NT Behind the Scenes: Jeeva Informatics, the Humanitarian Non-Profit Indo US Organization for Rare Diseases

Kimberly Hillyer, DNP, NNP-BC

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The following is an amended transcript for Neonatology Today Media of Dr. Kimberly Hillyer and Dr. Harsha Rajasimha.

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Introduction:

Thank you for joining us on today's broadcast. I'm Dr. Kimberly Hillyer, a Nurse Practitioner and the Media Correspondent for Neonatology Today. This segment features Dr. Harsha Rajasimha.

Dr. Harsha Rajasimha is the Founder and CEO of **Jeeva Informatics Solutions** (https://jeevatrials.com/). Jeeva Informatics Solutions is a digital health platform designed to provide a human-centric approach utilizing software technology to help clinical researchers and families dealing connect.

Dr. Hillyer: Thank you for joining us today, Dr. Rajasimha. You have an interesting journey in which you merged your educational concentration in computer software and engineering with the development of human genome sequencing. It seems like it's two very distinct pursuits. Can you explain how you put it together?

Dr. Harsha Rajasimha: Absolutely. I was graduating from my computer science engineering college at Bangalore University in India. I was coming for a Master's and PhD. program at Virginia Tech in Blacksburg, Virginia, in 2000. That was the year when the Human Genome Project was being completed. Then it was announced that it was really complete in 2002 when the annotations and the gene labels were all getting more cleaned up and formed up, and then again in 2004. So, the Human Genome Project has undergone minor revisions and new versions with the newer assemblies and annotations.

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That was super exciting to me at that time, coming from a computational background to get into the human genome. It seemed to have so much promise and potential to understand human health, aging, and diseases. Even the promise of curing many of those diseases by fixing those potential genes, which may be causative of all genetic diseases. Almost all human diseases have some genetic component. So, the promise and potential of the human genome was enormous and too enormous to ignore.

I started specializing in computational biology within the computer science department and later went on to specialize in my Ph.D. in the highly interdisciplinary program called Genetics, Bioinformatics, and Computational Biology. So, as I was going through those early days between 2000 to 2007, it was mostly bacterial and viral genome sequencing data that we were analyzing with the 454 and the early sequencers as well as the microarray chips. With the advent of the Illumina sequencers coming out in 2007, mammalian genomes could also be sequenced. Then eventually, the entire human genomes could be sequenced at an affordable price point. Now they have, of course, come down close to $1,000, and you can purchase the human genome sequence using a credit card for most Americans at least. It's becoming affordable in different parts of the world, including India, where the population is more than 1.3 billion. So, it's a really exciting space. A lot of computational algorithms to do string matching, string comparisons, comparative genomics, and even doing hierarchical analysis of the evolutionary basis of human evolution.

Dr. Hillyer: Now, after building academic expertise during the genomic boom. Your life merged with this new technology, and this journey became more personal. Can you describe that experience?

Dr. Rajasimha: So, it's been an exciting journey between 2000 to now. In the last 22 years, my career has spanned the National Institutes of Health at the Cancer Institute, the Eye Institute, and the FDA. Really the turning point for me was in 2012 when I had the experience of having a baby born, going to the Neonatal ICU—having to be put immediately in the NICU, and was diagnosed with Edward Syndrome, or Trisomy of chromosome 18. My daughter was named Kahushi. I have two daughters, one before and one after that incident, but the middle daughter Kahushi had Edwards syndrome and did not survive past four or five days in the NICU. So that experience really exposed me to genetic disease, congenital disease, and what patients and families go through in getting a diagnosis. In our case, we got a very quick diagnosis, but the majority of patients with rare diseases go through a seven-year diagnostic odyssey. If they eventually get a diagnosis, it may take about seven years on an average, and then, if they are lucky to be within the 7% or so of diseases that have FDA-approved treatment. Then they have some hope. If not, a majority of patients and diseases do not have any approved treatments.

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Dr. Hillyer: I'm so sorry that you had to go through this heartbreaking and life-transforming ordeal. As you were enduring this, you realized the connection between clinical trials for families dealing with rare diseases and gene therapy. Can you tell me more?

