EP.128 - Harsha Rajasimha

Narrator: You're listening to *BioTalk* with Rich Bendis, the only podcast focused on the BioHealth Capital Region. Each episode, we'll talk to leaders in the industry to break down the biggest topics happening today in BioHealth.

Rich Bendis: Hi, this is Rich Bendis, your host for *BioTalk.* I really have an interesting guest today, someone who I met when I first came to the BioHealth Capital Region probably 10, 11 years ago. He's an entrepreneur who has done many different things. I have trouble keeping up with him. But he gets me engaged in a lot of activities, whether I want to be or not. So he's a good partner for all of us in this region, has some unique assets and skill sets which we're going to talk about today. I have Dr. Harsha Rajasimha, who is with us on *BioTalk.* He is the Founder and Executive Chairman of Jeeva Informatics Solutions but also has a non-profit entity called Indo US Rare, which we're going to talk about as well, which has got a major conference coming up later this year, which a lot of the listeners are going to be interested in.

0:01:14 I'm just going to refer to Harsha as Harsha, from here on out. So, Dr. Harsha, how are you?

Harsha Rajasimha: Very good, Rich. Thanks for having me today.

Rich Bendis: It's great to have you, and welcome to *BioTalk*. Generally what we do is have each person introduce themselves, because you know yourself better than I do. So let's go through a brief introduction, or as long as you would like to take, about how you got to where you are today, Harsha.

Harsha Rajasimha: Certainly, Rich. I am originally a computer science engineering major, did my master's and PhD in computational biology, genetics, sort of in a highly interdisciplinary program from Virginia Tech. That was a long while ago, so about 23 years now in the DC metro area. And, experience spanning NIH, FDA, and academic research for the first 12 years of my career.

0:02:05 Then, personal experience of a child born with a rare congenital disease got me into social entrepreneurship. Since then, I started looking at, what are the unmet needs for patients affected by rare diseases. Until I had—

my younger brother was juvenile diabetic, and that personal experience got me interested in chronic conditions as well. So, essentially, for the last 10 years, my entrepreneurial journey has been trying to listen to various stakeholders—industry, researchers, and patients—on what are the barriers, bottlenecks, to developing or accessing therapies during clinical development and beyond.

Rich Bendis: You've done this basically as a clinician but having a very diversified background leading to where you are today. You mentioned rare diseases before you got chronic diseases. So, what interests you in rare diseases, Harsha?

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Harsha Rajasimha: Essentially, we had a newborn baby with Edwards' syndrome, which was a rare congenital disorder. We have two daughters, I and my wife, 16 and 9, and in between the two, we had a baby with Edwards' syndrome that did not make it back home from the NICU.

Rich Bendis: Sorry to hear that, Harsha. But sometimes, unfortunate personal experiences help guide your future, and you're looking to help solve some of the problems so that other people who have gone through what you have gone through hopefully might not have to go through in the future. So, again, sorry that you had to go through that with your child, but I think that what you're trying to do today is very admirable. And we're going to talk about that from both a for-profit and a non-profit perspective. Let's start with your entrepreneurial journey, first with your business that you have, which hopefully enables you to do some of your non-profit things, because of building a successful business, and that's Jeeva Informatics Solutions. So, talk a little bit about Jeeva and how it was formed, how the idea came about, and what does Jeeva mean.

0:04:05

Harsha Rajasimha: Absolutely. Jeeva literally means life, and Jeeva came about essentially to address this access problem. About 30,000 new clinical trials are started each year, these days, and out of that, about one third of these clinical trials are for rare diseases, or orphan indications. More than 80% of clinical trials are conducted in the United States and European Union, for

new drugs and therapies, leaving the rest of the world with very little or no access to these life-saving therapies. And the disparity is even more significant in rare diseases, compared to common diseases. Of course, if it's a tropical disease or infectious disease, those clinical trials happen in regions where they are more prevalent; not so much for rare and genetic diseases. The second is, even within the United States, people living far away from Boston, Bay Area, Bethesda, do not have equal opportunity to enroll and participate in these clinical trials, just because the location of the site is too far, and the frequency of visits to these sites is a barrier for patients to enroll and complete these clinical trials.

0:05:17 And so, this geographic access was the problem that I identified, listening to clinical trial stakeholders on how we can solve the problem.

Rich Bendis: Did you first observe this when you were working at the FDA, Harsha?

