[Webinar Transcript]

Understanding the Economics of Site-centric Imaging Assessments

Participants:

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Jeff Sorenson: I'll start by introducing Jessica Moehle, Research Administrative Director of the clinical trials office of Huntsman Cancer Institute in Salt Lake City, Utah. Jessica brings a wealth of information and experiences around imaging clinical trials administration at an NCI-designated comprehensive Cancer Center that supports a very wide geographic region with all of the unique challenges that brings.

We also have Dr. Dushyant Sahani, professor and chairman of radiology at the University of Washington. Dr. Sahani is passionately focused on the intersection of imaging, AI, and precision medicine, with insights and practical experience growing and managing an onco-rad department in the face of increasing demands and possibilities.

We also have Michelle Liendo, the Director of Clinical Research operations management at the VCU Massey Cancer Center clinical trials office. Michelle drives the day-to-day operations at an NCI-designated comprehensive Cancer Center that has taken a unique technology-driven outsourcing approach for the performance of imaging assessments that retains efficient on-site coordination of all stakeholders both inside and outside of her institution.

We also have Rajan Gopalakrishnan, the Director of Informatics and Information Technology at the University of Chicago Comprehensive Cancer Center. Rajan has led many imaging and clinical trials technology initiatives with an eye toward business-centric enterprise solutions. He brings people management and performance coaching into each of his transformation initiatives for optimal results.

Introducing myself, I'll be your host and moderator for this session. My name is Jeff Sorensen. I'm a 30-year veteran health tech executive with 25 years of experience in imaging solutions, mostly in software as a medical device. Most recently, the CEO of a radiology software company with over 1300 sites, some of which performed over 5 million studies per year.

After this, I went on a journey of discovery and learned that cancer centers don't work together on imaging clinical trials and that broken workflow is causing errors, data loss, and failed audits, and these occur all too frequently. As one example, "90% of oncology trials require imaging, yet there's a consistent 30% error rate in site eligibility assessments at the top research institutions doing the best site work. For imaging to have the impact that I personally know that it can, we must do a better job with site-centric imaging solutions across the board" (Sorenson).

So, with that, let's jump into it, and you're going to have a chance to hear from our expert panelists. So, first of all, welcome to all of you, and thank you very much for sharing your amazing insights and agreeing to do this. I think it is certainly an important topic and a passion of mine, and it's a great honor to have all of you here with us. Let's start with Jessica. Jessica, can you please summarize the role of imaging assessments in your clinical trials, who's involved, and how it impacts patient care, just to get everyone centered on what we're talking about here today.

3:24 - Jessica Moehle: Sure, as some of the other panelists, comprehensive cancer centers, or other major universities that are caring for patients can probably appreciate, we are enrolling a high number of adult patients to a myriad of clinical trials that are sponsored by industry pharmaceutical partners either written by our own investigators or federally funded in some way, so there's a wide spectrum of the types of studies that were enrolling patients to, primarily looking for intervention treatment of their cancer and across a myriad of diseases. "Almost every trial requires imaging, at some point, for a disease assessment. Having a rapid and consistent turnaround is critical to patient care and our provider's ability to make treatment decisions on what needs to happen for them to move forward, either in their clinical trial or in some other manner, to care for them and their disease. Having a platform that's consistent across all disease types, whether that be something that's in the hematologic oncology space or the solid tumor space, is critical."

"Our trial coordination teams are working closely with our clinicians and providers to utilize a site-centric imaging model which enables them to have a rapid turnaround. The timely response created by the Yunu platform is critical to overall patient care and experience, as well as the physician's ability to get answers and make decisions on what needs to happen next during one of the most difficult times of their lives."

5:20 - Jeff Sorenson: Awesome, thank you very much, great summary. Certainly, a must-have, not a nice to have to get these things right, and I think everyone's going to be surprised when they hear the current state of affair elsewhere where they haven't figured it out, so thank you Jessica. Michelle, what do you think are the biggest differences between clinical trials imaging reads, and standard of care reads? There's a lot of confusion between those two, and some people think, 'well, gosh, it would be nice if they all happened at the same time and they all had the same results.' Can you kind of break that down and kind of unpack that so people are educated about the differences?

