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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding no.	91251921
Party	Defendant Medpace, Inc.
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Signature	/Paul J. Linden/
Date	04/03/2023
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

* * *

PREMIER RESEARCH INTERNATIONAL, LLC,

Opposer,

vs. OPPOSITION NO. 91251921

MEDPACE, INC.,

Applicant.

* * *

Remote deposition of SEAN RUSSELL, Witness herein, called by the Applicant for cross-examination pursuant to the Rules of Civil Procedure, taken before me, Kathy S. Wysong, a Notary Public in and for the State of Ohio, at 3800 Paramount Parkway, Morrisville, North Carolina, on Thursday, March 30, 2023, at 9:11 a.m.

* * *

APPEARANCES:

On behalf of the Opposer:

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ALSO PRESENT:

Ellen Teplitzky, In-house Counsel
Matthew Lauren, Concierge
Chinyere Woods, Concierge

* * *

SEAN RUSSELL

of lawful age, Witness herein, having been first duly cautioned and sworn, as hereinafter certified, was examined and said as follows:

CROSS-EXAMINATION

BY MR. LINDEN:

Q. Okay. Good morning, Mr. Russell. My name is Paul Linden. I'm an attorney at Ulmer & Berne, Cincinnati, Ohio, and I represent Medpace, Incorporated in a proceeding in front of the Trademark Trial and Appeal Board, Opposition 91251921.

Do you understand that we're here today to depose you with respect to Premier Research versus Medpace, Incorporated in that proceeding?

A. I do.

Q. Okay. And good morning. How are you?

A. I'm good, thanks. How are you?

Q. Good. Mr. Russell, you just took an oath, correct?

A. I did.

Q. What is your understanding of the oath?

A. That I will tell the truth.

Q. Okay. And is there anything at issue today or circumstances here today that would prevent you from doing so?

A. No.

Q. Mr. Russell, you have submitted a declaration in this proceeding, correct?

A. I have.

(Exhibit 1, declaration, was marked for purposes of identification.)

BY MR. LINDEN:

Q. That declaration has been entered into the marked exhibit folder in Exhibit Share. You have access to that declaration. Can you see that declaration through Exhibit Share?

A. I can.

Q. Okay. If you wouldn't mind just taking a minute to scroll through the pages of that declaration and let me know when you've had a chance to, at least at a high level, review it.

A. Yeah, it looks like the one I signed off, and my signature is on the bottom of it.

Q. Okay. And that is -- just to confirm, let's look at page nine. That is your signature there on the signature line for Sean

Russell, correct?

A. It is, yes.

Q. And you executed this declaration on January 31st, 2023, right?

A. That's the date that's on it. I guess so.

Q. Before we get into any questions about the declaration, are you aware of anything in the declaration that you know is an error?

A. I'm not aware of any.

Q. And is there anything in this declaration, before we get into any questions about it, that you no longer think is true?

A. No, there aren't any.

Q. Okay. And you understood when you signed the declaration that you were signing it under penalty of perjury, correct?

A. Yes.

Q. And what is your understanding of signing the document under penalty of perjury?

A. That there's legal consequences for getting it wrong.

Q. Mr. Russell, how did you go about preparing this declaration that you signed for this proceeding?

A. Preparing the declaration? The declaration was prepared by our attorneys. I reviewed it.

Q. Okay. Did you make any changes to the declaration as prepared by your attorneys?

A. I made some edits.

Q. Do you recall what edits you made?

A. No.

Q. Do you recall how many edits you made?

A. No.

Q. And do you recall when you received the declaration prepared by the attorneys prior to signing it?

A. No, I don't.

Q. Was it a matter of days?

A. I don't know.

Q. Okay. I'd like to turn to page two of your declaration, Paragraph 6, if you could. Take a moment to read that, please, and let me know when you're ready.

A. I've read Paragraph 6.

Q. Okay. There's a sentence approximately midway through this paragraph starting on the left-hand column that begins with

the company's booth. Do you see that?

A. Yeah.

Q. This sentence says the company's booth is usually centrally located and can be visited or seen by anyone walking around the conference hall.

A. Yep.

Q. I read that correctly?

A. Yes.

Q. Is there anything in your declaration that verifies where Premier Research's booths are located in the conferences that you're referring to?

A. Not in the declaration, but I believe we gave you some exhibits which showed the booth -- or some of the booths and their placement.

Q. But nothing in your declaration that would inform this statement in Paragraph 6 that we just read?

A. In this nine pages?

Q. No, in your declaration in total, including the exhibits.

A. There may be some information that can be gleaned from the documentation that was

attached to it.

Q. Are you aware of any information that could be used to glean support for this statement?

A. I'd have to go back through the exhibits to see if it's in there or not or if it can be determined from it.

Q. Without doing that, can you tell me if there's any information that would support this statement?

A. I'd have to go back through the exhibits.

Q. Okay. Well, I know that we have the exhibits here that we can look through. I'd be happy to put them into the marked exhibit folder so you can do so. I think that might take a few minutes --

A. Okay.

Q. -- and I'm a little concerned about introducing them each as an exhibit so that then you can look through them. And by concern I mean I think that will take a few minutes. But if we're going to be referencing the exhibits, if you're going to need to look through them in order to answer questions about statements I'm going to ask you about in your declaration, I think it's

worthwhile to do so here at the outset. We talked about a concierge being introduced into the Zoom meeting.

MR. LINDEN: Kathy, I don't know if you have any update on when that's going to happen, but I will endeavor to do this, bring it into the marked exhibit folder so we can give Mr. Russell access to these documents.

BY MR. LINDEN:

Q. Do you happen to have your declaration in front of you, Mr. Russell?

A. I do.

Q. Yes?

A. I do.

Q. Including the exhibits?

A. Yes.

(Off-the-record discussion.)

BY MR. LINDEN:

Q. So, Mr. Russell, we've managed to get the exhibits to your declaration at least pulled into your marked exhibit folder for purposes of this deposition. Each document has a file name that begins with a number, and at least at this point, until they're labeled, we will just refer to them as Exhibit 2 because of the file names.

Do you see the file names and the numbers that go with them?

A. I do.

Q. Okay. So this is Exhibit A through K, which I believe are all the exhibits attached to your declaration. You can click on each one accordingly and pull it up into your viewer, and then when you do so, there will be arrows on the right and left side of your screen where you can toggle through the documents. For instance, if you pull up File Number 02, which is Exhibit A Segment 001, you can use an arrow on the right side of your screen to then get to the next document which is 03, Exhibit A Segment 002. There are twenty files. Some of them are voluminous, as you know, but I think it's worthwhile doing this to the extent that you're going to tell me that there may be support for your statements that isn't noted in your declaration paragraphs in the exhibits but it's not -- it's not cited in the declaration because I do want to know if there is support for the statements. I'm going to ask you this type of question fairly frequently. So we might be stopping so that you can look through your

exhibits and see if you can find anything that supports the statement.

But all that being said, I think we're at least logistically set up for you to do that now. I have no objection to -- if you have a paper copy of your declaration there in front of you to look at it on paper if that's easier for you. I just want to know, quite frankly, the answer to my question.

So all that being said, I think I'll strike whatever question was pending and reboot the question so that we can have a fresh record now that we have the exhibits introduced. So Mr. Russell, the sentence that we were referring to, Paragraph 6, the company's booth is usually centrally located and can be visited or seen by anyone walking around the conference hall, you are familiar with that statement in your declaration, correct?

