The Clinical Research as a Care Option (CRAACO) team is proud to celebrate Women’s History Month by highlighting three CRAACO women speakers impacting change in clinical research.

Jennifer Byrne  
CEO & Founder, Javara

Melanie Igwe  
COO & Co-Founder, Drugviu

Amy Nordo  
Global Product Development, Strategic Partnerships, Pfizer
What was your entry into healthcare?

I’m very typical of a lot of clinical research professionals in that I fell into this field. I entered college with the hope of medical school; my mother was a nurse, I worked in a hospital lab and had plenty of exposure to healthcare.

Upon graduating with a nutrition degree from Texas A&M and not pursuing medical school, I was priming for a job as a pharmaceutical sales representative when a friend of a friend told me about a research coordinator position. The opportunity ticked a lot of the boxes, because I would have direct patient care, while also contributing to the wider impact of drug development.

Within a month, after having had very early experience interacting with patients, pharmaceutical companies and protocols – trying to find patients that fit my assigned clinical trials and working with doctors and a variety of clinical research professionals – I knew that I had found my life’s work. That might sound a bit dramatic, but it was true. My work has been a very deeply personal, mission-driven career. It’s taken a lot of shapes and forms over all of these years, but the fundamental things have never changed.

Can you tell us about your company, Javara?

After having been in my former organization for so many years, when I came out of that company I had a one-year non-compete. And that really did give me an opportunity to focus on Greater Gift [the nonprofit Ms Byrne founded that honors clinical trial participants by providing, on their behalf, meals and vaccines to children in need]. It also gave me an opportunity to imagine something different.

I had the opportunity to gain fresh perspective and think more about root cause barriers and meet with healthcare leaders of larger organizations to understand why clinical trials are not typically reaching not only the average person, but also not reaching people with cancer and rare diseases. Why, when I get together with friends and family, I am still explaining and describing what clinical trial participation is all about?

From a healthcare system standpoint, oftentimes, research is very decentralized, costs the institution money and does not take advantage of the data assets it has to match the right trial to the right patient at the right time. These are the things we are trying to solve at Javara; standardize, scale and bring about a better financial and outcomes model that benefits the patients, the doctors and, thus, incentivizes the system to better advocate clinical trials to its patient and physician base.

How does Javara make clinical trials more accessible?

With our healthcare partners, our focus is very, very centered on understanding what the unmet needs of the patients within that healthcare system are, matching those needs to the drugs and devices in development, and then going after that work with CROs, pharma and biotech. Our greater value proposition is understanding the patient population for whom our healthcare partners are responsible for providing healthcare services, and using their data, leveraging their own data insight, to shine a light on where those unmet needs are. When we do that well, we stand to decrease the cost of care, possibly improve outcomes for patients and be a partner to the healthsystem to improve both the physician investigator and patient experience.

What is an IRO?

When Javara launched in April of 2018, we coined a new term: “Integrated Research Organization” (IRO). To me, IRO is really the new descriptor for the business that supports CRAACO. The IRO is to a healthcare organization what a CRO is to pharma. I believe there are five organizations now that have pivoted and are positioning themselves as Integrated Research Organizations.

To this point in time, from a data standpoint, the clinical research journey has involved the patient participant, and we are collecting data in a very standardized, very regimented way. That data has been, more or less, to support the scientific questions for that particular protocol and in support of that FDA submission and ultimate approval.
There's a tremendous amount of standard-of-care data and insights on that patient. We have a responsibility to think about how that data from that particular patient is used, in terms of the ongoing benefit of that individual. And for the overarching population, for whom that particular patient-volunteer represents in real time. You're leveraging data in the immediate sense, for immediate purpose.

Javara coined the “clinical trial navigator.” How does it differ from a clinical research coordinator?

I think of the clinical research coordinator as being the professional that works within the boundaries of the system, and ensures that all the logistics are managed in a way that ultimately leads to pristine data collection and patient safety experience.

As we started talking about the possibilities of intersecting research with care, and care with research, and thinking about population health opportunities, the role of navigator was a term that we were hearing time and time again to be valued on the healthcare side as a really important transition.

If you look at the definition “coordinator,” it’s somebody who’s really operating within the bounds. I think that “navigator” takes it to a different level, because you’re actually having to think on your feet a little bit more. In our role, the navigator now has a responsibility not just to do all those other things, but to be thinking about the individualized and personalized needs of that particular patient, that particular healthcare system and making sure that all the insights that are being collected are conveying in a 360-degree way.

You recently announced that Javara is partnering with Privia Health. Can you touch upon that, and some of your other collaborations?

