Adrian H.: [00:04] Hey, this is Adrian Hernandez and welcome to the NIH Collaboratory Grand Rounds podcast. We're here to give you some extra time with our speaker and ask them the tough and interesting questions you want to hear most. If you haven't already, we hope you'll watch the full Grand Rounds webinar recording to learn more. All of our Grand Rounds content can be found at Rethinkingclinicaltrials.org. Thanks for joining.

Adrian H.: [00:28] Hello there, I want to welcome everyone to today's Collaboratory Grand Rounds podcast and we are here today with Dr. Rachael Fleurence who'll be reflecting on launching the NEST Coordinating Center Data Network to improve the use of real world evidence in medical device ecosystem. So Rachael, thanks for joining us.

Dr. Rachael F.: [00:47] Yeah thanks Adrian, I'm delighted to be doing this podcast with you.

Adrian H.: [00:50] So first of all, NEST is new. So tell us a little bit about the origins of NEST and what you're aiming to do.

Dr. Rachael F.: [01:00] So the NEST Coordinating Center is fairly new and I've been doing this job now for one year but the idea of NEST is not new and actually had been thought about by the FDA CDRH or device division as early as 2012 in their strategic priorities. The idea back then was really help improve post market surveillance for devices but the idea has since morphed into really supporting wider needs in terms of medical devices. So both pre-market and post-market regulatory needs as well as coverage needs. So it's been in the ecosystem for a number of years now and this is really our opportunity to launch something operational to really help improve medical device evidence.

Adrian H.: [01:47] Great. And what do you see as the key challenges that NEST is addressing?

Dr. Rachael F.: [01:56] Yeah, so NEST is addressing some of the same challenges that everyone in the ecosystem who wants to see a real dramatic increase in the efficiency, quality and timeliness of clinical research is grappling with. So some of the problems and challenges are the same but there are also some challenges that are really specific to doing medical device clinical research. So in a nutshell, I'd say ecosystem wide, we're dealing with fragmented data. We're dealing with data that's not necessarily complete in any one place. We're dealing with high burden on clinicians to collect data and participate in studies. So problems that anyone involved in clinical research and who really wants to leverage the new world of electronic health data is grappling with.

Dr. Rachael F.: [02:51] But in the medical device space, there are real specific challenges as well, both around the availability of specific ways to identify medical devices in electronic health records as well as simpler things such as it's really hard to blind in medical device trials. There's a lot of outcomes that depend not only on the

functioning of the medical device itself but also on the operator's skills and experience and expertise.

Dr. Rachael F.: [03:23] So a number of variables that need to be collected to do robust methodological studies and devices that can be quite challenging to do. So these are things that NEST is thinking about and thinking about with centers of excellence around the country to be able to launch this national system.

Adrian H.: [03:42] That's a fairly ambitious set of issues you're going to be tackling. What do you see as the critical factors for success?

Dr. Rachael F.: [03:53] So my sense is that the opportunities to really streamline and improve the quality, speed, scale of clinic research are there but we have to be really careful about not boiling the ocean. My sense is that starting small with a small group of collaborators and centers of excellence and tackling some of the easier areas to show proof of concept I think are ways to take a bite at the apple without trying to boil the ocean.

Dr. Rachael F.: [04:27] So I'll give you an example to be a bit more concrete. In my early forays into this, there certainly are ways to identify some medical devices and electronic health data with the health systems I'm working with and starting to show that these studies are possible is a win. Now, can every device be supported by studies using electronic health records and claims at the moment? No, and there's still a ways to go for certain types of devices, but there are early wins out there and we're focusing on really establishing proof of concept with these early wins and then thinking about scaling from there.

Adrian H.: [05:09] Rachael, can you give us a sense of, say in the next year or two, how you're laying this road out here? It sounds like there's some key early demonstration projects but you're also putting in some other things in place.

Dr. Rachael F.: [05:31] Yeah, so the strategy has been threefold. So the first strategy has been to engage with key leaders and projects that are already underway. These are our demonstration projects. We have 11 of these. They span the spectrum of the product lifecycle, some are in the post-market space, in the surveillance space, others are clinical trails embedded in a registry. So there's quite a wide range of products there, but really engaging the leadership and the expertise nationally to work with NEST.

Dr. Rachael F.: [06:03] The second strategy is to leverage existing centers of excellence who have been working and made large investments in their electronic health data. Both their EHR data, but as well as linkages with other data sources such as pharmacy and claims. So working with these groups that may not, however, have specifically focused on devices to date. So bringing these systems in to start doing these fairly simple but quite powerful studies in the device field.

Dr. Rachael F.: [06:35] So the strategy has been to leverage that expertise, create a learning community between these health systems and see what kinds of studies we can support from there. I've been keen to not build NEST as simply a portfolio of demonstration projects, but really to build it as both a learning community and as an operational organization with a front door to which industry stakeholders, as well as other stakeholders interested in generating evidence in medical devices can come to do these studies with high methodological robustness, as well as high quality in the data standards that are being adhered to by the different systems.

Adrian H.: [07:19] Well, that's great. Now let's think about, say three years from now when we have you on again, what will others say about NEST? What will success look like in three years?

Dr. Rachael F.: [07:34] Yeah thanks Adrian, that's a great question. So we're in May 2018, so in three years, May 2021, my hope and vision for NEST is that we're able to provide better, more robust evidence around medical devices that will really help support patient decision making and clinician decision making and improve patient health outcomes. So the vision is really to significantly improve the scale, quality, availability and timeliness of data around medical devices, to really impact patient health outcomes in a positive way.

Adrian H.: [08:11] Well Rachael, I look forward to that in three years and really appreciate you spending time with us to discuss NEST and what's happening here in the future and also thanks for taking this on. It's a big challenge to address the needs for research and information for people to act on regarding medical devices and technology. It's not a simple task. So for our next podcast, please join us. We'll have Dr. Amy Abernathy who will be discussing research at scale, exploring what is possible with high-quality real-world data, examples from Flatiron, and that'll be posted the week of June 18th. So again, thanks for listening to this podcast and thank you Rachael for joining us.

Dr. Rachael F.: [08:58] Thanks for having me.

Adrian H.: [09:01] Thanks for joining today's NIH Collaboratory Grand Rounds podcast. Let us know what you think by rating this interview on our website and we hope to see you again on our next Grand Rounds, Fridays at 1:00 p.m. Eastern time.