2025 CFCCC EAB RECORDING

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2025 CFCCC EAB – QUESTIONS & DISCUSSION TRANSCRIPT

1. **Director's Overview**

L Weiner: What wonderful progress you're making. I mean, I think it's really quite extraordinary for those of us who have been, on this external advisory board for, for some time. And, I won't recount the many things that I think that you're talking about that are that are representing such great progress.

I am pleased to note that you seem to be fending off whatever competitive challenges there are from City of Hope, and by adding these other hospitals, that will be an interesting strategy.

I wanted to start off by asking a question regarding your patient base of 4714, patients in your registry. Is that only from the, from Orange and, and Irvine? How does that work? Who is that? Or is that for all the hospitals in your system that you're noticing?
RVE: Those are those are captured right now. Just UCI health without including the four community hospitals.

Okay, fine. So, okay. So, do you believe that the addition of these additional hospitals, which, by the way, I would say you're not surely not going to put into your your your next site visit, you know, preparation. I mean, that'll be a future plan to incorporate those, those hospitals. And, because you can't claim something where you can't show progress and then and yeah, accruals. But that will get you up to around, 7,200, the analytic cases. So the expectations of reviewers for clinical trials is going to be quite a bit higher.

Where do you see the greatest opportunities for expansion of your clinical trial, base moving forward? **RVE:** Well, I think that's got to be it. And we can we can kind of play to the extent that we can get, those patients on our interventional and treatment trials, you know, in the next six to, to 12 months, those will be those will add to our accruals.

And we can do that without necessarily putting them in in data table three. I think you're right. In long term, we have to figure out the best way to integrate the care at those hospitals. And it's complicated. The easiest way would be Fountain Valley, where we already control the rat onc there. It's very close to us.

We have great relationships and physicians already there. We have an infusion center we're going to build out there. It's more complicated at Los Alamitos, the one that's higher up further north, because that one is more complicated. It has a lot of outside community oncology groups, including City of Hope, that have influence there. So the last thing we want to do is to come stampeding in and completely, trample on the town gown relations. So that's.

Yeah, I'll just make a note that there's, the, you know, the Graveyard of Cancer Center initiatives is littered with attempts to incorporate, community sites as, as major contributors to clinical research. So just be advised, there's no requirement that you include them. You know, even if UCI owns them and until you're ready to have something that's useful.

I have one more question and then a comment. So the other, question is ***I noticed that in your write ups that, you know, you have I mean, you clearly have expanded immuno oncology research, as many of us have over the, over the last few years. Yet it seems like it's dispersed amongst your programs. Is that a deliberate strategy or do you intend to at some point, you know, home that home, that research in the in a particular program or in a new program or anything like that?***

RVE: Which research? Lou. Did you [LW: immuno oncology related] immuno oncology. Yeah, the way we have it and it's a little bit artificial, is we parked it in BIDD. And that's because a lot of the trials are early phase. And that's also where all our early phase trials, and drug development are, it doesn't have to be exclusively there, but just thematically, it seemed like a good, good place to do it. So as of right now, that's what we've done.

Okay. Because you're getting to the critical mass where you might even be able to expand programs down the road. Not for this coming, you know, renewal. So the comment I want to make is about the elephant in the room, which is that the, from what we're hearing, the new FOA that's coming out, it's not going to be the full new FOA, and you will not be subject to the full new FOA.

The one that's going to come out is essentially going to be an amendment, and it's likely going to focus specifically on scrubbing all the content from, from the CCSG. And, and there's, going to be a pretty careful evaluation not only of DEI, but also whatever artifices we will use to to hide DEI under a different name.

And you just need to be aware of that. I mean, and I think that's going to be the nature of it. And so, you're, you're, I think that you're probably going to need to think about how you refashioned that. Yeah. The statement that you had that you listed on the in your presentation was a good one, I thought, because it's very affirmative in, in a very broad sense.

But you may want to think about how you begin to create the language around that in order to protect the, the institution in the cancer center from, from, from silly attacks and from what I can tell you is we just submitted our, competitive non-competing renewal. And we were told at the last second that we had to scrub all the data out of, old references to DEI out of it, not just by eliminating the DEI section, but all references.

And then we got another call just this morning saying, well, you don't have to do that, actually. You just have to be willing to sign a waiver stating that you're not going to deal. You're not going to do any of that moving forward. So it's a it's all a moving target. But you got to really be mindful of what's going to happen with that.

And I'll stop with that and let Cheryl and and I think it's Lucky, make any comments or questions.

L Lara: All right. Well thank you, Lou. I'll reserve my comments. After Dr. Willman gives her, her, remarks, Cheryl.

C Willman: So, so thanks, Lou and Lucky and Rick. So I'll be a little bit harder on you. And it's only in this context because I've just come through, really, really tough competing renewal had to be done virtually, like we did during Covid, which was really challenging. Not what any of us want. It's not clear whether the CCSG site visits will go back to in-person. So the reason I'm making this point, Rick, is how your application is written is going to be absolutely critical.

So I think you have to presume that we may not go back to in-person site visits. Still, travel restrictions for the NIH and NCI staff are not clear when those will be lifted. So again, how you write this application is critical because your reviewers may not get that experience of that, campus visit, which I think adds a lot to the strength and feel of the institution.

So, where I want to go back to is I would have expected you to give me a talk today, given that you have a grant doing a year that talked to me about how you're going to move from an excellent to an

outstanding or better. And I didn't hear that. I didn't hear that strategy about here's why we got an excellent here's what the challenges were, and here's what we've done over the last four years to overcome them. And I think that's how you have to start thinking as you prepare this renewal. If you don't do that, they're going to be like, it's just the same thing I've heard before.

And and so what I missed is I felt there was way too much on the clinical expansion. That's great for UC Irvine, it's great for your health system. But that's not what the CCSG reviewers are going to want to hear. They're going to want to hear how you're doing science in that context. And I agree with Lou. I think it's dangerous to talk about all the clinical expansion, but I think you can lay that groundwork that in the future will do this. But just as Lou said, it's really tough to build clinical trials, infrastructure, community hospitals. Many of us have tried to do that for years. It's challenging. It takes years. It's very expensive, to build the staff out at these sites.

So what are you going to do within your UC Irvine system as it exists today, to increase trial pool and to increase engagement and make your disease groups even more functional, and build those trials and menus to meet the types of patients that you see.

So I feel that where you want to really put your eggs in a basket over the next 3 to 4 months so you can write the renewal is where were you 4 or 5 years ago? Where are you now? And tell me all the specific things you did linked to the things that you wanted to improve? Some of that was in the application, but to me it wasn't deep enough and I would have really spent a lot of my time on that.

And I think that's how you have to write your director's overview. You need to get out of this excellent bucket and get into outstanding. So what groundwork have you laid, and then how will you continue to lay the groundwork? I didn't hear enough about your strengths. So the fact that you skipped over your mission slide to me really bugged me, because I want to know what your strategy is.

And to me, your strategy is still way too vanilla. And that first slide, you've got these incredible strengths and physical oncology and biotechnology and engineering. How are you using those to do unique science that no other cancer center in the United States can do? I'm not hearing that in your talk at all. And I think that's where your focus needs to be.

And then what kind of translational scientists, Rick, do you want to take that kind of bioengineering, computational biology, physical oncology strengths into clinical trials. That may be a different type of clinical trials. And you kind of mentioned that. But to me, it wasn't clear enough.

For cancer centers. Now where's your AI? Where's your artificial intelligence? Where's your data science? What are you doing to do that? We've made huge investments in that space at Mayo. I'll tell you that. I think was the most exciting part of our site visit. How are you using virtual digital technologies to bring trials to patients beyond your walls? How are you using AI for early disease detection? So, with some of the physical oncology strengths that you have, biotechnology engineering, to me, you guys could be real leaders in that space.

I don't hear that vision. I think it may be there. So, I'm going to really encourage you to go back to rereading your critique, which I looked at on the plane yesterday or last night, flying back, about what the criticisms were. Tell me in a flow chart how you've addressed them that deserves to move you into outstanding and how you're going to continue to address them and really think, I think hard work.

I would be spending the next 2 or 3 months to develop a strategic plan that really highlights these unique scientific strengths that you have at Irvine, and how you will really lead in that space. I mean, the

nation's cancer centers, and make the case for why you're more than an excellent cancer center, which I think you are.

And I'll just stop with, again, I really would not spend a lot of time talking about the health system expansion in the KSG context. I would want to hear far more about how you're enhancing your clinical trials infrastructure and increasing accruals beyond what it is as your number starts to climb and data table three. That 397 therapeutic interventional course for me is just way too low.

I think you need to be in the 500-550 range with that patient number to be safe. So, I want to see you move out, Rick, to do even better because I think you really, really deserve that. But I want to hear up from more of a strategic approach related to accomplishments, future plans and how they highlight the really unique strengths of, of UC Irvine.

I really think you have, wait and hear more about COE, but you have really interesting patient populations. What I didn't hear about was whether you're really hitting your minority accruals to those populations. So, you've got 34% Hispanics, but I don't think your accrual is in your catchment areas. 34% of your trial accrual are 23% of your trial across Asians?