We are working within a couple of specific regions within the Privia Health footprint. Privia Medical Group of the GulfCoast and Privia Medical Group of Georgia are large, integrated practice management organizations. Collectively there are large numbers of patient records within one electronic health record, thousands of physicians/providers and hundreds of individual care centers. Privia is providing a lot of, what I would say, medical practice administrative and business standardization to independent physician practices. Now, Javara is partnering with them to provide clinical research personnel and expertise so that clinical trial access is readily available to the patients with the medical group.

Additionally, we have a research collaboration with Wake Forest Baptist Health as an academic health system. And the third research relationship is with Tryon Medical Partners. Tryon Medical Partners is a mega-physician, multi-speciality-owned group encompassing over 125,000 patients in one electronic health record.

Our current three healthcare partners are very different types of healthcare organizations. That is where I’m really encouraged about CRAACO, because this is not a cookie-cutter movement to address how we better connect patients to trials as a care option. All of our partners share the common commitment of bringing more of their patients to the choice of trial participation and making it easier for their physicians to participate as investigators.

You've spoken before about “research as a team sport.” Where does that mindset come from?

For the overall process to work exceptionally well for all players on the team, namely the patient, it is absolutely a team effort. That’s where the practice of medicine is really changing. It is complex. Physicians are juggling time and resource demands, coupled with the fact that the complexity of trials continues to increase and we ask patient volunteers to jump through hoops to participate. It is imperative that we work together to smooth out the process and ensure we are not duplicating effort, work to reduce as many barriers as we can for the protection of the patient and accuracy of the data, and improve the value proposition for every team member.

That’s where the technology, communication, trusted relationships come into play. You can have the slickest technology and state of the art electronic health records. You can have really great doctors. You can have really great research professionals around you. But if there’s a breakdown in even one of those areas, it can have a dramatic and negative impact. We are thinking about that complete architecture: What are all the different elements that ensure that there’s not a break in that chain?

In 2018, Jennifer Byrne launched Javara, an Integrated Research Organization (IRO). The company expands clinical trial access directly to patients and their trusted physicians, who are all part of a larger healthcare organization; currently reaching nearly 6 million patients.

She also founded Greater Gift, a 501(c)(3) organization that thanks clinical trial contributors with the donation in their honor of a lifesaving vaccine or meal to a child in need.
What is Drugviu?

Drugviu is a population health platform that is targeted to non-white patients. It provides relevant health information to people of color, captures post-market medication outcomes from therapeutic areas, such as depression, type 2 diabetes and hypertension, and connects motivated patients of color to clinical trials.

The reason why Drugviu has a focus on post-market medication outcomes and clinical trials is that clinical trials are not diverse and as a result medications that are on the market right now, side effects many times are not representative of populations of color who are taking those medications. The intent is to collect data to understand medication side-effects for our populations of focus and to show side-effect divergence from what was reported in the literature.

It’s by no means practicing medicine, however, it does provide a guide in terms of, “Okay, if I’m going to take Amaryl – I’ve been diagnosed with type 2 diabetes, and I’m an African-American woman – these are the side effects that I may experience.”

The other part is that we really want to close the loop. So what we’ve started to do is partner with organizations who are conducting clinical trials. We are leveraging our site to recruit motivated patients of color for clinical trials. The populations that we’re serving, it’s astounding how unaware they are of clinical trials as a care option, and just really a lack of understanding around what a clinical trial is, the care that you receive, and really demystifying the past relationship medicine has had with people of color, and also being very transparent about the historical ramifications of clinical trials and how that has changed.

Can you tell us more about your background?

I went to school for econ and math, was in business for some time and decided to switch to healthcare. Before we started our first company, I actually was getting a postbac in biotechnology. I was doing that with the intent of going to medical school, actually. I met my co-founder while I was a data analyst for clinical engineering. Clinical Engineering is the department in the hospital responsible for medical devices [and] safety. Our first company was invited to the FDA to speak about product safety. We had a very unique way of solving medical device optimization and improving safety. And for Kwaku, he had healthcare consulting experience. One of his longer engagements was with a hospital on optimizing their medical equipment and safety. So that’s how we joined all of this together.

What is the process of using Drugviu.com?

When you come onto the site, you type in a medication. Currently, we have medications that cover the conditions of cardiovascular health, mental health, endocrinology, oncology, and GI. So you would type in one of those medications. There are facts about different racial breakdowns. You can then go to the reviews and then you can filter for the experiences of people that are like you – by age, race, gender – and look at how this medication performed for people that look like you. There’s also news that we have as well.

What was the timeline and process for the site?

Kwaku and I had a startup in the medical device optimization and safety space. 2017, we were invited to speak at the FDA on product safety, for both devices as well as pharmaceuticals. And one of the points that someone made with respect to safety was, “Could there be bigger issues because of lack of diversity in clinical trials?”

