

## Transcript: What do you need to know about data management?

March 21, 2018

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**Kunal:** So, my first question is: what is data management and what does the life of a data manager look like? Karen, do you want to go first?

**Karen:** kay. So yeah, broad questions but they're questions I get asked a lot and I tell people ... actually to the point that I don't even say I'm a data manager. I say I work in clinical research and people don't ask any more questions.

But, data management is really the overview and collection of data for clinical trials, at least from the clinical trials perspective. So, there's data management for banking and lots of other industries but in clinical trials, it's planning for the collection of data, collecting the data, and then once you receive the data, cleaning the data, making sure it's an accurate representation of the patients that you have on studies. Life in data managing ... My life is meetings and looking at computer screens.

**Kunal:** And Gina?

**Gina:** Let me read you the definition that I kind of collected through the years and when I'm asked, I just open my cell phone and read. "Data management is a part of clinical organization that creates, maintains, and presents through use of technology, quality clinical data that supports an accurate and timely statistical analysis. It adheres to all the applicable standards and regulations and laws of quality and truthfulness in scientific research."

**Kunal:** It's good to have two different perspectives and a much more rigorous definition from Gina. I think that helps with some perspective.

So, what does the life of a data manager look like? Like, let's use someone who's in their second year of data management work, what would their day look like? What would happen along the way?

**Karen:** I think it depends on where you are in your career. Someone who's just starting out ... it's a much different day than someone who's maybe been through a few different places, like I have.

But even at a small company, it hasn't changed too much. A typical day for maybe a beginning or entry-level data manager is doing a lot of cleaning of data. An entry-level person is generally going to be brought in in the support role to help out when a study's already been built and is already collecting data. And once those of you in data management and those of you who are in the ClinOps side or Sass programming side, you know that once data starts coming in, it's not perfect. It's very far from perfect. So, you need cleaning, you have queries ...

## Transcript: What do you need to know about data management?

March 21, 2018

---

So, an entry-level person may be responsible for looking at data queries, looking at data listings and adding queries into an EDC system. And resolving, seeing how a site might respond to a query, to see if they can resolve that issue.

So, you know, a lot of time at the computer looking at listings. Someone's who moved on in their career is maybe starting to plan for studies, they're part of the study start-up process. Designing case report forms, doing some initiative and process planning to make things easier for sites to collect data and it progresses from there.

**Gina:** I totally agree. I just would like to add that there are specific types of people and specific skills that comprise data management. It could be a little lonely job at times when you actually are looking at data. What is data? Sometimes it's spreadsheets, sometimes it is reports, so you would need to be very focused, very detail-oriented and understand what to look for. Because you need to understand the meaning of what you're looking for. What does this data mean and out of that, again it's probably not when you are a beginner but maybe mid-level or senior, what are the issues with this study you see? What are the issues with the site that you see? And how to communicate those issues so that things are just and right.

So, you truly see part of the first people probably, you see the trends, you see the successes, you see the issues with your study and you need to be able to communicate ... great communication, even though it is a lonely job, is extremely important for you in our position. You need to speak right, you need to be able to know how to create those queries, so the site is not screaming murder. It is a written communication so there are written ways of dealing with how you communicate.

Sites, doctors, your project management. So, it is a difficult role or maybe interesting role.

**Kunal:** That kind of segues well into my next question: at the end of the day, sponsors and OCRs are serving their customers. That is, the clinical trial sites. Like you said, the data manager is expected to communicate effectively. So, what specifically do you think data managers could do better to serve clinical trial sites? Gina?

**Gina:** What can we do better? I think we need to raise proper data managers. There have to be seniors and leaders who raise people who are navigating well in this complex environment because again, to look for queries, to write queries, you kind of need to learn what you can.

But all that communication with this complex project, you know, that's probably what I'm hoping to do. I'm doing with my team. I'm heading constant trainings and conversations on how to communicate. And another thing, working on project management skills, which are, in my opinion, extra important.

## Transcript: What do you need to know about data management?

March 21, 2018

---

**Kunal:** That actually surprises me. We just had a dinner on Monday and Gina and Haj were telling me about how project management skills are sort of essential to being a data manager and I didn't know there was this thing about the project manager for data management but apparently, there is that need for those kind of individuals. Karen, what are your thoughts on what could we do better to serve our sites, as data managers?