So I'm not hearing in your presentation about whether your therapeutic, interventional and interventional course actually are matching the accrual of those populations in your catchment area, which you know, is really required. It may be or it may not be. So, the fact that I didn't hear those numbers also makes me concerned. So, I'll listen more about that during the day.

I also really think you shouldn't not present science, and I know you just did it a different way today, which is fine, but you really want to pick some scientific highlights coming from these programs and how they've led to trials and really met the needs of those priority cancers in your area. So, I think that's really important thing for you to do.

So, I just want to see you do well. Rick, I think you guys deserve it. Your new physical space is excellent. I think the growth of the health system potential is excellent.

I, the last thing I'll mention and it's dangerous is the FQHCs. So, if you're introducing screening programs there, how are you following up on the screening and how are those patients cared for?

I think you can answer that question because you said those FQHCs are in your system, but someone will want to hear about that follow up. And the final thing I didn't hear is the population science program, which was your weakest. What are you specifically doing to address that? And where is that going forward? So, we'll hear more about that today. And we can come back around and discuss these things again in our breaks and later today. Thank you.

L Lara: Well thank you Cheryl and Lou. Go ahead Rick.

RVE: Thank you. Cheryl, I think all your comments as usual you're right on the money. A couple of things. You mentioned the minority accruals. We're we're we're doing very well there. It was in that slide I didn't read the line, but Hispanics as you know, the proportion that actually show up, diagnosis of cancer at present at our cancer center are lower than that and we accrue above that level.

C Willman: But you should report that age adjusted rate, which would be lower. So then your numbers would match. So, you just need to careful.

RVE: Yeah. Yeah. Well Dr. Chow will show that in CPDM.

You mentioned the what are we going to do to get better than an excellent. I had actually had a slide on this and I took it out. Maybe that was a mistake, in part because I didn't want to be accused of being angry. But I'll tell you, just between you, me and the wall, the reason we got an excellent is that on the special emphasis panel that we had, because I was a member of the parent committee, and Lucky ran into the same problem, none of those people voted in the overall to give us an outstanding, despite the fact that over half of the 22 scored elements were scored outstanding or better, including five of the six essential characteristics, we didn't get a single outstanding vote. That's why.

Now, having said that, I think in our application never had a chance to go before parent committee because of that. Those were the rules. So having said that, I think, you know, your advice is well taken. We need to find specific strategies to try to increase that. And you know, when I look at it, I if if physical space does not get an exceptional there's something wrong with the system. Okay.

In terms of the what I put out there, I expect us to maintain at least the outstanding ratings and everything that we had before. I expect, our space program to come up from outstanding to excellent to frank outstanding or maybe even a little higher. And, I expect cancer control to come up from excellent to very good to maybe excellent to outstanding or higher. And you'll see the progress when those are reported. But I take your point. I think it should have been emphasized more in what I said,

L Lara: all right.

L Weiner: So lucky. Could I just interject interject for one second and then I'll cede my time the rest of my time to you? So, Rick, I'm glad you got that, off your chest just right now about how you felt about it, I really am. It's it's time to look. It's time we were giving you a group hug. Now it's time to let go. But what I will say that we've noted, on the EAB for a number of years, that we are hungry to see a vision for the for the for the cancer center. I just want to echo that because I am very impressed by the progress you've made, because I did review a lot of the, the, the sections here.

But what's, what's missing for the uninitiated reviewer, if you will, is going to be [C Willman: strategy]. What the what the what the vision is and you sort of should gave short shrift to the strategic plan. Said, well, we have a strategic plan and you were going to do another one and we'll want your help. But everything you have to be able to tell a story was we created a strategic plan, which is going to leverage our strengths and unique capabilities.

And let me show you how everything we've done is related to that strategic plan and how we're revising that strategic plan in order to increase the impact of the work that we do. Moving forward. And I think you've got such great stories to tell, and you do have the whole physical oncology piece that is really distinctive amongst the the NCI designated centers.

You got to do, you got to lean on it and you have and you can lean on it really well because you actually have the goods. I mean, it's not like this is not this is not an aspirational statement that you can make. You're doing stuff that other folks can't do. And I think that you gave somewhat short shrift, looking back at it now to that slide from the, from the BIDD program showing the 40,000 companies that have been formed, you know, there are very few, cancer centers that can claim that.

And you should be talking about how you made that happen, how you allowed that to happen, and, you know, and how this is a great, advantage for this cancer center. So, you've got some fabulous stories to tell. So, I would actually spend the next few months to go paraphrasing what Cheryl said, to work on the

pitch. This is essentially a pitch you got to figure out how to give and and then build the the grant around that pitch concept.

L Lara: So, so, I agree with, my colleagues here in saying that your leadership here has been transformative. I think without your steady hand, you would not have been able to maintain and exceed a lot of what the center has achieved in the past decade. So, I think our hats are off to you and and your your skill in guiding this, really fantastic center to where it is now.

I do share, some of the, concerns that were raised by Drs. Willman and, Wiener. What I did miss in the overview was the impact of the cancer center in, you know, the classic three Ps, paradigm shifting practice changing, policy change. I wish I had seen more of that and how those, impactful, deliverables that were, achieved under your leadership were intentional and that the cancer center, had had a role in achieving that impact because reviewers, are looking for, intentionality and that the cancer center is not just a decoration and a badge and that none of this would have happened had it not been for the CCSG investment in the center. So that is a bit missing in the presentation.

I think scientific highlights like Dr. Willman, had said would have brought that out had you given us some key highlights from the research programs showing intentionality there, linkage with a catchment area. And the strategic plan may have gone a long way in bringing that that vision that Lou was referring to out in, you know, out in the forefront, the translational pipeline, it's rich, right?

Especially with technology. But I also missed, how the cancer center itself was central to that success. I, it must be able to show reviewers that the cancer center had, through pilot funds, through a shared resources, through, faculty recruiting that had been instrumental in making all of those successes pay off. Right.

The publication metrics are problematic. I'm just going to let you know that. There. You pointed out behind the 7% intro programmatic, but everyone else is still either in the teens or in the low 20s that will, speak to the lack of interactions that the that there are occurring in the cancer center. What you could do now, because the data are what the data are, is show that you are investing in increased efforts to create interactions between the programs within and and across them through for, through seed funding rounds, something that gets these, programs talking to each other and interacting with each other because the metrics say otherwise.

The big wooly mammoth in the room would be how you should you must disentangle DEI from every aspect of your CCSG application. I know you're trying to thread the needle here and, walk that, tightrope, but it's now very clear to many of us, you know, with recent reviews and what Lou had said, even with this PR, that you must be able to take those, elements out of the, of your CCSG to escape the filter that is likely to be applied to these grants when they're when they're submitted.

It's it's disheartening because your values really didn't change. But, we are all applying for a grant, right? We're asking for money from, from taxpayer dollars. And we've done this for the last half century. There's an RFA that comes out. You write the grant according to what the RFA is asking. It's no different than than what we've been doing for half a century.

You just adapt to the situation, right? The situation is, there's an executive order that does not allow us to focus on these, values that we, that DEI, in your case, it's EDI. I think you have to make every effort to disentangle mention of DEI, in the CCSG, including your strategic plan, because that's submitted with the application and the reviewers will see that. And, I think it's going to be part of the review.

So, so I agree with what Lou had said earlier. I know there's a PED presentation today, but, I think my strong advice would be, find every way, to adapt and thread the needle. We're not a political action party putting in a platform where, we're writing a grant and doing grantsmanship.

C Willman: Lucky, could I add a comment really quickly. I know we're over, but. [L Lara: Yeah]. Just so you I again, partly because of just going through our site visit and having private phone calls with Doug Lowy, who's been so gracious to join our AACI meetings now and so many of you know, the cancer center directors are meeting with the NCI leadership every couple of weeks through AACI.

But I think one of the things that's really important is if you read about Dr. Bhattacharya's Senate confirmation visit, he did something that I think is a little bit reassuring if this comes to pass, Rick, and it's the point you made, which he strongly supports research in disparities, that that health disparities are not DEI from his perspective, he stated that adamantly to both Democratic and Republican senators who challenged him.

And so, I'm hopeful that the work that you're doing and different outcomes in different racial ethnic groups, he point blank said. That kind of science, it's really important. Clinical trials in that area have to go on. Research in that area has to go on. So I think where you're going to get scrubbed using AI tools, by the way, to screen your actual tab.

L Lara: All right. We lost Dr. Willman.

L Weiner: Yeah. So I'm going to finish up one thing for her if I can which is that make sure you look at your website also. I mean I hate to say this but that's where we are now. And you got to be careful about what the outward facing stuff looks like.

C Willman: Agree. But I do have a sense, Rick, that, that, that there will be the separation of what disparities are about, where health equity is about versus what's been labeled as DEI.

RVE: So, if I could ask a question, it certainly in the grant we can we don't need AI to scrub it. You can just do a word search and we can take out every reference to diversity, equity, you know, disparity and phrase in a different way. That's easy to do. And we certainly won't be requesting federal funds for any of these things that we're going to do. So in the grant, in the strategic plan, there will be none of this. The one and only one exception is in my mind would be our org chart, where we were going to have an associate director in this area.

And my question to you guys, is that enough to draw a fire?

C Willman: No. You have to be careful. You have to go deeper than that, you have to do that but you have to go deeper than that.