Dr. Rajasimha: So, the best thing that could potentially happen to that group of patients is that there's a clinical trial that they may enroll in, which potentially is a life-saving or curative treatment such as gene therapy. A majority of these known genetic diseases are monogenic and can be essentially fixed using gene therapy, which in simple terms is a treatment that goes in and corrects the mutation in every gene, in every cell, in the affected organ systems.

Certain diseases may only affect the muscle cells or the neuronal cells, or retina, etc. So, the technology is really getting better and more accurate. Certain challenges still have to be overcome, but with much hope and promise, close to 400,000,000 patients with a rare disease can really hope to enroll in a clinical trial or gene therapy. That's where the technologies and Neonatology with genome sequencing offer the opportunity to diagnose thousands of these rare genetic diseases in a single test. That's the promise and potential of genome sequencing.

Dr. Hillyer: By understanding the personal challenges for those with a rare disease and envisioning the future of genetics. You decided that your time with Kahushi, even if it was short, as her father, you would give her a legacy. You were able to combine this technology and advocate for families with a rare disease. Can you tell me about this new life work of yours?

Dr. Harsha Rajasimha: Absolutely, I never felt like I had a job in my entire career, as I really loved my job as a scientist between 2000 to 2012. After 2012, of course, after the life-changing experience of Kahushi being born and passing away. I really could feel the pain of many parents and families that go through this with children. What if the baby had survived and with a lot of special needs? Whether in a wheelchair with limited vision, hearing, and other disabilities. Parents go through a lot, sacrifice thirty years, and change their location and their lifestyle in a very significant way. You know, it becomes a financial, economic, and professional burden on not just the patient but the entire family. So, I started empathizing with that, and I felt like I had to be grateful that that was not the case in our case in some sense, but it could have been if it was a different medical condition, a chronic condition in which patients have to live with. There was so much more work to be done that essentially brought alignment and direction to my career, which was already involved in rare diseases to a great extent in my publications and research but also bringing the patient perspectives.

"That's when the FDA was really advocating for Patient-Focused Drug Development, the PFDD, and had started setting up a patient affairs team at the FDA, which engages with patient advocacy groups and also engages within patient listening sessions where patients with rare diseases were invited to speak, what matters to them for a given rare disease."

That's when the FDA was really advocating for Patient-Focused Drug Development, the PFDD, and had started setting up a patient affairs team at the FDA, which engages with patient advocacy groups and also engages within patient listening sessions where patients with rare diseases were invited to speak, what matters to them for a given rare disease. What kind of symptoms are families and patients most concerned about? What kind of drugs and treatments would they like to see? That would really help improve their quality of life. As many times cures are not available, but

only palliative treatments or treatments that address one or more symptoms of the disease but do not necessarily cure the cause of the disease. So, it was very important that the FDA allowed the sponsors to listen to what patients had to say and focus on addressing those problems.

It became clear to me that it was very important to the involved in patient advocacy, and informing and educating patients and families is such a critical component. In the United States, there are many nonprofit organizations and foundations, such as the National Organizations for Rare Diseases and also the Global Genes, which work not just in the United States, but on a global scale, helping very early-stage rare disease groups and also mature rare disease groups to work towards patient focus drug development with having the ultimate goal of finding treatments or cures for genetic diseases.

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When I look back at other countries outside of US and Europe, most countries do not have good patient advocacy and nonprofit ecosystem, and that's what I took the vision to India in bringing together a team of philanthropists and parents to form the National Organization for Rare Diseases in India from 2013 to 2019. I was co-chairing the board and contributed to establishing that as a sustainable nonprofit. Then in 2019, I founded the Indo-US Organization for Rare Diseases, which addresses a gap in rare diseases, genetic diseases, ecosystem, which is lack of genetic data, and engagement of the rest of the world with the US and Europe. Now, most of the genetic databases are American and European datasets, which is less than 10% of the world's population. So, we need to really do good science and understand the comprehensive genetic makeup. We need to look at data sets coming from the entire world or the representative of the rest of the world. That was a significant gap that I thought we should address. That's the goal of Indo-US Rare, to bridge collaboration between the United States and the Indian subcontinent, which together form more than a quarter of the world's population. There's also a need to engage Latin America, Africa, and the other neglected regions of the world. So, those are the gaps that we address through advocacy and nonprofits.

