FOR THE MEETING CONTINUED FROM

DECEMBER 28, 2023 OF THE

CITIZENS FINANCIAL ACCOUNTABILITY OVERSIGHT COMMITTEE

Organized Pursuant to the

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I N D E X

MAY 29, 2024; 10:00 A.M.

MS. COHEN: Okay, ladies and gentlemen, I want to welcome you. It's 10:05 on Wednesday, May 29, and we are gathered here remotely for the Citizens Financial Accountability Oversight Committee. Please note that this meeting is being recorded. My name is Malia Cohen. I'm the California State Controller. Thank you for joining us.

Before I proceed, I'd like to ask if anyone is able to stand and put your right hand over your heart and join me in saying the Pledge of Allegiance.

"I pledge allegiance to the flag of the United States of America and to the republic for which it stands, one nation, under God, indivisible, with liberty and justice for all."

Thank you very much. This meeting is now officially called to order.

Mr. Ryan Mueller, please call the role.

MR. MUELLER: Good morning. I will now call role for the COAC members. When your name is announced, please indicate your presence for the record.

Chair state controller Malia Cohen?

MS. COHEN: Present.
MR. MUELLER: Michelle Gasgle-Haynes (phonetic)?
MS. COHEN: She's not here.
MR. MUELLER: Okay. Dr. John Maa?
DR. MAA: Present.
MR. MUELLER: Alfred Rowlett?
MR. ROWLETT: Present.
MR. MUELLER: Dr. Gurbinder Sadana?
DR. SADANA: Present.
MR. MUELLER: Thank you, Controller Cohen. I will now turn the meeting back over to you.
MS. COHEN: Thank you.
Just a point of order. Mr. Rowlett, good morning to you. I have in my notes that you have a request to be excused? Is that no longer accurate? Mr. Rowlett? Mr. Rowlett?
MR. ROWLETT: Sorry about the delay. No, it's no longer accurate. I am able to attend the entire meeting.
MS. COHEN: Thank you very much. Thank you for making that accommodation.
Okay. Thank you, Mr. Mueller. A quorum is present. It's been established. Thank you.
Again, by introduction, my name is Malia

Cohen. I'm chair of this body, and the controller's office is steward of the fifth largest economy in the world.

And it's -- in my many functions and roles that I play in the state of California, my office conducts the annual citizens financial accountability oversight committee meeting. And this work is incredibly important and serious to the public dollars that we're spending -- making sure the public dollars are being spent appropriately.

For historical purposes, it's important to just acknowledge that the CFAOC was created by past Prop 71 which was called the stem cell research and cures initiative, and in 2004, it was continued to be -- and continued with the passage of Prop 14 in 2020. The continuation -- this continuating meeting continues the discussion which began in December of 2023, specifically allowing this body to formally approve the 2021-2022 independent financial audit, which was conducted by Macias, Gini, & O'Connell LLP.

This action is connected with the primary responsibility of the CFAOC in discussing the annual expenditures of the available bond funding from Prop 14 and the results of the annual financial audit of the California Institute for Regenerative Medicine, also

known as CIRM.

Another function of today's meeting is to receive an update from CIRM. During the December 2023 meeting, CIRM was undergoing a leadership transition, so this meeting was scheduled for a comprehensive presentation on their work. And you can look forward to today's presentation. It will focus on their strategic plan, program changes, clinical trials grants awarded, and a very exciting preview of their future work.

So before we discuss the audit review and CIRM's activities, I'd like to take a moment and welcome the committee members. You heard that we have joining us Michelle Gasgle-Haynes, Dr. John Maa, and Dr. Gurbinder Sadana.

Dr. Gurbinder, I apologize for butchering your last name.

DR. GURBINDER: That's okay.

MS. COHEN: Thank you, sir.

Again, thank you, everyone, for your service on this body, your expertise, and participation. It's an important contribution to the oversight efforts.

Also, Mr. Rowlett, you're a member of this body, are you not?

MR. ROWLETT: I am.

MS. COHEN: Well, sir, it's not in my notes,

and I want to welcome you too. And thank you.

So we're going to hear from CIRM leadership later. I also want to acknowledge the following agency representatives. We have Dr. Jonathan Thomas. We've got Rafael Sacasa. We have Dr. Vito Imbasciani. We have Maria Bonneville, and Scott Tosher. All right. Let's dispense with the role call and acknowledgment of our members.

Before we move into the details of the meeting, I want to reiterate how honored I am to serve on this committee. And this type of stewardship is incredibly important to us, as Prop 14 continues California trust in helping to support strategies for solving rare and complicated diseases.

So, today, it's about the numbers and also equally important in insuring that the funds are important that the funds are distributed in a way that serves as communities, especially those who have been historically underserved and marginalized.

So our first order of business is Item 4, the adoption of the minutes of the December 28 meeting.

Has everyone had an opportunity to review the minutes?

COMMITTEE MEMBERS: Yes.

MS. COHEN: All right.

Is there a motion to approve the minutes?

DR. SADANA: I'll make a motion to approve minutes.

MS. COHEN: Thank you. Mr. Rowlett has made a motion.

Is there a second?

MR. ROWLETT: Second.

MS. COHEN: All right. Second. I'm not sure -- who made the second?

MR. ROWLETT: Al Rowlett made the second. Someone else made the first.

MS. COHEN: Okay. Who made the first?

DR. SADANA: I made the first. Sadana.

MS. COHEN: Thank you.

Mr. Mueller, do you have that record?

MR. MUELLER: Yes.

MS. COHEN: All right. Thank you very much. A colleagues, are there any discussion on the minutes? If not, let's take a vote.

Please call the role for the vote.

MR. MUELLER: Yes, Chair Cohen. I will now call role call to approve the minutes for the December 2023 meeting. When your name is announced, please indicate your vote for the record.

Chair Cohen?

MS. COHEN: Aye.
MR. MUELLER: Dr. Maa?
DR. MAA: Aye.
MR. MUELLER: Mr. Rowlett?
MR. ROWLETT: Aye.
MR. MUELLER: Dr. Sadana?
DR. SADANA: Aye.
MR. MUELLER: Chair Cohen, I will now turn the meeting back over to you.
MS. COHEN: Thank you. The motion has passed unanimously. The meeting minutes are officially received and entered into the record.
The next item of business, Item Number 5, is the adoption of the 2021-2022 independent financial audit.
Now, while, as a body, we have had an opportunity to discuss this item, but I want to allow for any brief summary before we take up this item. If there's any further discussion, now is the time.
All right. Thank you very much. At this time, I'm going to call on Kim Tarvin who is in my office. She is a division chief for the audit division.
Ms. Tarvin, are you there?
MS. TARVIN: I'm here.
MS. COHEN: Thank you very much. I appreciate

you. Ms. Tarvin's going to be presenting a high-level overview of the financial audit report and findings from the report, as well as report out the quality control review of Macias Gini & O'Connell audit for the fiscal year-ending in 2/30 of 2022.

Ms. Tarvin, thank you for the presentation, and the floor is yours.

MS. TARVIN: Thank you, Controller Cohen-19.

Yes, I'll provide just a brief overview. We had a full presentation at the last meeting, by Macias Gini & O'Connell and myself. So I'll go ahead and just summarize the results of the financial statement audit and then of the quality control review.

Macias Gini & O'Connell spoke in detail last time regarding the financial statement audit for the serum, and the results of their audit was that the financial statements were fairly presented and in all material respects for the financial position of the governmental activities and the stem cell serum as of June 30, 2022, and the respected changes in financial position for the year then ended in accordance with accounting principles generally accepted in the United States of America. So that's the financial statement opinion.

They also had two reports related to internal

controls. Well, it's one combined report, really. It's internal controls and compliance. And they did not have any audit findings in the audit report, so it was considered a clean audit report.