On the device side, I said, “No, our anatomy is pretty similar based on race.” When it comes to the way that we metabolize medications there can be differences.

So that’s what sparked the thought around, “Hmm, if this is not being tested in diverse populations, what does that actually mean when people are taking medications? And furthermore, what does that actually mean when it comes to side effects?”
How are you accurately able to capture side effects when the trial that you have is not representative?

I also have a greater link; my father had a massive stroke. It took a very, very long time to put him on the right cocktail of medications where he was not having severe adverse reactions. It was really bad. So for me, it was kind of a lightbulb moment: “Why can’t we look at this?”

That was the inception of thought. Now, the action of that, I think for us, came in late December of 2018. The company that we had, we were happy with it but we knew that we had to do more. There was just more and more literature that we kept reading about the lack of representation in clinical trials. ProPublica published an article about the lack of representation in oncology trials. And that, for me, was really, “We need to take action on this,” because oncology is extremely complex. It is one of the areas that is extremely important when it comes to genetics and physiological pathways. For me, as well as for Kwaku, we felt like this was something that we had to really get going.

And how did you take that idea and begin to put it into action?

We went to churches, community centers, because my first thought was [that] there’s a narrative around populations of color, that they’re reticent to share health information. We did the beta, where we went to churches, community centers, and essentially asked people to share their medication experiences with us, just to see. The response was great. It was interesting how if you just ask people and you tell them what your intent is, how willing they are to share.

We then went into Techstars, which is an accelerator, revamped our site and then actually launched our site in August of 2019. It’s been incredible. We’ve had, to date, over 45,000 medication outcomes. We have a contract with a research organization to recruit patients of colors for their clinical trials.

How do you connect users to clinical trials?

The way that we’re doing that is through the reviews and health conditions. You come on, you leave your review, and then there’ll be a prompt that will let you know, “Are you interested in a clinical trial for the health condition that correlated to the medication?” Let’s say that you’re taking a hypertension medication. There’ll be a prompt, “Hey, are you interested in clinical trials in the hypertension space? If so, leave your information and then you can go on from there.”

And you recently won $75,000 from QBE and Ashoka’s Urban Resilience Challenge competition?

[Ashoka is] an organization for social impact entrepreneurs. Their big thing is about systems change and embedding system thinking into businesses to really have large, structural change, and literally using enterprises to change the world. I think the best way to make macro changes is at the intersection of business and social good. So with that, QBE, which is a large insurer globally, decided to have this challenge around urban resilience.

Essentially, the point we made was: for people to actually be healthy, they need to be included in therapies that actually ensure that they are healthy, that they are productive, that they are useful, can be people that contribute to society. It is extremely important to understand how medications affect you, have a better understanding of health and [make] sure that there’s news, as well as just a community that cares about you.

They were shocked at the stats when it comes to lack of representation in clinical trials; they were shocked at the stats of lack of representation in just medical research in general. Not only did they see the social impact, but they also saw the business opportunity with having data like this to make better decisions for the covered lives that they have.

Where do you see Drugviu in the future?

The end game for Drugviu is for it to be this wraparound population health platform that provides health information, health education, connects our users to clinical trials, but also has a community element, where there can be communication between physicians or clinicians of colors and Drugviuers, our communities. This larger platform that can help with the questions you have around your health if you are a patient of color.

Drugviu COO Melanie Igwe and co-founder/CEO Kwaku Owusu launched their company to increase information on the side effects of medications for communities of color and to close the gap by increasing diversity in clinical trials.

Since its launch, Drugviu has been named one of Built In Chicago’s 50 Startups to Watch in 2020 and won the QBE-Ashoka Urban Resilience Challenge competition.
What is your role at Pfizer?

My role at Pfizer is Global Product Development, Strategic Partnerships. We are responsible for innovating, leading and implementing solutions for clinical research and global product development at Pfizer through both internal and external partnerships.

We get to work with the entire community to look for solutions, and we collaborate for the greater research and patient community.

Why do you think it’s been so separate?

Some cite regulatory requirements as the reason that clinical care and clinical research are separate. And there is good reason for this. For example, clinical research is not a replacement for clinical care. Clinical research is different than regular medical care and this difference is clearly outlined in the informed consent form.

Now we’re looking at healthcare very holistically, just like now we’re starting to look at research very holistically. As we shift to how we look at a patient from “this is my specialty, my domain” to “this is the patient in entirety,” I think we’re also doing the same thing with research.

With your background as a care nurse, clinical research coordinator and now pharma, can you talk with us about integrating clinical research and care?

It’s fascinating to me that clinical research is the only way that investigational medicines will later be used in clinical care, and yet there’s an entire chasm – it’s not even just a gap – between these two. But what we’re really talking about is a singular individual at the end.