Harsha Rajasimha: I did observe a little bit of that at NIH and FDA, but more so after I actually did a discovery exercise. Then I had moved to healthcare life science consulting, working for the big pharma, going to their research and development centers in New Jersey area and visiting their big campuses. What's happening in one building is not known to what's happening within the same company, in another building; so, this "not invented here" syndrome.

0:06:01 And so, because the whole process of bringing new drugs to market is so complex, there is no single individual who knows it all. And so different functional groups have to work together in a collaborative manner, within a pharmaceutical company, but also with the contract research organization, or a CRO, along with the investigator sites and patients. So, it's a collaborative effort. And we heard various problems like having to log into 30 different tools to make one trial successful, and also having patient recruitment being the number one problem. Almost 85% of trials are delayed 30 days or longer because they can't recruit the right patients in a timely fashion.

Rich Bendis: Basically, how have you determined what the products and services are that are needed within this marketplace?

Harsha Rajasimha: There are a lot of tools—that's the good news—but what's lacking is a

platform approach. Because there are so many different tools, the sponsors and CROs have to select 30 different tools to make one clinical trial successful.

0:07:04 Point solutions—one for informed consent, one for telemedicine, one for patient-reported outcomes, electronic data capture system, and the list goes on. So what we identified was the significant logistical burden on the clinical researchers to execute a study. So we brought together many different pieces in a platform approach, in a modular and unified platform, so they don't have to go to many different vendors and validate them for regulatory compliance and data security, privacy stuff. They could do that with a smaller number of—platform-based approach.

Rich Bendis: And basically what stage is the company now? Are you still in proof of concept, pilot stage, or are you actually rolling the products outs?

Harsha Rajasimha: We have rolled out the platform and several products, and it's in use in biopharmaceutical pivotal clinical trials both in the United States but also recently started in India as well, for CAR T cell and gene therapy trials running Phase 2A, 2B type trials; ointment for an anal cancer pivotal trial in the US; multi-center trials are running on the platform, using many of these different modules.

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Rich Bendis: Basically you've gotten to at least one of the milestones every entrepreneur likes, and that's actually people are paying you for your product?

Harsha Rajasimha: Absolutely. Multiple of them. [laughs]

Rich Bendis: That's great. Congratulations! How are you distributing and marketing this throughout the United States and around the world?

Harsha Rajasimha: We have taken a PR, digital marketing, and sales—all three together—because all are necessary in this marketplace to build trust, communicate what we are doing, what problems we are solving. Because it's very noisy when a lot of people talk about patient recruitment. Which part of patient recruitment are you solving? Which part of clinical trial management are we solving?

0:09:00 And so we have done an effective job, or are trying to do an effective job, of bringing PR, marketing through social media channels, as well as through our word of mouth of our early customers. So that's one organic sales channel. The second is through contract research organizations who already have client relationships with biopharmaceutical companies. They could be our value-added resellers or distributors of our software as a service. So we have about 15 partnerships established so far, and half of them are already bringing those opportunities. We are constantly submitting proposals, quotations. So that's our second channel.

Rich Bendis: That's great. Let's talk about the BioHealth Capital Region as a place to start an entrepreneurial life science service business like you have. How has it been for you? When you came up with your idea, you probably went through many iterations of it. And what kind of resources have been in the Region to help support you to get you to where you are today?

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Harsha Rajasimha: Significant opportunities, actually, starting with the Small Business Development Center at George Mason University, where I have been an affiliate faculty in the School of Systems Biology, a program called ICAP—Innovation Commercialization Acceleration Program—which essentially told me, "Harsha, you are a scientist, an engineer, you can build products, but have you done customer discovery? Have you identified product-market fit?" The similar question came up when I came to BioHealth Innovation, did a pitch to the Entrepreneurs in Residence there. They grilled me on, "Where is the product-market fit? How do you *know* that? You are making wild assumptions, or have you really validated that?" And so, I'm glad that I went through this initial rigor and guidance that led me to start with our team focusing on customer discovery, early on. We got this grant from National Science Foundation, $50,000 for seven weeks, and 100 interviews within seven weeks, with target stakeholders, identifying hair-on-fire problems, and what is the value prop that our product or platform potentially solves.