L Weiner: Don't do it. Yeah. Do what you do but don't talk about it. Don't read it. That's right. Yeah. I mean, this is crazy. You know, the the analogy I've been using is it's trench warfare. We're all fighting the fight, but nobody in the in the battle of the trench warfare types, you know, sticks their head above the trench to get shot. Just don't do it.

R Bastani: So, this also applies to, you know, any reference to trainees and training or so on. Take care. You have to be really careful not just with faculty but also with trainees.

2. **COE**

R Bastani: Thank you. Sora. And, you know, I've been with your cancer center for a while, and you've made great progress, but I'm going to make the exact same comment that Cheryl did. I just don't get what you've accomplished. There's a lot of words and a lot of we did this and we did that, but I don't see the result of any of it or or an example of any of it.

So I think that. You may want to change your and it feels defensive almost, because of the critiques you got the prior, time, and I think you want to show what you accomplished more than the process of what you're going through. You know, we had meetings, we did that, where help, you know, give me a concrete example.

And even the examples have too many words on them. I it's like too hard to grasp what you're doing. So that would be the overall, comment that I have. I can give you, you know, many details up, you know, offline later. I know we're running late.

Even your logic model, for example, I don't know how logic or some of it is in terms of where you start talking, where you end. And I know people have been saying and site visits, we need to see a logic model. We didn't even put it in our application. We didn't show it at the site visit. We got, exceptional to outstanding. We just showed it in the poster because it takes away from like in ten minutes. You want to focus on.

We said we have a logic model. We, you know, use the term here and there. So, kind of just focus on examples with color and pictures and diagrams versus so many words.

In terms of, for example, your dashboard. So, we talked about this every single time we've been here. But like, so what does your dashboard do for anybody or the cancer center or it looks pretty and you have all these numbers. But you know, what did it accomplish that I would like to hear that.

The liaisons you know, what did they actually do? Specifically, to take your cancer center from here to here. You know, the the next step. What is the value added to your COE?

The same with clinical trials. You're not responsible for increasing accrual, but what specific things that you did might have helped with, accrual.

So that's kind of, you know, I had meetings I trained. So what did I do? Well, so I think those kinds of things are very important.

And then the whole CalOptima thing, Rick mentioned that to, it's a wonderful thing, but you don't have anything to show for it yet. So, what you may want to do is to talk about it more as a wonderful opportunity in the next five years, because nothing has actually happened. It's a great structure now.

And then the whole, the distinction between DEI and serving communities. I agree with Cheryl. We don't know how the, reviewers will make that distinction. But what I would advise, what you're doing is great, but I would not highlight the LGBTQ piece of it so much, I would just leave it out. You can do it. But I would not put it in there.

So, I think that's kind of it. In terms of the big picture, small stuff, I have a lot, to say, and I can give you examples I would not increase, you know, expand the catchment area. You can do it later after you get

funded. It's really tight and it's very easy to see. And that like a, like you said, you know, this is a grant, and it's grantsmanship and that's what you want to do.

L Lara: All right. Any additional comments? Cheryl.

C Willman: Yeah. Real quickly, I, I actually thought, Sora, you gave a very nice framework for the presentation and like Roshan, so I liked your framework very much, when you got into slide eight, here's what I would recommend: And it's what we got really pushed to do at Mayo, we have three catchment areas, give me 1 or 2 populations and a couple cancers you're really going to focus on.

So, when you got to slide eight I thought you were doing great in Hispanics. It's this in Asians. It's this in one group it's this. And then you talked about both. So, I would end up with a slide and then take that all the way through your presentation. So, in Hispanics we're going to focus on these 2 or 3 cancers in Asians it's these two. And then whatever other group you wanted to highlight it's these.

And then tell the story. As Roshan said, how did you facilitate science in those groups? How did you bring community members to the cancer center in those groups? And then what have you done in the community in terms of a trial or an intervention? So, so keep them separate when you come back to aid and then you just give me the swiss blood up cancers with all the populations jumbled, it's like, looks like a mess.

It's not a mess. In your prior slide you were really clear. So I would really narrow down it's targeted populations with targeted cancers. But then thread that through your whole presentation and keep it clustered. Don't go back and mix it up again. So, I like that.

I also like Roshan would want to hear very specific examples, then when you have those target populations and cancers, what you've actually done through the facilitation of research programs or trials to make a difference in each of those communities.

A real red flag that stood out to me that you didn't address is a very high smoking and the very low rates of colorectal cancer screening. I would want to see tobacco cessation and colorectal cancer screening programs in your FQHCs and community settings, very specific things you instituted with members of the cancer center to address those issues.

So again, I think the framework that you build is much improved over, over prior, presentations, I've heard, but I would like to I really agree that coming back and cementing the impact on what specific members of the cancer center did is important.

Two buzzwords I heard only two, which was very few, was the LB.., you know, sexual gender. Yeah. The other was the use of the word social vulnerability. That's a huge red flag. Take that out. Just talk about health disparities, incidence disparities, disease disparities. Those that was another red flag term they'll look for. I would take out.

R Bastani: There was also cultural humility. That was the other one. I would take that out.

L Lara: All right. Dr. Weiner, last minute here.

L Weiner: So, I agree with the very thoughtful comments and recommendations put by Roshan and Cheryl. I, I would like to I was kept on waiting after Rick's presentation and then your presentation. I kept waiting to hear something about what you were doing with the Vietnamese population.

You have this large, huge Vietnamese population. You have a very large Hispanic population as well. And where I think you have an opportunity here is you can show impact. I didn't hear the word impact throughout the presentation. And I think what the reviewers are going to be looking for is, you know, here's where we have impact. And it's not just that we did more things.

It's, you know, what was the how many more people got mammography screening or colorectal screening? How many people how many cancers were detected? You know, how many people were, you know, attending your, your, your, your various activities and had behavior changes of some kind of guidance, smoking cessation programs, things like that, you know, and can you show a couple of really successful clinical trials or in translational activities that were facilitated by the work you did, where you can actually show how you engaged, you know, the constituencies and made it work.

And I think if you do that, it's going to it gives you the chance to really raise the level of the, of the of the COE activity.

3. **CRTEC**

L Weiner: So Ed, very nice presentation. I'll make a few comments. It's clearly nice to see an increased funding and an activity. And it's good to see that you're able to track your, your trainees. And the examples that you provide of people who are, making progress in their careers through the help of this, the cancer center is, is very impressive.

I will make the again I it breaks my heart to have to say these things, but, you know, a lot of the focus on the presentation of the underrepresented minorities, for example, is exactly what they're going to be targeting with the DEI initiatives. It's okay to focus on minorities from the perspective of disparities in care. But this is exactly what drives the the, haters crazy.

And, yeah, I am afraid, my recommendation is you're going to have to think of a way to soft pedal it, not talk about it or or, you know, make it. You can still use people as examples, but not say this was focused on minorities. And I hate to say it, but I don't see any alternative to it based upon where we are at this moment. Maybe that will change down the road. I don't know the end. That's really my major concern when I when I see the presentation, because I know it's a major focus of one of your aims.

And I and I think that what you know, there has to be a rephrasing of it to somehow, perhaps to say ways to provide appropriate training for all people. You know, to reduce barriers for all people. But you're going to have to do something like that, because otherwise, I think it's going to really leave you guys at, in a vulnerable position, as we hear. So and again, it's not I like that it's not in your aims here that you don't have any of the the buzzwords in here but I can guarantee you that if you present the data the way you did, it's going to cause trouble down the road and you have time to fix it. Obviously, I'll stop with that.

L Lara: And then, John has comments and he'll point out number two

J Poundarjian: Yeah, aim 2, including underrepresented populations is going to be probably a challenge to keep going.

So for me, my question is, and maybe it's better for Rick to address or think about, there were deputy directors named as part of this leadership initiative, but none of them had real roles. So, I think you need to be careful with the deputy director model and and make sure that they each have distinguished roles. Right. So, like if your role is to focus on the medical programs because you're an MD and then there's a PhD to focus on the basic pathways, then let's just say that right.

And for me, I could accept that as sort of the why there's two roles. Right. But until, you know, there's some clarity, I think I think you're missing that.

And then, you know, CRTEC and CEO, often get criticized for evaluation. So, what are you doing to evaluate your programs that didn't come across. So, think about what evaluation looks like, for your CRTEC programs and, you know, sort of talk about that in your write ups. And that's really all I had.

L Lara: All right. Well, thank you. I think to keep, time going will like to, thank Dr. Nelson.

RVE: Lucky could I ask one specific question?

L Lara: Sure. Go ahead.

RVE: You mentioned this, we mentioned this DICR grant that we just got from ACS, how do you want us to handle that one?

J Pounardjian: Sure. So so, don't talk about it. Yeah. So it's to say do what you have to do to make DICR work, and you know, for us, it's sort of hiding the, the minority concept of DICR right? We're still training these students, or we're still including them, you know, in the programing, but we're not talking about the how we select them or what their races.

L Lara: Yeah. Don't talk about it.

L Weiner: Yeah, yeah. And I think if you if you get challenged by them at the site visit Rick, you can say so, like many other places, we're always looking for opportunities to provide additional training opportunities to everybody. This was an opportunity that was available for this particular demographic and we were lucky enough to get that award. But you don't you don't focus on the fact that it was an intentional strategic strategy on your part, that you felt you had to advertise.