A. Yes, I am.

Q. Is there anything in your declaration, including the exhibits, that indicates where Premier Research's booths are located in exhibit halls for trade shows and conferences?

A. Okay. I'll need to go through and find them. So just so you're aware, I'm still waiting for the document to download. Okay, it's just coming now. And now I'm waiting for the second page. That's up.

Okay, Mr. Linden, I can answer your question. There are numerous incidents in those attachments of evidence to support the statement in 6 that the booth was centrally located --

Q. Okay.

A. -- and could be seen by anyone walking around the conference hall.

Q. Okay. Let's start with the first instance you've seen.

A. Go to Exhibit F.

Q. Actually, now that I think about it, let me strike that question because we're going to have to introduce these documents and get them labeled as exhibits, so strike the last question about go to the first instance you've seen and we'll just walk through them to make sure they're of record.

So in answering that last question, Mr. Russell, did you have the opportunity to look through all the exhibits attached to your

declaration?

A. I did.

Q. And are they labeled Exhibits A through K?

A. They are.

Q. And did you look at them using Exhibit Share?

A. I did.

Q. Okay. Terrific.

(Exhibit 2, PREMIER000441-446, was marked for purposes of identification.)

BY MR. LINDEN:

Q. Let's go to the document that's labeled 02.

A. You mean Exhibit A Segment 02?

Q. Yeah. So the file -- let me refer to it as the file name. I'm having a hard time -- I'm having a hard time viewing the documents.

MS. GALLAGHER: Yeah, I'm not able to view that one. It says I need to download it.

THE WITNESS: Mine is starting at 03.

MR. LINDEN: Matthew, are you able to pull it up for us to view?

THE CONCIERGE: So I don't know if you guys want this on the record or not.

MR. LINDEN: That's fine.

THE CONCIERGE: So as you guys are going through right now, I am introducing the exhibits and adding the stamps. So if you look all the way at the bottom, I've done Exhibits 1 through 6 as of now. They're just labeled -- they're, like, properly introduced now so it's going to be Exhibit -- they're still Exhibit 1 through 6 in order, it's just not how you had it labeled before but they have the stamps on it as of now.

MR. LINDEN: Okay. So --

THE CONCIERGE: Well, Exhibits 1 through 6 do. I'm still working on it.

THE WITNESS: I can see Exhibit 2 now.

THE CONCIERGE: You're just going to have to refresh, everybody. So just reclick on the marked exhibit folder and you'll be able to see it at the bottom and then once I'm done, it will be back in order.

BY MR. LINDEN:

Q. So then pulling up what's been marked now as Exhibit 2, Mr. Russell, do you know what that document is?

A. It hasn't loaded yet. Okay. It's up now.

Q. Okay. So looking at the document that's been labeled as Exhibit 2 for purposes of this deposition, are you familiar with that document?

A. The content looks familiar.

Q. Are you familiar with it as an exhibit -- at least part of Exhibit A to your declaration that you submitted in this matter?

A. Yeah, this does look familiar. Originally looking at it, it's just familiar. I don't remember where I've seen it.

Q. Okay. Did you, prior to signing your deposition, review the exhibits that were attached to it?

A. I did.

Q. Okay. So just looking at it on screen, you see the cover page says Exhibit A, Part 1, correct?

A. Yeah.

Q. So this is Exhibit A, Part 1 to your declaration that you submitted in the opposition proceeding that we're here to depose you about?

A. It is.

(Exhibit 3, PREMIER000447-452, was marked for purposes of identification.)

BY MR. LINDEN:

Q. Okay. I think if you use the arrows on the right-hand side of your screen, you should be able to toggle to the next one, which will be Exhibit 3. Are you able to do that?

A. I'm waiting for it to load. It came up as Exhibit A, Part 2.

Q. Okay. And it's in the lower right-hand corner, the first page at least, labeled Exhibit 0003. Do you see that?

A. Yep.

Q. Do you recognize this document?

A. Yeah.

Q. And did you review this document prior to signing your declaration?

A. Yeah.

Q. And is this document part of -- at least the second part of Exhibit A to your declaration?

A. Yeah, it's numbered as such.

Q. Okay. Let's go to the next one.

(Exhibit 4, PREMIER000447-452, was marked for purposes of identification.)

BY MR. LINDEN:

Q. Toggle to the right so you can see what's been labeled as Exhibit 4 in the lower right-hand corner. Do you see that?

A. Still waiting for it to load.

Q. Okay.

A. Yep, Exhibit 4.

Q. Okay. And do you recognize this document as --

A. As -- is there a question, Mr. Linden?

Q. No. No, I'm trying to figure this out. So it looks like it's the same document as Exhibit 3, unless I'm mistaken.

MS. GALLAGHER: That's what I can see as well.

MR. LINDEN: Yeah. Okay. I think that one has been marked twice, Matthew, but I think we'll just go with it at this point since you're probably well into the teens on marking exhibits.

BY MR. LINDEN:

Q. Exhibit 4, I'll just put this on the record, looks like also Exhibit A, Part 2 which has also been marked Exhibit 3. It's labeled the

same file name, which you can see at the top of the screen.

(Exhibit 5, PREMIER000453-460, was marked for purposes of identification.)

BY MR. LINDEN:

Q. So let's move to what's been marked as Exhibit 5, Mr. Russell. Okay. Document marked as Exhibit 5, hopefully you can access that, let me know when it's loaded.

A. Yeah, it's loaded.

Q. Okay. And do you recognize this document as Exhibit A, Part 3 to your declaration?

A. Yeah.

Q. And did you review this document prior to signing your declaration?

A. Yes.

(Exhibit 6, PREMIER000461-465, was marked for purposes of identification.)

BY MR. LINDEN:

Q. Okay. Let's go to the next document, Exhibit 6. Tell me when it's loaded, please.

A. I've got it. Exhibit A, Part 4, Exhibit 6.

Q. Okay. Do you recognize this document as Part 4 of Exhibit A to your declaration?

A. I do.
Q. And did you review this document prior to signing your declaration?
A. I did.
(Exhibit 7, PREMIER000466-476, was marked for purposes of identification.)
BY MR. LINDEN:
Q. Okay. Are you able to toggle now over to a document marked Exhibit 7? Are you able to do that, and if so, please tell me when it's loaded?
A. I toggled to 5 and it did nothing.
MS. GALLAGHER: Sean, you might have to refresh the full case file site. That's what I had to do to get it to load.
THE WITNESS: Oh, he must have moved those since I started looking at them. So I'm going to Exhibit 7?
BY MR. LINDEN:
Q. Correct.
A. 007-06?
Q. Correct.
A. Okay, I've got it open. It says Exhibit A, Part 5, and Exhibit 0007.
Q. Do you recognize this as Part 5 to

Exhibit A of your declaration?

A. Yeah, it's our material.

Q. Okay. Did you review this document prior to signing your declaration?

A. Yes.

Q. Okay.

(Exhibit 8, PREMIER000477-483, was marked for purposes of identification.)

BY MR. LINDEN:

Q. The next one, Exhibit 8, please let me know when it's loaded for you.

A. Okay, it's up. It's Exhibit A, Part 6, 08.

Q. And do you recognize it as Part 6 to Exhibit A of your declaration?

A. Yes.

Q. And did you review this before signing your declaration?

A. I did.

(Exhibit 9, PREMIER000484-489, was marked for purposes of identification.)

BY MR. LINDEN:

Q. Go to Exhibit 9. Please let me know when it's loaded for you.

A. Okay, it's up. Exhibit A, Part 7,

009.