0:11:13 Within that seven weeks, we were able to at least determine that there is a hair-on-fire problem for which our solution could be a fit. But that was not sufficient, and we continued to do about 10 to 15 customer discovery

interviews per week, over the last three or four years. So we have now interviewed over 3,500 stakeholders. And, went through a couple more accelerators along the way, all in the BioHealth Capital Region, including the RAMP regional acceleration program, and also the Virginia Venture Partners became a lead investor in our pre-seed round. And, got about 25 to 30 angels who have invested over a period of time, most of them in the BioHealth Capital Region. So, it has been a fantastic journey, and leveraging a lot of resources that exist, and very willing and eager to help entrepreneurs be successful in this area, more than most other regions, I would say, where maybe there is too much of demand—or too less demand—for these types of support services. So, it has been a good journey so far.

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Rich Bendis: Are you actually working virtually, or do you actually have a physical office where people come to the office?

Harsha Rajasimha: It's a combination of the two. Obviously during the pandemic, we did mostly virtual, almost entirely virtual. After that, we now have an office in Manassas, Virginia. Another local resource—IGNITE grant for entrepreneurs, especially in the life sciences, with the Prince William County IGNITE grant that we were awarded competitively last year. So, we moved our headquarters to Manassas, and we have a Regus building there, shared office space, which is meeting our current needs. It's very scalable, and so as we need to grow more physical space, we can do that. But being a software company, much of our activity happens remote and online.

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Rich Bendis: That's good. I know Prince Willian County and their incubator program because they have been a sponsor of the BioHealth Capital Region Forum, and offered some of the services to people who had applied to our Crab Trap competition. So, yeah, it's a very good partner for the region, and a very good area for you to have your business. So, glad to see that you've settled in Virginia, which is part of the BioHealth Capital Region. We have not had as many guests from Virginia, and that's going to grow, because

we're starting to spread more to VCU and Virginia Tech and of course we work with Amy Adams, at George Mason, which you know. So it's a burgeoning and growing part of the region now.

Harsha Rajasimha: Absolutely, it is, and so exciting.

Rich Bendis: Yes, it is exciting. Based on where you are with Jeeva right now, when did you decide that it was also time to get involved in forming a non-profit 501c3 around rare diseases?

0:14:05 How did that evolve? Because entrepreneurs are generally busy enough for their *for-profit* business. You decided to tackle a non-profit entity at the same time!

Harsha Rajasimha: Absolutely. The journey began in 2012, soon after our personal experience, and both Jeeva and rare disease non-profit work both began at the same time. I ended up cofounding the National Organization for Rare Disorders in India, at that time, and then founded the Indo-US Organization for Rare Diseases. Because I saw that India cannot do it on its own all by itself. This is a global issue. The United States has come as far as we could from last 35, 40 years. In fact, we are celebrating the 40th anniversary this year of the U.S. Orphan Drug Act of 1983. And so, we need to collaborate and do more cross-border collaborations. That was my insight as I started.

0:15:02 Especially talking to many patient foundations and groups in the U.S., their big question was, India has such a huge population. Even with rare diseases, you've got to have several thousands of patients with these diseases. So how do we identify, connect them, and engage them in the process of discovering and developing new drugs, which is the patient-focused drug development paradigm that the FDA and NIH have been really fostering in the U.S. So, we decided to take that mindset and approach to India, and with that vision, we were able to bring together a team of entrepreneurs, scientists, physicians, all together, and philanthropists, to found this non-profit there as well as in the U.S.

Rich Bendis: Basically, as an entrepreneur, it's challenging enough to run a for-profit business. But to run in parallel, a non-profit business, can be probably even more challenging. How do you balance your time and your priorities

between the two?

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Harsha Rajasimha: Roughly I would say almost half and half. [laughs] It's two full-time jobs, running in parallel, and takes a very supportive family, which I'm fortunate to have. So I get to do what I do, because my wife allows me to do that [laughs], driving kids around to classes and other programs and such. But essentially, leveraging other people's and other institutions' resources, is how we do this. Entrepreneurship is all about how do we leverage the community. Mindshare is another community that I became part of last year, which is a community of product company CEOs in the D.C./Virginia/Maryland area, over the last 25 years. We have a community of 1,100 or more CEOs that have come through at least certain success in this area. It's a peer-to-peer community. We can post questions or request help, and someone else who has faced the same similar problems can chime in, and so on.

0:17:02 But also leveraging all of these economic development resources that are available. Grant programs. We were fortunate to get the Virginia Governor's Commonwealth Commercialization Fund grant, and stuff like that. So, we have been trying to effectively leverage as many external resources as possible to build both this for-profit and non-profit together.