For me, it’s really quite fascinating to have these different perspectives of being a registered cardiac critical care nurse, working in health care quality administrative pieces, working as a clinical research coordinator, working in the informatics piece at a world-class academic medical center, and now working on the pharma side.

I find that so often, we speak the same meaning but not the same language. Individually, these stakeholders are working on very similar opportunities, and they’re coming up with almost-identical solutions. But they may have no idea that the other person is doing it. And there’s just a little bit of a tweak to each of them that make it different.

But there could be a very easy solution to combine them, into a solution that would work for all of the different stakeholders. And I find this over and over again in the research community.

Why has there been that change?

Patients are really taking an active engagement in their own care now. There’s a lot of ownership now. And I don’t mean just ownership [like] “This is my data” but actively being a part of the decision making.

And what caused that shift? Is it the accessibility to the data now? Is it regulations? I’m not quite sure. It’s just a cultural shift, that’s occurred in the U.S. specifically, and it’s starting to occur in other geographical reasons.

This is a topic for great research, and I can’t attribute it to any one thing. But I think that what’s shifting the world of bringing clinical care and clinical research together is that shift to patient centricity.

How do we begin to knit things back together?

The first thing is bringing all the stakeholders to the table. And the CRAACO conference is a perfect example because you have multiple stakeholder perspectives there. Oftentimes, the groups will become very homogenous: we have groups that are for pharma, we have groups that are for academia, and we have groups that are for patients. And now
in the industry, you start seeing there are groups that have stakeholders from all of those perspectives.

Once that starts happening, then we start to be able to have the conversations. And when we have the conversations, we start to have the realization that, “I’m calling it one thing, and you mean the same thing, but you’re calling it something else.” Or “We’re using the same term, and we mean two completely separate things.”

There’s an ability to bring awareness into what exactly is going on in the perspective of the individual, whether it’s the clinical trial site or the patient or the pharma industry. Then we can start to figure out where are the gaps so that we can have a common language and communicate. And as we’re doing that, through these items like the CRAACO conference, that enables us to organically come up with the solutions.

Are we at a better place than ever to have those conversations and incorporate the two?

Without any doubt. This is really exciting. I have a mentor of mine who has been in this field for 60 years. And he shared with me [that] this is the most exciting time of his career because now it’s all starting to come together. You see it coming together already in all sorts of different areas. It’s probably the most exciting time – the industry as a whole is going under a huge paradigm shift. And what’s phenomenal about this paradigm shift is that we’re collaborating to make the paradigm shift be a very positive disruption.

What do you see as the next steps?

If we look at things as simplistically as how do we deliver regular clinical care, and how do we conduct clinical research – moving from all brick-and-mortar to being more location flexible, and allowing patients to have flexibility in how and where their care is delivered and how and where they participate in clinical research. You can have your care delivered and clinical research conducted in all sorts of locations, as well as in all sorts of ways.

Look at the ways that we’re collecting data now. We used to do patient histories when they came back in and they were feeling absolutely awful. We would ask them everything that had happened since the last time they were there. And of course, when you’re in pain, all you want to do is get out of pain. Maybe you don’t want to talk about three weeks ago, when it started.

We’ve completely shifted that and how we’re interacting with patients, from just those touchpoints that are at the crisis level, to having regular touchpoints so that we can have better communication with people. It’s just so phenomenal in the flexibility that’s now occurring. That’s not just happening in clinical care; it’s also happening in clinical research.

When I was a clinical research coordinator, we did brick-and-mortar. Now we had some pieces of where it wasn’t all brick-and-mortar, where we would send people home with remote blood pressure, and so forth. But for the majority, they had to actually bring that back and we had a special computer that can only download that information. We’ve moved more and more away into having this completely flexible way to participate in research: hybrid-virtual, full-virtual, still brick-and-mortar.

What are you really excited about in the next few years?

In one year, I see true interoperability coming down the pike for patient data. It allows the patient to be able to have their data at their fingertips, so that when they go in for clinical care, they have it and they are not waiting for that information to be sent across.

In the next three years, what’s really exciting to me is having more and more engagement from the patients. Not only in their clinical care, but in clinical research, and finding ways to make it improve the research participant’s experience. To really make it more accessible for people to participate in clinical research.

In the next five years, we probably will be at a point that will be so different from where we’re at, in the delivery of clinical care and the way we conduct clinical research. I think we’ll be at a place where it won’t be “clinical research” or “clinical care.” It’ll be a more comprehensive understanding of how the two are so closely related and inform each other.

Amy Nordo is Global Product Development, Strategic Partnerships at Pfizer. All opinions Ms Nordo discussed were her own, and not representative of Pfizer as a company.
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