L Lara: All right. Well, thank you.

E Nelson: Could I, could I ask a question to the the review panel?

L Lara: Sure.

E Nelson: So, we we live in a county that is extremely diverse in terms of its socioeconomic and its ethnic and racial background. And to what extent if we say that we are trying to reflect the diversity within our catchment area, how is that going to be perceived by the by the NCI and the review committee?

L Weiner: I don't think they're going to complain about that because you're serving your catchment area. And as long as you say that you're doing the work that serves your catchment area, that reflects your catchment area, no one's going to care what you have to say is, and we're not going to discriminate against anybody in that catchment area with what we're trying to accomplish.

4. **PED**

C Flowers: To start things off, I really commend you for a thoughtful presentation and really well-developed data to be able, to describe your program and describe your aims based on what the prior feedback is. And I think you've heard it, fairly loud and clear from others, from the other presentations, kind of where things stand with PED at this current time.

You know, as someone, who has spent more than 20 years of my career developing programs for the American Society of Hematology and Workforce Development and wrote the ASCO or co-wrote the ASCO plan for workforce diversity, I mean, it pains me to, to say where we are at this place, but as a grant that you're submitting, you know, within the next year, I think it's fairly clear where things need to be, with the submission, on this deadline. First, in terms of the intersection of PED with other programs and what needs to be removed there, but also, components of the program that you described here.

A few things that I think can help you internally in terms of, understanding are the dashboards that you've created and would be interested to hear more about the timeline for, collecting those data and whether those are data that you feel need to be collected quarterly, and how those might be able to inform other components of your cancer center mission, particularly around having a workforce that best addresses the needs of your catchment area. And I think those are things that you can work into components, of the grant in terms of describing that as well as describing some of your pathway programs in terms of how they enhance, particular mission areas.

But that would clearly need to be folded into CRTEC in ways that have already been mentioned.

U Worsham: Thank you.

J Pounardjian: So, you know, as a reviewer, this is hard because this is actually quite good for a PED component, right? But it's going away, plain and simple. You're not going to have a component to submit to. I think the work is still very important. Right. And I think with your role centrally, I think you have a, opportunity to really capitalize. You know, obviously the passion for the work is clear, right? With you, with Rick and the whole UCI team.

So, you know, I think you keep doing the work. We're just not going to talk about it in this CCSG application, grantsmanship. We're not writing to it. There's no component. You know, the RFA is down right now. And we all suspect to remove the PED component before it goes back up. So, you know, I think the work is important. We're just not going to be able to write it into the grant at this point. Yeah.

U Worsham: Understood.

C Willman: But I I'm sorry.

L Lara: Go ahead. Who is that?

C Willman: This is Cheryl. Sorry.

L Lara: Well go ahead Cheryl

C Willman: I do want to make a comment here. So, at Mayo our view is this isn't going away at all, we're just calling it something else, and it's what you said may not be in the CCSG Grant, but what you can

have in the CCSG grant – and Dr. Worsham, I thought you did a marvelous presentation and you've done marvelous work – so we chose not to ghost our DEI person. They were at the site visit. They're actually called the Director of Leadership Development, People and Culture. The NCI was perfectly comfortable with that.

So, one of the strategies you can take is to focus on leadership training and development and Emerging Leaders program. So, you have these new aids in your cancer center, I'm not sure how they were selected, what the process was, but if you present your program as a leadership development program for all and facilitating emerging leaders, you're going to be fine. And that's exactly where we went. And we were allowed to actually present that.

So, this will evolve as everyone says. But I really think it's important that your work continue in your cancer center, give it a different name and make it be about everyone.

So, leadership development, people and culture, assuring the movement upward of of how do you have new faculty in your institution come into your institution. How do they move to tenured faculty? How do they move to leadership opportunities? What are those mentoring and alignment programs? How do you facilitate that with the rest of the institution? All of that's going to be allowable, I think.

So that was our advice that we received from Dr. Ptak, who's the head of the cancer center's branch. He happens to be our our program officer as well, though not for long now in his new role. I think he'll give that up. But but I do think there's a role for what you do captured in a different title.

So, that's my advice, but.

L Lara: Well, thanks. Well said. Cheryl. So at our place, we, have renamed the office of, DEI, or IDEAL to, the Office of Workforce and Leadership Development. It's right on, point with what Dr. Willman had said, because you're not we're not abandoning our values here. Right. Nothing changed with the values that we hold, we all hold dear, we are just writing to the grant. And so, I agree with all of my colleagues here.

You, have to keep doing what you're doing, but you have to write to the grant and just, just be smart about it, all right? So, I think…

RVE: Can I ask one question?

L Lara: Go ahead.

RVE: Just to follow up with Cheryl. When they presented this, leadership and development thing, how did you do that? Under what piece of the P30 did you put that forward at your site visit?

C Willman: We aligned, and for us, it's Dr. Felicity Enders – and Dr. Worsham I'm happy to connect you two because she kind of went through hell and trauma fire as the first person who – we I just refused to ghost her, I would not, and and nor did our institution want us to do that, make her go away.

And so what we did is we tied it to COE [CRTEC]. She didn't actually present at the site visit, but she was or I'm sorry, she was part of the CRTEC team as an expansion of leadership development. And then she reports to the director. This is her role. But we we presented it as part of CRTEC.

So in CRTEC, you know, you've got to go from pipeline to actual faculty mentoring. So, as part of that faculty mentoring piece, at the end, this was all about how do we how did we pick, emerging leaders?

And, and another thing I did want to mention, I forgot in COE, Sora the the community scientist program, we've trained 65 community scientists. It's a different way of bringing equity and diversity into the center without ever saying those words. They're embedded in our research programs. They come to our research program meetings, they give the community voice to those research programs.

So, there are ways to take these activities that might today be considered not okay, but still to do it if you're talking about science.

So we aligned it with CRTEC as a part of faculty development, going all the way now to leadership development and assuring that there's a broad representation for all in our tracks to move faculty up through tenure, up into leadership, up into cancer center leadership. And I think that plays very well.

We showed one slide of our emerging leaders who were like 60% women, and virtually everyone was diverse. You never said the word. The pictures. The picture said it all.

So again, we're happy to share slides or talk about strategies in this, but I think there are ways to still do this using different words. Just as Lucky said.

L Weiner: Yeah, yeah. So we're doing exactly the same thing by the way, Cheryl. We moved decided to fold DEI into CRTEC, and we're thinking of actually changing the name from CRTEC to, you know, cancer research training, education and faculty development or something. And then and then also having a little bit of that activity bleed into COE for exactly the reasons that you indicated. And I think that will likely be a path that many cancer centers take. And it's going to be very difficult for, you know, the DEI hawks out there to go after this if we fashion it this way.

L Lara: All right, Rick

RVE: last quick question here so we can change and we will all this stuff. Thank you for your advice. At the end of the day, UCI is a different matter. That's our parent institutions. As of today, there is still a UCI Office of Inclusive Excellence and Dyonne Bergeron the chief diversity officer and vice chancellor for DEI

L Lara: it's the same at UC Davis.

RVE: Well, you don't think that's going to be a problem correct, well, okay.

L Weiner: No

C Willman: Well, I'm going to be the exception, let me be the exception. I think it could be. So. So this is our so where Mayo started is we're not changing any of those names. We have. We're going to people culture and leadership. And so, I do think if you look at what's happening to Colombia today in the ten universities that are now being targeted, up to 60, they're going after these terms.

And so I do think these activities need to be renamed and realigned. I really do, just as a protective measure. But none of the work actually stops. It's just how you align it and what you call it.

5. **BIDD**

J Bushweller: Yeah, really nice presentation. I want to just highlight the translational pipeline slide is extraordinarily effective. That's really, really compelling. Both in terms of how technologies are moving, that you've covered all the aims and how the, program and the center are contributing to that. So I, I'm a big fan of that slide.

And I would echo something I think Lou said earlier that that's a strength for you guys. And these unique imaging capabilities is also a really unique strength. And you should just hammer that over and over, to make sure the reviewers get it in their heads. So with that said, a couple of quick comments and questions.

The and I'm sure you know, this the intra programmatic percentage of publications is quite low. That's going to be a red flag that's already been mentioned.

Secondly, in the grants, your, I think splitting hairs by trying to make 50% and 75% delineations. I don't think that's going to be viewed favorably the way we do it is zero 50 or 100. And I think that, you know, nobody gets bent out of shape than if you start splitting 50 and 75, they're going to like, you know, how did you decide that? What's the I think it's unnecessary risk. I guess, from my perspective.

Somewhere in the I believe in the slides, you mentioned you're going to build out the DMPK capabilities, but I didn't hear how or what.
AG: Sure. Brian can, kind of, expand on that a little bit.
BP: Yeah. So kind of building out our current biological mass spectrometry facility, capabilities, ongoing in the School of Pharmacy and Pharmaceutical Sciences or bringing online, new mass spectrometer to do small molecule work. Does that answer your question?

