

MEDTECH

When to Engage a CRO

Sam Kasierski

Business Development Mgr., IQVIA

Interview by Darwin Shurig

CEO/Founder, Shurig Solutions Inc.



INSIGHTS
2021

Do you have a challenge currently with a strategic initiative relevant to RA, Quality, Engineering, Clinical, Operations or Marketing talent?

Let's schedule a Needs Analysis Conversation!

Please feel free to schedule directly [on our calendar](#).

 **MRINETWORK**

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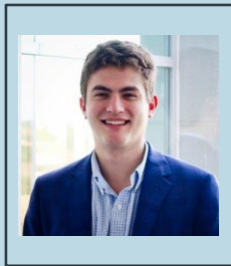
DARWIN SHURIG

PRESIDENT - SHURIG SOLUTIONS INC.

Darwin Shurig understands the key qualities that companies look for in candidates to grow market share, while enhancing their positive culture and team environment. He has a clinical background of over 20 years, including 15 years of sales experience within:

medical device, diagnostics, medical distribution, and sleep therapy; 8 years in sales management success; 3 years in operations; and extensive experience in negotiations and business development.

SSI has been growing for over 6 years with a focus on RA, Quality and Engineering within the Medical Device and Pharma industries. With over \$3 Million in revenue and a 91% offer acceptance rate, SSI is helping companies find unique talent that makes a difference, brings value, and decreases the risk of a mis-hire.



Sam Kasierski

BUSINESS DEV MANAGER - IQVIA

Current: Business Development Manager, IQVIA MedTech Clinical, Real-World Evidence & Regulatory Solutions. Business Development with IQVIA since October 2018.

I was one of the first BD's to join the branded IQVIA MedTech CRO (legacy Novella and genae) in April of 2019, and it has been an amazing journey and have learned so much about the MedTech industry in my short time in this role.

Education: University of North Carolina at Chapel Hill, B.A. Biology

Interests: Medical Devices, IVDs, DTxs, Clinical Development, Clinical Technologies, Regulatory Strategies, Market Access, Commercialization, Emerging MedTech, Life Sciences VC's/PE's/FF's

Personal: I have lived in Raleigh, NC for 15 years and it has been fascinating to watch the 'Triangle' grow into one of the fastest growing Life Sciences and Tech markets in the country. I am the oldest of 6 kids, and hold 'family' and those close to me above all else. I like to snowboard, run, write (mostly comedy) and spend time with friends in my free time.

[Link to Full Webinar](#)

Picking a CRO Partner

Darwin: If I'm a CEO of a company thinking about preparing my product for market, what type of resources should I be considering?

Sam: Companies come to us and ask us to liaise for them, and that's my role as a business development manager is to listen to what the company's objectives are. Where they are in their development stage, are they pre-first in a human study, are they in a pivotal study stage, and have collected some data to that extent. Have they had conversations with the FDA pre-submission, where are they in protocol development?

[Video Link](#)

The one thing that I think is important for emerging MedTech companies to consider when approaching a CRO is understanding that it is a two-way street in terms of how we collaborate. We can be as helpful as you want us to be in terms of helping you with those investment conversations. It's commonplace that we have customers approach us asking for price points that they need to use when presenting to investment groups and dive into what the CRO costs might look like and what they're going to need the CRO to help them execute in a clinical study.

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CRO Partner vs Vendor

Darwin: Some people don't realize that you want to understand where they are in the process and can give them pointers or direction on how to get that additional funding they need.

Sam: When we issue our proposals it's not a standard number; we view each study on a case-by-case basis as I think most CROs do. We don't have fixed pricing that we just put onto the paper and say, here you go take it to your investment group or whomever you're speaking with. Rather, we try to put strategy, input and considerations as to why we budget for certain scopes. So, when we scope our project management hours per se or what we foresee for data management or regulatory support, it depends on what the company will need when approaching an investment group.