Rich Bendis: I think that it takes entrepreneurial skills to run both a for-profit and a non-profit. But I think one of the things an entrepreneur who is running either one of them needs to know—the best skill is, how do you put your hand out, and have somebody put some money in your hand? As you're always looking for money, right?

Harsha Rajasimha: One hundred percent. That's the first job! [laughs]

Rich Bendis: It's the toughest job, but yet one that the CEO can't get away from. Because if you don't do it, then it's very hard to delegate that, right?

Harsha Rajasimha: One hundred percent.

Rich Bendis: So, let's talk a little bit about the patient registries, and what impact they have in rare disease research, Harsha.

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Harsha Rajasimha: Patient registries that NIH and FDA have both pointed out for several years now is very critical, especially for rare diseases, where the scientific literature is very limited, because of lack of funding to study or research these rare genetic diseases that affect fewer, smaller population. And so, what that means is since we don't understand the science, the physiology, and the etiology of these diseases, we have to create a registry of all these patients who self-report our clinically curated database of, what are the symptoms, what are the pain and severity of those symptoms, of each of these patients. And understanding them over a period of time, which is often called the natural history of the disease. All that has to be well curated, and that should supplement the limited scientific literature—together would make it a very compelling or necessary data to advance any drug discovery or development programs in the biopharmaceutical space.

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Rich Bendis: So the key—I would imagine it's not easy, though, when you're trying to look at all of these patient registries. So what are the major obstacles, when you look at rare disease research and treatment of those rare diseases?

Harsha Rajasimha: The obvious one is the smaller patient population for a given rare disease. Historically, these diseases have been studied in a single country, funded by often government programs. And so, this nationalistic view of a rare disease is not going to help even the same country that is funding this program, because we can only find small number of patients within any given single country. Even a very populous country like India, for example, which is now the largest population in the world, has probably tens of patients with an ultra-rare disease such as Pompe, which is a lysosomal storage disease.

0:20:00 And so, same thing in the United States. We have been building these registries, and some of these are starting to be global, where patients from outside of the U.S. can participate in these patient registry programs. But the need for making these registries global is very clear

and obvious, particularly for rare diseases. That's what we are trying to do with Indo-US Organization for Rare Disease, is to help make these connections. Yes, the intent is there, the recognition is there. We don't need to sell on that. Everyone understands that. But how do we make it happen? How do we find these patients? Where are they hiding? There is social stigma for patients to come out and speak up, and be known, as a person with a particular rare genetic disease. It may affect their insurance or other lifestyle and other programs. But they have to be the champion for themselves. And the family members have to champion for the person suffering from a rare disease.

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The best thing they can do is get into these patient registries and natural history studies. Because when there is a new drug, a gene therapy which could even be curative—one-and-done gene therapy solutions, which increasingly are targeting single-gene rare diseases—the sponsors are going to look into these registry databases for, "Where can I find patients to recruit for a clinical trial?" For some of these diseases like Duchenne muscular dystrophy, there is five, ten different companies running clinical trials and looking to recruit patients. Where would you think they all go to find these patients? Obviously in the patient registries for Duchenne muscular dystrophy. So if you are a patient out there listening to this, and you have a particular rare genetic disease, you definitely want to be part of as many databases, be discoverable, identifiable, so researchers can contact you and see if you would be interested in enrolling in a research study or a life-saving clinical trial, which could actually benefit your health outcome over a period of time.

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Rich Bendis: I'm sure we're going to give them contact information of how they can get in touch with you, so you can put them in contact with the other resources that may have an interest in their specific disease. But before we get into some of those things which we'll close on, I would imagine if you've got a chronic disease, it's easy to get the attention of a pharma or a biotechnology company, because there's a potential large market out there for a product. But when you're dealing with rare diseases, generally they're very small markets. They're not the multi-billion-dollar opportunities that the pharma companies are looking for. So, how do you

get the attention of the pharma and bio companies, and which companies seem to be most interested in rare diseases these days?

Harsha Rajasimha: Interestingly, in the last few years, tens of billions of dollars have gone into cell and gene therapy biotech companies.