J Bushweller: ***So, is the idea to be have in-house PK and other kinds of capabilities?***
BP: Yeah. Correct. And then, with kind of more advanced capabilities than just kind of simple Microsoft analysis and that sort of stuff. And again, building additional capabilities in that as an academic center and not necessarily kind of CRO type activities.

J Bushweller: ***And does that include chemo proteomic capabilities as well?***
BP: Yeah, chemo proteomics is actually, housed under the current the existing biological mass spectrometry facility. So this is more, small molecule work.

J Bushweller: Great. Thanks. That's it for me.

L Lara: Thank you so much, Dr. Achilefu.

S Achilefu: I feel again really great work. This this was outstanding before. And the goal is to move to exceptional. And so my points are just based on going from outstanding to exceptional. Great program.

When you look at the instrumentation new equipment you put in a here translational pathways one of the areas that I really think, COE can help is to give priority of the disease to the cancer types. Right? Because it currently looks as if it's haphazardly done. I'm working, you know I'm working on XYZ without correlating it to the impact it's having.

And the second point is that you have excellent examples of how you responded to the previous reviewers' question, but what I do see is that next line of the impact is made or what it has changed in community. Okay, so getting more [unknown] was by different people doesn't make any impact. But what they did is very important for us to to have there.

You also mentioned quite a lot of startups and that came across several times. I never saw any startups, never saw the number of companies that you created. Or even what these companies have done to support the cancer center, vice versa, so that would be nice to see along the way.

And the issue about this intra programmatic collaboration and other raised, I think your examples actually gave the wrong impression in one of them. There's one that has one PI. In the future that goes to being, has that perception that is siloed individuals doing their stuff, that ends up integrating into the cancer center. So we use examples that have more people, more investigators, preferably through the different groups.

One area I would have liked to see in that clinical translational slide, which is excellent, is how people came together. All right. You have people from the BIDD working on it, but that program has people from one area is, yeah, I would have really liked to use that opportunity to emphasize it all the way.

Okay. Excellent program. I really like it. But I think that there should be one aspirational aim that will take you from outstanding to exceptional.

AG: Thank you so much.

L Lara: All right. Do you have any questions for the reviewers? Oh, I see Lou has his hand raised Lou. You're muted I think Lou you're on mute.

L Weiner: Sorry about that. Maybe in five years I'll figure out how to use zoom I don't know, but, so I want to echo, you know, my, you know, my appreciation of the progress you guys are making. It's really terrific.

But I think you're going to run into trouble with that 7% intra programmatic, collaborations. You know, the review committees are very sensitive to that. And they're going to say, how can you call yourself a program when you guys aren't publishing together? And, you may not have time to get those numbers up to anything meaningful at this point, but I do think you have an opportunity to explain that you see the problem, you you recognize the challenge, and here's the actions you're taking. You know what pilot funds are you applying to this? What are you doing to try and foster communications and how and people really showing up at your meetings, things of that nature. This can be really critical because one of the things that may happen is that every cancer center calculates it's it's, intra and inter programmatic things a little differently.

So, for example, if the review committee picks on this, they might then say, well, so how are you calculating inter programmatic. Are you double dipping. You know, so that one publication is being claimed by two programs, etc., etc.. And you just don't want to get into that mess.

So I think the one way you can really address this is by acknowledging you have a problem and then demonstrating that you have a clear path towards fixing it.

L Lara: Okay. All right. Well, Dr. Willman, you have your hand raised or is that from earlier?

C Willman: No, no. A very quick comment about how I think your program can go from the score it has to even exceptional and I think you're really underplaying the translational aspect to trials, that's what's going to get you to exceptional.

So, if I go back to your slide, your slides aren't labeled, but it's using VTMs to study rare cancer and cancer therapies, you can give three applications, and you mentioned an IIT. You need to pick one of those and show me the whole arc to the trial. Okay. And how that trial attaches to a specific cancer in your catchment area. So, you need to take that one step further. That's what takes these programs into the exceptional range.

And then when I look at your slide 12, which is the translational pipeline dashboard, it's impressive as heck, but you didn't show me where those went to trials. So, if you could pick 2 or 3 of those doesn't have to be five, and then a year from now show that that device, that technology was tested in a human trial in your patient populations, particularly a priority cancer, then you're going to get to exceptional so that that's what's gotta happen here.

And so what's the problem to me is when I look at slide 12, you've got your pipeline of all these really cool technologies, then you've got your disease team interactions. It's not a continuum. So, somehow think about how you create phase two of that pipeline chart in 12, and then show where the disease groups step in and take some of those to trials in a continuum.

Are you following me? [**AG**: Yeah]. So here's our pipeline on our cool technologies, which is a strength of your center then, oh, here's our disease group stuff and they're kind of doing trials related to it.

If you can take the discoveries and show that they're going into human interventions, you're going to get an exceptional. So to me, that's where I would love to see the orientation in the program because I think you're close.

I just think you've got to show, if you're showing all these cool startup companies, you also have to say UCI is the place that's going to do your first in human trial. In fact, if you're not protecting your first in human phase I IP, you're crazy. So usually when most companies develop the technologies, they say, sorry, we're going to give you the IP, but you got to do the phase one with us.

You got to do the first in human with us. And if you can show three of those, I swear to God you'll get an exceptional, and then if you can come back around to show 1 or 2 of those was a priority cancer in the catchment area. So just look at your side 12, 13, 14 if you can give me the whole arc of that, you're going to get an exceptional.

L Lara: Great. All right. Well, thank you so much.

RVE: Can I respond to that one. Lucky?

L Lara: Go ahead, Rick.

RVE: So I think, part of the issue is that a lot of these, these small molecules are just in that pipeline. They're they're not ready for, you know, to be really commercialized yet. We have at least two examples that will be hopefully in clinical trials by the time we submit the P 30. One is the glitter. If we get that back from next and we already have the trial written, that's fine.

The other one is actually not on this table. I would say, it's from the idea. It's from, Dr. Kwan, Yong Kwan, who has an anthracycline, nanoparticle, which is partially pharma sponsored, but we're going to get, I think, data into trials as well.

So we'll have at least two whether we can get three. I'm not sure.

C Willman: Yeah. But, Rick, if you had two, I actually. And you could show 2 or 3 more close. So there's we're we're taking them over the next two years of the next five years. I really think that's all you need to lift this program up into that outstanding to exceptional or exceptional range.

6. **SPT**

K Shokat: Yeah. Thank you for that. And so that was great. I have a whole list of things I'll just run through, but I'll send you the list so you don't have to write things down.

I, I didn't hear any highlight of single cell dynamics, and that's in the title. And, and, I think would be good to somehow point out either in the examples you've already pointed out, that just sort of, mentioned that somewhere.

I think on slide four, the response to reviewers, the ordering of some of the bullets, I would put the most impactful response first. On slide. Yeah, I think that's there. Like, I think interventional clinical trial accruals increase 50%. I would put that first. You have one DOT meeting per quarter is dedicated. I would overall my feeling is there's a lot of highlighting of meetings that I would not sort of I would put more concrete examples of things.

And then on the clinical integration, I would start with the interventional clinical trial accruals that I already said.

In the catchment area, I would mention specific cancer types in, in the responses.

Collaboration outcomes, I'd find more hard numbers exemplifying improvements. The five listed bullets are very soft. Maybe grants or papers.

I like slide ten, the statin phase one trial. It it was a little hard to know whether that bar graph was actually a clinical outcome of the trial, but now that I see that the figure legend it is. But maybe could touch that up, just sort of what the outcome of the phase I and then why you selected maybe a subset of patients in the phase II.

Let's see. Slide 11. I'm a little confused with the graphics. Which people are the DOTs and which people are in your program. It's. So, that slide somehow doesn't like for me that those are the connections between the program, the DOTs.

And then slide 12. Maybe this is just a formula for that slide, but it doesn't seem to highlight the your program focus. It seems more clinical and not about signaling pathways and therapeutics.

And then slide 16 I like.

I think the feature plans, the last one, I think again, if you could be more specific, I wouldn't use the valuable space here to highlight, you know, meetings, but more tangible, concrete things you've implemented or are implementing. Those are my comments.

L Lara: All right. Well, thank you, Kevin

J Lowengrub: I think we could I add one thing.

L Lara: Oh, sure. Go ahead.

J Lowengrub: So, regarding the single cell, question on slide two. So there we were, trying to highlight the, cancer systems biology TL1, one where single cell interactions are a key part of that. So both good

for single cell and spatial, because we're trying to understand how cells are interacting together and to generate these transitions.

K Shokat: Wonderful. Yeah. Just highlight spatial when that and dynamics that just put those in because I think that's a huge strength of the program. Then the teams just it didn't quite come up.

AF: Would you recommend in order to highlight that bring that to the forefront. Have one of the vignettes focus, have that a one of the vignettes..

K Shokat: I thought maybe I thought maybe you were going to do it on the T cell slide, on slide eight, sorry, nine, but then it didn't come out, so I don't know, did you guys use single cell transcriptomics to look at the PD1 responses?

[unintelligible]

K Shokat: Yeah perhaps. Yeah. That could have been a place because you have that. Right.

L Lara: Dr. Lam

K Lam: Okay. Well excellent presentation I don't have a lot to add, but I think I like the arginine methylation story. You, highlighted there. There's a really outstanding work in terms of the circadian regulation of tumor suppression. I thought interesting.