5:59 - Michelle Liendo: So for standard care reads, you know, it's the clinical read that you get for any patient coming through having imaging, and you might have a different radiologist reading each time it comes through. Somebody might see certain things on the images one day, and the next scan, they might not compare the exact same lesions or measure the same ones, and they might just talk about a couple here and there, and so that consistency that we need from a clinical research perspective, you won't always find. You'd have to go back to the radiologist doing the clinical read and ask them to adjust their report to reflect what you would need for the study. So, as we know, clinical research has their protocol very specific, and a lot of studies, especially solid tumors, will follow RECIST criteria and now we have other iRECIST, we have Lugano criteria, all the different criteria that we need to follow to really dictate how many lesions we're looking at. So, we have target lesions, non-target lesions, what meets the criteria for all those, and so at a baseline assessment for clinical research read, you'll identify those target, non-target lesions that you're going to follow throughout the study, and each time you'll have that consistent read of those same lesions. If a new lesion appears, then that would be considered progression, but for the ones that were there from the very beginning, you have that consistency of always getting those looked at and measured throughout the process. And then I just want to add to that, for the sponsors, that's really important so that they ask for that level of detail in their data capture systems. Where we transmit all that information to them and then they check that report to make sure it matches to make sure all the data quality is intact.

7:43 - Jeff Sorenson: Thank you very much. So yeah, I mean everyone talks about it like radiologists doing RECIST measurements, but it's just not nearly that simple because of all of the shades of gray, and all of the different criteria involved. That's an underappreciated fact so, thank you. Dr. Sahani, as Chair of Radiology, how do you balance the desire to participate in more clinical trials with the daily demands of clinical care, and what role can technology or what role does it typically play today, and what role do you think it could or should play?

8:17 - Dr. Dushyant Sahani: Jeff, first of all, I appreciate this opportunity to serve on this panel on a very important topic. You know, as a chair of the department of radiology, a field that has become an indispensable part of modern medicine, it enables physicians to make accurate diagnosis. We can now screen for various diseases, we have very impressive therapeutics, and also we have capabilities to be more precise in guiding with therapies. But, this has led to tremendous demand on radiologists and radiology departments, and oncology has been a particular specialty that has very specific needs. We need to take a lot of gratification that imaging is integral to making those decisions, and over time, the decision-making of the response assessment criteria have become more nuanced. And based on new therapies, the decisions are then based on future treatments, and imaging provides those quantitative measures. Now, the clinical trials have also grown substantially. At a given time, I would say

each year I see growth in about 15 to 20% more participation in clinical trials. It is impressive to see new therapies come to treat our patients, but too, we need to balance our clinical needs along with other academic endeavors, such as education and research. "I personally think clinical trials are part of care delivery now. In this time of staffing shortages and tremendous demand for radiologists' time, it's critical that we embrace modern technology. These technologies include impressive IT platforms and AI solutions to make workflow more seamless and create some automation when it comes to tumor measurements and integrating response assessment criteria, so radiologists don't have to keep track of what criteria is being applied for that trial. It is critical that we leverage modern technologies to sustain the current clinical need along with the demand from clinical trials and the future forecast of both."

11:07 - Jeff Sorenson: Those are sobering statistics when you think about the fact that there's a 3% enrollment rate in trials where most Americans get care, and then you think about the demand that would create, the demand you're seeing clinically, and then the demand in clinical trials that are becoming more complex, and there's more participation. There definitely has to be some smarter ways that we work together, and more be efficient. You know, one thing that became obvious when I saw one of the AACI presentations they had on labor force statistics is it was just stunning how many open positions there are, even for study staff, let alone radiologists so we have to be working much more efficiently. So, thank you for bringing such an expert voice to this conversation.

11:55 - Dr. Dushyant Sahani: Jeff, one point I also want to add here. You know, physicians and many healthcare providers are leaving the workforce because of burnout with tremendous demand on their professional, time and they have to balance many other responsibilities. So, it's incumbent on us to really make clinical work more manageable. For that, whatever it needs, whether it's new technology platform tools, automation, AI, we need to embrace these technologies to support our workforce better while meeting the expectations from patients and our clinical colleagues.

12:42 - Jeff Sorenson: Thank you very much. Rajan, maybe you could sort of pick up here, and in terms of current technologies today, as an expert in that arena, can you share some of the top challenges that sites are facing with imaging assessments and maybe tie that in directly to workflow, staffing, efficiency challenges, and let's break it down a bit and drill in a bit for us into why is this so hard today?