**Karen:** I think project management, you know, a lot of places you call that data management/project manager, the DM/PM is a really key role or a really defined role or just part of what the data manager does. And that is our customers really are the ClinOps and programmers and the sites. And somehow, we're in the middle and we have to make all those people happy. So I think that's the challenge. You can make your Sass programmers really happy and really annoy your sites, or you can make your sites really happy and ignore your sass programmers and ClinOps in the middle there, is also an oversight.

But I really find you can make everybody happy if you start with your sites and make them happy, they enter the data accurately. The challenge is getting that done. There's never a perfect world but I think taking a step back to be very practical about what you're doing. I think that's what served me well in my career. I think anyone who knows me knows I'm just a regular, practical whatever, keep it simple kind of person. Not one to over-complicate anything.

So, asking questions and very straight forward ... You don't want to treat the sites like they're dumb. They're very intelligent, highly active people. They're busy with patients. You just have to make things obvious for them. So, ask questions in a straight forward way.

We need to query in a very straight forward way. Make sure the site knows the problem and the possible solutions. You know? I had a lesson just last week at my company about how to query appropriately. Don't say, "This is wrong." What does that mean? You don't know.

Don't say, "Correct this. Change it. Delete an AE" That's not a good one. So being very straight forward with instruction, make it obvious. Communication, again, to go back to that. It doesn't have to be over-communicated. You don't want a lot of words there to bury the query request but be really straight-forward, the sites are really busy. The last thing they want to do is to enter data or respond to queries. So, the easier you can make it for them, I think, the more success you have, as a company collecting data.

**Gina:** When you are data manager for a long time, you have many interesting stories and answers to queries from the sites. One of my favorites is ... "I'm not going to think about it today. I'll think about it tomorrow." A direct quote.

## Transcript: What do you need to know about data management?

March 21, 2018

---

**Karen:** If they respond in all capitals, you know you're in trouble. So you want to avoid that sort of thing.

**Kunal:** So, the next question I have is can you share with us the number one problem people are facing today when it comes to data management? In the 21st century.

**Karen:** Number one problem? I think we're honestly just really playing catch-up with technology. I think the Medrio solution of why do we have to take source documents, the site enters the data and then why do we have to make them to enter it again and then query it. I think if we could figure out a solution to that, it would make everyone's life simpler. So I think that would be a great way. Why make people enter data and then we have to query it? Good for business, keeps me employed. Keeps all of us employed in some way.

But I think that's maybe the number one solution for the future.

**Gina:** I'll answer from another side. I work a lot with start-ups. They know they need data management but don't really know what you do and why. So, probably education and working with them so they see your value. That's number one thing. You know, we're often in the background doing our little thing.

**Kunal:** So, to be able to proactively show value that as a data manager ...

**Gina:** Right and not being asked why are we taking so long? You know? Not a hindrance to the progress but actually part of it.

**Kunal:** I see. So the comment you made, I was wondering why do you think that's happening with the challenge that you ... Is there a solution that you have in mind?

**Karen:** No, not necessarily ... I mean, I think there's a lot of people working on that solution.

But I think ... I mean, I date myself a bit but I worked long ago when EDC was coming up and people were like, "Oh, that will never fly." "We can't have sites entering data. They'll never want us to do data." Yeah, we have them entering data now. So there's change. And then with EDC when it came in, too, there were people who didn't think regulatory agencies would allow it or accept it.

So, I think as a regulated industry, we're afraid to do something different because we don't want the FDA to not accept our data. That would be bad.

## Transcript: What do you need to know about data management?

March 21, 2018

---

**Gina:** Right. I would agree. Do to the regulatory oversight and we're going slow and we're waiting for FDA to make decisions and give us guidance and for this technology to kind of settle so we know how to answer those regulations, those general regulations.

**Kunal:** The FDA probably wants the investigator to figure it out and come up with the proposals.

**Gina:** Well, that's why ...

**Kunal:** Right. So let's assume that there's a start-up with one or two clinical trials that are in their pipeline. They've never done data management in a very small team, they have one or two people in clinical and it's the first time they're setting up an EDC system. What does their system/supplier selection process look like? The more details that you can give, I think that would be helpful.