But how is it going to be translate to the clinic? Maybe you can mention that, you know this, what has been done otherwise? I still don't know what you're trying to do here. What what is the practical translation?

And then, I like to intra programmatic, activity that you, trying to get through. And 17% is your programmatic, publication is quite good.

And the IIT you mentioned, the, the, the setting and also the magnetic corrects, is excellent. I wonder, you know, are there any interaction between SPT and, and the BIDD has some in-house developed drug actually going to clinical trial or getting there if you have some of those would be good to highlight. Okay. Okay. That's all I have.

7. **CC**

M Birrer: Sure. Let me just start out by saying, congratulations in the sense that, I think you've made a tremendous amount of progress, from my program that the at least, the, the time I've spent on this EAB has been concerned by. So, congratulations. The increase in NCI dollars is spectacular and NIH funding, the aims rewritten, which we all felt very strongly about.

It's unusual to see a reduction in a thoughtful reduction in membership. I congratulate you on that because usually people, want to stay on these programs forever and even though they don't contribute.

And then your integration to other aspects of the cancer center is, is laudable. You clearly have great leadership. Great investment. And I would point out from the vignette standpoint, I think the lung cancer effort is spectacular. You got a big problem. I'm sensitive that I come from Arkansas. We have a huge problem with tobacco abuse. And so how you're approaching it, I think, is, is exciting.

Now, having said that, there I still have some concerns, and I want to just, bring them up.

So, it wasn't clear to me. But maybe you can provide a little more elucidation on this, how the aims were rewritten, were they, were they ground up. Were they from the ground up, meaning you looked at the talent you had and then rewrote them to match it? Or was it top down things that you wanted to do?

JM: Yeah, it was ground up, ground up. We reviewed the research profile, met with our members. Multiple rounds of leadership meetings. It was difficult, but we wanted to make sure we captured the primary research occurring in the program and be as inclusive as possible with the the verbiage we used.

M Birrer: Yeah. I think you were successful in that in the sense that what we noticed before was that there's a disconnect. And that's a red flag for review. But having said that, and I think I know the answer it is, but ***there is as far as I can tell, there's no population science in this. Or did I miss it?***

JM: in the program? [M Birrer: Yeah] yeah, we have, behavioral and observational equity, cancer registry based work as well. Population based work.

M Birrer: Okay. Based on that population, ***but no, no apiary, genomic or any of that.***

JM: Wendy, do you have….[WC: unintelligible]

M Birrer: So that's okay. It's terrific because a, somebody's looking at looking at it from 40,000ft level didn't come clear to me. So I think you might think about both the presentation and of course, how you write it up. [JM: Yeah].

To say look at we looked at our strengths and most of it's behavioral [JM: Right]. But we're still doing [WC: unintelligible] Yeah [JM: Okay. Right. Yeah. Okay.] To me that was that was a little confusing. And I think that's important.

As I said, you reduced membership was this, one day you just said to people don't come or I assume was strategic, you ***it'd be nice to know what the membership rules are for you all. What do you demand to be a member of the program?***

JM: Yeah, we went we went through the membership, requirements and then went through the roster. One by one. And then if there was a case where, you know, someone was, I guess, on the bubble, you know, they had funding, but the funding, it ended, but they have high potential for future funding, we

would arbitrate that, and in most cases we would keep the individual, for many of those who were dropped, you know, there was a lack of, not only funding but publication history that's cancer relevant.

M Birrer: Okay. Again, I think that's a terrific exercise is what as leaders, you're supposed to do. And so you might want to at least point out that that was an exercise you did and you put some effort into it.

Just some details. Number of high impact comes a little a little low in my view. [JM: Yeah] I know why, because these are not easy to get. Don't lie about it. [JM: Nope. It's it's a perennial issue for cancer control programs.] Yeah. And intra program publication is low too. [JM: Yeah.] So be helpful if whatever you can do, try to get them up.

And then I noticed on your bar graphs, which I love those bar graphs and funding, you will be covered technically when you submit, but you've got about a million bucks expiring very rapidly after the submission. So, don't know what you can do about it now, but if you can get some more grants to come in, please do. [JM: Yes.]

In terms of the vignette, I really like the lung cancer screening effort because I think it's very relevant for your patient population, and it's something you can add some interesting scientific questions. I was less convinced about the Hawaiian cohort. Now I'm not a myeloma doc, but, the way it's presented, you know, you've got you've got the graph and like the standard deviation is about this big, it's barely above one. So, I'm not sure that would be something I would highlight. Unless you have more data. Now, I know there's an R01 attached to that, I think. So maybe there's some more data there where you could bolster that.

There's smatterings of DEI through the whole all the slides, and that's separate. I won't go into that. It needs to be addressed as you go forward.

And, Future aims again, I don't I don't see anything there that suggested it and you can think about how you want to write it. An emphasis on population science. So you might think about that carefully. Again, I think if you're emphasizing, quality of life and survivorship and things, it's perfectly reasonable. But make sure they know you've thought about this rather than, oh, well, okay, we just take what we get.
SL: We have to open search right now and going for this cancer control program faculty. And we'll keep that in mind as an evaluation criterion to prioritize. Thank you for your comment.

[WC: unintelligible]

M Birrer: So, yeah, yeah.

WC: Because, all of it is population science.

M Birrer: But yeah, but I come from a double stranded approach, so that's why I'm all right. But and you don't know that, there was. It's fine. All right.

WC: [unintelligible]. Environmental work.

M Birrer: Yeah. So that was also in the future directions which is unclear to me. Which is what what environmental risk. Yeah. This is this, you know, burn pits. Is it smoking.

SL: So we we have funded project, recently funded project, for us and how that may affect cancer incidence. We also have radiation exposure and cancer incidence and some other environmental studies.

M Birrer: Yeah. So you really want to make sure you link those. So it's very clear what you're talking about. I'll end with something that may bother you, but that's what we're here for I, I think the program, the trajectory looks good. You did a great job. I still think this is the weakest program.

And I would think you could get to excellent rather than excellent-very good. I'm not sure, from what I'm seeing, it's going to get better than that. But.

L Lara: Okay. Well, Dr. Bastani.

R Bastani: Yeah. I thought, you know, I was very impressed with the progress you've made. I've been with this cancer center for a long time, and it's a combination of Rick's leadership, thr people you've recruited or what you, have done, as the leaders of this program and I feel like it's night and day almost from from where you started. And I was impressed by what you presented today. I thought it was very well done.

I to me, everything you do is population science. Population science doesn't mean sort of hundreds of thousands of people out there just means not in the clinic necessarily or bench. I think this is absolutely population science, including epidemiology all the way to survivorship. So, I don't think the cancer control reviewers would have any problem with what you're doing.

I also think you have particular really good strengths in the epidemiology part. And I actually liked seeing the myeloma example because it's unusual. You're looking at things that the whole world is not looking at. You're trying to find new things. And it may be kind of what aspect of that to present. But I thought that was great.

There may be other examples, but I liked that you presented examples from both the, the you know, risk factor piece as well as, outcomes among survivors.

So one thing I would suggest that you do with your aims is you have identify, you know, risk factors, I would say identify and address because that's what cancer control programs are supposed to do. And you're doing it. You have the lung cancer. You know, you have I think something on colorectal cancer. So you you want they will want to see that you can't get away with only I'll show you the risk factors. But I'm not doing anything about it. So I think highlighting some examples there and putting the address.

And then in the future plans we want to do more. We are recruiting. Maybe you want to recruit interventional faculty, not just, epi, that kind of thing, but I would definitely put that in there.

So I, I was actually very impressed with where you are now. And I think some tweaking will, I think, get you some portion of outstanding. I'm sure.

L Lara: Great. Thank you. All right. Well, Dr. Weiner

L Weiner: so I'm a little less confident than Rashan is at this moment, about, but the near-term trajectory will be. There's a lot of good stuff that's happened. And, like, you know, I've been I've been with this group for a long time now. And the the, the trajectory is really quite encouraging.

But I still couldn't figure out from the presentation, is there what is this program about? What is it rationale? What is it? What are the it's driving the themes and ideas that will make it both responsive to the needs of the catchment area, which I didn't really see as much out. There was sort of lip service at the end. And also you know, are there unique features of your program or the science you're doing that are bringing added value at a national level? And how is this connecting to this? The the Comprehensive Cancer Center strategic plan, where do you fit in that?

I mean, I feel as if that kind of, present, framing of the presentation would make a lot of the improvement really, really good. I mean, I would have loved to have seen something you say something like so we started almost from scratch, a few years ago, and we decided we wanted to build around the following key areas. We wanted to build around those following key areas, because they were particularly relevant to the needs of our catchment area and because they built on the strength of our science.

And I think you did all those things. But you're not explaining that and how you accomplished it. And I think if you could get a little bit more into the storytelling aspect of it, I think it would frame the work. You're doing in the accomplishments that you have and a much more favorable light. And so you might want to consider some of those thoughts.

JM: Thank you.

L Lara: Any other questions? Dr. Van Etten?

RVE: can I make an editorial comment? Yeah. So I think, you know, maybe I should have said this in my overview that this is a program, and I, you know, I, I echo what everybody said about how much it's, really improved and I think we'll continue to improve.