13:10 - Rajan Gopalakrishnan: Absolutely. So again, you know, thank you for giving me the opportunity to speak at this forum. "Our team embarked on a strategic reorientation several years ago, looking at the digital transformation of the landscape of our cancer clinical research operations and applying more realistic solutions to a lot of the problems that we see here. Our finding was that imaging was a very big and significant pillar." To a point where we had a special group where we spoke to all the folks involved in imaging - upstream, downstream, part of clinical research operations, and we tried to figure out what some of the key problems here were. So, I would say that of the top four recurring themes that we saw in talking to the various stakeholders, one certainly, operationally, was you know, turnaround times for imaging assessments. So very often, we have these patients who come to us maybe from Indiana or maybe from Michigan, and they're here, and we want to assess whether a clinical trial is appropriate to offer to them. That decision is dependent on a research read, and so we see that the turnaround times were completely not compatible at all in terms of being able to make any kind of an assessment for that patient when they were here, given that they would be here for maybe half a day, or even if we made them wait the whole day. So, there was a big incompatibility, a big gap, to the point where we would have to scramble and then pick up the phones and ask somebody to do an initial assessment so that we could at least make some sort of a summary judgment about 'yeah maybe the clinical trial may work, may not work.' That was a very big inefficiency that we saw out there, and some of this actually ties in with staffing and all of those needs as well. Whether it is having enough radiologist staff to be able to do the reads on time, whether it was the clinical research staff, there was always that tension about not having enough people to follow through the whole workflow and just go back to the patient and say 'yes, you do match the criteria for this trial and we would like to offer it.' So, it was all tied in pretty intimately with that. Then, coming back to workflow and efficiency again overall, through the life cycle of any clinical trial, there's the whole aspect of around figuring out what needs to happen next for a patient. Given a read has been completed, do we have all the information needed? What is happening with this particular patient? So all of these things tie back into the whole workflow efficiency, so, most of the time, they were threads of emails as you've seen at many different sites. Just keeping track of five different threads of e-mail and sub-threads launched from there, excel spreadsheets, word documents - it was it was a highly inefficient process overall. So, workflow issues were burning bright red, and then going back to 'what happens if all of these things have not fallen into place' or data quality issues. Many things are communicated back and forth by notes somewhere in there, and somebody comes up and says, "the last read was noted incorrectly, it should have been a 11MM read and not a 10MM read." And then you go back, and you see

it was actually 9MM in the notes, and so you're like, OK, who's saying what? Who's correct? So, all of the data quality and then trying to figure that out very often, it could be a biostatistician, or it could be a data quality person who tries to bring all of the data together and say, "Well, this doesn't make sense. The notes say this, the image says this, who's tracking what lesion?" So data quality was a pretty big issue as well, and we spun a lot of cycles trying to get everything in a form where we could say, "Okay, we have everything we need to now make a decision," or it could stand the rigors of an internal audit, for example. "We have established an entire team for the imaging efficiency side of things and ask, "How can we do better? How can we bring in modern generation platforms to make the life of everybody involved in a clinical trial better, prevent burnout, have better data quality, better coordination, and deliver excellence as a clinical research site?"

17:36 - Jessica Moehle: I just wanted to add to that a little bit if that's OK for Rajan's points. I think as we've seen the staffing turnover and the staffing plaguing of the clinical trial offices across the country, one thing that we found that is actually supporting our ability to kind of plug people into holes that are coming up without having such dramatic impact I guess to their workflow, moving their disease teams for example, is that that site central imaging plan is the same across all these different teams. We can take coordinator A and put them into team B, C, or D, and they still know how to use the Yunu platform and how to apply it into the clinical trial research that they're doing. It empowers them to interact seamlessly with the physicians to ensure that reports are looked at, signed off on, pulled into the EMR appropriately, and become that source record for the data that their team is responsible for capturing. It's been a really big advantage in a time of seeing staff massive turnover rates across the sites". The other component is just that "having a site-centric imaging platform is the golden standard from the auditing and compliance perspective. The reports that are generated in the platform are so critical and so highly praised by auditors" (Moehle). As big sites, we are audited by not only the National Cancer Institute but also pharmaceutical companies a dozen or more times a year. Knowing that we don't have to be concerned about how the process flows for disease assessments or compliance with the protocol in the radiology read gives us confidence it was captured and stored correctly, whether that's Lugano, or Chesson, or irRECIST, or whatever, just ups the compliance level that is expected at our institution and for the care that we're giving to those

patients. So, I think those are two key components operationally that should be mentioned as well.

19:51 - Jeff Sorenson: That's great, and you have a kind of a network of sites also, right? So, it allows you to think flexibly across facilities too, which I think Is really exciting. And Rajan, you sort of started off part of your statements about starting with data quality, and I think Jessica's hit on that, too. I mean, ultimately, that's what people need, right? That's what the sponsors need, that's what the patient needs, that's what the physician needs, and you know when I went on my journey of discovery here, finding out you know how things were happening and how I might be able to help, it really came down to that if you don't have an organized way of working and you don't have an organized way of communicating, then you can't expect to have good data, right?