**Gina:** The selection is going to be for a little while, maybe a month or so. It depends how fast they want to move. But first of all, I would ask them to create a questionnaire of looking inside of what exactly are my trials and what do I need? What are the features that I need? What is the company that I need to be associated with? I mean a big company that has been in business for a while or a new company that promises the moon and I'm ready to experiment but probably most ... and of course cost is very important, too. So, you know, what is my budget?

So, I would start with a questionnaire, first of all, what features do I have? What I often see, especially with start-ups, they are looking at very large EDC companies that have all the bells and whistles and above and beyond and they are becoming very little person in this pool of huge companies and support their data and is not exactly what they need. So, again, several things to look for. You know, who am I for this company? And of course, how long this company has been in business is important, too.

I like a well-developed and mature system, even for my one or two little trials. And then scalability. What is next for me, what do I hope to accomplish? Do I need a safety system that is big? Do I need the laboratory management system that I need to connect with the CTMS's of the world. Depends what you need. You start with your requirements.

**Karen:** Yeah, I think that's a great answer. One of the things I see most ... I've been at a number of small companies where I've started as the first person in the data management department and grown. So that's been my life probably the last five or six years, with companies that size. The challenge I've had at most of them is that they bring someone in with data management experience after they already have those first one or two or four or five studies up and running and they're having problems.

## Transcript: What do you need to know about data management?

March 21, 2018

---

So, they haven't planned for what they're going to do. I think the typical M.O. of a company that size, with a couple people in ClinOps, they select a CRO for their ClinOps portion and data management is kind of an afterthought. It just comes along with the ClinOps CRO. So, they don't really do due diligence on each functional area. That person comes from a ClinOps background, so they kind of naturally do due diligence on the ClinOps part of it. But if they haven't planned and done all the things that Gina has suggested they do, they may run into problems when it comes to an intro analysis or final clean-up when they have maybe a data management EDC system or a data management vendor who is not performing.

And they may not be performing as well because they didn't have anyone really performing data management oversight.

**Kunal:** Is it better to hire a consultant rather than a full-time employee for data manager or data management?

**Karen:** Yeah, I think it depends on the size of the company. You know, that's a challenge in a small company, is having an FTE approved or maybe they don't even know a full-time person. Maybe they need a third of a person, so yeah, bringing in a consultant that knows how to set up and have oversight. But then, as Gina mentioned, planning for success. If you're a company that's starting up, are you planning on just having one or two studies in the next two to three years?

I think most people who starting a clinical trial are planning for success and planning another phase one or two study and if that's successful, then moving onward. So, you might not want to join with a system like a EDC system where you're going to move from a ClinOps vendor to a ClinOps vendor, you may want to take a little bit more of a future planning for standards, like selecting one vendor ... Even if a ClinOps or the CRO is the one that's working with that system, you still may want to have your own system, in house, for future standards.

**Gina:** This is a very good point. I actually have a client right now exactly like that and we are discussing the fact that they will have more studies and the next study is going to be built faster because in tiny companies, the next study and the next study are usually quite similar, you know? It's not a huge organization that has many products. So, that's something to think about.

**Kunal:** Sure. So, what are one or two pitfalls that the start-ups should be watching out for?

**Karen:** I think planning for standards. Planning for that. Don't plan for each study to use a different EDC vendor. Plan on doing your due diligence up front to select a single EDC vendor or provider. I think that helps, to have your progressive index-successive study to be faster.

## Transcript: What do you need to know about data management?

March 21, 2018

---

I think some of the pitfalls I've seen for small companies are a lack of using standards, a lack of having them yet because they're so small. But then, I don't want to say lack of planning but changing your mind very often.

**Kunal:** Is it the nice shiny objects syndrome?

**Karen:** A little bit of that. But a small company that's growing to bring more people on board and hopefully highly intelligent, really gung-ho people who have great ideas and then, you know, your great ideas are ... So, that is something that I think, as a data manager 'cause I like stability insights, little boxes and everything, but that's, you know, trying to be flexible enough to plan for the changes that are coming up. In our company, we call our protocols "flexible" 'cause there's some gray area about what we might do next.