So the second process that happens every year that's required by the health and safety code is that the controller's office does a quality control review of the audit work that's completed by Macias Gini & O'Connell.

So basically what we do is we take a look at their working papers. We take a look at the report. We ensure they meet all of their professional auditing standards, which they're generally accepted auditing standards as well as generally accepted government auditing standards in the business and professional code.

And we also look at the competence of the staff and whether they've taken their required continuing professional education and so on. And the results of our review were also that they had conducted their audit in accordance with all the professional standards.

So that is the summary of the process that we had discussed in December 2023.

MS. COHEN: Thank you very much. Colleagues,

do you have any questions for Ms. Tarvin?

All right. Seeing that there's no discussion, is there a motion to accept? Is there a motion to accept, and then I'll need a second?

MR. ROWLETT: I move to accept.

MS. COHEN: Thank you very much.

Is there a second?

DR. SADANA: I second.

MS. COHEN: Thank you very much. Let the record reflect Mr. Rowlett moved to accept and Dr. Sadana seconded.

Please call the roll.

MR. MUELLER: I will now call roll on the motion to approve adoption on the 2021-2022 independent financial audit by Macias Gini & O'Connell.

When your name is announced, please indicate your vote for the record.

Chair Cohen?

MS. COHEN: Aye.

MR. MUELLER: Dr. Maa?

DR. MAA: Aye.

MR. MUELLER: Mr. Rowlett?

MR. ROWLETT: Aye.

MR. MUELLER: Dr. Sadana?

DR. SADANA: Aye.

MR. MUELLER: Chair Cohen, I will now turn the meeting back over to you.

MS. COHEN: All right. Thank you very much. Those minutes are unanimously adopted, Ms. Tarvin. Thank you for your presentation.

All right. Let's go on to the next item. The next item is Item 6, an update on California institute for regenerative medicine strategic plan, program changes, clinical trials, grants awarded, and the future.

Next, we will hear from the team to share an update. And good morning, Dr. Jonathan Thomas.

Are you there?

DR. THOMAS: I'm here, Madam Chair. Very nice to see you.

MS. COHEN: Thank you. Good morning. Welcome to you and your team, and we're looking forward to your presentation. The floor is yours.

DR. THOMAS: Thank you very much. We'd like to just give a bit of additional context here. From my left to right further to the roll call so everybody understands who everyone here is in the room with me, from my left to right, we have senior director of board governance, Scott Tosher; vice chair, Maria Bonneville; General counsel, Rafael Aguirre-Sacasa; and Chair of the

Board, Dr. Vito Imbasciani; and VP of operations, Jennifer Lewis.

It's a pleasure to greet you and members of the CFACC. A special shout-out to longtime board colleague and good friend Mr. Rowlett. It's always good to see you again. It's an honor to be able to present on behalf of CIRM to the CFAOC on a number of items dealing with where CIRM is at present in its continued efforts to provide the highest quality work for the taxpayers of California in funding stem cell and gene therapy research throughout the state, further to Propositions 71 and 14.

So, with that, I will get into my presentation here. There is a fair amount to get through. Please either ask questions as we go along or when we get to the end of the presentation, I'd be happy to entertain in and all questions that you may have.

So next slide, please.

We always begin any of our presentations with a reference to our mission, which is: Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world.

Next slide, please.

So very briefly, CIRM, founded in 2004 with

the passage of Proposition 71 which created the agency and authorized the issuance of $3 billion of general obligation bonds to fund principally grants, but also loans, to academic institutions, research institutions, and biotech companies in the state of California.

And that last statement is very important because everything we do has a nexus to the state because it is, after all, the taxpayers that are funding the service for the bonds which fund the work that we do.

You can see in the middle there that we fund a number of different things, starting with the full research spectrum, basic research, what we call translational research, which is a sort of bridge between basic research discoveries and human clinical trials, as well as the clinical trials themselves.

And we have a couple of other pillars that we call. One is infrastructure, which in its original form, meant a number of stem cell institutes that were instructed throughout the state of California to specifically fund the work that our stem cell scientists are doing in the different institutions that I referenced above.

It's now been expanded to include a very robust what we call alpha clinic trial network of

institutions. There are nine such throughout the state which actually provide a soup to nuts service to patients who are involved in clinical trials that we fund as well as others that are funded by other entities to take advantage of the alpha clinic network.

It also includes a number of things I'll reference in a few minutes that have been mandated by Prop 14. Lastly, we have a very robust education program. We put out $250 million to date. We'll get into a bit more of that as we go down the road.

As Madam Chair you referenced in your comments in 2020, we have run through our $3 billion in initial funding authorization, and it went back on the ballot. I'm very careful to say we didn't go to the ballot. We as a state agency can't be involved in an election. It was done through an outside entity, Americans for Cares, the Road to Measure, put it on the ballot, funded the campaign, et cetera the passed and authorized an additional $5.5 billion in funding, which we are now in the process of deploying.

Next slide, please.

Okay. So Prop 14 basically took the program that was put in place by Prop 71 and added a few additional items to it. I'm going to go through these very quickly, just highlighting a few. It added that

5.5 billion. 1.5 billion, importantly, is targeted towards neurological disorders which actually is consistent with the amount of funding that we had -- on a ratio basis that we had given to neurological diseases under Prop 71, but it sort of codifies that. So we have a special program for that.

It put a very major emphasis on making sure that anything that we fund is accessible and affordable to all citizens of California with the particular focus on underserved communities.

Towards that end, the alpha clinics that I referenced is a new program which is essentially a set of satellite, little, small alpha clinics, if you will, is set up to make sure that what we fund reaches those underserved communities in particular throughout the state. The education programs are all geared towards developing the future workforce in the areas of stem cell and gene therapy research, and those include different programs which involve training and what we call shared labs, which is making places that have stem cell research available to other research institutions that don't so that they can come and share with the setups at these stem cell institutes so they can themselves be involved in research with their students.

We have lots of enhancements and oversight

issues -- not issues -- protocols that you can see there listed, which happy to go through if anybody's interested. And it posed staffing limits of 70 employees at CIRM plus an additional 15 for the accessibility and affordability working group, highlighting again the importance of the outreach to underserved communities.

Next slide, please.

A couple years back, we had our current five-year strategic plan approved by the board. It's the latest in a series of five-year plans. The general themes were to advance world class science, deliver real-world solutions, and provide opportunity for all. These are very sort of general thematic positions, and everything that we do at CIRM, which is a great deal, is further to all three of these basic topics.

Next slide, please.

Here, again, I referenced our work in basic research, translation, clinical, education, and infrastructure. And you can see here that we've put out 4.1 billion in grants to date. And I should note, by the way, this report that we've prepared that I'm discussing here was developed early in the year. So there will be in some instances numbers that, since the drafting of this report, have increased, and I'll give a

couple of examples of those as we go along.

But this will more than suffice for giving everyone on the CFAOC the general ideas. You can see here how much we've put out to the different pillars of our programs and specifically what we've done since the passage of Prop 14 in November of 2020.

Notably, at the bottom, you see that the 1.5 billion mandated to neuro research, we've put out 249 million under Prop 14 to date and have a very detailed plan for the implementation of balance.

Next slide, please.

Again, this is something I'm not going to go through in any detail, but just to give you a sense of the fields that we're funding, the different diseases and conditions, this is the basic research portfolio where you can see that we've given out, as of the drafting of this report, 692 awards, covering all of these different areas. You see the biggest bulk of that so far has been in discovery and cardiovascular, but many others as well.

Next slide, please.

This now is again the translational portfolio. Recall that that's the bridge between basic research and clinical trials. You can see that we, as of earlier this year, had 103 such awards. Again, the bulk of

those to neurologic disorders, hematological malignancies -- that's blood cancer of one sort or another -- hematology, which is blood-forming stem cells in general, then cardio, and then the other different topics that you see there.