Now, technology innovation is also a critical component of this, and that's my engineering background in computer science and data science during my doctoral dissertations. So, I continue to see how technology innovation can help address these problems. That's where I founded Jeeva as a software service platform posted on the cloud to help clinical researchers accelerate the clinical trial process. Going from phase one, phase two, and phase three clinical trials to getting a regulatory approval which has a very time-consuming process and can cost upwards of two and a half-billion dollars to get one successful therapy to market. Now that's very unsustainable because to spend ten to twelve years of R&D and spend two and a half-billion. Now in rare diseases, there are not enough patients to recover the cost of the investment. So, it's very important that we want to speed up the process as patients are waiting and dying. But also achieve that acceleration without increasing the cost.

In fact, there is a need to decrease the cost by a couple of orders of magnitude for it to be made affordable and accessible to patients, not just in the rest of the world but even to patients in the US or Europe. That's the goal of Jeeva. Jeeva literally means life. Jeeva Informatics is analyzing and helping accelerate patient recruitment, patient retention, and patient engagement in a very flexible, easy manner where patients don't have the undue burden of having to travel to a clinical trial site or a hospital whenever it's not necessary. Making the whole process go streamlined and faster. That's what we do at Jeeva as a technology innovation company.

Dr. Hillyer: You've pointed out ways Jeeva Informatics can help, but it starts with the correct diagnosis. Can you tell me about your experience with Kahushi once you received the diagnosis? Did you have an opportunity to participate in a clinical trial?

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Dr. Harsha Rajasimha: Yeah, that's a very heartbreaking experience to recollect, Kimberly. Immediately at birth, the Neonatologist observed the visual cues on the baby and predicted that it was Trisomy 18 or Edward Syndrome but sent the samples for confirmatory testing. Then the baby was immediately put on ventilators and in the NICU. What we were told is that you know this is not a viable baby. The baby is not compatible with life, and that was devastating for me to see my wife hear directly from a doctor. With much hope, we had the second baby, and so that was a pretty disheartening and disappointing experience. How that was communicated to us, as to what the diagnosis was, and what it meant. It took us a couple of days to recover from the shock and understand what really was going on. By the time we got the confirmatory diagnosis, we were told you may want to get prepared

to pull the plug because you can't keep the baby on the ventilator forever. If you want to do that, we can do that, but it may be twenty days or ten months, but the baby is not going to be viable. You need to make a decision very soon. So, we had a consult with the spiritual leaders from the faith that we follow, Hindu. We contacted the Hindu priests on what's the right thing to do in a situation like this.

" In this particular instance, there was no clinical trial going on. No clinical trial aimed to treat or cure Trisomy, so there was no such option. But there are many diseases where that's not the case; about 2,200 clinical trials are registered on clinicaltrials.gov that aim to develop interventions to help patients with rare diseases."

We had to make the tough decision of having to not forcefully hold the life. You know the baby is unable to sustain life on her own, and we had to let her rest in peace. So, we had to pull the plug on day four, which was a very tough decision and thing to do.

In this particular instance, there was no clinical trial going on. No clinical trial aimed to treat or cure Trisomy, so there was no such option. But there are many diseases where that's not the case; about 2,200 clinical trials are registered on clinicaltrials.gov that aim to develop interventions to help patients with rare diseases. If the child happens to be in that category, then certainly enrolling in a clinical trial would have been the best thing to do, but that was not the case in our case.