You know, it's all okay from a regulatory agency and IRB approvals and all that but we might do to different dosing schemes and an EDC system has every week dosing or twice a week dosing or every third week dosing, you can't plan for that up front. So, yeah. Being able to move quickly, you need some people who have experience.

**Gina:** Along those lines but just a little different, when bring data management specialists and expert early ... that's actually what one of my clients will always ... because at the time the protocol is created, at the time the protocol is being read by data management, we are planning the data that is built, we're planning the data collection and we see and we choose, through the protocol in the way nobody else does.

We find inconsistencies; we find changes to the protocol that must be incorporated. So, it's very critical to have our ... set of eyes on the protocol data correlation.

**Karen:** Yeah and actually that's, I think, a great point. And anyone here who's a medical writer or from the ClinOps side or the medical monitors, when a protocol gets handed off to data management, we have to turn it into an EDC system. The only way we do that is if the schedule assessments seem correct and there's not inconsistencies between the check boxes and the footnotes and the body of a protocol.

Nothing worse than finding it the day after the protocol has been approved. So, if you have a data manager, someone who's really ... I mean, most data managers are very detail-oriented. We're looking for the needle in the haystack.

**Gina:** Can I cross reference your protocols to ... yeah.

## Transcript: What do you need to know about data management?

March 21, 2018

---

**Kunal:** So when we be advised to make sure that there's a signature field on the DOP that says the data manager makes you sign off on the protocol?

**Gina:** We don't always need to sign off but we need to review, absolutely.

**Karen:** Yeah. And that's part of the QC review ... that data manager looks at.

**Kunal:** So my next question was what are the top two factors that affect EDC department timelines and how can sponsors, what steps can they take to accelerate those timelines?

**Gina:** Bring in data manager early. I can say it again and again. In our heads, we're already built in a database before the database is being built. Bring in somebody who can manage the timelines because we can create a proper project plan for the build and will be on time with your first patient in or whatever timeline so that's my two ...

**Karen:** Yeah, I think that's really important. If the data management group, whoever you have doing it, even if it's your functional provider, if they're not given the protocol 'til after it's final, you're not going to get a database filled four to six weeks after your protocol is final.

You can really only hit that if there's planning up front. So, someone has a look at the drafts of the protocol, they're planning for what needs to get done. There may be changes in what you're going to do for schedule assessments or what visit time points but the bulk of the data you're going to collect is pretty well set when you start writing a protocol. You know what sort of assessments you're gonna do, you know what's our efficacy data you're looking at, safety's a given. So, those are standard things that you can know about in the early drafts of your protocol when we're still fine-tuning a lot of the details.

So I think early involvement and if we could go back to the project manager side of data management. It's really important to have someone strong who can try to drive that process and have oversight of your vendors. If it's the EDC provider doing the build or ... you know, there's other functional service provider doing an EDC build. Any other, any service provider that you hire for any functional group, you need to poke them and make sure they're doing it. And let them know you're expecting something on Friday and on Friday, let them know you're expecting it that day. And if they didn't deliver, that's a problem. But if it's radio silence from the sponsor side, you know, the squeaky wheel gets the oil, so they're gonna work on the one that poking them and be the squeaky wheel.

**Kunal:** Sure. So, when I started at Abbott there was this big backlog of data that wasn't clean, and I think we get back on track but things again fall behind schedule and there's this humongous data, there's staff turnover, there's, you know, just backlog.

## Transcript: What do you need to know about data management?

March 21, 2018

---

So what steps can a sponsor or CRO take to accelerate their data cleaning process? Like, what has worked for you? Can you share some ideas or ...

**Karen:** Sure. So, again, it goes to the project management side of data management. Having a data review plan and data review is actually not just a data management task. We can tell if data is inconsistent from one thing to another but from a medical point of view, are those AEs and those medications appropriate, from a safety point of view? Is that AE a major safety concern or you know, from the staff's point of view the site entered data the way it makes sense but it's going to blow up the TLFs when they're starting to program things.

So, combining all of the functional groups into a data review plan is something that we have. We generally try to have it. It's part of our data management plan. It's in an appendix or a separate document, depending on your organization, but it clearly defines who's going to look at what data. 'Cause you can't just sit and review the AEs. The data manager is gonna look at it and if your start and stop dates are consistent, things like that but if medical monitor is going to look at it, by the fact that they just said they had a fatal stubbed toe, you know, that's probably something more complicated. Data management can figure that out.