Next slide, please.

Finally, on the clinical trial front, here is the pie chart for that. I just want to draw brief attention to the top bar there. So our clinical program actually starts before human trials. The process when you're developing something, whether it's a drug, or in this case a living drug, if you will, in the form of cell therapy or gene therapy, the last process you undertake to get to authorization to actually begin the trials is to file a -- what they call investigational lead drug application with the FDA or IND. And that IND, if approved by the FDA, is the go ahead to start your clinical trial process.

So we began our clinical programs with what we call IND enabling, which is that last effort to get to the trial approval itself. You can see, if you go across the top bar, we've had most of what we've funded has been either in that or in early clinical trials with the lesser amount in Phase II or mid clinical and a smaller amount in Phase III.

Next slide, please.

Okay. So with a -- that as sort of a base for discussion, we are now in the process of figuring out what we're going to do as we deploy the balance of the Prop 14 funds. And towards that end, we have this sort of summary of impacts of what we've done to-date, which I'll give a bit more discussion on, but you can see the general categories. These are establishing collaborative networks for basic research, training and workforce development, commercialization of cell and gene therapies, advancement in regenerative medicine technologies. These are all the things we're going to be doing as we proceed from here.

Next slide, please.

So an example of each of these. On the collaborative network for basic for discovery research, with respect to the neurological disease funding mandate of Prop 14, we have started with a program that's targeting very importantly the area of Mr. Rowlett is very involved and in very interested in in particular, which is neuropsychiatric diseases. We've put together our so-called ReMIND program, which as you can see is an acronym down there in the asterisk at the bottom, which is the first search program to tackle these sorts of diseases specifically that CIRM has had.

I think the first such program anywhere has funded in the country.

You can see that's broken down into a couple of different types of ReMIND project groups. One is collaborative projects involving multiple parties, and then the second is sort of higher risk, high-impact projects, which we call ReMIND-X.

Next slide, please.

On the training and workforce development front, this gives you an idea of just how extensive what we've been doing is. You see the chevrons at the top going across, and if you look below, you can see the four different education programs that we have and what stage of student body is affiliated with each. There are many, many kids and young adults who have gone through these programs very successfully, highly enthusiastically.

And if you ever want to bring a smile to your face and be really impressed by the future youth in the field, I would invite you -- would note specifically as an example the SPARK program on the left, which is a summer high school program where kids who have principally AP biology knowledge and sort of rudimentary knowledge of stem cells go through a six- to eight-week intensive course.

At the end of that, they convened for a statewide meeting, and they have posters of their work and they give talks and you sit there and you listen to these kids, and it's unbelievable. They sound like they're PhDs when they knew virtually nothing about the subject matter going into it.

And then you just go on to there from these different programs that involve undergraduate, post-docs, et cetera, et cetera, and it's something we're really proud of because it is building the workforce of tomorrow.

Next slide, please.

This is just a bit more on this. And what this is meant to depict is there are different programs that serve to set up, whether it's the alpha clinics, the satellite community care centers of excellence, a robust manufacturing program -- and I'll get into that in a minute since it's kind of an odd concept for cells -- the shared resource labs I mentioned.

These students are involved in all of these different things and are -- acquire expertise that helps them to be prepared to enter -- whether it's further education down the road or industry or whatever.

But notice -- just make sure to point out, at the upper left, the reference to DEI, we are acutely

attuned to the principles of diversity, equity, and inclusion in absolutely everything that we do. And if you go through and look at all of our programs, education being a great example, we are very cognizant of the need to make sure all communities are represented in everything we do. And you will see that they are all highly diversified in their demographics, and that is something that allows for making sure that all communities have a voice in everything we fund.

Next slide, please.

These are just a couple of examples, and we'll go through them. They're meant to depict how people that have gone through these different educational programs have gone on to do, like, brave work. There are countless other examples of that, but you can see just from those listed here, they're all in positions of responsibility. And if you ask them, they go back and say how they benefited greatly from having gone through our educational programs at whatever level, and it really inspired them to go into the fields that they're now pursuing.

Next slide, please.

On the commercialization front. So the goal of any sort of research in the medical field is to get products to patients. And so we're very much looking to

do whatever we have to do to push the work along towards the commercialization goal. And as we do that, we have sort of the collateral things that we have done that will help facilitate that.

One is we put in the funding we have, but our grantees all have access to additional funds that leverage what we have given them. And so out of the money I've referenced that we've put into grants so far, our awardees have gotten at least $24.7 billion of additional investments into their projects, whether that's in the form of co-funding or spinouts that have raised private equity or IP O-rings or acquisitions or whatever.

So we are viewed as a -- very much a seal of approval for things that are looking to put additional funds into the projects, and that's led to that very significant 24.7 billion number which rises every year.

Also have additional examples of that at the bottom. A couple of the companies or pieces of work that we funded won in neurona therapeutics, which is a recent example, which is doing work in epilepsy raised $120 million in the capital markets. Another work that we funded, Dr. Cherqui's work at UCSD in something called cystinosis was the object of an acquisition for 87.5 million.

Those are just examples. There are lots more. If anybody's interested, I'd be happy to give you the chapter and verse on that.

Next slide, please.

Thank you.

One of the things that's very important to note is that CIRM operates at what is called the so-called volley of death, which sounds like a disease term, but it's actually a financial term. It's that that early period of research that funding sources, particularly venture capital, et cetera, it's too early for them to get involved. So there are really no appreciable sources of funding other than government grants or philanthropy.

So we are operated first and foremost in that space, and that's typically from basic research all the way up to early clinical trial work.

And in so doing, by funding the work, we -- what we call de-risk the investment for those funding entities down the road who would ultimately be able to take the work into more expensive later-stage clinical trials and on into commercialization.

So one of the things that's sort of interesting is there are a number of projects that we've funded repeatedly as they've moved through the research

spectrum to get their product from, in some cases or most, basic research all the way to the end of the stage where they would do clinical trials and on to commercialization. You can see this is just one such example.

What later became neurona, but I referenced the work on epilepsy before began at UCSF and we funded that UCSF and various others six times to get them to where they are now. And it's definitely one of the success stories of -- we call these progression events in CIRM lingo.

Next slide, please.

You can keep going. We don't need to go into that additional detail. Next slide or what -- okay. Keep going. That's fine. Next, please. Next, please. Oh, the progression.

Similarly, this is another example of the company that started at UC Irvine doing research in retinitis pigmentosa which is a very serious degenerative eye disease. Here again, we funded originally the work at Irvine, Dr. Klassen, who's there on the left, who's been the key science person throughout that spun out into a company called jCyte, which we funded those two entities four different times to get to where they are today.

Next slide, please.

Finally, a very interesting -- these are all very interesting -- another terrible condition, spina biff du, research being done at UC Davis by Dr. Farmer and her lab which involves actually going into the in utero to alter the mutation that's responsible for this degenerative spinal condition, which is remarkable work, showing sort of the promise in a field. We've funded their work four different times to date. Again, these are all progression events at CIRM.

Next slide, please.

Partnerships that we have that, again, are taking product towards commercialization, there's a branch of NIH which we've partnered with in funding sickle cell disease, which as you know, is another mutation based disease. That's in the hemoglobin gene, which is -- afflicts many people across the U.S. and the world. This is something where the NHLBI and CIRM have jointly funded. We have a number of projects in that particular condition going forward.

I should add, an abundance of others as well outside of this collaboration in this particular condition.

Next slide, please.

So, here, without going into great detail,

here, a number of the projects that we're funding in the sickle cell arena. If you take a look at that white column in the middle there, you'll see that there's lots of acronyms which our field, as lots of fields are, awash with acronyms. They're not something the general public would recognize, but the key point here is there are different ways of attacking the problem that -- many of which involve gene editing in one sort or another that are tackling this terrible disease from a variety of angles.