The most important thing to note is that getting that faster diagnosis is the very critical first step. Then 93% of the time, rare disease patients fall in a category where there is no FDA-approved treatment. The best thing that they can try and do is be part of databases. Be proactive in identifying patient registries for a particular rare disease or be part of the natural history study, unlike common conditions, like diabetes, cardiovascular, metabolic, and cancer, where the natural history and the progression of how the disease progresses in patients are well understood. There's a number of patients in most countries, and doctors are gathering data researchers are studying that. So, there is a lot of information available and known to understand the natural progression of a disease. Whereas for rare diseases, that's very poorly understood because not many doctors are educated in rare diseases, necessarily. They are not experts or specialized in rare diseases. Medical Genetics is a profession where if it happens to be a genetic disease, which 80% of rare diseases are, they can hopefully help diagnose faster using genome sequencing or other genetic testing methods. Once that's done, the important thing to understand is these genetic diseases are very simple from a genetic test point of view. There are these monogenic diseases. There is a single gene there's a mutation that causes a particular disease, like cystic fibrosis. If there is a mutation in the CFTR gene, it causes cystic fibrosis. When you look at the symptoms, those can be very complex. They may affect multiple organ systems, and the severity of symptoms may vary from patient to patient. Even within the same patient, the severity may vary over a period of time. Also, which symptoms are more severe or less severe, can be very significant. So, there's a lot of heterogeneity in the symptoms that have homogeneity or consistent, easy single mutations. Single gene mutations are easy to diagnose from a genetic point of view.

What that means is that we need to understand the symptoms or the phenotypes of these patients and understand that's called the Natural History Studies. The FDA and NIH have been proponents in advising the rare disease communities to focus on building these patient registries and natural history databases that are a necessary prerequisite before a treatment can be developed for a given rare disease.

No good tools were available, and even now, there is a scarcity or lack of good affordable, well-designed technologies that can enable faster creation and maintenance. Because these studies may go on for five, ten, fifteen-year duration over a long period of time. It's important to have the necessary patient engagement. The patient should come back and be able to report the data and how the child or the patient is progressing over an extended period of time to help the researchers and doctors understand the disease better. Only then can they find potential treatment options and measure whether the treatment actually helped or not. That's what we enable with the Jeeva technology platform is a consistent, easy, simple, and affordable way of collecting data, engaging patients from the convenience of their homes in uploading lab reports, being able to share data, answering questionnaires, and signing electronically informed consent forms for data sharing. So, that's before the clinical trial begins, during the patient registry and natural history study phases. Once the trial begins, that's where the Biotech and Pharma companies get involved, and they are regulated by the FDA. The more premium version of our software helps Biotech Pharma companies set up and configure a complex clinical trial protocol within our system and run the entire clinical trial, and engage patients during the course of an actual clinical trial. So, it does both.

Dr. Kimberly Hillyer: Thank you for helping us gain perspective from the parents' side of obtaining these types of diagnoses -- Then further describing the aspects of a clinical trial. How can healthcare providers connect and collaborate with Jeeva Informatics? Do we have to wait until the child is born and have the genetic testing done before we can utilize your software?

Dr. Rajasimha: Great question. They can do both at the very early stage or after the baby is born. Either way. It just depends on the goals of the particular group. We are not a clinical care or a Neonatology hospital software. We are software specifically meant for the use of clinical research and for research use only. Hence it depends on the goals of the research that particular neonatology group may be conducting. For example, there is a hospital here in Fairfax which is working on preterm birth, studying, and understanding preterm birth. So, any baby that's born seven months or sooner will be enrolled in a clinical study to understand the mothers' parameters, the babies' parameters, the genetics, the symptoms, and the environmental factors. What causes certain babies to be born premature or preterm? If that is the goal, then certainly the neonatologists will have to be engaged very early during the pregnancy and start a collection of data. They could be leveraging the Jeeva software to enroll mothers, and expectant

mothers. Early during pregnancy, using our apps and a collection of data even after the baby is born, there may be certain sample collection, lab reports, and data collection that may need to occur after the birth.

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So, depending on the goals of a particular research study. All of this is plausible; it's also possible that certain Pharma companies, you know, like Johnson and Johnson, may make baby products and or even for expectant mothers, like the nutritional supplements. If they want to study the comparative study of before, on after, or compare the effectiveness of two different nutritional supplements, or say a certain treatment option meant for treating certain babies with the genetic diseases. That's where Jeeva comes in. The sponsor, either a Biopharma company or a Neonatology clinical researcher, can subscribe to the Jeeva software, which is very simple and easy to set up and it's a subscription-based service. If they have a three-month study or a three-year study, they only need to subscribe for the duration. They need only the features of the software. We have a very comprehensive suite of features for telemedicine, video conferencing, electronic informed consenting, collection of patient-reported outcomes, or obtaining and performing certain critical assessments by the Neonatologist on sort of babies or mothers. Not all of these features may be necessary for every single study because we have modular software; they can pick and choose the specific modules that are relevant to their particular clinical research and can subscribe only to those modules as well.