Q. Okay. It says Exhibit A, Part 7, as you said. Do you recognize this as Part 7 to Exhibit A of your declaration?

A. Yes.

Q. And did you review Part 7 of Exhibit A to your declaration before signing your declaration?

A. I did.

(Exhibit 10, PREMIER000490-496, was marked for purposes of identification.)

BY MR. LINDEN:

Q. Keep going. The next one is Exhibit 10.

A. Yeah, it's up.

Q. It says on the first page Exhibit A, Part 8. Do you recognize this document?

A. Yes, I do.

Q. Is it Part 8 to Exhibit A of your declaration?

A. It is.

Q. And did you review this document prior to signing your declaration?

A. I did.

Q. All right. Before we move on to the

next one, I want to draw your attention back to your declaration, which is Exhibit 1. And in particular I'd like to ask you about Paragraph 8, so if you could perhaps read Paragraph 8 and let me know when you've had a chance to do that.

A. This is from the affidavit?

Q. Correct. So if you go back to Exhibit 1 for this deposition, it's your declaration that you signed. I'm going to ask you about Paragraph 8 which begins on the bottom of page two and carries over to page three.

A. Got it. Yeah, I've read it.

Q. Okay. The last sentence of Paragraph 8 says Exhibit A is a true and correct copy of the website at premier-research.com, correct?

A. It's not a true and correct copy of the website. It's got elements of the website.

Q. Okay. What do you mean by that, Mr. Russell?

A. Well, the website is enormous. If I were to print out every page that's on the website, it would be the size of a document that we wouldn't be looking at on the screen here.

Q. Okay. So we just marched through several parts to Exhibit A to your declaration.

Your declaration says it's a true and correct copy of the website at Premier Research. Did you recognize the documents of Exhibit A to be copies of portions of your website at premier-research.com?

A. Yeah, those are pages that were used on the website. I don't know for sure if they're still up.

Q. Okay. And I'm going to ask you to go back to Exhibit 2, which should be Part 1 of Exhibit A. I'm currently trying to do so and waiting for it to load. You might have to wait a little bit too.

A. So give me the number to go back to again.

Q. Exhibit 2, 002.

A. Yeah, I'm there.

Q. It's loaded for you then?

A. Yes.

Q. Okay. So let me scroll down to page two of that document, not the cover page but the first document with any sort of images and text on it.

A. Yeah.

Q. So according to your declaration,

this document is pulled from your website, correct?

A. Yeah.

Q. And if you look in the top right-hand corner, you should see text that begins screenshot-premier-research.com. Do you see that?

A. The top right-hand corner. I'm seeing nimbus screenshot app print.

Q. Right. And just below that to the right there's a right justified paragraph of text that begins screenshot-premier-research.com.

A. I don't see that. Under nimbus screenshot app print, I've got a blue box with read more in it. Am I on the wrong page?

Q. No, I think you're on the right page. It's very small text.

MR. LINDEN: I don't know, Matthew, can you zoom in on that so we can --

THE WITNESS: So let me make sure I'm on the right page. I've got a title page and then the next page says -- I've got biometrics screen panel on a visual panel. Is that the one?

BY MR. LINDEN:

Q. That is the one.

A. I've gone down to the second page.

All right. So, yes, I do see screenshot-premier-research.com-2021-05.06.

Q. Okay. So does that indicate to you what date this information was pulled from the website?

A. It looks like it was pulled from the website on 2021, May 6th I guess; but I don't know who pulled that and what format they were using.

Q. Okay. And if you could then, Mr. Russell, scroll down to page four of the pdf.

A. Page four.

Q. It is --

A. What does it look like?

Q. I'll give you a document number. So if you remember from our deposition for discovery in this matter, all these pages are, I believe, should be anyway, marked in the lower right-hand corner with a particular number. If you scroll to the bottom of any page, you should see a number that begins Premier and then a series of six or seven digits. For instance, the document -- the page that I want you to refer to has PREMIER000444 on it in the lower right-hand corner.

A. Okay. I'm there.

Q. So that document at the top has a

blue box that says biostatistics. Do you see that?

A. Yes.

Q. Okay. And again I'm going to ask you about the label at the top right-hand corner, it says screenshot-premier-research followed by what appears to be a date. Do you see that?

A. I do.

Q. And what date was this information pulled from Premier's website?

A. 2021, May 6th.

Q. I'm sorry, what did you say?

A. 2021, May 6th. But I'm seeing another date underneath that says -- it looks like it says July 5th, 2021. So I can't tell which one is referencing when the screenshot was made.

Q. Right. Let's make sure we're looking at the right page here. If you go in -- it's a little bit confusing because the page break isn't terribly large in these documents on the viewer, but there's a document that in the lower right-hand corner of the document is labeled PREMIER000444.

A. Yep.

Q. And then I need you to scroll back up

to the top of that document. And then asking you again, the label on it, it says screenshot-premier-research.com and it gives a date.

A. Well, there's two dates in that paragraph. The one right after the screenshot-premier-research.com says 2021, May 6th. And then the end of the paragraph there's a date that says July 5th or -- yeah, July 5th, 2021.

Q. Right. And then if you look over on the far left-hand top corner of that document, you might see 5/7/2021. Do you see that?

A. No. Over on the top?

Q. Top left --

A. Oh, yes, I do.

Q. -- corner.

A. Oh, yeah.

Q. I'll submit to you then the date at the very bottom of this label for this document is not in the standard American way of doing dates, it's actually day, then month, then year; is that right?

A. I can't tell.

Q. So are you familiar, just looking at

this document then, when it was pulled from Premier's website?

A. Not at all.

Q. I'm sorry?

A. It was pulled in 2021 by the looks of that.

Q. Okay.

A. I can't tell whether it was done in June or July from those dates.

Q. Okay. Now, I -- we have -- this is a voluminous exhibit, Mr. Russell. We've just walked through several parts of it. I don't necessarily want to go through this exercise for the entire exhibit; but generally speaking, were all the copies included in Exhibit A of Premier Research's website pulled from 2021, to your knowledge?

A. I don't know. I didn't pay attention to that going through it.

Q. Are you aware of when Premier Research first used built for Biotech on its website premier-research.com?

A. 2017, 2018.

Q. On its website?

A. Yeah.

Q. Do you have any evidence in your declaration that shows Premier Research using built for Biotech on its website in 2017?

A. I don't in the documentation that we're reviewing today.

Q. And is that answer based on the review of the exhibits that you just conducted for purposes of this deposition when you were answering a question earlier today?

A. Could you be more detailed with the question? Is what? What are you trying to get to?

Q. Well, you said that there's no information in your declaration that shows use of built for Biotech on premier-research.com in 2017, correct?

A. I didn't say that there was no use of built for Biotech on premier-research.com in 2017.

Q. There's no information in your declaration that shows use of built for Biotech on premier-research.com in 2017, correct?

A. That's correct.

Q. Okay. And there's no information in your declaration that shows use of built for Biotech on premier-research.com in 2018, correct?

A. I would need to go back through the conference images that are in there because some of them are going back quite a ways.

Q. Well, I'm not --

A. If you're only looking at the website, then I'm not seeing it on the pages that we just looked at.

Q. Right. I am only looking at it on the website. That is the nature of my question. I'm looking at whether there's anything in Exhibit A that shows use of built for Biotech on premier-research.com in 2018?