And these, as you can see, projects that we've funded are at various stages of development here and moving along the research spectrum.

Next slide, please.

I referenced this soup to nuts stem cell clinical trial program we call the alpha clinics. These are the institutions around the state which have those. You can see that we've already had 200-plus clinical trials implemented at these sites, over 1,000 participants, 40 different diseases.

This network is a one-of-a-kind as far as we know. They collaborate in a number of fashions to use their resources jointly to make for more efficient clinical trials and getting through the bureaucratic analysis that needs to be undertaken before you can

start clinical trials at any given institution.

They have shared resources for that, et cetera, and this is -- they refer patients to each other. Many of these trials have particular expertise in specific diseases, and so they are sort of the go-to places. One side will refer to another. And it's a very collaborative effort. We have on our team Dr. Jeff Lomax who oversees the alpha clinical work, and they meet on a monthly basis with a steering committee that talks about the issues of the day, how they can enhance the performance on the network. It's a really ground-breaking setup that we've got going here that's really paying imminence to patients.

Next slide, please.

So I referenced the term manufacturing, and everybody sort of things of manufacturing as textiles or shirts or stuff like that. But in the course of being able to deliver therapies, if you develop particular treatments that involve integrating cells into a patient, you need to have lots of cells. And these cells can be gene edited. They can be a variety of things. But you need to multiply the number of cells to be able to have the critical mass that's needed to affect the therapy or hopeful cure that you're pursuing.

And that's done through something called

manufacturing. And that is a particular dialect which we are very attune to. The -- what we've set up is a number of the sites around the state -- and these are basically the same that have the alpha clinic programs -- have manufacturing capabilities that we sought to enhance by funding additionally their work. And once that funded, took various forms. But the net result is to increase the capability of each, and they too, as with the alpha clinics, are now working as a network.

They too have monthly steering committee meetings to determine what any science particular issues are to get suggestions, guidance, facilitate collaboration, et cetera.

Another thing I should note here is that industry itself, outside of academia, there are a number of players who are in the cell manufacturing space, both in California and around the country. And part of what we do in helping with the manufacturing is to get these industry parties involved in collaborations with our science, to further enhance their ability to produce the cells for whatever that are needed for the treatment.

Next slide, please.

So this is very important. Again, I referenced how we are -- one of our real areas of focus

is accessibility and affordability for any sort of treatments or cures that we help fund.

And so towards that end and further Prop 14 and under the auspices of something called the accessibility and affordability working group, chaired by Vice Chair Bonneville, we have what we call patient support program, which is set up to help patients with all of the details that need to be attended to in connection with getting to clinical trials, staying in hotels while they're there, transportation, food, all these sorts of things that are for things that -- the details that need attending to.

That patient support program, in turn, oversees a patient assistance fund which is something that is used specifically to cover the costs of the things under the patient support program. We have engaged a firm who is going to oversee the development of the patient support program and the deployment of the patient assistance fund to make this program a reality.

And if you have specific questions about this, I'd be happy to have Vice Chair Bonneville comment on this.

Would you like to say anything further at this point, or are you good?

VICE CHAIR BONNEVILLE: I'm good.

DR. THOMAS: But if you have questions, she is more than happy to chat about this.

Next slide, please.

This -- I'm not going to go into a lot of detail, other than to say I referenced this before. We have these alpha clinics in the major academic centers, and we're now in the process of putting together this community care centers of excellence, which are these satellite, little alpha clinics out there that will be accessible to the areas not served by the academic centers to make sure we have comprehensive coverage for what we bring to the table for all citizens of California.

Next slide, please.

So the -- one of the things, as I said, our ultimate goal is to get projects to commercialization. I should note that the field, which began in 1998, is in sort of early/mid-life at this point, and it takes a long time to develop drugs in general. The normal things you're used to taking, pills, et cetera, those take 10 to 15 years to develop.

So too it takes a long time to develop something in a new area, which is what cell and gene therapy is. And so we are really focused on getting projects that we've funded all the way through

commercialization, and that's triggered by something called a biologics license application with the FDA, the so-called DLA. And we've established a new clinical trial funding program specifically to help our projects that are furthest along get across that finish line.

That, we call the CLIN4 program, which is now open for application, and we expect to get the first of the projects close to that point applying shortly.

I referenced that our numbers are a little off based on the fact that this was put together earlier in the year, so prime example, we're now at 106 clinical trials funded as opposed to 98, crossing the 100 threshold in February. It's a number we're very proud of. Those clinical trials cover everything from the ultra rare to highly prevalent disease and everything in between.

Next slide, please.

Okay. So I don't think I need to go into this in too much detail. I mentioned this earlier. Shared resource labs is the program, again, that we make available at institutions that have stem cell programs to other entities that don't so they can share in what those programs have to offer.

For example, we have many of the Cal State universities are affiliated with different state

academic institutions that have stem cell programs and have a very robust relationship. When they get their students to be involved and all of that work, it expands the scope of the workforce.

Next slide, please.

That's it.

So I just want to make a summary statement, Madam Chair. As I think everybody knows, the advent of Prop 71 really turned California into the absolutely major forest in first stem cell, and now stem cell and gene therapy research funding in the world. There's nothing comparable to CIRM.

Other states have tried but not been able to duplicate this model, which arose sort of -- it's all part of what we like to think of as California's frontier spirit and willingness to get out on the cutting edge as embodied by the approval of the voters of the two propositions. And it's led to a situation where this is a continuing, developing success story for the state that, I will say, given that all of us here deal with our colleagues in the stem cell/gene therapy arena throughout the nation and the world, is the envy of everybody.

The ability to have this funding on hand, the talent that we have in the state of California, is

unsurpassed in the field, and it's allowing us to enable research that is really -- when the history of this golden era of medical research is written ten to 20 years from now, we'll look back and CIRM will have a very prominent chapter of which we've all been a part and can all be very proud of.

So with that, I'm open for any questions you might have.

MS. COHEN: Thank you, Dr. Thomas.

Colleagues, are there any questions?

Dr. Thomas -- oh, I see a hand. We'll start with Dr. Maa.

DR. MAA: Thank you, Controller Cohen.

Thanks for the great presentation. It's really impressive. It's wonderful to see all the work that's being done. I really look forward to the continued success in the future.

I just wanted to share -- I was at a meeting with the leadership of UCSF, UC office of the president, and UC Berkeley recently, and there was a preeminent researcher who learned that I was involved with the committee and asked questions about the number of FDA-approved therapies that have been derived over the 20-year history since Prop 71 was first initiated, and also questioned if there are ways to increase the

royalty revenue, particularly into the future.

I think CLIN4, you know, in the efforts to really accelerate bringing these therapies, you know, into FDA approval is essential. And I was just wondering -- I guess my question, really, is -- I think it's at that final finish line where I think great steps forward can be made to really demonstrate to the scientific community and to the voters of California and to the general public of the value of this program. Thank you.

DR. THOMAS: Thank you very much for your questions.

So as I was alluding to, the field of stem cell and gene therapy itself is still in a relatively early stage. And so if you look around the country, there have been very few products that have actually made it to market in the states. There have been some notable exceptions. You may have read recently about a couple of sickle cell gene therapy approaches that were approved. But by and large, the field itself is continuing to mature, and the projects in California are no exception.

So we have products that are close to this BLA finish line. We have had none that have gotten commercialized yet. But we do expect that's going to be

changing in the not-too-distant future. And as you get further along and more products get through that stage, we'll have more of an answer that.

Having said that, I will tell you that we have some work that's produced some remarkable results that has not yet made commercialization.

I'll highlight just one, work of Dr. Don Kohn at UCLA. He's working on something that's colloquially known as bubble boy disease, or technically severe combined immuno deficiency, which is babies who are born without functioning immune systems, who do not live very long, and have to live a bubble existence, if you will, where they're not exposed to anybody.