Dr. Hillyer: There are a lot of elements to what I hear your software is being able to offer. Thinking about one of the barriers you brought up earlier, you highlighted the global discrepancies regarding clinical trials when the concentration of work is in European and US countries. When clinical trials focus on less than 10% of the world, it is apparent that healthcare needs to work on incorporating a framework addressing diversity and the lack of inclusiveness that brings about disparities in the US and globally. How does Jeeva help to bring about change with this software technology?

Dr. Harsha Rajasimha: Great question. You know a number of different ways. One aspect is that most of the clinical trial enrollment has historically been restricted to clinical trial sites. In these neonatology units, for example, if it's a newborn scenario, not all mothers are necessarily going to the hospital systems unless they are in metropolitan areas. Many even now, in the United States, a lot of mothers give birth to babies in their homes, or in the bathtub, or in multiple ways. Having midwives and doing deliveries at home, and other modes of giving childbirth. So, it's very important that we, one reach out to patients and communities and mothers who may be living in far-off regions, rural areas, mountain areas, and other hard-to-reach geographies. These medically underserved populations, who are less likely to go and access the healthcare system in major medical research centers, which is where clinical trials usually happen. In the community setting, the mothers, even if they go to a community hospital, they will never be offered in a clinical trial. just because those hospitals are not involved in clinical trials.

It's very important that we enable reaching out on social media, for example, on the internet, and whoever has access to a digital device can now be accessed.

In the United States, 82% of the people have access to stable internet and access through some digital device to the internet. Whereas historically, less than 2% of patients or subjects are offered the opportunity to enroll in a clinical research study. Going from 2% to 82%, if you can go on the internet and inform and educate the potential mothers, who can enroll in a clinical study, that's a significant leap, and that's what the Jeeva software enables that, bring your own device. Where anyone can enroll with any device, whether it's a smartphone, tablet, computer, or laptop, it doesn't matter as long as it's a device with a browser and internet connection. They could be potentially reached through some channel, like Facebook or social channels or email or SMS. We offer multi-channel communication, engagement, and enrollment of patients via social media. Once they are enrolled, they can participate from whatever device they already have without requiring any extra cost of having to purchase a new device, either by the sponsor or by the patients. So, it's very cost-effective. That's how we enable more diverse patient engagement, even in some of our patient registry studies.

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We are working with the University of California, San Francisco, with Dr. Julie Saba on an ultra-rare disease. They have patients distributed globally, so it's not just within the US, but patients may be living in Pakistan, India, or other parts of the world. That may need to be engaged over a long period of time to collect data and information. That is all supported within the same platform with a single login and from any device. That's how we support diversity, equity, and inclusion programs. (32:11)

Dr. Hillyer: Supporting diversity, equity, and inclusion programs is vital. I also hear a logistical problem that plagues participation in these clinical trials. Yet, Jeeva Informatics coming up with the solution is critical. Tell me about your process within the clinical trial? Because one issue that I know is the everyday expense those in clinical trials have, and it appears Jeeva may even help families with that financial aspect.

Dr. Harsha Rajasimha: 100%. Kimberly, there is a direct cost and indirect cost, right? So, the cost of traveling to the site itself is expensive, but that's less than the indirect cost that the mother and father may incur in having to take time off their daytime work.

They are actually losing money from their income and also spending money on travel. The indirect cost of having to go to the site, especially when it's not required, is very unfair to the patients and families. That's what we hear from many of our Children's hospital collaborators at the National Children's Medical Center in Washington DC or other places. Where they say, as much as possible, we should engage patients where they are. It's easy to step out for an hour for consultation than to travel to Washington DC for an hour wait for an appointment, and then they would have spent three extra hours commuting, parking, and waiting, which is where they have to end up taking half a day off.