A. Well, I haven't seen anything yet, what we're going through here.

Q. Well, so Exhibit A are true and correct copies of the website at premier-research.com with the caveat that you said it's not the entire website, it's just portions of it you testified earlier. So if you need time to look through Exhibit A again and check all the dates as we have been doing, I'll be happy to give you time to do that. It's very important for this case to determine whether there's any use shown in your declaration of built for Biotech on Premier Research's website prior to June 26th, 2019. So I

would be happy to give you time to look at Exhibit A if you need to to confirm an answer to a question -- that question, but if you just know the answer to it, you can tell me.

A. So we were using it on the website, but it looks like the screenshots have been pulled from 2021 and they don't -- didn't pull screenshots that have built for Biotech on it. So to answer your question strictly to the letter in terms of the attachments to this declaration, it does not appear that we attached the evidence of the use of built for Biotech on our website in the exhibits.

Q. Okay. So I know that we haven't actually asked a lot of questions and answered a lot of questions but we have been on the record for about an hour. I'd like to take a quick break. Five minutes is fine for me. Is that enough for you?

A. Yeah, sure.

MR. LINDEN: Okay. Can we take five minutes, please?

(Pause in proceedings.)

BY MR. LINDEN:

Q. Okay. Back on the record here,

Mr. Russell, after a fifteen-minute break. Prior to the break you testified that the first time Premier Research used built for Biotech on its website premier-research.com was sometime in 2017. What is that -- what is your understanding of that based on?

A. I would have been involved in the content that -- and the design of the website back then, and if we were active with a trademark, we would have used it there, especially since we started using it in front of customers. I'm not sure if we've got an archive of the content of the website going back that far. We do have an archive of a lot of our material going back to 2018, 2017 I think, but I don't think we've got one on the website.

Q. Do you recall being deposed for this proceeding before today?

A. By you, yes.

Q. Okay. And that deposition, I'll let you know, was October 25th, 2022. Is that about when you think it happened?

A. I have no clue.

Q. But you do recall being deposed by me for purposes of this proceeding?

A. Yeah. It was a very good experience.
Q. Between that deposition and today, were you able to check any archives of premier-research.com's website?
A. No, I did not.
Q. Do you recall being asked during that deposition when Premier Research first used built for Biotech on its premier-research.com website?
A. No, I don't.
Q. Would you be surprised to know that I asked you the question when did Premier Research first use built for Biotech on any of those domain websites and at that time we just marched through the various websites that Premier Research used?
A. I don't remember that specific dialogue.
Q. Do you recall what your answer to that question was?
A. I don't remember the dialogue.
Q. Would you be surprised to find out that your answer was I don't know?
A. Okay.
Q. Would you be surprised to find out that was your answer during the deposition, I don't know?

A. I would not be surprised that that was the answer.

Q. And you just told me that you didn't check any archives between then and now so I'm just wondering what have you done since the previous deposition to now tell me during today's deposition that the first time Premier Research used built for Biotech on its website was 2017?

A. Because I'm aware that we first started using it in 2017 with customers, and we had a different website structure back then. I was involved in it. We would not have had a website that didn't reflect the current branding so it's reasonable to assume that the Biotech trademark was being used on the website back then.

Q. So your testimony that it was used in 2017 is then based on an assumption; is that right?

A. It's based on my understanding of how we operate and my involvement in the production of the website content and design, and an assumption that we would have been using our primary market positioning on our website at that time.

Q. It's certainly not based on any documentation that has been submitted in this

proceeding, correct?

A. None that I've seen.

Q. And it's certainly not based on any documentation that you submitted with your declaration in Exhibits A through K, correct?

A. I might need to look back at the latter ones. I might need to look at the latter ones again. I was looking for something different the last time I went through.

Q. Yeah, sure, we can do that. If you want to take some time to do that. I don't know if it's easier for you to do it through Exhibit Share or leaf through the physical declaration that you have in front of you. Either way is fine. We can locate it on the Exhibit Share documents which have been entered into the record, so whichever is easier for you, Mr. Russell, but I am looking for any documentation that supports the statement that you just testified to that Premier Research first started using built for Biotech on its website in 2017. And actually while you're doing that, because my next question is going to be are there any documents in your declaration that shows the use of built for Biotech by Premier Research on its website prior to June 26th, 2019.

A. What dates in 2019? Mr. Linden. You're on mute.

Q. Sorry about that. June 26th, 2019.

A. Okay. So I've plenty of uses of built for Biotech prior to June 26th, 2019. I've got an exhibit -- a photograph of an exhibit here with our website up on it with built for Biotech on it but I'm trying to find a date for that.

Q. So is that in your declaration somewhere or the exhibits thereto?

A. Yeah, this is the declaration I pulled out of Exhibit G. It looks like it was in with the files from 2017, but --

Q. So let me just be clear. I really need you just to look at your declaration and the exhibits because that's what we're -- that's what we've noticed you for deposition today; you put in a declaration with the exhibits attached. So if you have something for me that's in your declaration with the exhibits attached, A through K, that shows use on Premier Research's website of built for Biotech prior to June 26th, 2019, that's what I want you to show me. So let's see it.

A. So I'm only showing -- I'm only looking through the exhibits that were attached to

the exhibit.

Q. Okay. Great.

A. And what I've got is what looks like a TV screen running our website at a trade show. And the point I was trying to make is that while that one is not dated, I'm looking at the other images to see if it's part of another package that was dated. It was mixed in with the 2017 pictures.

Q. Well, which document are you referring to so I can look at what you're referring to? And it might be easier, while you could tell me the exhibit first, but you can also reference it by the number in the lower right-hand corner that we've talked about that begins Premier and then has a list of digits.

A. I'm in Premier -- I'm in Exhibit G, Part 1.

Q. Okay.

A. And go to PREMIER000154.

Q. Okay. I see that, sir. So what are you saying that PREMIER000154 shows?

A. It shows a TV screen with website content running on it, and the website content is showing built for Biotech, among other things.

Q. What is the basis for your understanding that that is showing Premier Research's website?

A. Because I know how we work.

Q. And is that included in your declaration anywhere?

A. Is what included?

Q. The testimony regarding what is being shown on screens on your trade show website.

A. What's being shown on screens? I think the declaration said that we had presented examples of the evidence of built for Biotech being on our website.

Q. Correct, in Exhibit A. If we go back to Paragraph 8, you said Exhibit A, which is a true and correct copy of the website at premier-research.com.

A. Yeah, but I think that's evidence that we were using built for Biotech on our website which has been shown on this exhibit conference, and it appears to be -- I don't have a document date for when that ran yet. It's before June 3rd, 2019 in this list of documents here. I need to do more research if you need something more precise than that.

Q. What else is shown on that screen during trade shows?

A. What?

Q. What else would Premier Research show on screens at its trade show exhibits?

A. Look at 00160 and you'll see another screen on that same screen.

Q. But generally speaking, since you testified that you know how it works, what is running on the screens during trade shows at Premier Research's display?

A. A promo loop.

Q. And what does that mean, a promo loop?

A. It's the -- either a section of the website or the graphics from the website collected into a loop like you do a slideshow, which are photographs.

Q. And has Premier Research -- well, no, strike that.

Have you in your declaration shown any images from this promo loop beyond what's just in these screenshots?

A. I think there's bits and pieces of them in the other conferences -- conference

images. Yeah, there's another one there in blue.

Q. What -- what indicators from what you're seeing on the screen -- TV screen shown in PREMIER000160 indicates to you that it is from a website?