And that disease is caused by a specific mutation in the blood-forming stem cells in the bone marrow. Dr. Kohn has successfully developed an approach that gene edits out that mutation and puts in the functioning genetic sequence, replants that -- the blood-forming stem cell back into the bone marrow, which then produces a normal immune system when it cranks out the blood for these kids.

And he's had dozens and dozens of kids who have -- who are essentially functionally cured of that terrible disorder. That's an example of the promise of the field. That's not yet to commercialization, but

it's moving along. And that's the sort of thing that ultimately we'll get across the finish line.

To answer your question with respect to the royalties, that's something that's dictated by the propositions themselves, so that isn't something that if CIRM, as a board, for example, decided it wanted to change, we can't do that. But that royalty provision is something that's written into all contracts that we enter into with grantees to the extent that what we fund ultimately does produce revenue royalties, now, under Prop 14, those royalty payments go back into this patient assistance fund that I referenced earlier, which makes -- is available to patients to help who are involved in clinical trials.

So hope that answered your question.

MS. COHEN: Thank you for that.

DR. THOMAS: Madam Chair, Mr. Tosher has a follow-up probably correcting what I just said.

MR. TOSHER: I apologize. Dr. Maa, just to your question with the royalty, JT's correct that the proposition requires certain balance the state's interest in sharing in the revenues that are generated by its CIRM-funded research, but allows CIRM to balance that -- requires CIRM to balance that against rules that would unduly hinder the research or limit the ability of

these programs to partner with the commercial partners that are necessary to bring them to market.

So while it is correct that it is written into law that this balance must be struck, the agency does have regulations that implement that and establish the precise formulas for that revenue. I would just note that in 2010 the legislature actually codified our regulations into statute and provided that if there are further revisions to the formula, that we notify the legislature before doing so.

Thanks, JT.

DR. THOMAS: Thank you.

Mr. Tosher's been with CIRM almost since the outset and is a very valuable member of the team, not just for what he knows today, but for his historical context of what has come before.

So thank you, Mr. Tosher.

MS. COHEN: Thank you.

Mr. Rowlett, I see your hand up.

Do you still have a question?

MR. ROWLETT: I do. Thank you, Controller Cohen. I appreciate the opportunity to ask questions.

And I would be remiss if I didn't say thank you to the staff at CIRM, many of whom I know and Controller Cohen consider friends. And especially where

appreciate the acknowledgement by the current CEO, JT. Appreciate that. And hello to the board chair. Appreciate, again, the acknowledgement.

That said, Controller Cohen made a point of really highlighting and underscoring the importance of CIRM having an impact in underserved or poorly served communities. And so surprise to you all that I might ask a question about this.

But specifically in the area of neuropsychiatric disorders, and even recently, in March the citizens of the state of California passed something called Proposition 1, which again is another reference to mental health. And that is my area, and so an area of great interest.

And so, if you could, maybe elaborate a bit because the presentation was filled with lots of information. Very helpful. But if you could elaborate a bit on if there are specific strategies that the neuropsychiatric task force is working on to impact or to ensure that underserved or poorly served communities are included in opportunities for participation in trials -- and I use that word somewhat loosely -- that will hopefully ameliorate neuropsychiatric disorders at some point in the future.

DR. THOMAS: Thanks, Al, for that question.

So I think the important point to note in the so-called ReMIND programs that I referenced earlier, these are, first and foremost, at the basic research stage because there's so little developed in the area of neuropsychiatric disorders that, in order to advance the field in those particular conditions, there are a host of basic research issues that need to be addressed. And so both of those two programs that were listed there are directed at the basic research programs throughout the state. And they're spread out.

We can get you a list of exactly where they are, but they are -- as everything is at CIRM, spread out amongst various institutions. But the field does not have, to my knowledge, a great deal of progress in neuropsychiatric to the point where you've got a lot of things in advanced enabling work, let alone clinical trials. But that's clearly the goal of this.

We needed to kickstart the area, develop a knowledge of the basic underlying mechanisms responsible for the various conditions, and to then go into our normal progression sequence where we would look to fund projects that followed thereafter that took advantage of discoveries in the basic research to develop the field.

MR. ROWLETT: Thanks for that.

Again -- Controller Cohen, if I can ask one

more question.

MS. COHEN: Please, yes. As many as you want.

MR. ROWLETT: Okay. Thank you so much. Thanks so much, Controller Cohen.

The other thing that I've always been intrigued by -- and when I was a participant on the CIRM board, very proud of -- was the educational program. And that is, again, an area in which I think you highlighted one of the goals of this controller, and that is to make sure that we not only have a workforce that represents the unique diversity of the state of California but is opportunities for individuals in -- who typically are not represented in large numbers in the science field.

And so if you could just talk a little bit about representation. I know I might be asking you to pull out some numbers and if you have those and you can speak to those, that would be great. And then, again, if you could also say a little bit more about some of the anecdotes from those students who otherwise would not have had an opportunity to participate or be a part of the science physical it hadn't been for this program, and specifically SPARKS and Bridges.

DR. THOMAS: Thanks, Al. You absolutely were the champion of these programs, as well as wearing many

other hats when you were our colleague.

So the underlying purpose of these programs is specifically to ensure that the kids, young adults, adults, et cetera, that are admitted do reflect the diversity of the state. We go above and beyond to make sure that that happens.

And were you to -- as I know you have, were you to go to any of the meetings of these different programs, you'll see that diversity reflected across the student body in a very impressive way. They are drawn from areas all throughout the state, specific emphasis in trying to recruit students from underserved communities to be a part of this.

Getting kids interested in this sort of thing is not necessarily the easiest thing in the world. It's sort of an esoteric subject matter. So we spend a lot of time. We go out to schools. We give talks at schools. I've given a bunch over the years, encouraging the younger kids to get an interest in the stem cell space. And so when the programs are open and recruiting participants, there's, more than anything else, the attention to diversity. So I think we're very much on the forefront of that.

As far as the sort of anecdotal examples, so what you typically see is kids who go into the SPARK

program, for example, the vast majority of them will go on to major in some sort of biological science or related field, whether it's bioengineering or biochemical, molecular biology, et cetera. So, really, they will all tell you that they are highly inspired to make that as sort of their -- not only their major in college, but it establishes a firm intent to go on to be in this field.

And you asked -- we have stats. And if it's okay, Al, and Madam Chair, we'll get you some numbers on this, because I think you'll be very impressed with where these kids go. And a lot of them are now teaching. A lot of them are in the industry. A lot of them have risen to high positions in the industry. You saw one on that slide who's a VP of a company which is in -- working in developing -- sprung out of the Gladstone Institute, is working in the cardio space.

The examples of where they have gone on to are many, and they -- I think importantly, they, in one fashion or another, stay in the field. Very high -- very high percentage of the kids who go through these programs are in the field in one way or another. They don't just sort of take it and say, gee, that was fun and go on and do other stuff. So it's achieving precisely the objective that we set out when these

different programs were initiated.

And they should note that they weren't all started at the same time. They've been developed over time in response to perceived needs and gaps and the particular level of student body that doesn't have exposure to whatever we're providing, et cetera.

And we will continue to expand over time. We're really -- as you know, Al, we're really happy with our education program. Dr. Kelly Shephard here at CIRM oversees that, has done a fantastic job in driving this whole thing and just continuing to get bigger and better with more alumni and more workforce and on and on.

So thank you for asking that question.

MR. ROWLETT: My last question, Controller Cohen. And just a note, JT, I think it would be very helpful, I think, in interest of the controller, in consideration of what she said in her opening remarks, to see geographic distribution, demographic data, as well as the workforce data that you alluded to.