[Video Link 1](#)

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Questions to a Potential CRO Partner

Darwin: When looking into using a CRO, what questions do you need to ask?

Sam: The number one question to ask is timelines. What is my path to the first patient enrolled? There's a lot to consider in getting that first patient enrolled, it can be a tedious process, and we are very methodical in approaching those timelines. The benefit of an established CRO is that they will give you sound advice on what those timelines look like, which will help you develop your build-to-market strategy for commercialization.
(continue to video 1)

The next question to ask is budget. Many companies think the proposal we submit to them is final; that's not the case. We are open to discussion on where we can meet you halfway and create that partnership. Understand why certain things cost what they do and why specific units are priced out the way they are.
(continue to video 2)

The third question should be how will you grow with me, and listen to the company's approach, and their end goal. Is it a company that will be able to help you through that initial pilot but no further than that? Or is this a company that can go from pilot, to getting that FDA approval, to helping you manage post-market surveillance or post-market regulatory requirements? Maybe different market access reimbursement initiatives as well to help you with your commercialization. Ask the company how far in the process can you be with us?

If you're looking to create long-term partnerships and build trust between organizations, whichever CRO partner you choose will do a successful job of helping you with the end goal of bringing your product to the patients that needs it most.
(continue to video 3)

[Video Link 1](#)

[Video Link 2](#)

[Video Link 3](#)



What differentiates IQVIA

Darwin: What differentiates IQVIA from other CROs?

Sam: Our biggest differentiator, especially within our IQVIA MedTech clinical or CRO, is our expertise and experience. I think that it boils down to is that we have a vetted QMS with vetted operations and SOPs. So often, CROs have the therapeutic knowledge in-house but don't necessarily have the SOPs or the proper structure in place to carry out that clinical execution. The SOP's that I'm referring to have been vetted through audits, reviewed by regulatory bodies, FDA, Ethics committees, etc., to build that credibility.

If you're going to do the clinical execution, you're relying on the CRO to have that experience to know what that clinical execution needs to look like. So, I think a significant differentiator of ours is that we have decades of experience and expertise running these studies and being able to help companies manage that regulatory pathways to get approval.

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[Video Link](#)

MDR – IVDR

Darwin: What are you seeing on the CRO side relevant to MDR/IVDR?

Sam: MDR originally was supposed to go into effect in May of 2020 and IVDR in May of 2021. Once COVID 19 hit, the EU decided to accommodate the pandemic and push some of these deadlines and applications to transition from the traditional MDD to MDR and then IVDD to IVDR. MDR application began in May 2021, IVDR is scheduled to go into place in May of 2022. The EU recently did announce that the transition period for IVDR will be extended and in some cases, it depends on the class of diagnostic product from what we've seen, so depending on the risk level of your diagnostic product the transition period is either shorter or longer. We certainly have seen more companies that are in a stage of determining which market to start in and electing to go FDA first instead of battling the MDR and IVDR requirements and changes. (Continue to video link 1)

[Video Link 1](#)

Darwin: One of the prominent aspects of those regulation changes is the increased liability across the board. I think there's a certain aspect of consideration in what CRO to go through in terms of liability and how you're protected?

Sam: A MedTech company needs to evaluate what the risk of a prolonged transition from MDD to MDR, IVD to IVDR, and how that will impact the overall market and commercial presence. That's something that IQVIA can help companies manage and understand, what that transition period will look like and what the regulatory requirements will look like. (Continue to video 2 link)

[Video Link 2](#)

Decentralized Studies

Darwin: How has IQVIA MedTech adapted to the increase in decentralized and streamlined trial options?

Sam: We have an internal decentralized trial platform that we can use for hybrid and fully virtual studies. We have experience running both, and it is something that we are continuously seeing growth in, and more companies are approaching us with these types of strategies. So, we have the technologies in place, be it mobile applications, ECOA platforms for subjects to be able to enter in or to complete different forms from their home, upload their data to various data management platforms, EDCs that the companies can then use to run analysis or whatever they might look to use the data for.