20:40 - Rajan Gopalakrishnan: I think one critical point to always center ourselves back to is, for applicable trials where imaging is a modality, we forget how central imaging and imaging measurements are to the decision-making of where we take the patient from here. It's so central it's almost crazy if you think about the fact that there has never existed an organized way to work through it until now.

21:08 - Jeff Sorenson: Does anyone have any thoughts about patient dropout, in terms of if you don't have an organized system? I would say most don't if they're using standard-of-care systems and trying to do the math manually or sort of off the grid with data teams etc. Does anyone have any sort of comment on what that might do for patient dropouts? Why it might cause it, and how significant of a role that might play?

21:37 - Michelle Liendo: Yeah, I can start. I think definitely the timeline - so if it's going to take weeks to get a read back, that's delaying a patient's decision or knowing if they're going to be eligible to go on a study. Some studies might require very specific data - they have to have shown, you know, 20% progression or progression over the last two scans, and so a lot of that stuff is more detailed than maybe what, clinically, the radiologist would be looking at. So, having the ability to get that addressed quickly is necessary for you to be able to put the patient on as quickly as possible. We all have our screening windows that we have to abide by, but certain things that we know that would kind of disqualify or make a patient ineligible, we try to do that quicker so that we're not wasting their time and they can go on to something else to get treatment faster, so we don't delay their treatment. That's a big reason, potentially, of losing a patient if we're not able to get those reads in a timely manner to get them on.

22:36 - Jeff Sorenson: Thanks, Michelle and Dr. Sahani; question for you. Doesn't this put the radiologist in a really tough position in terms of the importance of these turnarounds and the

stress of clinical work and then maybe not having the tools necessary? What's the perspective of the radiologist when being asked to do this kind of work with the tools they normally have?

22:58 - Dr. Dushyant Sahani: Jeff, to some extent, it is very flattering to know that a lot of these critical decision hinges on providing quality radiology interpretations, which have become very quantitative, when it comes to, and not only quantitative, nuances based on the response criteria that is being defined for that type of therapy, it also is challenging. How do you meet service guarantees when it comes to clinical care but also for clinical trial support? And patients are very involved when it comes to oncology care. They really read their reports. Many patients I know, they've actually maintained journals of things. They even write down measurements and all that for themselves. So, patients see this extremely valuable service, and it also causes a lot of anxiety and dissatisfaction if we are not able to meet those types of demands. Oncology care is multidisciplinary. It is very involved. It is also a great opportunity to serve our patient, who needs us desperately in a difficult time. While that is a very fulfilling mission, it also puts some tremendous stress on the radiology workforce, so we need to ensure we are doing everything we can to deliver accurate, on-time assessments. At the University of Washington, we use Yunu to support imaging for clinical trials. It enables seamless processing of the images, which are prepared by an image analyst and reviewed and finalized by the radiologist. The platform is so integrated in our workflow that it makes assessment of those trial time points much easier for our radiologists. The quality of care and the quality of reads is preserved. The platform allows you to embed the response criteria up front so radiologists don't have to keep track of it while helping generate the quantifiable information. As a result, we are meeting our dual needs of efficient quality reads for clinical trials but also not burning out our radiologists.

25:31 - Jeff Sorenson: Let me tie into that and thank you for all that. If standard practice in clinical trials all of a sudden became that you were preserving all of the measurements on all of the lesions of all of the time points on every criteria of every patient on every trial, if all of a sudden we had all of that, I know in part of your role and your passion, you have a lot of designs around what could be done with the data, what should be done with the data, and what the world should look like. Clearly, we have a lot of work to do to make sure we have all of this data. I think sponsors could even be more demanding in the future that things be super organized, and if it were, could you just give everyone sort of a little teaser on what that might mean for precision radiology, oncology, and even prognostic tools?