So, something that or an adverse event that they say is either mild and it can never be mild or it's a fatal event that's really not a fatal event.

So, making sure the functional groups that have the expertise to look at the data are going to do it, plan for it, what frequency. Different organizations have different frequency- once a month, once a quarter, once patients hit a certain time point. But I think plan for that up front.

**Kunal:** So, just, I have a couple follow up questions. What is TLF stand for, for those ...

**Karen:** Tables, Listings and Figures.

**Kunal:** And then in terms of you said communicating with safety or safety owning their piece of the data review, for example? Who kind of takes the lead ... do you expect safety to come to you or do you go to safety?

**Gina:** It really depends how strong your data manager/PM is. Quite often I have seen them take the lead on everything data. On all the vendors, IWRS, Design, for example, and QC and UHC and checking the data that comes in time after time, because I've seen a lot of let's say duplicates coming through and cleaning that.

So, it really depends on the strength of the PM's skills of the data management. No, you have asked what do you do when you come into my very favorite term is "rescue status" when you're

## Transcript: What do you need to know about data management?

March 21, 2018

---

called on to rescue the study. Besides creating a plan, sometimes you cannot. It's such a huge study. Thousands of patients, a couple of thousands of patients. You cannot rescue every data point.

So, if you sit down with the clinical team and all the organization and figure out what exactly are we going to clean? What are the points that you're going to clean? And then you start establishing the relationship with the sites and the people at them. 'Cause quite often it is such a forgotten study that nobody looks at it for a little while.

So, another role of yours, after you truly define what you're going to clean, field by field. What is important for this study? If not everything, then what? And it is a plan. Then you start establishing relationship with the site again. You say, "Hello. We're working on this study, and I'm here again, and I'm supporting you and this time, I'm good." So, that was the plan, to reestablish a relationship, actually, with the whole team that is a communication part, PM part, again, those soft skills that are very critical for data management.

**Kunal:** That's great. So, I think, talking about soft skills. I'm curious, what resources do you keep yourself going back to over and over again? I'm specifically looking for insights that would make somebody great at data management.

**Karen:** That's a good question. I have my own history and my own favorites and for templates and how to design forms and one of my challenges is, as someone who's been in the industry for a while and wants to support the future of data management, is figuring out how to get someone into data management. I don't have a good answer. I can tell you that the last ten or twelve years, I've never hired someone without experience.

How do they get experience? That's really hard. I mean, one of my answers is CROs need a lot of people and they're more willing to train. So I think starting off there is a spot where you're exposed to a lot of different type of studies. You're exposed to a lot of different sponsors, so a lot of different ways of doing things. But the companies I've been at have been small start-ups and anyone that comes in needs to hit the ground running but it's ... I don't know how you learn how to hit the ground running without five years' experience or something like that.

**Kunal:** There are people in the audience that have not worked in data management and want to get into the field? Are you saying they need to start at a CRO?

**Gina:** Not necessarily.

**Kunal:** How can they learn and, I mean ...

## Transcript: What do you need to know about data management?

March 21, 2018

---

**Gina:** They kind of fall into data management. That's kind of my experience and then, they like it. It's analytical skills, it's focus skills, it's very close to technology, the site came from the technology.

**Kunal:** That's a good point.

**Gina:** So, that's the path you kind of look and fall into it.

**Karen:** I think not just the CROs, I shouldn't say. Some of the larger companies, too, are more able to train and mentor someone right off the bat. Or if you have people within your organization who are in different functional areas, bringing them in and exposing them, if they're interested.

A good organization will want to keep good people so if they're interested in other functional areas, that's another way as well.

**Gina:** Yeah, there are certifications for already experienced people but there is no college degree in data management.

**Kunal:** So you guys both mentioned about soft skills. Is there a resource that you recommend?

**Gina:** Project Management course. There is a SCDM site that is very helpful. For me, since I've been in business for a while, it's all the people I know. Through the years I keep in touch with them. They are my support, they are working with me and advising me when I need to-

**Karen:** Just to cover the acronym, SCDM is the Society of Clinical Data Management. That's actually a really good resource for people to understand what data management is like. You know, a professional organization and they have training classes and DIA drug association. They also have conferences and seminars and trainings, as well. For anyone who ... that's it. DIA is a cost industry.