0:23:06 They have the potential of being one-time treatment and curative. They come close to being called a cure for those diseases. And there have been success stories, with the CAR T cell therapy for leukemia, lymphoma, that Novartis came up with. Affordability is a whole different question. How affordable are these therapies? But given that their lifetime effect or long-term effect—let's say 10, 15, 20 year potential quality of life improvement or long-term survival effect that some of these cell and gene therapies have had—it offers a significant hope and significant promise to address many of these debilitating, severe, terrible diseases, like spinal muscular atrophy, which now has three cell and gene therapies approved from different companies that have come up with long-term treatment options, which affect children under the age of five.

0:24:02 With this treatment, if diagnosed and administered in a timely manner, can give them a significant less painful longer quality life. So, essentially that's where we see the big opportunity, is patients living anywhere in the world can access a clinical trial for these one-and-done gene therapies, travel to the investigator site. Often times, these sponsors may not be able to set up a site in every single country, but if they have a small number of sites, patients can travel to those investigator sites, get the one-time shot, and be monitored remotely, go back to their own countries and be monitored from there. That's the opportunity that these offer.

Rich Bendis: I would imagine that when you're talking about these opportunities, it's all about connections. I would assume there's a role for government, and a role for NGOs, and foundations, charitable foundations, that might play here? Talk a little bit about the government and NGO role here.

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Harsha Rajasimha: Absolutely. Essentially these individual rare diseases have at least one or more patient advocacy groups that focus either on research, or

government advocacy, or industry advocacy engagement type activities. So these non-NGOs essentially are member organizations of Indo US Rare, where we now have about 40 member organizations covering about 500 rare diseases. Eighty percent of them are U.S.-based organizations that sign up as our member, and about 20% currently are based out of India. They are mutually interested in connecting with each other, and with industry. Especially patient groups coming from India request, "How do we connect with pharmaceutical companies that are working in our rare disease?" For example, the Rett Syndrome Foundation of India, they already know through ClinicalTrials.gov that there are several companies developing drugs or repurposing drugs for Rett syndrome, and they are all mostly located in U.S. or Europe or Australia. How do we connect with these companies?

0:26:07 So that's where we play a role, by bringing a Patient Alliance Program, a Corporate Alliance Program, and a Rare Disease Legislative Advocacy program—that we work with EveryLife Foundation—to go talk to the Rare Disease Congressional Caucus, here in the United States, as well as we have an India Caucus on the Capitol. So we try to connect the two together—senators and congressmen who are part of either of the two, we encourage them to be part of the other caucus, so they can make those connections and make India one of their allies. Even the patient population and the rich genetic diversity of the patient population that comes from India, they can actually help American biotech companies be successful in timely patient recruitment and bringing treatment options to market faster.

0:27:01 And it also is humanitarian. It helps patients access these lifesaving treatments faster. That's not denying any opportunity for patients already in the U.S., because they are all covered already, because they are enrolled in one of the clinical trials. So, it's a win-win, for everybody.

Rich Bendis: You've mentioned the United States and Europe and India. What about South America, Africa, China, and some of the other large populations? Are they engaged in this process or becoming engaged?

Harsha Rajasimha: "They are becoming engaged" is a better way of saying that for now. We have an organization called Rare Disease International, which is

independent, located in Europe, that works with the World Health Organization, United Nations. I have been invited to a couple of the United Nations meetings. There are some global initiatives. Industry is also involved in these global initiatives. Like Takeda, Microsoft, and European Rare Disease Society—all three came together to launch the Global Commission to End the Diagnostic Odyssey for a Rare Disease.

0:28:07 A mouthful to say, but it was a one-of-its-kind program that was launched a few years ago, about four or five years ago. We need more such global initiatives to address rare disease as a global public health challenge. So they have come up with this "universal health coverage," as a mantra, or a motto, which requires engaging Latin America, Africa, Asia, and other countries, which have not been as engaged historically in rare disease research. And so currently, many countries are now putting together a national policy for rare disease, starting with the U.S. being the first one in 1983. We have had European Union have their own version of Orphan Drug Act. And then Japan and then a few other countries. India adopted a National Policy for Rare Diseases in 2021, and now they have set aside a budget of 50 lakh Indian rupees, or 5 million Indian rupees, to individual patient affected by a rare disease that is recognized officially by the Indian policy.