26:25 - Dr. Dushyant Sahani: Yeah, Jeff, as you know, imaging is so data-rich and technology-intense. Unfortunately, we use less than 10%, and I think that's the upper number. It might be one or two percent of the data that is available. The reason for that is we really don't have the tools, technology, or research to parse out that data and apply it meaningfully to make current and future decisions. But now, with the technology that is available, if you have the data available to be analyzed for looking at patients who might have future challenges, or future bad outcomes, or better responses to therapies, we might be able to take, instead of few hundred patients, tens of thousands of patients. Data can be applied to making better decisions. I personally think that when we look at precision oncology, it will move away from the current response criteria. It will be more on the integrated diagnostic criteria that will integrate the radiomics information, the quantifiable response information, along with patient demographics, EHR, and body composition information. For example, how much is the muscle mass, or is there sarcopenia, visceral fat, atherosclerosis? All those might also influence patients' outcome to therapies. Currently, we don't have the capability to integrate that information, but we have tremendous knowledge that all these impact outcomes, not just in non-oncology, but will also impact oncology care. Just to think about anti-angiogenic therapies, which were very popular sometime back. They might not be as effective in patients who have advanced atherosclerosis, but we don't apply those criteria in selecting patients for those therapies. So, I'm thinking that the future approach in precision medicine, especially on the precision oncology side, will integrate a lot of this information. We might have the capabilities in the future to do that.

28:58 - Jeff Sorenson: I agree, there's a ton of signal in those images and there's a lot of exciting papers coming out along those lines, particularly this year. I have a question for you, Michelle. So, you know for those that are just going on this journey and thinking 'something really needs to be done, and that's why they're consuming this content, what would be your thoughts about the effect of imaging assessment performance on site selection rates? In terms of being a successful site for sponsors and in terms of attracting more clinical trials, any thoughts on what upping your imaging assessment game means to sponsor selection?

29:42 - Michelle Liendo: Yes, I think it's really important. A lot of sites are moving away from doing some site feasibility questionnaires because there's a lot of standard questions that we get asked from sponsors regularly. So, we've actually put in place an SOP where we're not really doing those anymore, and we're giving you a site information packet so they can know what we can do. In there, we talk about our imaging capabilities, what machines we have, and what we use typically, and then also what our process is for those reads that we need to do and what we're able to do there. That is very important. So again, it goes back to the turnaround time of getting that information to report into the database. For any study, you

typically need five days to enter the data from when the visit happened, and that's really important. Especially crucial if you're doing any phase one, first in human, any early phase trials because that data impacts you going to the next dose level and proceeding with the study. So having that in a timely manner to be able to do your data entry timely impacts that, and so, just like we know which sponsors we like to work with, sponsors also know the sites they like to work with. So, they keep track of sites and may say 'Oh this site has done a great job of always entering data in a timely manner into our systems and providing high quality work'. So, if they're like 'Oh this is taking way too long, and we're not getting the data. We're constantly having to follow up." They probably won't recommend you as a site or if they are, you might be on the bottom of their list to be selected for a study that could be beneficial for your population.

31:21 - Jeff Sorenson: I was kind of surprised too, you know, something that doesn't get talked about, but was surprising to me just on my personal journey here, was that patients who drive a long way, they get scanned and their images are evaluated, and then they're going to get treated the same day. So, if you have inaccuracies and broken workflow at the site, the five-day turnaround time that the data is going to the sponsor is entirely too late to follow the protocol. It's important to have accurate measurements at the site. I want to throw out a question to the group. This one will be a fun one. We're looking for a number. Let's see if the group can put one together. How many hours of total study staff time are associated with each hour of radiology reading time? How many hours do you think it takes total for people managing the imaging data, getting the data, making sure it's read? Now we might want to discuss this in the context of a typical site, or a site before you major technology improvements that you've made, but what does that generally look like for clinical sites that you're aware of in terms of how much time it takes because I have a number in my head, but your number is more important so any thoughts?

32:48 - Dr. Dushyant Sahani: Jeff, I would say as you've mentioned, that depends a lot on a staff experience, your platform technology, your imaging protocols, all the things in your workflow. I think based on my experience here, at the minimum, and this is a guesstimate, we haven't actually measured it, I would say at least the ratio might be five to one or six to one. Five hours of staff time, one hour it could be higher, I'm taking a very conservative number. Don't quote me on that. I haven't done a formal analysis, but that's based on my assessment.

33:27 - Jeff Sorenson: Great, and I was very close because you said conservative. My number was eight. That's what I get from the data I'm able to find. As much as the goal is to help radiologists be efficient, and they are a rare specialty, and if you gave them more time, they could spend it on clinical work with no problem. Economically, I think cancer centers are not really looking at the economics properly. That eight hours of study staff time is in many cases as expensive, or more expensive, than the one hour of radiologist time and all of that is just

doing very pedestrian things of trying to make stuff happen that we could automate out and we're short of CRC's, we're short of radiologists, we need to be running more trials, more patients, more enrollment, so to me it's about pulling waste out of the system. It's not about replacing jobs. We have to replace waste because we can use the people to do other things. Any thoughts on that number, but I thought it would be, you know, an impactful statistic for our audience to hear.