**Gina:** And many extension colleges like Berkeley and UC of Santa Cruz, now have ... or for a while, had courses in data management but it's not a separate course, it's part of clinical research certification.

**Kunal:** So, I have one last question, then we'll open it up for questions. So, what does the future look like for data management? What opportunities lie ahead of us?

**Gina:** It is so exciting. It is wonderful. We are, as data managers, very technical. I'd like to emphasize it once again. So, all the technology is wearables, it's AEs, the artificial intelligence

## Transcript: What do you need to know about data management?

March 21, 2018

---

with EHR combining, coming here with the patient, with direct input from the patients. All kinds of devices that you can think of. We collect data and get introduced to and interface with. So, from the technology perspective, it is awesome area to be in.

**Karen:** Yeah, I agree. I mean, I think those are all the sources of how we're collecting the data that are really exciting and how we can move forward with it in the future. But for me, personally, I think to go back to Haj's point earlier, that when I hear about one of the drugs that I've worked on getting approval, that means we're helping people and I think that's a really powerful thing. I think that's why almost everyone who is in clinical trials, everyone, got into it in the first place.

You had a little bit of a scientific angle. I like the science part and I'm technical, so I do data management. But to be involved with a drug that ultimately gets approval, that's the goal.

**Kunal:** Do you think the role of data manager will evolve with the technology advances? And if so, how?

**Karen:** Yeah. I mean definitely. Over my career there's been the evolution of ... We used to have a room full of people doing heads-down data entry that was just pounding away and entering data and that's not happening anymore. I think that's a benefit to the career 'cause it's just more interesting. Doing heads-down data entry is not very fun but looking at the troubleshooting, putting the puzzle together for how we're going to collect data, to me, that's much more interesting.

So, I think as a day-to-day job, you've taken out the maybe menial tasks that are not very interesting and kind of raised the level.

**Gina:** Technology, data analytics, artificial intelligence is in our future but you also need to truly be analytical yourself and have a connection to look and analyze and see the data trends.

**Kunal:** So I'll open up for questions. You go first-

**Mark:** My name's Mark Bant. I'm CEO of a company that's looking, really, at software in the space and so forth. So, I was actually going to ask you a question about tools, SQL, cleaning. Do you have raw access? I'm new to the industry so please bear with me in terms of ... when you say the words "cleaning" and so forth, are you comfortable with your tool kit and if so or if not, why or what would you do otherwise? In other words, are you just straight querying the source data or do you have interfaces that you use to interact with and analyze and understand?

**Gina:** We have EDC that we use as a tool, for example. For acquiring data, yeah.

## Transcript: What do you need to know about data management?

March 21, 2018

---

**Mark:** So like Tableau? You understand what I'm asking?

**Karen:** Yeah, Tableau is one way of doing visualization and seeing where there are problems. I think most of us, when we're looking at data are looking either at listings, Excel spreadsheets, and other ways to present the raw data than just long lines of listings. Sass is a programming language that we can do a lot, have our programmers pull out things that are known possible inconsistencies. So, they can give us a list of problems. We don't have to go searching through it. But an EDC is where we would query back to the site and say, "The stop date is before the start date so fix one of them."

**Mark:** The reason, I asked this question is because a couple meetings ago they were talking about how they've changed ... The FDA is comfortable now with sampling as opposed to when you go back and verify the source of data, you don't have to now go back to every single record.

So, I guess, my question, sort of moving into that model, how does that affect your need for tools and what you just described and so forth? Kind of where I was going.

**Karen:** Risk-Based Monitoring, which needs its own set of tools. You know, you can't just ... we decide today that these are the data points we want to monitor, there has to be some sort of plan and risk-based rationale for what you're gonna look like and if you hit a certain bar, like a bad bar, you have to look at more. If the first patient at a site you look at more than the fifth or sixth patient at the site. So, there are tools and modules you add onto EDC systems or CTMS systems.

**Gina:** I heard about a tool that allows you, through some algorithm, to check which fields are to be monitored so ... I have not seen it in implementation yet but there are some.