Last question is a bit naive, and this is not intended to be a "got ya" question. I just -- I am acknowledging, I don't know.

But you referenced -- and I'm familiar with your patient assistance -- CIRM's patient assistance program.

Is there -- are there data points associated with the amount of dollars that have been given out in patient assistance? And then, also, I believe CIRM tracks those grantees that are required to have patient assistance as part of their response and the dollars that they have also made available to participants in research or in trials.

So that's, again, my last question. Thank you so much, Controller.

DR. THOMAS: I'd like to ask Vice Chair Bonneville if she can --

MS. Lewis: Thank you, Al. You are correct that the clinical trials CIRM funds includes in their allowable costs reimbursement for education expenses.

However, CIRM's awards are a total direct cost amount. So there is only a limited amount of funds that we are earning in those awards. So the patient assistance fund, we are actually in the process of developing a lot of these rules and how these two pots of money are going to work together. But it really is -- we're seeing it as something that's going to serve beyond the -- a larger need that we're seeing.

So there would be kind of an allowable amount going to a clinical trial award. But for those exceedingly excessive funds, that would come under the

patient assistance fund. We're working through the logistics, but the idea being that this provider, the patient support program and persona, would be the one-stop-shop for patients, so they would go -- not having to be tossed around between alpha clinic sites & providers and really just get their needs met there and then CIRM and the provider will worry about the logistics of working between those funds.

So you are correct that we do track those funds, and they're an allowable part of the CIRM award, and what we're building now are the policies and procedures to ensure we have two funding streams that can be compliant and have clear rules that can be audited.

MR. ROWLETT: Thank you very much.

And again additional -- at future meetings or meeting, it would be great to hear more about that.

That's the last of my questions, Controller.

MS. COHEN: Okay. I do have a question.

What's the rate of return? What's the rate of return -- or what's the metric -- what metric do you use for the rate of return when considering which projects to invest in?

DR. THOMAS: That's a bit of a comp -- thank you, Madam Chair. Bit of a complicated question.

So when we put -- first of all, we -- investing in is sort of a loose term. We're, as you know, a granting agency. And so what we are always looking to do is to fund the best in class science that's out there towards developing therapies or cures for all these horrendous diseases out there which have nothing at this point. So the process is -- weave a very well-oiled grant application and review team that evaluates grants as they come in, as advised by a very sizable pool of stem cell and gene therapy experts, all from outside of California so we don't have any conflicts who do peer review on our projects.

And as a result of that peer review, which having been the former chair and now CEO, have sat in hundreds of these over the years, they are extremely detailed and robust in their analysis in looking for these best in class projects. They make recommendations to the board, who then entertains which grants it wants to fund for whatever the particular program is that's under discussion.

The -- when we're doing this, it's not with an eye towards what the return is going to be down the road financially because that's -- there are so many variables getting something true to the point where they're going to generating revenues, that it would be

very difficult to try to speculate on the ultimate potential return to the state.

So what we're about is funding the best science, enabling the scientists to get this work done in these early stages of research that I've identified, de-risk, and ultimately get ultimately either spin-outs or industry acquisitions or whatever to take those projects through to commercialization, at which point you generate revenues, which would come back in the royalty form that we discussed, et cetera.

But short answer to your question is the return on investment is not something that's part of the process because it would just be too difficult to ever speculate on what that might be.

MS. COHEN: Thank you. I can appreciate that. I'm sure you can appreciate my question, given the seat that I sit in, we look at investments and we're evaluating things all the time.

So I like that you've kind of augmented the lens that I look through.

And actually for the best part, when you think about the future of medicine, the future of research, you want it to be outside of politics, you want it to be outside of making money. I appreciate that.

Question: Now, DEI was a good talk during the

presentation, spending time developing relationships and research for and by people who are underrepresented. And there's a little bit of a political bend. There's a little bit of a political bend. That's the other lens that I look at the world through, so bear with me.

These programs are under attack. Corporations are pulling back their budgets for diversity, equity, inclusion. Universities are also kind of scaling back. What's the temperature read for CIRM when it comes to diversity, equity, and inclusion? You said you're still committed, but what -- you know --

DR. THOMAS: That's a great question, Madam Chair. I'm going to ask Vice Chair Bonneville to address that issue.

MS. BONNEVILLE: Great comment. Thank you.

Specifically with clinical trials, we have -- all applications that come in have a community outreach plan that is presented as well and is scored by the patient advocates that sit on our peer review panel. That's not going away. That's increasingly important in order to attract and collect a diverse trial population. It only makes the research stronger.

Our applicants take it very seriously. When we first rolled that out in 2020, our member Al Rowlett was instrumental in making sure that the rubric that was

developed evolved over time and that the researchers understood what was -- what was being asked of them.

I sit on the peer review panel, so I myself score DEI plans. And over the course of the last four years, they've become more robust in the way they look at their own institutions and the resources that their institutions provide, insofar as community outreach and diversity, equity, and inclusion. So that's definitely -- that's definitely not going away.

MS. COHEN: Okay. Got.

All right. Thank you very much. We're going to continue moving forward with our meeting, seeing that there are no other questions.

Great.

Mr. Mueller, correct me if I'm wrong. This is just an information item, so no action is required.

Is that correct?

MR. MUELLER: That's correct. Yes.

MS. COHEN: All right. Great.

So then let's go on to Item 7. While some of this information may have been captured in Item 6, Item 7 is an opportunity for CIRM staff to provide any additional information on the CIRM performance audit.

So now we're going to hear from Rafael Aguirre-Sacasa to provide detailed overview of the CIRM

performance audit process.

Mr. Sacasa?

MR. SACASA: Thank you, Chair Cohen. And thank you members of the committee.

This is usually a 45-minute presentation, so I'll try and keep it a little bit fast, but we can get it going.

Next slide, please.

We always start off with our mission: Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world.

Next slide, please.

We're going -- our agenda for today is two-fold. The first is to discuss management's response to the '22-'23 performance audit and then follow-up on the 2019-'20 performance audit as well.

Starting off with the '22-'23 performance audit.

Next slide, please.

The highlights: No compliance findings. In the 2019 and 2020, we had three compliance findings. So trending in the right direction.

Next slide, please. Next slide, sorry.

All right. We're going to get into them

specifically. They're all set up in the same format with the finding up top, recommendations from the auditors Moss Adams in the middle, and then current or respective action by CIRM at the bottom. I'll try and go through these relatively quickly. Please do stop me if you have any specific questions, or hold them until the end. I will try to do that so that we have some time at the end.

Finding number 1: Eleven staff members reported to the CEO versus an industry standard of four to six. Presents a risk to the capacity of the executive role.

The recommendation was that: Alongside the search for a new CEO, we explore an organizational structure that reduces its CEO's span and align similar functions.

Did you want to speak on this, JT?

DR. THOMAS: Yeah, just simply, I've already begun to implement changes in this regard and already evaluated a number of additional moves that are going to be announced in the coming weeks.

MR. SACASA: Thank you.

Next slide.

As we know, we have 35 -- up to 35 members on the FCAOC. The meetings are held in a hybrid

environment. Both of these factors could present a potential risk to full board engagement and productivity.

The recommendations were to assess our hybrid meeting practices and board engagement, the relationships among the board members and meeting effectiveness. And then continue to leverage committees and working groups to engage board members.

We leveraged the important work of subcommittees and working groups, and these allow us to provide a robust policy analysis and development, which are ongoing efforts, of course. We assert our board governance team, of which we have Scott Tosher here and the Vice Chair Bonneville. They conduct an engagement survey with the board where they identify specific areas of opportunity for further engagement. We're now spending extra effort to encourage in-person attendance of board meetings.

Oops, sorry.

We're at five per year. And this -- and we're also providing opportunity to engage in small-group meetings outside, for example, directors come and meet the certain staff at dinners, et cetera, and ask questions of course.