34:39 - Rajan Gopalakrishnan: I want to echo Dr. Sahani's ratios as well. In my mind, I was kind of going with an unmeasured, unscientific estimate of about six to seven. It's kind of what I was thinking, but again, these are experienced research coordinators. They're pretty experienced reading through all of these. They have the context; they don't have to be trained. Like Jessica mentioned, if somebody is new that you throw into this, you can probably expect a much bigger multiple of that and that's a concern.

35:11 - Jessica Moehle: Absolutely, trying to track down investigators to be sure they saw things, they signed things, they feel like it's in the space to be signed off as source and put it into the data systems, learning the data systems, they're new. This is like a 12 to 15 plus-hour endeavor per scan potentially if they don't know what systems and how to access it and it's all very new. So conservatively, a lower number if they're very experienced, familiar with what they're looking at, familiar with how to do their jobs correctly, but it still continues to be something that, absolutely if you can cut out the non-value add activity to the best of your abilities, to try to streamline that efficiency, it benefits everybody and especially the patient that is voluntarily putting their time into participating in a clinical trial.

36:07 - Dr. Dushyant Sahani: Jeff, if I may add a comment to this great discussion here that is the root issue here is how do we make radiologists more efficient without compromising the quality of clinical trials' needs. Over time, if you notice, the pressure on radiologists time has increased. We have so many competing responsibilities. And when you look at one oncology patient, if we touch that patient's imaging at least three to four times - so first, is we might be giving an outside study interpretation, then they might have imaging at our site, we will do a formal diagnostic interpretation, then they will have a clinical trial need, then there will be a discussion and tumor boards, and you can imagine the number of times we touch this patient's charts and have a conversation on the imaging side. So it is incumbent on us to make the process more streamlined. The model, I can say, is in many other specialties, including ours. In interventional radiology, we have used advanced practice providers to assist in less complex tasks so physicians can be more focused on patient care and high-value, more complex work. It has improved the quality of physician's experience at work, but also it hasn't compromised the academic mission. If anything, it has enhanced it. This shouldn't be looked at

any differently. We need to use tools, technology, and processes to make the work more enjoyable.

37:51 - Jeff Sorenson: So, AI to me is just a how, not a what, right? It's just a technology that you can use to do intelligent things, maybe train it to do things with images or train it to look for things in terms of workflow. Does it have a role here in terms of accelerating either the workflow or the image analysis or reducing stress on the radiologist and the study staff, adding value to the PI? What are some ways that the group can think about that we should all be looking at? Artificial intelligence, or automation in this process, where should we go next to have the biggest impact and why?

38:38 - Dr. Dushyant Sahani: I can start, Jeff, and I will be brief. I would say if you looked at just some 20 to 25 years back, when digital platforms like PACS were introduced to radiology, there was so much concern that radiologists will become irrelevant, we will lose this connection with the referring physicians who might come to review those studies, and PACS did the opposite. It really amplified our impact, and it provided us efficiency to improve patient access, but also meet those high demands on cross-sectional imaging, and that is the reason we are here right now discussing all the demand that is on radiology. So, having said that, we need efficient tools, technology, and platforms, and AI fits right there. And physicians' care or all the healthcare providers, in general, don't care what name you call it - whether you call it advanced computation, you call it AI, you call it a better IT solution, no one cares - what we need is AI that fits in that paradigm of integrating, making workflows seamless, and integrating information to make the old process much easier.

40:05 - Jeff Sorenson: Great! Does anyone have any thoughts or comments to add to that? What about from the study staff perspective? It seems like there's a lot of opportunities to just put some intelligence around the workflow so you all don't have to follow up and push things around. Any thoughts, Michelle?

40:21 - Michelle Liendo: I'm very big on automation, so anything that we can use to automate workflow and eliminate waste to increase efficiency makes everybody's life easier. We talked about tracking down investigators to sign off on things, and a thing that we're doing on our end is we're working on a dashboard so an investigator can just log in and see everything they have pending to do. It has links to take them there to complete it, and you're not trying to chase them down or e-mail them 20 times to get an answer. Not just AI, just any IT solution really, that's going to automate and avoid any rework. Backing up a little bit, so we're talking about the hours of a staff member, I concur with what everybody said on the panel about a minimum five hours, but then you have that rework. If you don't have an IT solution in place and you're using the clinical staff reading, you might

have to go back to them and have them go back in and re-read, re-measure. That takes up more time and you're doing rework that adds, too, and then that causes some more inefficiencies, right? So, I think that helps us. Anything that could be automated to reduce and remove that excess is always helpful.