A. Well, I know the content.

Q. So it's based entirely on your personal knowledge; is that correct?

A. It's based entirely on my expert knowledge.

Q. I've asked you if it's based on your personal knowledge?

A. Well, yes.

Q. So when I deposed you in October and asked you when is the first time Premier Research used built for Biotech on its website, premier-research.com, and there were a number of other websites listed before that question, you said I don't know.

A. Yes, I don't know when was the first time that we used it on our website, but I'm showing here evidence of it being used on the website fairly early.

Q. And then I asked you, well, how would you find out, and you testified I would have to

check the archives.

A. Uh-huh.

Q. Okay. And I asked you here today if you did check the archives, correct? I asked you that earlier, didn't I --

A. Yes.

Q. -- have you checked the archives? And you testified that you didn't have any archives to check, correct?

A. I was -- I don't think I said that. I think I said that I didn't know if we had archives going back that far.

Q. So you're saying that sitting here today, you still don't know if you have archives going back that far, correct?

A. For the website.

Q. Correct. So that's -- I'm sorry, we may have talked over each other. I just want to make sure. So sitting here today, you don't know if Premier Research has archives of its website going back beyond June 26th, 2019?

A. Yeah, I can't say that for certainty without checking.

Q. And do you recall during your deposition that we did previously in October

looking at documents such as or similar to the one that we're looking at currently, PREMIER000160?

A. Yep.

Q. And at the time you were deposed previously in this proceeding, did you not think to recall that these screens are what you're telling me now is showing website content from as early as 2017?

A. What was the question you were asking at the time?

Q. During the deposition that you and I did back in October of 2022 when you were asked when is the first time Premier Research ever used built for Biotech on its website, did you not think about these images on this screen as evidence of when Premier Research may have used built for Biotech on its website?

A. No, the question was specifically about the website. That's what I was focused on at the time.

Q. But what you're telling me here is that these images and those like them, similar to PREMIER000160, are in fact images of Premier Research's website, correct?

A. Yes.

Q. And that understanding that these are images of Premier Research's website is based on your personal knowledge, correct?

A. Yes.

Q. And is it based on anything else?

A. Right now the personal knowledge.

Q. Okay. Back probably about an hour ago we were talking about Paragraph 6 and instances in your exhibits that demonstrate where Premier Research's booths are set up at trade shows. And I'll reboot the whole -- the whole series of questions here so we don't have to just go on the memory of what was happening an hour ago. But let me have you again look at Paragraph 6.

A. It's in the affidavit, right?

Q. Yeah, so that would be Exhibit 1, Paragraph 6, and it's on page two.

A. Yeah, I've got it.

Q. Okay. And we were focusing on the sentence in the middle of the paragraph, the company's booth is usually centrally located and can be visited or seen by anyone walking around the conference hall.

A. Yeah.

Q. Do you see that?
A. Yes.
Q. Now, we went through all the exhibits, you took some time to review your exhibits, and you said you found several instances that support this statement and we've never gotten back to what those instances are. So I'd like to get back to what those instances are. Can you direct me to the first instance that you are -- that you believe supports the statement that we just read?
A. I can. I'm just missing one more. Let me look here. Bear with me a second. So the statement that centrally located, can be visited or seen by anyone walking around the conference hall.
Okay. If you go to -- I think I'm still in -- I think I'm still in Exhibit D -- or G. G.
Q. Okay.
A. Looking for PREMIER000154 -- no, sorry, 160.
Q. Okay. I'm there.
A. Do you see the number up in the top right-hand corner, 41, in the image itself?

Q. Yeah, let me -- I'm looking at a paper copy. Let me get to the Exhibit Share version. I might have a cut-off image.

A. It looks like that.

Q. Okay. I'm looking at it now on screen. And you're directing me to a number in the top right-hand corner; is that right?

A. Yeah, 41.

Q. 41. Okay. Yeah, I do see that.

A. Okay. That refers to 4100 because I've seen another picture here of a different angle that says 4100. 4100 is the row number for the conference hall where Premier is located. I think I was at that one, but they're all kind of similar. If you're in Row 4000, you're in a pretty centrally located position. To address the visibility, go to --

Q. Well, I'm sorry, let me ask you about that. So your testimony is if you're in Row 4100, you're pretty centrally located. Is that based on your personal recollection?

A. The 4100 rows are pretty centrally located in all conference halls.

Q. Well, I mean, not all conference centers are laid out the same, correct?

A. 4100 is going to be fairly well centered. It's likely to be you come in the front doors and turn left and you get 4100. They run from one, two, up to ten or more.

Q. Okay. But there's nothing in your declaration that gives me a layout of any conference hall that any trade show has ever been held in, right?

A. There's plenty of that online if you want to research it, but we didn't include it for you.

Q. So that's a yes, there is nothing in your declaration that shows me the layout of any conference hall for any trade show?

A. We didn't include any layouts for any conference halls.

Q. Okay. Now, you were about to tell me about visibility and point me to some other --

A. Yeah, look at PREMIER000684.

Q. And is this in G as well?

A. I think all of this is coming from G, yeah.

Q. Okay.

A. Do you see the circular banner at the top of the exhibit that's lit up?

Q. Yes.
A. Did you say yes?
Q. Yes.
A. That's there so the exhibit can be seen right around the hallway. It hangs from the ceiling and it's lit marking the location of Premier's exhibit. So that supports the statement can be seen by anyone walking around the conference hall.
If you go to 748.
Q. Are we still in Exhibit G?
A. I can't really tell. It should look like this. Does it look like this?
MS. GALLAGHER: Paul, it's in Exhibit 18, Exhibit G, Part 2.
MR. LINDEN: Thank you.
BY MR. LINDEN:
Q. Mr. Russell, give me that number again.
A. 748.
Q. Okay.
A. So if you look at the layout of the booth, you can see that it's an island -- central island. There's other exhibitors all around it. So it's centrally located. It's got a tower on it

that goes up above. You can see PRA in the red next to it. It goes above there, that exhibit booth. And if you look at the front where the lights are burnt in, you can see built for Biotech in the blue.

Do you want me to keep going with the rest of them?

Q. Well, if you have other instances. Let's go back to centrally located. If you had other instances that you would like to reference as far as centrally located, yes, let's go through them.

A. Go to -- I can't find the number -- okay. If you go back to 748. Let's see if I can get you there. The pages aren't numbered. So -- are you at 748?

Q. Yes.

A. Okay. Just go down one page and then the next page should look like this.

Q. Is it 688? It's difficult to read, it's black lettering or numbering --

A. I can't see anything.

Q. -- on the image itself.

A. I can't see any numbering on it.

MS. GALLAGHER: I have it as 785.

THE WITNESS: Is this what you're looking at?

MS. GALLAGHER: That is what I am looking at, yes.

THE WITNESS: Okay.

MS. GALLAGHER: It looks like it has Premier 7 -- it could be a 6 but I think it's an 8. Yeah. No, 765.

BY MR. LINDEN:

Q. Oh, yeah, I'm there.

A. I still can't find the numbers on it. You'll see that booth is an island. It's got traffic all around it, very centrally located, and you can see the banner at the top is lit up and it's above the height of the other exhibitors to attract attention for the logo, and you see built for Biotech is on the main stand underneath.

Q. Okay. Any others?

A. There are more but I think you've got the best of them.

Q. So then you're testifying that what we have just gone through are the best examples of the company's booth being centrally located at a trade show and being able to be seen by people walking around the trade show; is that right?

A. I think it adequately supports the statement that you are challenging in Paragraph 6 that the company's booth is centrally -- usually centrally located and can be visited or seen by anyone walking around the conference hall.

