+

Clients Advised<sup>2</sup>

(1) As of Sep 2022. Excludes professionals from strategic partnerships where Alantra holds a minority stake (Singer CM, ACP, Wealth Management, Asabys and Indigo / Includes Corporate Services professionals

(2) Since 2013

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Possibility is in the ascent

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Belgium  
Brazil  
Chile

China  
Colombia  
Denmark  
France  
Germany

Greece  
Hong Kong  
Ireland  
Italy  
Netherlands

Portugal  
Spain  
Sweden  
Switzerland  
UAE

United Kingdom  
United States