[Video Link 1](#)

In terms of technologies and platforms, that's something we do have and offer for MedTech companies. Again, it comes back to the strategy, why do you want to run the study in a hybrid or decentralized manner. We have enough experience running those studies to advise companies on what sort of decentralized design might make the most sense if they're looking for that type of input.

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MDR / IVDR

Career Choices: CRO / Business Dev

Darwin: Why did you pick a career in business development?

Sam: I'd always enjoy interacting with people, being a people person, being extroverted, and having these sorts of conversations. I think sales and business development were lucrative in that regard, being able to be customer-facing. I didn't necessarily know that going into my first role at IQVIA, where I am today within our MedTech group, as I started on the sales side of the business.

[Video Link 1](#)

There was a strong push for us to look at company updates, study updates, financials, et cetera, send that information off to our business development team for the biotech and pharma space and ultimately with the angle of growing our customer base within IQVIA biotech. (continue to video link 1)

Darwin: So, you're looking at industry trends, total accessible market, and trying to identify what is potentially your serviceable market?

Sam: That helped me gain a strong understanding of what that market looked like and how CRO operations work. I think just getting my foot in the door was huge and working at an established CRO like IQVIA and learning how our processes work and relating that to how we help our customers was beneficial in helping me where I am today.

I was sold on IQVIA MedTech and what we were looking to do, disrupt the marketplace and become a strong MedTech presence in the CRO world. So, I joined that Business Development team in April 2019, and then in that role, the benefit of it was I got to work not only with our CRO but also our commercial team as well and the part of our business units that help companies with market segmentation, targeting, building out sales forces for instance. So not only was I exposed to the clinical and regulatory part of a company's development but also many things on the commercial side as well that allowed me to learn the complete end-to-end process of what it looks like for a MedTech company or what your larger MedTech customers look for as well in those solutions.

[Video Link 2](#)

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Pandemic Perspective

Darwin: What are some of the things that you're seeing from a product or a CRO perspective regarding the disruption the pandemic has had on the market?

Sam: Some reports say venture capital investments for pre-commercial MedTech's globally increased 34% from 2020 to 2021. It shows you the inflow of capital going into these companies and the continued growth that we're going to see in the trajectory. There's been a huge increase in non-invasive diagnostic products, monitoring, seeing a lot of innovation in the diabetes space with different CGM plus insulin pump combo products. The obvious one is COVID 19 diagnostics and COVID 19 IBDs rapid tests, your PCRs antigen antibodies; we've talked to those companies and have done some substantial work and helping some companies go for the EUA and be able to provide those tests to COVID 19 positive subjects.

[Video Link](#)

Career

Study Demographics and Design

Darwin: How do you help companies with select patient populations and ensure balance in the total value of the outcomes the study brings?

Sam: The benefit of IQVIA is that in addition to the CRO or traditional CRO components we also have our IMS health group, the world's largest brokerage of health care data analytics. Which is extremely important when you start looking into patient populations, site networks and figuring out where it makes the most sense to set up sites, recruit, conduct the study, and informs your study design. So, we're able to tap in and leverage those data resources to inform the company on patient selection.

[Video Link](#)

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Growth from Disruption

Darwin: Have you seen anything coming down the pipeline or becoming more accentuated over the last six months to a year in the marketplace?

Sam: With a rise in digital therapeutics, the FDA issued new guidelines for AI and ML device products with more structured guidance in getting FDA approval. That's going to be a huge market and any established CRO will start to see an uptick in companies needing clinical development.

[Video Link](#)

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Full Webinar

Do you have a unique product? Are you in a growth phase or lead a company disrupting the MedTech market?

[Video Link](#)

Reach out to see about setting up a webinar for your company to promote your product.



If you have an inquiry for Darwin, you may reach him at:
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