To provide greater transparency, we're working

with the board governance team to provide small-group primers and activities for board members. For example, we did an IP policy development with various members of the IP and industry subcommittee last year where we went over our IP regulations and answered any questions they might have.

We're still developing those, and we do need to meet with our subcommittee members obviously and answer opportunities to gain knowledge about CIRM and our performance.

Next slide, please.

The finding was that we -- that they sampled sole-source procurement contracts and they complied with our policies. The Fi$Cal system limitations resulted in CIRM inconsistently recording sole-source contracts within the procurement module, and this lead to opportunities to improve contract recording and enhance transparency.

Recommendation was to develop a process which insured sole-source contracts are consistently recorded in Fi$Cal, and as a best practice, in the biannual report to the governance subcommittee and annual report to the governing board, that we should highlight sole-source processes given our reliance on the contracts.

CIRM worked with Fi$Cal, and we, and our finance team identified and implemented a new process whereby sole-source contracts are recorded consistently with Fi$Cal. We as -- shifting to the order recommendations, we as management already disclosed sole-source contracts to the board as a part of our contracts reporting process. We have improved that process based on the recommendations where we are now identifying sole-source contracts so that they can be specifically called out in the contracts report.

Next slide.

Under our loan election policy, which is within the grants administration policy, it contains references to outdated information that could impact the terms of a potential loan.

The recommendation was to ensure that the loan policy is comprehensive and no longer references outdated CIRM regulations to ensure requirements are up to date. Specifically to replace any references to LIBOR in our regulations with an alternative benchmark such as the secured overnight financing rate.

I'd like to point out that we are in compliance with all of our policies here. Under the grants administration policy, we are permitted to use another index if it's stipulated in our notice of award,

and since LIBOR has been replaced, we have been doing that. We are also in the process of reviewing, and we will revise our grants administration policy to make the change for -- from LIBOR to SOFR.

Next slide, please.

We wanted to -- the finding was that our monitoring of grantee compliance with our technology disclosure requirements, as outlined in our IP and revenue sharing requirements, continues to be ad hoc, which can create a risk of non-compliance and negatively impact revenue sharing.

We -- the recommendation was to continue to submit disclosure surveys to our awardees. This is implemented back on -- based on discussions that we had at Moss Adams at '22-'23.

What we did was conducted an initial survey of our clinical level grants to identify any projects associated that may have been licensed or commercialized per our IP regulations. We received responses from over 60 percent of our grantees. We're going to be following up with the 40 percent that didn't respond, and we're going to continue to implement this process triannually and if not try to bring it in more often than that. And we're going to expand to include it in our TRAN awards. We obviously consider this an important feature of CIRM.

Next slide, please.

I think we mentioned the patient support program. We're in the process of developing that, and that has inherent uncertainty related to some financial sustainability related to the patient assistance fund itself, anticipated number of patients served, and the program duration.

The recommendation is that we should conduct regular reporting to the ICOC on the number of patients served and average cost per patient as well as to develop a data-informed evaluation of the patient support program's possible reach and duration.

Reporting on these performance metrics is a requirement in the PSP application process. Specific operational details are part of the business rules that we agreed upon with the successful applicant. This data will also be to the AAWG so they can also provide recommendations for reach and duration.

Next slide, please. The finding is we collect a considerable amount of data, and this is valuable to stem cell and regenerative medicine for researchers. We do not have established a data governance structure or process to collect, compile, or this date, which would help our mission.

The recommendation was to establish a data

governance structure to capitalize on the reporting and facilitate data sharing capabilities.

We're actually in the process of developing a data infrastructure framework for the data, and this will include a full implementation of data sharing and management plans for all of our research awards and the deployment and development of public metadata dashboard for CIRM-funded data. We hope to have that in the near future.

Next slide, please.

As we revived our operations and added new programs, leadership restructured some functions, which impacted workload distribution within and among teams. This elevated work loads for specific groups, which includes likely continuing to evolve along with our various areas of focus.

The recommendation was to incorporate a date driven workload analysis that includes realistic timelines and staffing needs into operational planning to promote right sized work loads among employees.

The CIRM HR team is working with the leadership team and managers on setting expectations regarding timelines and proper staffing levels to make sure that we support our operational requirements and goals. And this is an ongoing process, to make sure

that the science programs have the best support necessary.

Next slide, please.

The finding is that the pace of programmatic and operational changes that CIRM has led to staff challenges in maintaining and understanding priorities, work streams, and awareness of our operations.

Recommendation is to adopt a standardized change management temp eliminate and promote communication and accountability throughout all change processes and also to create a change of deliberate -- a culture of deliberate change management to so ensure new programs and initiatives are effectively, communicated, implemented, and adopted.

The leadership team is reviewing options for change management for consulting in order to identify organizational gaps. We want to implement best practices and training for the staff and improve our transparency so that people do have a better awareness of our operations and our priorities.

Next slide, please.

The finding is that we've historically relied on manual and undocumented HR processes, with minimal employee self-serve options.

The recommendation is to continue to pursue HR

process automation and ban employee self-service through opportunities like the full integration of BambooHR which is an online portal for HR self-service if you will.

The other recommendation was to document key HR procedures in a centrally available location so that it's accessible and consistent for CIRM employees.

The HR team has been reviewing out of date policies and procedures, and they are drafting new policies where there are gaps. Certain policies will be presented for the ICOC for approval. Another example of sort of modern automation is that HR implemented the cal employee connect for HR in 2023. This ties payroll data from the state controller's office and CalLearns for our employee training and professional development as well.

We used to have a manual process, so this is at least a step into the 20th century.

Next slide, please.

Continuing the theme, we had some limited HR policy documentation, which constrained our personnel, and significant hiring needs following Prop 14 resulted in delayed hiring and new employee onboarding and training.

The recommendation was to develop standard operating procedures for hiring and onboarding to

promote a consistent experience. As necessary, differentiate onboarding experience for different employee types.

We hired a new director of HR in '23, and we now have two full-time employees, two RAs. I think that may be three RAs, excuse me. And as part of our refresh of the aforementioned HR policies and procedures, our HR team has standardized and streamlined the hiring and onboarding process. Whereas the process used to take on average four to six months, we're now less than two months. We've also started to pre-start date meetings with our employees -- with our new employees so that the onboarding experience was a little bit smoother, a little bit more consistent, little bit more valuable to our onboarding employees, if I may say.

Next slide, please.

Due to historical compensation practices, pay inequities may have developed between tenured and new employees.

Recommendation is to complete a revision of the compensation policy to prevent future instances of pay inequity.

And in alignment with the new comp policy, please examine existing pay inequities among employees and develop a plan to remedy them as appropriate.

We've reviewed the -- we the HR team has reviewed and revised the comp plan as discussed and salary levels. These updates will be presented to the ICOC for approval to address any gaps or inconsistencies.

Next slide, please.

Many CIRM employees questioned the efficacy and consistent application of the hybrid work policy, or the then-existing hybrid work policy, which may have hindered productivity and employee morale.

The recommendation was to evaluate the work-from-home policy. Employee productivity and determine the degree to which it was applied consistently and supports operational goals.

Consider creating and documenting allowable exceptions to the policy in support of consistent application.

We've done that. We did that at the end of 2023. Our telework policy has been revised to reduce these inconsistencies. We've implemented anchor days -- two anchor days per week where employees are expected to be in the office physically. We feel that the -- feel strongly that these anchor days have provided greater collaboration in staff, increasing any productivity, and any morale issues that may have existed because of the

previous policy.

Next slide, please.

Okay. So that's the end of the 2022-'23 management response. I'll stop here for a second, see if there are any questions with respect to that. If there are none, I'll just move on to the open items for the 2019-2020 performance audit.

MS. COHEN: All right. Thank you very much. I just want to let you know that my phone has died and so I've had to engage just via audio.