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That's basically what our platform enables to help clinical researchers to design clinical studies. Keeping, taking these logistical barriers and burdens into account. When they are designing the protocol because once the protocol is set, it's hard to change during the execution phase, whatever is the protocol that has to be executed. Now can we avoid every other visit, or eight out of ten visits, or five out of ten visits that can be done through the report, telemedicine, a video call, or a questionnaire that can be filled out from their own device online, or signing certain documents, and informed consent forms on the electronically from their own device? Just simple things like this, which technology exists, and we have followed a human-centric approach to making sure it's easy to include you. We can even provide training and support to help handhold certain patients who may need more help than others in helping them complete the process in a compliant manner for both the Institutional Review Boards and also for the FDA 21 CFR part 11 compliance. That's basically what I realized, and it's not the hard science of genetics and genomics where we are lacking. They're brilliant science that's going on, but it's really in these human problems in really understanding the logistical burdens. What's the pain that these patients and families go through.

That's what we did in the first year of our Company's existence. We did not develop the software immediately. We interviewed hundreds of patients, families, and researchers to understand what are their barriers and burdens? What do they go through? Where are the barriers and bottlenecks, and problems that we can solve? Most of them were human problems. Those were not scientific problems. If that's what it takes to help accelerate clinical research, let's just fix those problems. That's the difference between a social entrepreneur, and a general business person is that we are motivated to solve societal problems. Whatever tools, technologies, and science it takes to solve them, that's what we bring to the table.

Dr. Hillyer: I love that, and I love this concept of Human Centric software. Think about the barriers you discussed; I know another barrier is enrolling children, who we consider our most vulnerable population. I imagine getting parents to participate in clinical trials is challenging, especially those families with a child who has a rare disease. How do you help these parents understand this process?

Dr. Harsha Rajasimha: 100%, Kimberly. As we all saw during the COVID-19 pandemic, the vaccines came first for adults, the older adults, the young adults, and then finally the children, twelve plus and then five plus, and then newborns, and others, right. So, it's an underserved population, our children, and women in some cases as well, for certain diseases like cardiovascular, as we have seen over the years.

When we talk about diversity, the first thing that comes to mind is race and color, and so on. But age has been a significant diversity indicator significant lack of investments going in pediatrics for various logistical challenges that we discussed, right? These children have a very low-risk tolerance to drugs because they have an entire lifespan ahead of them, and a clinical trial could potentially affect that. So, the FDA is very right in emphasizing a very high level of scrutiny and setting very high standards for pediatric trials, which makes it hard. The other thing is the complex logistical problems of coordinating with their guardians, many times legal guardians. What one mother may feel is good may not be necessarily approved by the father or vice versa. So, making sure everyone understands the risk and benefits and having an assent that we can obtain in the case of pediatric trials. Whereas adults can consent on their own, the child is dependent on at least two parents many times. That's another challenge. Then finally, the children are growing as the trial begins because many of these clinical studies can last several years. A two-year-old child will grow into a six-year-old by the time a trial is complete, for example. Whereas adults going from twenty-five to thirty wouldn't make much difference. For all these reasons, the investments, in general, going into pediatric trials have been historically very low, and less than 10% of all clinical trials have some applicability in pediatric scenarios. More than 90% of trials target the other populations. What also resulted is a lack of digital engagement tools in the neonatology settings and the pediatric settings. We made it a point that even though the market was not as big for pediatric clinical trials, we still made it a priority to address that unmet need. I'm proud to say that our platform helps obtain remote inform consent in pediatric assent as well as consent in adult trials.

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We are disease agnostic, age agnostic, gender agnostic, and device agnostic. It's a generic platform that addresses these logistical and operational issues, irrespective of all these other factors.

Dr. Hillyer: Your Company is making a huge impact. I love the focus and that you've taken on the societal barriers. The global advocacy that you are looking at and addressing. What type of collaboration do you need from the healthcare community to help

support this goal?

Dr. Rajasimha: Yeah, absolutely. I think there is a need for more clinical research. Now that's the biggest message!