It's one that the cancer center has poured resources into, including many, many, many recruitments are to, program leaders being one of them. We have an FTE I released last year that we have an active recruitment, and we're going to release another one this coming year. And we're going intentionally after mid-career, the senior people that have developed research programs and extramural funding, we target pilot projects specifically toward cancer control in the catchment area and disparities.

We, I put out an RFP in the fall for, large projects that addressed cancer, health disparities in the catchment area. We're going to fund for them. We're funding them at quasi R01 levels, $150,000 a year for two years. The expectation is a clinical trial and or a multi PI grant will come out of that. That's actually where the lung cancer screening thing came out of.

So I guess is an area that we really, like I said, put our foot on the gas on. We're not going to take the foot off the gas. So I just want to clarify that.

8. **Clinical Research**

L Lara: I think I'm, assigned to CPDM. So, my first remark would be, this is perfect timing to hit it out of the park on your accrual, at least compared to the last, four years before this. And, you've been able to tame time to activation. Congratulations. And showing us where you pulled levers, in, making those, metrics look like they are now. So, congratulations for that. As you know, those are the main driver metrics for CPM reviewers. And, it's great to see that happening. Now, I just have a few, questions, maybe some clarifications on on a few things.

One would be the data that you presented last year on time to activation metrics, the number of trials activated over, the past five years are slightly different. So I don't know whether it was cleaned up or last year's data were, Anyway, they're they're a bit off. Okay, so, maybe just make sure that it's all consistent before you go in, to a CCSG submission so that we're talking about the, the data. I was referring to the slides from last year.

The, 397 accruals that you, that you saw, in 2024 is impressive. And you broke down that, that was mostly from national trials, so I assume NCTN and ETCTN, as well as IIT. So, there was a doubling in the number of national trial accruals. ***Were there lessons there that you learned about those, that experience that then allows you to, make that a sustainable observation? What was it that what what tumor type did you see that led to those trials accruing like gangbusters?***
WC: Well, one key trial was for it for prostate, for the use of in indocyanine green. It's, accruing like gangbusters. The participation in the ETCTN has, certainly helped, our trials, accrual. So, those are, I think, two key features.

L Lara: Yeah. Unfortunately, as Dr. Van Etten knows, those are lost leaders in terms of dollars, right. The ETCTN and especially density and don't pay per patient rates, that matches the cost of doing business.

How were you able to support, this great performance on your national trials or was there institutional support that came in?
WC: So, so as, as a it showed on the bar graph that we only received 16% of our funding through the institution versus 24% for AACI benchmark. However, most of our funding does come from industry, sponsor trials.

L Lara: Right?

RVE: Yeah. Lucky. Our our trials are backstopped. Deficits are backstopped by the clinical enterprise in the School of Medicine, subject to metrics. And it's we try to keep it in the teens as a percent of the total budget.

L Lara: ***So what is the absolute, backstop that you, that you got in 2024***?
RVE: 16% of 17 million or something like that. Yeah, I know it's a couple of million.

L Lara: Yeah. So it's fairly typical right across cancer centers. You did show on slide 14, John was pointing this out that you're sticking your neck out with this 10% data table 4over data table 3ratio. I know that's a historical legacy benchmark. We've work we meaning the royal. We have worked, over the last decade disabusing that metric from reviewers minds. And in fact, that the last set of site visits I, I had been involved in, we had to keep reminding folks from carrying that baggage into the room. So, I don't think you need that slide. You're just sticking your neck out of neck out too far.

Then, you mentioned how radiation oncology, had been, augmented. We talked about it last year, but that still has not resulted in an increased activity in terms of accrual from that group. So you said, well, you said in your response, your strategic plan here is you'll submit more LOIs to the ETCTN that, you know, don't count on that. You know, you know how it is. That's probably not a, a great strategy for enticing radiation oncologists to participate in trials.

WC: So so, they've almost doubled the number of faculty since the last year. So I've done quite a bit of harm. Yeah. And again, they're in a national search for a chair for their radiation oncology department. So.

L Lara: Yeah, since they've doubled their faculty, that's a source of accrual. So you might be an IIT that the center is. so you know, there are so many questions in radiation oncology dose, you know, time frame. SBRT vs… There are so many questions to be asked. And you don't need an IND. Right.

So anyway, the data that you showed for sex minority, and, across the lifespan compares or benchmarks it to Orange County, California and, and national. You don't put in the statistics for people who actually walk through the door of Chao Family Comprehensive Cancer Center. We usually see that, at, at CCSG presentations.

It's not just your catchment area. It's also how about your clinical? [WC: Sure.] The clinical met you know, the folks, the folks that you actually take care of. [Yeah.] So that might give us that might protect you as well for some of the metrics. That may be a little off. [WC: Yeah. Yeah. Yeah.] If, if, if there's less women actually coming into the cancers that are been maybe that's the answer. Right. Maybe that's why there's a little, disconnect there.

And I do have a few more, but I'll just put that in my written comments. But congratulations on getting the time to activation and accrual metrics squared away. And Dr. Flowers has other comments.

C Flowers: Great. Well, thanks, Lucky. And Lucky described most of my positive comments. So, I will try and be brief and maybe not as positive, just. Yeah, just, for time, sake.

The first is, around, something that may just relate to, by our relative, newness to, this group and that's the relationship between the Stern clinical trials group and ClinROC, at least the described in their organizational structure, but it's not entirely clear throughout the write up, as the terminology relates back it back, back and forth between, the SternROC, and, and and the ClinROC,

A few other things that were described in the write up were related to the institutional trial approval since, 2015 was where there seems to be quite a bit of variability over time between the, the accrual to institutional trials that went up, and went down over time and now is back up again. And so that would be useful, to clarify in, in, in specific around, those institutional investigator initiated trials, what strategies are being implemented to improve accrual there.

In the slide here that you showed us today, you showed us essentially six trials that were investigator initiated, trials that were poorly accruing and showed that, but didn't really describe what specific targeted strategies there will be to improve accrual for those kinds of trials that are unique from the general approval, I think you know, opening more trials and other things will help to improve your trial accrual as well, but not necessarily targeted towards those institutional and investigator initiated, trials.

The the other thing that was, that I saw parts of, but did not see completely is how trial identification and selection and prioritization relates to the top catchment area disease sites, for the CRC, either from what was described earlier in COE or for the, the, Director's Overview as a whole.

A couple of components that you described today around the genomics module, I think it's important that epigenomics is being implemented, and that CARIS will be able to order directly, but obviously genomics, in order to be utilized within the context of clinical trials, will be coming in all other sorts of various and sundry ways in terms of written reports and other things that patients bring in. And so I think if you're going to describe that, you need to be open to understanding how, you know, the critiques will come in regarding how those other data sources, which will likely outnumber what you're getting through Epic, will be utilized to be able to drive your clinical trials.

WC: I can I just answer those two to the last point. So there are those most of the those investigations of trials, with the exception of the, Adapt team trial opened in the last year. So they're brand new. And then regarding the, Epic, so Dayyani, along with the, Suzanne Sandmeyer, chair, this discover work group, which will implement, all next clinical next generation sequencing, into both epic as well as into this, genomics information management system so that for future genomics research,

C Flowers: I think it will be important to highlight how those could come in, and how those will drive will help to support trial accrual that, okay, that are targeting group.

I thought overall, the improvements in the PRMC submissions were extremely impressive. In terms of the development of those timelines. But it would be interesting to know whether there are more focused approaches, like the ones that you're applying in urology and how those would apply to other diseases areas as well. You showed that nice example.

The other one was around your faculty performance dashboards, and how those are ultimately being utilized. It shows nice metrics for each of your faculty. But are those associated with incentive plans or they associated with other sorts of, support from the CCSG as a whole for faculty who do well in terms of their performance on those dashboards?

And I won't comment about the clinical trials, quality assurance, unit, I think you're waiting to see kind of how that's going to be reviewed, in terms of, the performance there.

I would encourage that the Investigator bootcamp, that you're launching be launched for all investigators and not for just, new investigators.

And maybe as the final comments around the disease-oriented teams to be more aggressive about closing, trials with zero accrual. And you should at least blame the EAB for closing those trials when you need to close them with your investigators.

L Lara: All right. Well, Dr. Wiener.

L Wiener: Just one second. So, I want to be sure that I was not on mute. Well, first of all, now that you've gotten successfully the, the clinical research operation off of life support, you're now going to be judged, I think, at a higher standard than you would have been otherwise. So people will acknowledge the trajectory, but now they'll see where there are some potential gaps that need to be filled.

And so, I agree with many of the comments that you've already heard, and I won't I won't revisit them, but I wanted to make a few more if I could.

Firstly, I don't understand why you have 30 trials that are not yet closed. I mean, that is a responsibility, and I can guarantee you that if you have these these studies hanging out, you know, unclosed, they'll get hammered at the site, visit for it.

And I'm sure that there are going to be institutional and personal sensitivities about closing some of these. But you got to be able to justify every one of those studies that you're keeping open as being open. So, I really urge you to do that. And if the DOTs won't do it, then then you have to or Rick has to however, whatever mechanism you guys use.