Colleagues, do you have any quick questions?

Okay. Let's keep going.

MR. SACASA: Thank you, Chair Cohen.

Next slide, please.

So when they tested the grants management process, we identified three exceptions to the grants administration policy, SOPs, the sample of 20 grants in process.

They recommended adding a requirement for separate individual due dates entered into the GMS, grants management system too, ensure there are no data entry errors and to prevent late reports.

The three exceptions identified were all related to two grants under the education 1 conference grant program. As of 2022, the following improvements

had been made: They created a conference -- we created a conference grant progress report type in the grants database that is approved buy both the grants manager and the science officer; we've also ought mated the contract amendment template to include pre-populated data from the GMS to avoid any errors; and we've updated the grants management SOP with a compliance check evaluation by director of grants management on all amendments to notice of awards.

So we feel we addressed all of the concerns there.

Next slide, please.

We adopted regulations in 2018 outlining the technology disclosure requirements. Sorry, let me take a step back. This is a follow-on from the earlier slide. So, again, this is a similar recommendation. Similar action is what we would have taken.

We talked about that although they found no exceptions, we noted that the ability for CIRM to monitor and determine compliance with the grantees appeared challenging. We talked about that. As I mentioned earlier, we implemented -- back then, we had implemented an IT control. We now have the aforementioned survey for clinical level grants that we're going to expand to TRAN level grants as well.

Next slide, please.

CIRM did not have an effective policy for proactive monitoring and enforcing awardee publication disclosures.

The recommendation was to consider options such as implementing a customer relationship management system to support automated proactive monitoring of awardee publication and press releases.

Publication disclosures are required as part of the awardee reporting requirements and the program teams closely monitor these submissions.

The CIRM policy is to withhold funds in the absence of complete reporting.

So we do have an enforcement mechanism.

And CIRM is evaluating third party solutions to track publications. We have not yet found a suitable solution, but we're continuing our work in this area and hope to have one.

Next slide, please. The finding was that CIRM has historically relied on scientific experts and partners with a connection for the organization for grant review. As a public agency with a mission of cures for all, it is important for CIRM to seek diverse perspectives and expertise to ensure perception and independence in the application review.

The recommendation was to continue to implement recently adopted practices to actively seek more diverse members and to monitor and evaluate the grants working group to promote diversity, backwards, perspectives, et cetera.

CIRM launched an organization-wide DEI initiative and engagement with subject matter experts dedicated to assess and encourage diversity among the GWG. We hired -- in December, our consultants, diversity north.

Did a presentation about the review of the GWG rubrics and some recommendations for improving those, which the team is reviewing and implementing.

As a separate matter, leadership team, taking a step back, we're reviewing our overall DEI strategy for the entire organization, and we are looking at and coming up with a plan moving forward. So we're looking at it from a programmatic perspective and also from an organizational perspective.

Next slide, please.

The record -- the records retention schedule in the state of California expired in 2018. We continue to report -- there was confusion with respect to the record retention requirements, which could -- which can negatively impact our organization's response to

information requests.

Their recommendation was to update its record retention schedule, establish policies and procedures for records management, and consider developing annual trainings to support a better understanding of records requirements.

The state of -- Secretary of State records and information management division provided training to CIRM's staff in March of '22. Certain select CIRM staff completed records management training and certification. And to close it out, we sent an updated records retention schedule to the Secretary of State in September of '22. We received feedback from the Secretary of State. We replied with an updated records retention schedule, and we're waiting to hear back.

Next slide, please.

The use of three document management systems continued to present confusion among CIRM employees, resulting in inconsistent user adoption and records management practice.

Recommendation is to, while implementing a new document management system, to develop an adoption strategy that includes ample communication, policies, and procedures, and accountability practices.

The IT staff of three full-time employees with

contractor partners -- we had a departure of our IT director in '22-'23, so we had to delay the implementation of the new document management system to keep other critical projects, such as the technology build-out of CIRM's headquarter and the state payroll systems in-house on track. We now have a new director of IT as of November of '22.

The CIRM team has now performed a needs assessment, piloted solutions and selected Microsoft office 365 for an integrated document management platform. The associate director has also built an adoption strategy which will be implemented by the end of this calendar year.

Next slide, please.

CIRM made significant improvements to the grants management system in the recent years. However, additional opportunities exist to leverage the GMS to improve operational efficiency and effectiveness.

The recommendation was to continue to identify and pursue these opportunities to enhance the GMS capabilities and to automate processes, centralize data, and enhance access.

Again, with the departure of the director of IT who had actually created the grants management system, we engaged with a consultant to evaluate the

future of the database and perform a needs assessment. The consultant recommended that we keep our in-house grants management system as it is technologically stable and well-integrated into our unique operations. And the consultant also provided a roadmap for evolving the system. Our software development team has begun implementing these recommendations, starting with the system performance improvements and enhanced reporting solutions.

Next slide, please.

Again, we talked about our data here. We host a significant amount of scientific and business data but lack a strategy to integrate information in an optimal way.

The recommendation is to consider implementing an integrated system to better analyze the scientific and business data in support of our mission.

With the new director of IT, we had begun implementing CRM solutions that integrate with our other solutions and programs here. And we will select one by the end of fiscal year '23-'24 with a goal tool complete full implementation, employment, and adoption by the end of fiscal year '24-'25.

Next slide, please.

That's it. Thank you.

DR. THOMAS: Can I just make one comment here, Madam Chair, if I might? I want to give a special shout-out to our VP of operations, Jenn Lewis, who you heard from earlier, who recently promoted to that position. Now very capably oversees grants management, IT, and finance, and a lot of what you just heard is a product of steps that she has taken to address these various issues. So I just wanted to make sure that she's recognized for that.

So thank you, Jenn.

MS. COHEN: It's always good to recognize those that are outstanding and that deserve it.

Does that conclude the presentation?

MR. SACASA: Yes, Chair.

MS. COHEN: Okay. Great.

Let me see. Colleagues, any questions?

I don't see any. I don't see any.

So thank you, again, Mr. Thomas and Mr. Sacasa. I do have one quick question.

This has to do with finding Number 7 that was in the first presentation. I guess it's more of just a statement of idea. I'm just thinking that finding seven in the performance audit part of the agenda, it's a key issue that the SEO should be further discussing. Essentially in this new AI data mined world that we're

living in in data with AI, San Francisco being kind of the home of AI. So just something to think about.

My next question is, we've got a whole bunch of findings. What's the timeline associated with accomplishing those findings?

MR. SACASA: Honestly, we're always trying to resolve the findings sooner rather than later, Chair Cohen. We have some of those that are longer-ranging, like the IT one, for example. Those obviously have a little bit longer timeline.

A lot of the HR ones have already been implemented and addresses, if you will. As you know, these performance audits are every three years so we won't be able to officially close them out until the next one, but we feel that we're moving rapidly to address most of these issues, if not all.

MS. COHEN: All right. Fantastic.

Okay. I don't see any hands up, so we're going to keep moving. We're going to move on to public comment. I want to specifically invite any of the CIRM leadership team members who would like to speak, please do so. And if there's any members of the public, I also want to encourage them to speak during this meeting.

>> For members of the public, if you would like to speak, you may press 1, then 0 on your telephone

keypad. Once again, press 1, 0 on your telephone keypad for members of the public if you wish to speak.

And we have no public comments.

MS. COHEN: All right. Well, great. Let's keep moving forward, then.

Let's go to Item 9, board comment. Let's see if there's any fellow board members that have any comments for the record.

All right. Seeing -- I think people are anxious to move on with the rest of their day. Okay. All right, folks. Well, do not let me be an impediment to you.

I think this convenes our meeting, and this meeting is officially adjourned. Thank you for your service today, everyone. I appreciate you.

(The meeting adjourned.)

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