Q. But these are the best examples; is that right?

A. They're the best examples that I pulled out of this document here, but we didn't talk about this one. That's a pretty good one too.

Q. Can you find a number on that one, Mr. Russell?

A. It is 684. June 20 of 2017.

Q. And are we in Exhibit G?

A. In Exhibit G? No, J.

Q. Okay.

A. Centrally located, very high, big logo up on top so it's visible over the others.

If you advance in the same section to the next page, you'll see a centrally located booth with a very high banner that's visible.

And skip the next two and you'll come to another booth with a very high banner but go to the next one, it's 766, and you'll see the aisle

number there is 4000, another centrally located --

Q. I see it. We're in Exhibit J still.

A. So I think that's sufficient evidence to support that statement in 6.

Q. Okay. Let's stay in Paragraph 6 then, Mr. Russell. The last sentence of that paragraph, employees of Premier Research, as well as its competitors, walk around at these industry events to see what competitors, clients, or innovators in the industry are marketing and discussing. Do you see that?

A. Yeah.

Q. And I read that correctly?

A. Yeah.

Q. Now, Mr. Russell, you don't have any personal knowledge regarding what any specific employee who works for a competitor of Premier Research has seen at a trade show, correct?

A. At any trade show -- I've had conversations with Medpace employees at our exhibit booth so I'm aware they're looking at our booth.

Q. Okay. And do you recall specifically when one of those conversations would have happened?

A. Probably could eventually dig it out by looking at some of the photographs. I have a recollection that there was somebody there taking pictures, but I do not remember. It was quite a bit a while ago.

Q. And do you remember the name of any specific individuals at Medpace that you talked to at a trade show at your booth?

A. No. I'm not very good at names I'm afraid. I do remember it was a sales guy.

Q. I'm sorry, a sales what?

A. A sales guy.

Q. Beyond the conversations that you've had with Medpace employees, do you have any personal knowledge of what employees of your competitors do or have seen at trade shows?

A. I don't see how I can answer that question.

Q. Okay. Mr. Russell, I'd like you to turn to Exhibit B of your declaration.

A. Yep.

Q. Take whatever time you need to look it over at a high level and I'll ask you some questions about it.

A. This is the Pivotal Financial

Consulting document.

Q. Yes, just Exhibit B to your declaration. It begins with PREMIER000885.

A. Okay. Some of the text is not legible but I've made it through.

Q. I agree with you, it's difficult to read, especially when it's printed out. It might be easier to read on screen, at least I found it is sometimes, and you can zoom in if you need to, but before you get around to doing that, let me ask you some questions. What is Pivotal Financial Consulting?

A. It's a company that Jason Monteleone set up. It's his personal consulting company. And Jason Monteleone was the CEO of Clinipace, which is mentioned throughout in here, and he was under contract, he wasn't actually an employee, as the CEO.

Q. And isn't it in fact Mr. Monteleone who is authoring this article?

A. Yes.

Q. Are there any statements from Premier Research employees in this article?

A. None that we would have provided, and I didn't read any quotes from us. Did I miss

them?

Q. I don't believe so, no. Are there any statements from Medpace employees in this -- in this article?

A. I didn't see any.

Q. I don't want to interrupt you. Are you looking for statements from Medpace employees or is that your answer?

A. I didn't see any. I don't think he's got quotes from anybody in here. It looks like it's a white paper.

Q. Okay. Let's move on to Exhibit C. Exhibit C of your declaration begins with PREMIER000936 in the lower right-hand corner.

A. 936?

Q. Correct.

A. Yes.

Q. Okay. And what do you recognize this document as?

A. It looks like a list from an investigator site of the companies that they worked with.

Q. And this is a website for an organization called Upstate Clinical Research Associates, correct?

A. Yes.
Q. Are there any statements from Premier Research employees in Exhibit C?
A. No.
Q. And what about Medpace, any statements from Medpace employees in Exhibit C?
A. No.
Q. Okay. Mr. Russell, let's walk down to Paragraph 12 of your declaration, so Exhibit 1, Paragraph 12, page three.
A. Yeah, generally.
Q. Correct. So generally, the identity of other companies participating in a bid defense is kept confidential, although it is not uncommon for us to learn of the companies through a careless comment or e-mail exchange. Do you see that?
A. I do.
Q. I read that right? I read that correctly?
A. Yes.
Q. Did you include in your declaration any examples of careless comments or e-mail exchanges?
A. No.

Q. Okay. Paragraph 13, when Premier Research learns of a competitor's identity, we make a note of that for opposition research. Do you see that?

A. I do.

Q. I read it correctly?

A. Yeah.

Q. Did you include in your declaration any notes kept of competitors' identities for purpose of oppositional research?

A. We have the notes. We didn't include them in the declaration.

Q. And in Paragraph 14, rather than me reading it to you, it's a little bit longer, why don't you read it and let me know when you're done.

A. Yeah, I read it.

Q. Okay. Have you included in your declaration any evidence to demonstrate that there are over thirty times since 2017 when Medpace and Premier Research directly competed in a bid defense?

A. We have the evidence. We didn't include it.

Q. Approximately how many bid defenses

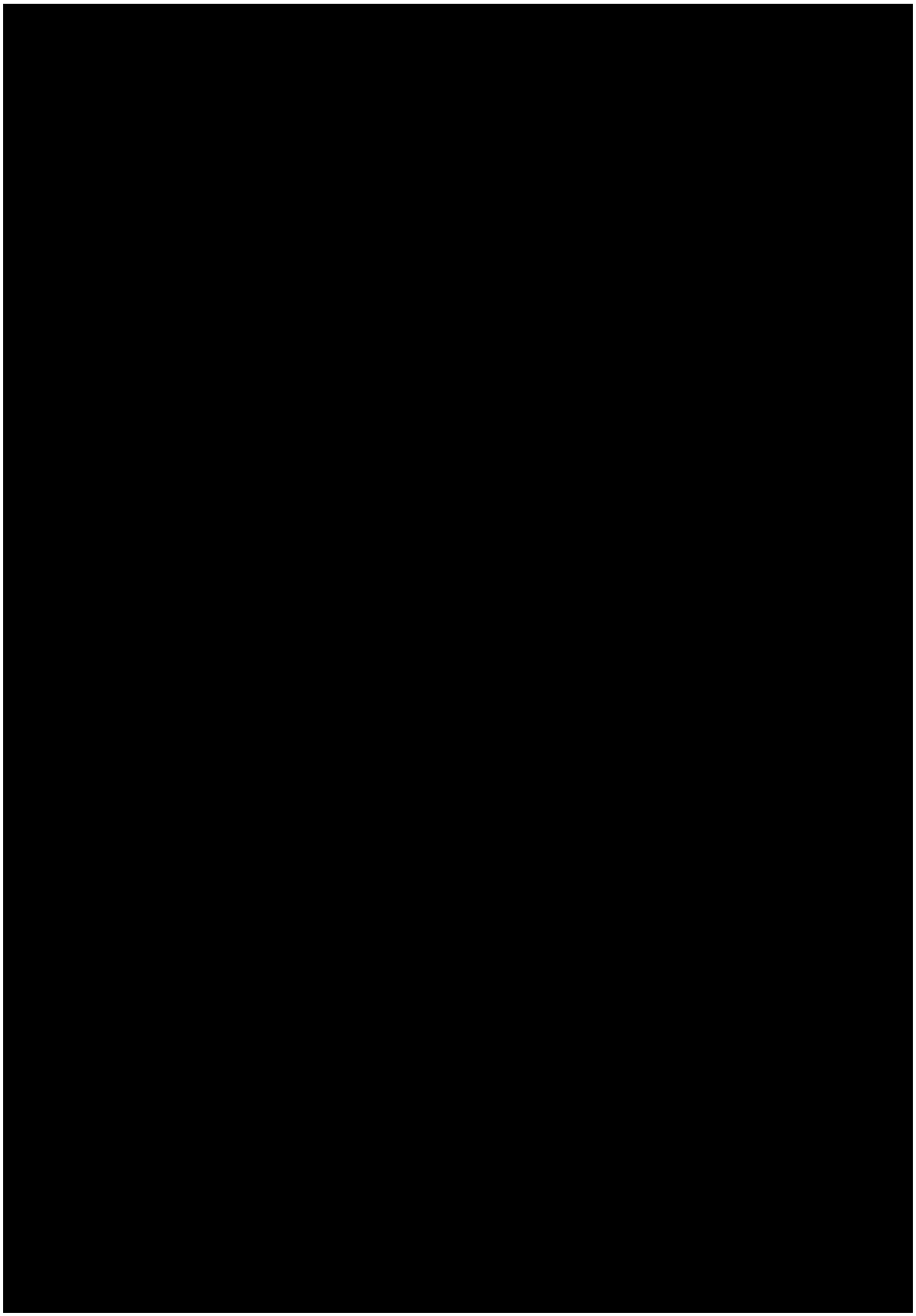
has Premier Research done since 2017?