0:29:18 So that becomes a market for launching orphan drugs. Even though that may not cover the similar pricing that we may do in the U.S.--the purchasing power of a large number of the Indian middle class, and the upper middle class, and even provided by the government, of this five million Indian rupees, we are now asking U.S.-based orphan drug companies to think of their global launch strategies. You want to think beyond U.S. launch and Europe launch and Japan launch. You want to concurrently think about launching in India and many other countries. So the economies of scale can help you realize the value of your [0:29:56] investment.

Rich Bendis: It sounds like an admirable challenge, Harsha [laughs], and not an easy one. But whenever you're doing new initiatives like this—and this isn't totally new, but it's still emerging—there has to be someone as the recognized leader, visionary, champion.

0:30:13 If you look globally or even nationally in the United States, is there a recognized individual or organization that is the driving force around orphan drugs and rare diseases, around the initiatives that you're focused on now?

Harsha Rajasimha: There are many different champions, and there's a growing number. We have one on our board at Indo-US Organization for Rare Disease, which is Frank Sasinowski. He has singlehandedly been responsible or influenced the approval of 10% of all approved orphan drugs, and so far we have about 1,100 approved orphan drugs over the last 40 drugs. He is a regulatory attorney, and he was working for the FDA during the 1980s in the early years of implementing the Orphan Drug Act that was signed into law by President Ronald Reagan back then.

0:31:05 And so, he is one of the legends of rare disease, and we are fortunate to have his guidance and advice on our board, right from the beginning. And we have had Dr. Stephen Groff, the Founding Director of the Office of Rare Disease Research at NIH. He has been a mentor and advisor for not just me but many other patient foundations and entrepreneurs. And we have Dr. Bill Gahl and several other individuals that have touched our journey and guided our focus, in shaping it. I view it as an elephant—the problem as being an elephant—which many different champions have looked at the elephant from ten different angles. My job, as a social entrepreneur, is to stitch the puzzle together, build the whole elephant, by listening to various different perspectives, from patient, from regulatory, from industry, from government and policy.

0:32:01 And these restrictive, nationalistic policies, how do we break these barriers? Essentially that is what ensures progress in rare disease, is we've got to be warriors, who are good at breaking barriers down. Breaking barriers often means building bridges, and that's what we are doing, is building these collaborative bridges between the United States and India, as a starting point. We can't solve all of the problems at once, but it's a starting point. If it can bring U.S. and India together with their complementary strengths and resources, that's solving a quarter of the world's population, and that's a huge starting point.

Rich Bendis: Well, that's a good start! And from now on, I'm going to refer to you as

"The elephant whisperer," right?

Harsha Rajasimha: [laughs] Yes.

Rich Bendis: You're going to bring all of the elephants together, and all of the—you're an intermediary to bring all these groups together and create greater awareness of this societal need that we have. And one of the ways to create awareness is really to host global conferences, and to elevate the knowledge for everybody by getting extremely good speakers to come, talk about this, so everybody can understand what the challenges and the opportunities are, and trying to work together.

0:33:12 I know you're planning an Indo US Rare Summit for October 29th and 30th, which is going to be held at George Mason University campus in Arlington, Virginia. Talk a little bit about this. Is this going to be the first or second one, Harsha?

Harsha Rajasimha: It's the first in-person inaugural Indo US Bridging RARE Summit, that we call. I am super excited about this event, as we are seeing a lot of interest from industry, academia, government, as well as patient advocacy groups, coming together here in Arlington. What we are hoping to do is, like you said, bring all these key opinion leaders and movers and shakers in the rare disease—many people have been doing great work in their own way, and so by putting them all together in a very open dialogue and conversations, over two years [sp] of immersive discussions on hot topics, and topics that we have been hearing matters to these groups, we hope that collaborations will grow, and new ideas will come, and we will take action items and take it forward.

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Rich Bendis: Who can attend and how do they get invited to this conference?

Harsha Rajasimha: There is a website, IndoUSRare.org/summit, and we are currently inviting speaker proposals, so if you have an opinion about how we can solve some of these problems in rare disease, particularly between U.S. and India, and how we can make this happen at scale, please submit a speaker abstract. If you'd like to attend as a government, patient group, industry, you can start registering very soon, maybe later this week or

next week. Registration should be opening up very soon. But you can look up the program outline agenda and learn about the various sessions that we have planned, from starting with the keynote panels; through diversity, equity, inclusion and access in clinical trials in rare disease; but also the diagnostic odyssey of rare disease and screening programs; and care pathways.