41:32 - Rajan Gopalakrishnan: I wanted to bring a different lens into this as well. Since we're talking AI, one of the things you know that I wanted to mention was last week, I was at CI4CC where the discussion was all cancer informatics, all the time. One of the things that we all discussed with each other is the future of cancer data platforms. In each of these institutions, our respective institutions, when we think about the data that is captured as part of these reads, maybe Dr. Sahani had mentioned the metadata and all of those things that that go in with this as well. It's not just about capturing the data of the images, but also about the metadata and the context within which of these decisions were made. The reasons why are really important. The future is all going to be about real-world data and inferring patterns from real world data. Whether you call them machine learning, AI, or assistive tools, in the future, we are going to be looking at the data sets that we looked at in the past with a different perspective. We are going to be recasting them in the lens of whatever we have learned in the last five years, reevaluating, and using that data to make predictions and decisions. In that context, it's very important to look at all of these holistically, not just from an automation standpoint, but also from the standpoint of 'what is the future value of what I'm going to be looking at?' The cancer data platforms of the future, that we would train localized AI algorithms and all of those on, so there is that angle that one needs to look at as well.

43:15 - Jeff Sorenson: Context is really key, and this is why I'm a little bit flummoxed by this concept that's used by sponsors called "Collect and Hold", where all they collect is the source imaging data, but they don't collect any of the measurements, or any of the labels that attach to the measurements that were taken. And in one breath it's done because they're not trusting the site assessments, which we need to make sure that they can audit and have traceability to accuracy because the efficiency gain there would be incredible if they if they could just trust them, and then the second thing you lose is the context. You lose all of the context between what you learned before and the measurements and the source images, which means you can't learn how to do things better and you're kind of starting over. So, there's this missing connectedness between what's happening at every step on the journey with these medical images and there are some long standing practices that we just need to rethink, and I think to me, "Collect and Hold" is one of the biggest ones. Even now, when you have data systems that are pristinely labeling the data, the data is being collected and held

without annotations for potential future use, which is crazy. I hope we can all focus on that. Any thoughts on this as we improve workflows. Does anyone have any real-world examples of being able to use technology to move faster and more efficiently with respect to imaging and then what that's meant in terms of your study starts, or staffing requirements for clinical trials? Does anybody have any stats that they could put around what it means to work more efficiently?

45:09 - Jessica Moehle: I think that we, when we're working more efficiently, I think we're seeing that, hopefully, there is a higher level of job satisfaction. We've seen reduced levels of staff turnover in the last year. Tying that into the imaging, specifically, is maybe not the only reason, but just having operating systems within any one institution to alleviate something that could be extremely burdensome and challenging and then ethically compromising. Putting coordinators into a situation and space where they're doing what they believe they're supposed to be doing to get information to providers and to patients' families about what the next step is for their care and having some inefficient system is very troubling. Not only the providers, but to those individuals that are attempting to coordinate that care and have a trustworthy system. We need sponsors to believe and trust that there is not this investigator bias when they're not using a site centric imaging. The fact that sites with site-centric imaging solutions are the ones that are seeing that independent and timely review occurring are really critical points. So, I think any removal, raising a flag of an ethical concern or something that you see slowing down a patient's care or ability to receive treatment fast or have decisions made quickly, are things that will always just keep the continued burnout or feeling that they can't make the right kind of difference they want to.

46:52 - Jeff Sorenson: Yeah, attrition is a huge problem and at the same time I think it's universally true at least in my experience, people don't get involved in clinical trials unless they're really committed and very altruistic about their work and then it's super disheartening if you know you're not doing the right thing, or you can't do the right thing and I think, you're right, that's a big driver of burnout. Question for you Dr. Sahani. I think you had mentioned to me that you had some impressive stat of growth, in terms of radiology demand. Something like doubled in five years on the clinical side and then meanwhile you have to sort of argue and make the case for technology investments and to build out your precision onco-rad capabilities. Any thoughts or advice you have for the group about how best you can champion change and technology inside an institution? Like how is it budgeted, or what's the business case that you've used successfully? Any advice?