We need to engage, inform, and enroll patients in pediatric settings, and more research is needed. More data collection is needed, more high-quality patient engagement with minimum burden on the patient. So, with those types of tools now being available, there is no excuse or reason to delay any further in really ramping up. Especially with the advent of gene therapies, which offers so much promise or single-gene disorders for which there are more than 1,000 clinical trials going on. For gene therapy, the products call for an urgent need to educate and inform pediatric researchers to take the lead in the picking of multiple studies for various types of diseases where patients can be educated and enrolled in political research and patients are partners. They are not subjects, and they have rare diseases. People realize that more than anywhere else, where patients are driving and pushing the needle, and even pushing the researchers. They are demanding treatments. How can you say that my child has no treatment? You've got to something! You are a doctor! That's when there is no standard of care; clinical research is the answer. For long there has been Clinical Research as a Care Option (CRAACO), which is not a new concept, but that needs to be fully embraced by Neonatologists and Pediatricians to enroll and identify research opportunities when there is no standard of care for certain medical conditions. That's what I would say is the way to engage, and when they do, they can utilize the Jeeva software to enable and run those studies in a very cost-effective and simple matter.

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Dr. Hillyer: So now we've discussed how healthcare providers can utilize and collaborate with Jeeva Informatics, but how would you suggest we garner that same kind of collaboration on a national platform? How should we be talking to our healthcare advocacy groups in Washington?

Dr. Harsha Rajasimha: Great question again. There is a lot of public health focus, the kind of focus that COVID-19, brought about by our Senators, Congressman, local, regional, state-level, and Federal government levels. The same level of public health initiatives should be launched for every single disease. There are more than 7,000 named rare diseases, and most of them do not have any approved treatment right now. So, if we take up any single disease, that is the need to create a national patient registry, and there is a need to engage patients with a given disease in a single database and group on a state level, national level, and international level. Those are the types of things we need to look at. I think there are already a few couple 1,000 patient registry programs underway, both for common and rare diseases. So, it's not specific to just a rare disease; even for common conditions, patient registries are very important tools for policy decisions and for asking certain economic or policy level questions. Having those public health databases is key for surveillance like we did for COVID-19 surveillance contact tracing. We should be doing that for genetic diseases. In terms of surveillance and keeping a record, there are these genetic disease patients because we say there are more than 30,000,000 people affected in the United States with rare diseases, but a majority of those 30,000,000 patients are not in these databases right now. In any of these databases, we need to have accountability and track these patients in a responsible manner.

Making those datasets available for medical research in a responsible manner, in a compliant way, and in a de-identified manner where they're appropriate. That's what I would say can be done to really speed up. Just like we brought the COVID-19 vaccine in six months, which is never heard of before, that's the fastest that mankind has ever produced a vaccine on a drug in history. It's a very complex process. It really deserves kudos, but the same can be with the will of the government and the stakeholders. We can make that happen for many of these genetic diseases and rare diseases by identifying treatment options and comparing diagnostic tests or vaccines for certain diseases. All those research can be accelerated with a technology platform like Jeeva.

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Dr. Hillyer: We live during the age of COVID and being there from the beginning of the pandemic. We were able to see how quickly the world, the government, and healthcare were able to work together and tackle this devastatingly deadly virus. It is exciting to hear how your Company changed the focus and considered the logistical and social aspects that historically delayed medical progress. Your background with Indo-US Organization for rare diseases and this human-centric software could be the necessary change to overcome genetic conditions as we did COVID-19.

To collaborate with you and garner that change of support, how do we find out more?