A. Whoa. Roughly a thousand. Very roughly.

MR. LINDEN: I'm going to mark the next few questions until I tell you otherwise, Kathy, attorneys' eyes only, please.

(See that testimony designated as confidential/attorneys' eyes only beginning on page sixty.)

[redacted]



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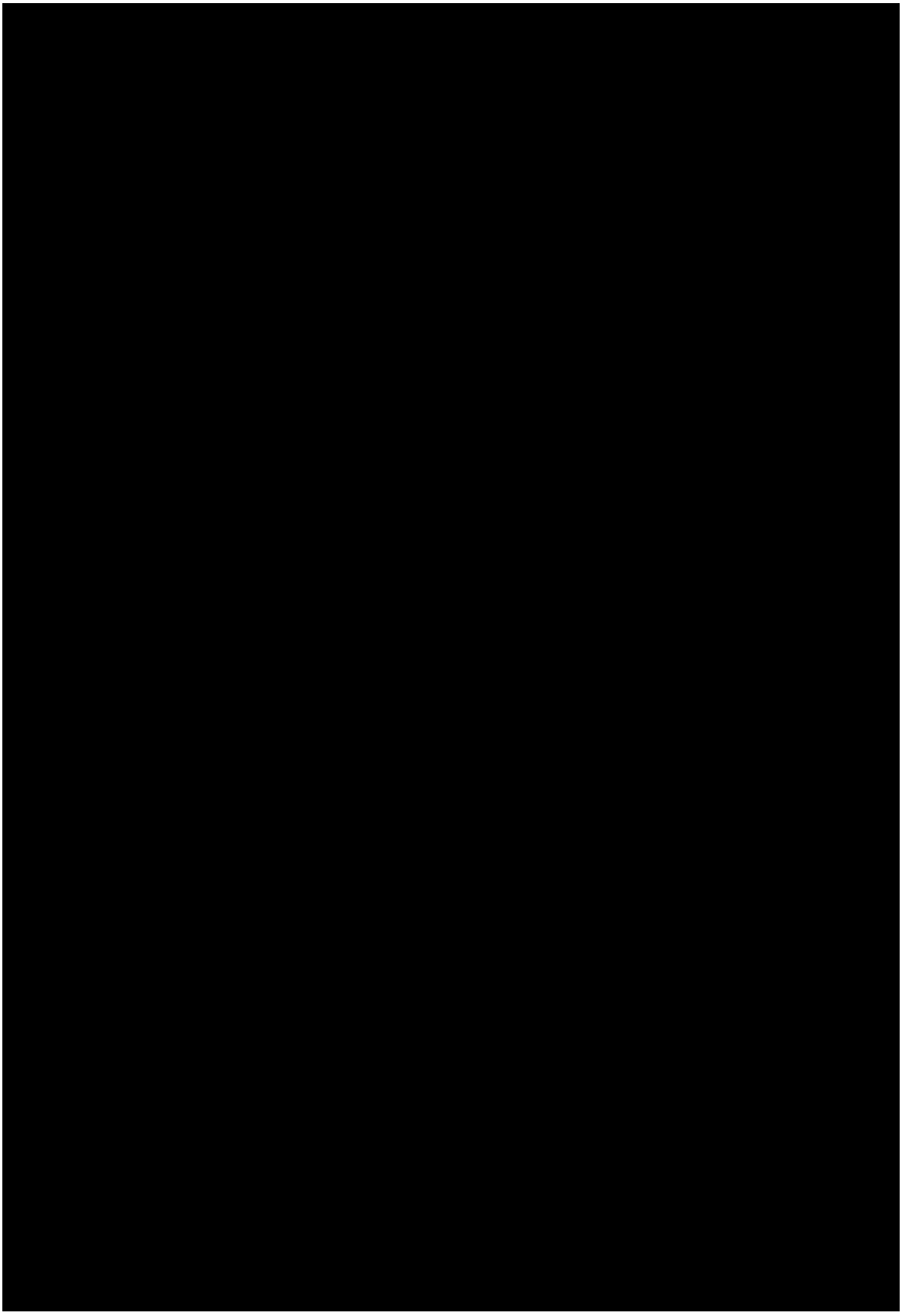


MR. LINDEN: All right, Kathy, that's going to end the portion of the transcript I'm going to currently designate as attorneys' eyes only. I think it's also a good time for a break. I'd like to take ten minutes. Is that fine with everybody else?

THE WITNESS: Okay.

MS. GALLAGHER: Yes.

MR. LINDEN: All right. Let's go off the record, please.

(Pause in proceedings.)

(See that testimony not designated as confidential/attorneys' eyes only beginning on page sixty-eight.)

BY MR. LINDEN:

Q. After a ten-minute break, back on the record. Mr. Russell, I'd like to draw your attention back to Exhibit 1, your declaration in this proceeding, and specifically Paragraph 33 on page seven.

A. Yeah.

Q. It says, I recently became aware of a third-party, Vial, who was using, quote, built for Biotech. We promptly sent a cease and desist letter to Vial who have now stopped all use. Do you see that?

A. Yeah.

Q. I read that correctly? I read that correctly, correct?

A. Yes.

Q. Who is Vial?

A. It's a small start-up CRO. They appear to come out of Silicon Valley, and they're trying to make a big splash without having a lot of content.

Q. And when you said you recently became aware, can you put a finer point on that? When did you become aware?

A. Actually I don't remember offhand,

but I think it was before our deposition because we were preparing a letter for them at that time, a cease and desist. So it was sometime in the second half of last year. I can't be more precise than that without going through my e-mails.

Q. Well, and just looking at the paragraph above it, Paragraph 32, you say up until December 2022, you were not aware of any third-party use of the built for Biotech mark other than Medpace, does that help you recall perhaps when you recently became aware of Vial using built for Biotech?

A. I don't know. I'll need to go through the e-mails. It seems like it was longer ago than that. No, it was going on December.