48:00 - Dr. Dushyant Sahani: Jeff I think that's a great question and I will give my perspective and not necessarily it might apply to every site. I feel that we need to partner with our stakeholders and drive a vision around what a radiology practice will look like and what tools, technology, and platform it should entail and then how we can support that because from

radiology revenue or how radiology is supported, we can sustain a lot of those technology and tools, but showing value, what it means for our providers, for cancer centers and then driving some of the investments through that partnership is critical. But also, showing the return on investment when it comes to not only the timeliness of care, but the quality of care and providing additional solutions like image biomarkers with more integrated diagnostics that is very future of precision medicine advances. So, I think that partnership is critical, but also you need to have a strategy beyond oncology. You need to pursue this strategy for the entirety of radiology, and lead it with the right type of vision for that. AI and informatics is a big part of our vision. We already have a platform for AI, but we have also launched about 8 to 9 commercial, FDA approved tools. I will give you an example. In one solution to triage, an acute or unexpected incidental finding, we have seen tremendous change in the time to communicate that has dropped substantially more than 50%, and then time to treatment for this life-threatening condition has also gone down. I'm just giving you an example of one condition alone. You can see value in terms of return on investment in this type of technology. AI and informatics will be a critical strategy for the success of any radiology department. I cannot speak on everyone's behalf, but based on where I sit, it's very critical for my success in the future.

50:27 - Jeff Sorenson: Tying into that that potential, when we're running clinical trials, they're actually, of course, getting new drug candidates evaluated, and the correct ones are getting approved for use. There really should be imaging companion apps. Dementia for example, you should be using the data you've collected in the clinical trial to make some of these assistive AI tools that you could then be applying in clinical care. One of the biggest passions for me behind all of this, is if we can start collecting good data, you can start to transform everything from clinical decision support to patient triage, to trial matching. Imaging can have a role in many of these things, but not if the industry is losing its well labeled data like it has been before now. We're almost at time here, so I wanted to go around and just have everyone share a success story, or some plan for the future. Give the group some final inspiration, just in a quick thirty second blurb. What are you excited about or what's something you've accomplished or some inspiration that you could share just to leave everyone with a positive final thought?

51:48 - Michelle Liendo: You're not alone, we all are struggling with the same things even though maybe we don't always publicly say it, but we're all in the same boat. So, if you're feeling some pains, we are too, and there are a lot of different options. I've worked at different academic centers, and we've used different options of how to handle imaging, so there is a lot out there that you can use as a resource or figure out a plan that'll work, that'll best suit your needs for your institution and your site to be successful with the imaging rates.

52:26 - Jessica Moehle: I'm excited to continue to partner with you Jeff and some of the sites that we're trying to get going in the Inter-Mountain West. We're located in Salt Lake City, UT, but we are the NCI-designated Cancer Center for Montana, Idaho, Wyoming, and Nevada, which is a huge land mass and responsibility for patients. Bringing the few affiliate sites that we have and some of those other states into clinical trials is number one, but then also when appropriately able to leverage this type of technology to help support them as they keep patients close to home in these rural and frontier populations and care for them on clinical trials, we're very excited to see where that goes in our future.

53:16 - Rajan Gopalakrishnan: The thing that gives me hope is tied to some of the things I was mentioning. After so many years of facing all of these inefficiencies and listening to all the folks, I think the leadership has kind of turned around. It's not just Cancer Center, but all the other ancillary leadership has all turned around to acknowledging this as a big enough problem that we're corralling ourselves around finding technology and process solutions for all of these. We are looking at the nitty gritty of how exactly to make that work. What a pilot implementation for addressing these problems would look like, and so I'm very excited that everybody is on board. Finally, we have some concrete actions to take to address such a critical problem.

54:03 - Jeff Sorenson: That's great to hear. Thank you very much. Last but not least, I thought Dr. Sahani, you could put it all in perspective for us and have the last word, so please go ahead.

54:13 - Dr. Dushyant Sahani: Jeff, thanks for that honor to go last, but it's also a tough act to follow. Post-COVID, healthcare has been fundamentally transformed, and nowhere are the changes more evident than in radiology. We are at the inflection point, and if we need to preserve our impact and leadership, we need to be patient-centric and collaborate better with our radiology partners, as well as preserving our workforce. For that, we need to have a strong strategy, and digital strategy will be key to our success, along with additional investments we need to make in this space. Oncology is one part of that strategy, but I think the same approach applies everywhere else in healthcare. I think by doing that, we will really do very well in supporting our patients and also keeping the impact of radiology pretty strong.

55:13 - Jeff Sorenson: That's amazing. Thank you very much, and you know, there's nothing I could say better than that, so thank you very much, Dr. Sahani. I want to thank all of our panelists here for an amazing, engaging discussion. It's really important work that you're all doing. As much as we have a long way to go, we've made amazing progress in a very short period of time. It's been an honor to lead the discussion. Thank you all very much and I'm sure the SCRS community will really appreciate this dialogue so thank you all very much.