Secondly, I think would be really helpful for you to emphasize how it is that the clinical research operation allowed the cancer center through its research programs and translational activities, to do studies that were practice changing, paradigm shifting, policy altering, I mean, and, and then maybe show an example of how it is that this the clinical research office made it happen, you know, as a way of illustrating them what you accomplish and how you do it and how you contribute to impact.

Okay. The other thing that the reviewers are going to want to know, I think, is you've heard both. They'll have heard a lot by the time you talk about catchment area, catchment area needs. And, they'll want to know exactly what is the office doing to make sure that not only are there trials that are being done are relevant to the catchment area, but also how you're assuring that the people who live in your catchment area are gaining access to it given that these trials are largely being done at the you know, you know, you know, at the mothership.

And then the fourth thing is that I and I may have missed this, and if I did, I apologize, but multidisciplinary studies, everybody understands that, you know, medical oncology takes a big lead along with hematology, but where you can emphasize true multidisciplinary engagement would be very, very helpful. I'll stop with that.

L Lara: All right. Dr. Willman.

C Willman: So, I just want to I won't go I'll go quickly, Lucky. That I really agree with Lou. I still think for a, data table 3 number approaching 5000, the therapeutic interventional accruals are too low.

So, while you've had a jump, one of the things that just bothered me about the style of presentation is you keep using percents and a percent sounds good, but when the raw numbers are low, that works against you. It's like you're trying to slide over the actual data. So, I want you to be really careful about these. Oh, we double this, we triple this. That sounds great. Except when the numbers are low, it's like you're hiding the fact that they're low.

So, I just would encourage you to use the standard ways we show these trial accruals and tables and speak to the raw numbers and give us strategies.

Now, clearly your interventional trial accruals went up this year. That's great. It's going to be critical that they're even higher in this present year to show that continued trajectory that you're really fixed things and it's sustainable.

So, a lot of centers, as you know, go in that prior year with a really high number, and then it falls again. So, they're going to look very hard at the 2025 accruals to see if you're sustaining.

So, I want to go back to Dr. Flowers comment I know we've had this extended conversation about Stern Center versus cancer center, but it really gets confusing. I would just ask you not to use that term in a CCSG site visit. Every institution has an overall clinical research sort of entity, and their research arm or their Office of Research and then the cancer center has its own. But cancer center's authority has to be aligned, usually through the institutions. Ours is everyone else's is. But you talk about CPDM, and I just you know, ***when you show that budget of 20 million, is that Stern's total budget or is that just the component of stern going to cancer? Can you answer that question?***
WC: So so the Stern is our business unit for the cancer. So yes, that's all cancer.

C Willman: So the so for a $20 million budget you've only got 300 and some therapeutic interventional accruals? That's a huge disconnect that really concerns me. So, they're going to come at this by multiple comparators. So, that's a very low therapeutic interventional accrual or a clinical trials budget that's that large.

So just I'm just warning you about the real numbers and what you're presenting. So, I would be really clear in the first slide that the Stern Center I don't know why it's named that, but this is just CPDM. And be very clear that your budget's all cancer. But a budget that large though, and again makes your trial accrual look quite low in that context of an operating budget okay.

L Lara: All right. Michael

M Birrer: Just a quick point and nice presentation. I relatively you and you brought this up relatively concerned about the gender distortion. That's that could be potentially a red flag. And my concern is a little bit is, you know, having been on this equation because I'm a guy in medicine, I'm not so sure that's going to solve it, the patients still have to come from gynecology. So I don't know if you can think about some other proposals meaning more breast cancer trials, you know, so on and so forth and sort of, embellish that, those solutions, okay. Because I think that's a that's a, you know, that's a trendy issue right now.

WC: So, yeah. Yeah. We are targeting those two diseases for sure.

L Lara: Dr. Wiener, you still have your hand up. Are you are you done with your comment or.

L Weiner: I was totally done with my comments. I was just put my hand down, I apologize

L Lara: all right.

RVE: Could I make an editorial comment?

L Lara: Okay. Go ahead. Rick.

RVE: So, I appreciate the feedback. We're aware of the treatment trial accruals issue. But you know, here's the deal. You can see the DOTs that are underperforming. It's the big ones are going on head and neck. And the major thing that we need to do there is to recruit seasoned clinical trialist to oversee that and run it in. Gyn/Onc unfortunately, the surgeons just are not capable of doing it. We're hiring a fellow, who's very committed and very productive and to that role in July.

And we have, you know, to Mike's point, where it's hard to find these people. We have an excellent candidate, 90% sure we can land, but they're not going to be here in time to really impact this number. So, to quote our president, it is what it is. It's going to have to we're going to have to show that we

continue to accrue in the next six months or the next four months, really, so that the numbers that we report on the P30 look good, and then we'll have one more shot on goal when the site visit comes, because we'll have another nine months worth of data.

And we just need to show that trajectory upwards. But that's that's what we're going to deal with. And it is what it is. Yep.

L Lara: All right. Well, I hope you we all have a second chance on go with site visits, because now that all reviews are centralized, that the NIH. I'm actually wondering whether the NIH, with its new central review of all things, NCI, whether they keep the site visit because that's the only, program in, in the portfolio that still requires site visits. Right? So, I don't know what will happen, but, you still need to make the written application as robust as it could be, because I think we all are feeling the the possibility that that's what's going to be the score that will get right the written application.

C Willman: But Lucky can I ask a question, if you know anything more with your involvement in subcommittee A? So, we're hearing that all of the NCI review branch will probably be centralized and move up. Is that what you're hearing?

L Lara: Yes. That's what we're hearing. But yeah.

C Willman: So I think what you said is true, that the written application is going to be ever more important than it was before. You don't I don't know how much of a chance we'll get after the fact to defend that.

9. **SRM**

L Lara: All right. We have five minutes for Q&A, Dr. Lam.

K Lam: Yeah. Excellent presentation. Certainly the Shared Resources are well run and managed. And the same question as you mentioned earlier, the director replacement seems to be last time last year, we're talking about find replacements. Do we do not have any. Now the question is will you have one ready for the renewal or not. What is the bottleneck for that?

And then in terms of Rick mentioned about merging some shared resources, for example, with IVFOI the utilization low only six unique member and 27 hours may be merged with OBC. I think that seems to be reasonable because if it continue to be very low, using utility and I…

M Waterman: Yeah, you're pointing out something very important, but may I speak to that for a moment? Usage is underreported because some of IVFOI users are not using ilabs, so we're not capturing the full usage of IVFOI. And IVF is presenting, providing a very valuable, contribution to the cancer center and working on this Lumitron system. So it's an ongoing discussion.

I really appreciate your feedback that you think that would be a reasonable avenue if we decide that the usage is still too low to justify. But I would like to point out that the numbers underreport its usage, and also that it's more one of these, like we say, for some of the other resources, a boutique shared resource for very, very customized high end, imaging.

K Lam: Right. And, and, regarding the, Mass Spec Imaging, I mean, Mass Spec Shared Resource, you know, certainly looks like a very mature to be able to launch that officially with, all the instrumentation and different aspect, the three different components you have with metabolomics as well, proteomic and all the standard small molecule mass part.

I think that could be, good one to you. Also, there are a lot of, utilization as well. My understanding is there. So, I think you could be a good time to launch it. That is my opinion. And, some of the other cancers and I, I, have eyes on they do have a strong Mass Spec Shared Resource and looks like your center here whether you can use it.

M Waterman: Okay. Thank you very much.

K Lam: Oh, one other thing. It was mentioned AI is really getting popular. ***How is AI being used in the Shared Resources?***

M Waterman: AI, to my knowledge, unless one of the Shared Resource leaders, wants to dive in and disagree with me, is not being used to and a great extent yeah in any of the shared resources although our biostatistics shared resource, might be developing that capability, in big data, that's, headed by Director Zhang.

K Shokat: ***And can we hear your answer to the gaps question about the director?***

W Cozen: [unintelligible]… We do have Vizio Farm in the, experimental tissue resource, and that does use machine learning, and I, you know, it's not super sophisticated at this point, but it does incorporate. Okay, we will make sure to talk about that.

L Lara: And, Rick?

RVE: I can address a little bit the, the AD issue. I've been holding off on it, in part because we do a lot of recruitments and there are a lot of people that want to come and have leadership roles in the cancer center. So it's kind of in, in, in the, back pocket around that. There was a recruitment that I can't go into last year where we had a perfect candidate, who would have come and that would have been part of the package, and that didn't go through. But, I understand the need to get this position filled.

L Lara: All right. Your final comments, Kevin.

K Shokat: Oh, that was my question. So that's great. I think John has a couple question.

J Bushweller: I just want to reiterate what Kit said, that, this Mass Spec Shared Resource looks great. I would launch it and include it because it will be compelling.

M Waterman: Thank you, John. Thanks.

L Lara: All right. Any other comments from the EAB? Well, there, there, which one? So I can't see. There's a there's a pillar. I don't know. Go ahead.

S Sandmeyer: I don't know if this is live or not. Suzanne Sandmeier for the GRT Hub. So, we are incorporating my machine learning and AI into into especially the open source software that we're using, but also some of our commercial, support, software is is certainly incorporating that in as well.

For example, our next workshop will be focused on statistics, and the second one after that on machine learning to help users. So yes,

M Waterman: thank you, Suzanne.