

## Narrative Writing Challenges and Approach

Episode 2 – October 18, 2018

**Featuring:** *Tatyana Wanderer, Executive Director of Services Operations; and Kelly Danyow, Associate Director of Workstream Leads*

### Transcript

**Intro:** This is Synchrocast brought to you by Synchrogenix regulatory and communications strategy, science and solutions.

**Tatyana Wanderer:** Hello, good morning. This is Tatyana Wanderer. I am the Executive Director of Services Operations.

**Kelly Danyow:** Hi, this is Kelly Danyow. I'm the Associate Director of Workstream Leads.

**Tatyana:** Hey Kelly, it's great to talk to you today. I'm really excited to speak to you because I think both of us have been leading narrative projects for quite a number of years. It's been about ten years for me. How long has it been for you?

**Kelly:** It's been about five years for me, so yeah, quite some time.

**Tatyana:** Wow. That's awhile. And as I kind of think back on these years, from my perspective, it seems like the narrative projects are getting bigger and bigger. We are working with many projects that I'm seeing now come through that are in the thousands where else in the few years ago we were really seeing projects in the hundreds most frequently. And I feel like we're getting faster and faster. Do you feel the same way? How is that possible?

**Kelly:** I do, I think we've evolved our narrative process over time to meet with kind of the needs, as you mentioned, with often, a lot of these larger scale projects that require even shorter turnaround than we'd seen previously, and I think this new integrated approach that we take, that really makes us successful. Now that we have our technology solution in place, I think it's really helping the efficiency of the process for our writing team as they might start with a narrative that's already up to 80% complete. And our narrative dashboard and designer platforms really are providing the sources and a manner that makes it very easy for the writers and the QCers to access them. And I think it really streamlines the process for everybody. Obviously, I think as you mentioned, we have a lot of strong experience in this

area. We've always had a focus on strong project management and I think our global team approach is also certainly a contributing factor to how we're able to be so successful. Recently I think one of our greatest successes was completing over 700 narratives in five business days.

**Tatyana:** Certainly that was pretty amazing. I watched that unfold and that seemed miraculous. What kind of client feedback have you received?

**Kelly:** I think overall we've had some great feedback from our clients. Everyone has stated that they're very pleased with the quality of the narratives and that they've been very happy with the process and working with us as well. I think we hear that what it's helping them with certainly is streamlining the review cycle. A client also noted recently that they had done an internal QC of our final narratives and they found no errors and that was great to hear too, that we're still providing the same quality and not sacrificing any quality. We're just able to kind of alleviate some of the other burdens of the process.

**Tatyana:** Sure. So what are some of these challenges that our clients are seeing that you and your team are able to really alleviate?

**Kelly:** I think the biggest challenge with narratives is pretty much always the time. So as you know, narratives are written primarily from clinical data and after a database locks, it will take several weeks to generate the study listings and even more time often to generate patient profiles if they're being used for narrative writing. Some sponsors obviously try to get ahead of this and so they may choose to start writing narratives from draft data, but what we've found in our experience is that unfortunately this then sometimes creates more obstacles later in the process when writers are trying to update to the final data once it is available.

And I know what we've heard and seen from some clients is that this could then lead to some errors in the final output. Because narrative projects often also involve many different functional groups and reviewers, especially for larger projects and we're often also using large teams of writers and QC personnel as well. This can lead to some variability in the content. Another thing we often see is, again, with the reviewers in large groups of reviewers for large numbers of narratives, you will have some misalignment among the reviewers. And at the end of the day, this can add up to rework on these narratives unfortunately. So altogether all of these factors can lead to extended timelines and possibly even delay completion of a clinical study report. The narratives are often the last component to be completed for all of these reasons.

And so I think you asked how we alleviate that and I think that our approach, especially when we're using the technologies that we use the SAS data to develop narratives per template specifications and what this does is it creates some consistency, number one, so we're kind of trying to eliminate that

variability upfront and it also number two, helps us with time as it allows us to generate drafts sooner because we can even start writing then prior to the creation of the tables, listings and figures. I think again, then speaking about time, this is going to allow a lot more flexibility in the review cycle. And so reduces that burden on reviewers. They're able to see narratives sooner. We can align on content in smaller quantities. I think that's really important. And another thing, and I'd love to get your perspective here as well, is I think our clinical review services really can be helpful as far as reducing reviewer burden as well, because it allows them to focus on cases of particular importance when we use our clinical reviewers to assist. How do you feel about that?

**Tatyana:** Absolutely. I mean for me just looking at how things play out on the client side very often where very frequently working with the safety physician who is trying to manage their team of independent contractors who are doing review and there's just not enough time in the day frequently for that safety director to both review submission documents and review the CSR and also keep alignment among these independent contractors.