0:35:14 Because there is no standard of care for many of these rare diseases, as patients have to go to multiple specialists before they get a proper diagnosis. Then, leading to industry panels. Data is a huge part of rare disease, and so we will have a session on rare disease digital ideas, AI, ML, ChatGPT being hot topics these days, on how those can help accelerate diagnosis or R&D for rare disease. Global launch strategies will be another focus, where we will bring emerging and mid-market biopharma companies, thinking about launching an orphan drug or product, how they can think differently now knowing that India has a national policy for rare disease, but also many other countries are opening up as markets, emerging markets.

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Rich Bendis: So really, people might be interested in talking to you about one of three things, or all three things now. Because you have three full-time jobs now, Harsha. You're CEO of Jeeva Informatics Solutions. Are you Chairman of the Indo US Rare Disease Foundation?

Harsha Rajasimha: Yes, I am.

Rich Bendis: Okay, you're Chairman there. Then you're also the Chair of the Indo US Rare Summit that’s going to be held. Having planned conferences myself, and also running a non-profit and a for-profit, you have three full-time jobs and you only need 120 hours a week to do all three things.

Harsha Rajasimha: That’s right. I did not realize what I was getting into. [laughs] I thought it was just one of many events that we organize as part of the Indo US Rare. And it turns out it’s a full-time job in itself. [laughs]

Rich Bendis: Yes. Well, you know what, though? If you want to get something done, you know how you get it done, right?

Harsha Rajasimha: Absolutely.

Rich Bendis: You take on the challenge, and it takes great entrepreneurship and vision to do this, and people who are committed to a special purpose. And you definitely have a special purpose here, driven by personal experiences, which have brought you to where you are today.

0:37:07 If people want to learn about Jeeva Informatics Solutions, what is the website there that they can connect with?

Harsha Rajasimha: I am relatively easy to find on LinkedIn, Facebook, Twitter, YouTube, Instagram, so you can go to any of these with #JeevaTrials being the hashtag in all these channels. J-E-E-V-A-T-R-I-A-L-S; #JeevaTrials. And the website is JeevaTrials.com. You can look up my name, Harsha Rajasimha, and you'll be able to find me on any of these channels as well.

Rich Bendis: Please spell your name for everybody, Harsha.

Harsha Rajasimha: First name Harsha, H-A-R-S-H-S-A. Harsha@JeevaTrials.com. Or, on LinkedIn, with my first name and last name—Harsha, R-A-J-A-S-I-M-H-A. Rajasimha.

0:38:04

Rich Bendis: Great. And so they can find you very easily there. And also, as you know, when we do the *BioTalk* podcast, we'll do a transcript, and we'll have all the connecting points in the transcript which will release on all of the social media that we do as well as in our newsletter, which will hopefully come out either next Tuesday or the Tuesday following, depending on when we can get this edited and ready for airing. Is there anything that we didn't cover that you would like to let our listeners know about, Harsha? We're talking to Dr. Harsha Rajasimha, who is the Founder and Executive Chairman of the Indo US Rare Foundation, as well as Jeeva Informatics. So, anything we didn't talk about?

Harsha Rajasimha: To learn more about this Indo US Bridging Rare Summit, please go to IndoUSRare.org. That is I-N-D-O-U-S-R-A-R-E dot org.

0:39:03 I invite all of you to join us on October 29th and 30th. It'll be an exciting two days, so I hope you will all consider joining and supporting the

summit.

Rich Bendis: Harsha, it has been great to learn about all of the initiatives that you're engaged in. I wish you the best of luck, and we'll have to do a follow-up and see what kinds of cures you can come up—for some of these rare diseases in the future.

Harsha Rajasimha: Absolutely, Rich. Thank you so much for also being on the planning committee for the Summit, and your support, over the years, to me and many others entrepreneurs in this region. One last thing I forgot to mention is that day one, the 29th of October, of the summit, is a Sunday, and we are having an evening gala. So those who are unable to join both days, I encourage you to consider joining the evening awards ceremony and gala, where we will recognize some of the champions that are advancing and moving the needle for rare disease patients, globally.

Rich Bendis: Great. Thank you. You also have the last word, Harsha.

0:40:00 For all of the listeners, a lot to capture here. We'll summarize it all for you when we publish next week, hopefully. Harsha, best of luck in all of your ventures.

Harsha Rajasimha: Thank you, Rich.

Narrator: Thanks for listening to *BioTalk* with Rich Bendis.

End of recording.