Dr. Harsha Rajasimha: Absolutely, if you are a patient or patient advocacy group dealing with a genetic or a rare disease. Please contact the Indo-US Organization for Rare Diseases. We have a patient concierge technology where individual patients can look up IndoUSrare.org website. There is a patient contact form that you can submit, and someone will be in touch with you to support your specific need. Now it could be access to diagnosis, access to treatment, and access to critical trials irrespective of where you are located. That may mean that our staff will connect you with

the right researchers, stakeholders, and other organizations that may already be doing the good work. The concierge is meant to make connections with the right organizations and individuals. So, we are very happy to provide that as a free service to patients. So, you can contact us at IndoUSrare.org. The second, if you are a clinical researcher, a biopharmaceutical sponsor dealing with clinical operations, or a clinical research organization, a CRO, you can contact Jeeva Informatic Solutions, the human-centric software as a service platform that helps researchers accelerate patient recruitment, retention, and evidence generation from any device on any disease anywhere in the world on the internet. You can contact Jeevatrials.com, and you can submit a contact us from there or request a demo, and we will be very happy to assist you with your research programs in collaboration.

Thank you so much again. I can be reached at Harsha@JeevaTrials.com, that's my email address. I can also be found easily on Linkedin or other social channels.

Thank you, Kimberly, for having me today appreciate the opportunity and look forward to collaborating with the Neonatologists and other researchers.

Dr. Hillyer: Thank you so much, Dr. Rajasimha. I enjoyed our conversation and look forward to seeing how you and your software are working on making a social and global change within healthcare to address the needs of these vulnerable individuals.

Dr. Harsha Rajasimha: Thank you so much, Kimberly. I'm very hopeful that in collaboration with you and other researchers and patients, we can definitely change the world, and we are committed to doing that.

Preemie Spotlight

Kimberly: Your daughter Kahushi, who changed the way your life course went. Can you tell me what her name means?

Dr. Rajasimha: Absolutely, Kimberly. Kahushi literally means "Happiness" or "Happy," and that's the meaning of my name as well. My first name, literally being happiness, is just a male version, and Kahushi is the female version.

Kimberly: Does your company name Jeeva have a special meaning as well?

"Jeeva Informatics Solutions is the name of the technology human Centric SAS platform for research. Jeeva literally means "Life" cheaper meets life. And so the Company is dedicated to addressing life from, you know, which are mostly human, using digital technology."

Dr. Rajasimha: Yeah. So Jeeva Informatics Solutions is the name of the technology human Centric SAS platform for research. Jeeva literally means "Life" cheaper meets life. And so the Company is dedicated to addressing life from, you know, which are mostly human, using digital technology.

Disclosure: Dr. Rajasimha is founder and CEO of the decentralized clinical trials software company, Jeeva Informatics Solutions.

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About the Author: Kimberly Hillyer, DNP, NNP-BC:

Title: NT News Anchor and Editor

Title: Neonatal Nurse Practitioner & News Anchor, Editor for Neonatology Today

Organization: Loma Linda University Health Children's Hospital

Neonatology Today in partnership with Loma Linda University Publishing Company.

Bio: Kimberly Hillyer, RN LNC, NNP-BC DNP, completed her Master's degree specializing as a Neonatal Nurse Practitioner in 2006 and completed her Doctorate of Nursing Practice (DNP) at Loma Linda University in 2017. She became an Assistant Clinical Professor and the Neonatal Nurse Practitioner Coordinator at Loma Linda University. Her interest in the law led her to attain certification as a Legal Nurse Consultant at Kaplan University.

As a Neonatal Nurse Practitioner, she has worked for Loma Linda University Health Children's Hospital (LLUH CH) for twenty years. During that time, she has mentored and precepted other Neonatal Nurse Practitioners while actively engaging in multiple hospital committees. She was also the Neonatal Nurse Practitioners Student Coordinator for LLU CH. A secret passion for informatics has led her to become an EPIC Department Deputy for the Neonatal Intensive Care at LLUH CH.

She is a reviewer for Neonatology Today and has recently joined the Editorial Board as the News Anchor.

About the Author: Dr. Harsha Rajasimha

Dr. Harsha Rajasimha has over a decade of experience working on various interdisciplinary projects involving genomics and big data as a consultant for clients, National and International Institutes, and Corporations. He is the founder and chairman of the humanitarian nonprofit Indo US Organization for Rare Diseases.

He is a precision medicine data scientist-turned social entrepreneur on a mission to accelerate human-centric clinical research through technology innovation and global advocacy. He is the founder and CEO of the decentralized clinical trials software company, Jeeva Informatics Solutions.