**Kelly:** Absolutely.

**Tatyana:** So when we have a kind of a one on one connection between the safety physician and our lead physician on our clinical review team, who then takes on that burden and keeps all of our clinicians aligned and on task, then there's only that one point of contact that the safety physician needs to talk to and really communicate it that same kind of clinician to clinician level. So they don't have to explain or re-explain. I've seen a lot of very positive client feedback when we have been able to engage this way and much calmer safety directors through the kind of late end stages of submissions. So how about yourself?

**Kelly:** No, I would 100% agree. I think that that's another kind of key way in which we're really kind of alleviating some of those larger challenges. Especially for these large-scale projects of thousands of narratives with potentially short timelines.

**Tatyana:** Absolutely. So I know that we talked about different clients and different clients need their own approaches. What are some of the things that you do tailor in your approach from client to client?

**Kelly:** I think the main thing is the first step of any of our projects with our clients is we'll kind of work together to determine the template. During the process of reviewing and creating the template, we make sure that we're spending a lot of time communicating and aligning on the presentation of information and the content. We often, also will take a lot of time and discuss the source format. As I

mentioned, we're using the SAS data, because obviously this allows us to start providing narratives sooner, but we can use different formats based on the client's needs and the availability of data. So I would say we have a lot of flexibility and we really want to take the time to kind of understand their needs and tailor the process in a way that's going to work best for them.

Another one of the kind of first steps we do is that we'll generate some sample output, bring in all the different members of the team to get their feedback and review and then we can adjust it as needed. So I feel like really what we're doing is we're creating a very customized, collaborative way of working with each client. How about you?

**Tatyana:** Yeah, I completely agree. I think what I find sometimes very interesting and very rewarding is that, and this actually happens frequently, is that we sometimes are the first people who start speaking across different functions. Bringing together statisticians and clinicians and publishers, all of the people who are involved in this process to really get them on the same page and work together instead of working in their kind of functional silos which are overstretched because it is critical times and they have a lot of other activities on their plates. So getting everybody on the same page proactively and removing those silos has been really my focus as I come in into a given client environment and understanding what people's boundaries are too.

Some clients are a little bit limited by their systems or their SOPs. And so, and some clients have a little bit more freedom to operate and to experiment and to take up some of these innovations and technology and really step up in the efficiency there. So we've worked in every paradigm and I think we've been able to work within limitations to still continue to innovate on the process and create a paradigm that works for each client.

**Kelly:** Yeah. I completely agree. I think you make a really good point there about eliminating those silos and bringing teams together and kind of emphasizing that we have worked in all these different paradigms. And so that we really do have the flexibility to make sure that it's a process that's going to work best for our clients. I feel like we've really tried to take the time to listen to their needs and as you mentioned, to break down these silos, bring everybody together, get everybody on the same page and make it really a team approach. Is that what you feel makes Synchronix a client's best choice for narrative writing services?

**Tatyana:** For sure. Truly, I think there's also kind of a bigger picture thing too. I think coming from years of experience is a huge value. So it's adding technology to the experience, adding technology to a space where we have already worked through many scenarios of troubleshooting and problem solving and we know all of the unexpected and we can expect them instead of trying to start with the technology and then arrive in that space where there isn't experienced there. And we can sometimes hit things that are unexpected. So being there for our clients with that experience, not having to invent a way out on the spot because we do have that bank of experience to rely on, I think is really critical when we're talking about the timelines that are that short. You don't have time to lose.

And so for me, that's really a differentiating factor. It's not necessarily what happens when everything goes to plan. It's how we can support turnaround, reinvent and still deliver when things don't necessarily go according to plan, but we know what these things are, we know how to preplan for them. And to me that's what really enables us to bring these projects and on time.

**Kelly:** I completely agree with you and I think that to your point, we've got so much experience and strong leadership in this area, the technology is really just adding efficiency and helping to further simplify processes that we've already kind of worked through. As we know, narratives, they get very cumbersome very quickly and I think what we've done is just kind of further honed our process in a way that allows us to still be successful, meet timelines and not compromise quality. Certainly, that's one of kind of our core and that's really what kind of gives our clients the peace of mind.

**Tatyana:** Yep. I agree with you. Well, thank you so much Kelly, for speaking with me today.

**Kelly:** Thank you.

**Tatyana:** It's a pleasure to think about these things and I hope you have a great rest of the day.

**Kelly:** You too.

**Tatyana:** All right, take care.

**Closing:** Thanks for listening. For more information, visit us at [synchrogenix.com](https://synchrogenix.com).