**Kunal:** Is there another question ready?

**Guest 1:** So, from a sponsor perspective, when is it the right time to change from a CRO owned study-based EDC to a sponsor-owned study-based EDC? What resources are needed from a sponsor when you make that transition?

**Gina:** That's an interesting question. Well, just from experience, I have seen that sponsors like to own data so when is the right time? I don't know, it really depends on a sponsor, when they want to. But if it is one sponsor, it can choose a proper system, build many studies in that system, and cross-analyze studies using that same standards and system. So, maybe after when sponsors has grown from a little one to a little bigger one, that question will arise.

## Transcript: What do you need to know about data management?

March 21, 2018

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What does this sponsor need? Well, they need a full-blown data management department with programmers who can build and support this study. And they will have help desks so it is, honestly, in the transition. You need to think through when you need to build.

**Karen:** I would say as early as possible. The company I'm currently at was amazing. They brought me in and said, "How do you want to do data management?" And I told them how I wanted to do it, I wanted to own our data. I think part of it, though, you can't do that without considering the consequences. You can't have a group that just does this, they don't exist if you don't have data management experience.

So, one of the key parts is planning for who's going to do the build. A small company is not going to have a pool of programmers, so you do have to have functional providers and how you're going to delegate responsibility. If you're going to follow that service provider's SOPs. So, you can be a very small company and still own your system but have qualified personnel working at it and being responsible for the validation, UAT and tests like that.

**Guest 2:** So as we introduced more digital technologies or wearables to trials, what kind of challenges do you see for data management?

**Gina:** I recently had a study with wearables and the challenges are the same as with any data transmission or data input. Data may or may not be very clean. That's the main challenge.

**Karen:** I think, to add to that, understanding the limitations ... What is the validity of the data you're collecting? Is it true, accurate data?

**Gina:** Well that's, actually, a very interesting point I just wanted to add here that with time we'll have more and more data sources and figuring out what you're actually need out of that and it's not necessarily everything you need, is another challenge for our profession, eventually.

**Kunal:** Do we have another question?

**Guest 3:** My name's Deborah. I am a project manager and I have actually been in this role for a lot of years, not aging myself here. My question for you is I hear data management is very detail-oriented, you must be analytical, as a project management, generally project management is very high level, they're task-oriented. That's how they're built. Do you find that you're finding project managers that are analytical that can support your team? Because in my experience, I have not seen it ... I usually hire a business analyst or someone that is very detail-oriented. Just wondering.

## Transcript: What do you need to know about data management?

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**Karen:** I think it's a challenge. Every person you hire has their strengths and weaknesses. So, you may have someone who's really good on the project management side but maybe not as good at the details, or vice versa. So, it's just about trying to figure out that fine line. I think the people in data management who advance and excel are people who can balance both of those.

**Gina:** I usually prefer to see the path for these people as they are data managers that go into project management so they have all the basic skills and understand what tasks are and what it takes to get the tasks ... 'cause hopefully they have done some of them, but then they can have a strategic view as well, which is project management.

These are the best.

**Kunal:** One last question.

**Guest 4:** You know, earlier you said what makes a good data manager and I was a CRA for twenty years and now I'm in quality for the past ten, so I kind of date myself. But I remember reading queries that ... If I were to say what makes a good query, that it's clear and concise, it doesn't sound punitive, and then it gets results. So, as you start with new data managers, if you read those queries, those three things. Clear and concise, doesn't sound punitive, it sounds more like, "Can you help me understand," you know? Like, "This is this and this is this. Please clarify." That's a way of, "Please help me understand." And that will get results.

I would read some queries and no wonder the study coordinator said, "I'll deal with this tomorrow." Because it didn't make sense. And it hurt them. And it added to their burden of their day. So, the soft skills are important. I thought of that early, when we were talking, that soft skills are so important and everybody on the planet responds to a message that has the underlying tone of "Please help me." And if you have that thread in anything you ask of anyone, "Please help me," it gets better results than a punitive kind of thing. So, anyway, that's my thought.

**Gina:** This is an awesome addition, actually, and when I train data managers, I actually spend a lot of time on wording, both of those queries and messages. You are absolutely right. It's very important and people could be on the other side of the world thinking in a totally different way so you need to consider that.

**Kunal:** We'll call this a wrap.