Q. Okay. Are you aware when Vial began operation?

A. No.

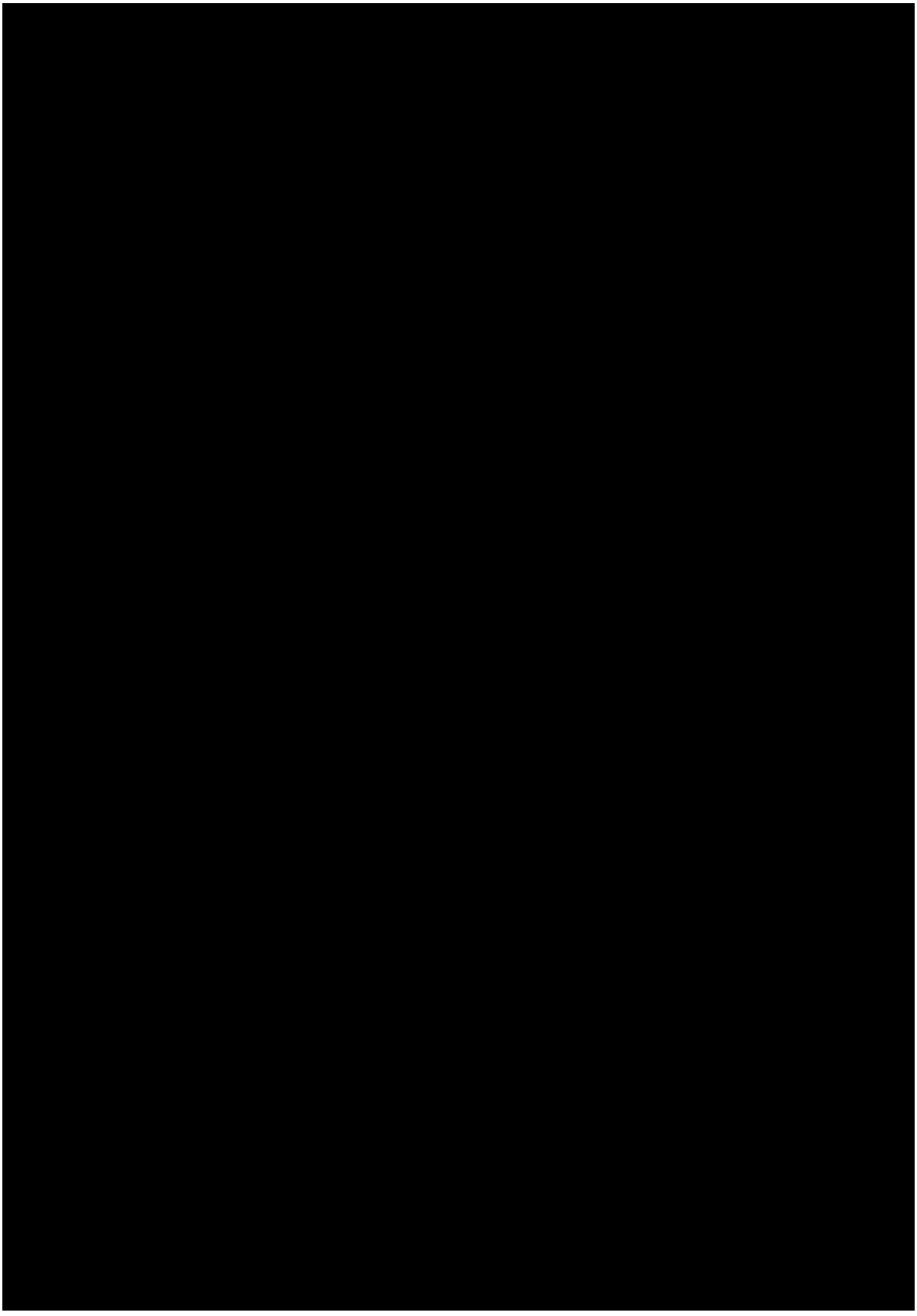
Q. And have you seen Vial representatives at trade shows?

A. I have not been to any trade shows since June last year so I have not seen them and they've not been reported to me. That doesn't mean that they haven't been there.

(See that testimony designated as

confidential/attorneys' eyes only beginning on page seventy-one.)

[redacted]



[redacted]

(See that testimony not designated as confidential/attorneys' eyes only beginning on page seventy-four.)

BY MR. LINDEN:

Q. Okay. I'd like to draw your attention back to Exhibit G, and it's specifically Exhibit G, Part 1.

A. Yeah. I tore mine up so you need to tell me where to go.

Q. Okay. So Exhibit G, Part 1, and I'll draw your attention to document PREMIER00154 which we talked about earlier in your deposition.

A. Oh, yeah, I've got it.

Q. Is it your testimony then, Mr. Russell, that all of the images that appear on the screen, in other words the wall-mounted TV screen, in Premier Research's trade show booth are images taken from Premier's website?

A. Yes, that's either created for this and used on the website or they take content from the website, turn it into a loop and use it on here, or sometimes they'll put up the website.

Q. So let me just back up your answer and make sure I understand perfectly well. The images on the screen and screens used in Premier Research's trade show booths are first created for the website and posted on the website and then used in the trade shows; is that right?

A. I can't say that for certain. We create assets for use in communications and then they get directed to various channels. So I can't say for sure the one that you're looking at there was created first for a trade show and then used on the website or the other way around.

Q. Okay. Is it possible that the images used on -- in any particular trade show on these screens was created for the trade show but did not end up on the website?

A. It's possible, but we try to maximize the value that we get out of the assets that we create so we roll them out in as many channels as we can.

MR. LINDEN: Okay. Mr. Russell, that's all the questions I have for you today. Thank you for your time. I'll pass the witness.

MS. GALLAGHER: Can we take a ten-minute break?

MR. LINDEN: Sure can.

MS. GALLAGHER: Thank you.

(Pause in proceedings.)

MS. GALLAGHER: We're not going to have any redirect.

MR. LINDEN: So after a brief break,

we're back on the record, and we wanted to put a stipulation on the record. Mrs. Gallagher and myself, Mr. Linden, wanted to indicate that although not specifically asked questions about all the exhibits attached to his declaration, because Mr. Russell did, in fact, review all the exhibits attached to his declaration in order to answer some questions here today, that all exhibits, A through K, will be entered with his deposition transcript and they will be labeled as they've been labeled for purposes of this declaration -- I'm sorry, deposition here today. I don't know if that was sufficient, Mary Grace, or if you had something to add?

MS. GALLAGHER: Yeah, that works for me.

MR. LINDEN: All right. Very good. I think we're done, and, Mr. Russell, thank you for your time.

(Thereupon, the deposition was concluded at 11:54 a.m.)

STATE OF OHIO)
COUNTY OF MONTGOMERY) SS: CERTIFICATE

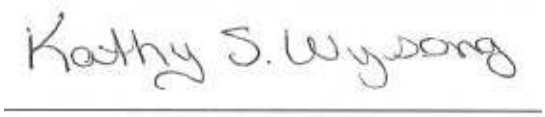
I, Kathy S. Wysong, a Notary Public within and for the State of Ohio, duly commissioned and qualified,

DO HEREBY CERTIFY that the above-named SEAN RUSSELL, was by me first duly sworn to testify the truth, the whole truth and nothing but the truth.

Said testimony was reduced to writing by me stenographically in the presence of the witness and thereafter reduced to typewriting.

I FURTHER CERTIFY that I am not a relative or Attorney of either party, in any manner interested in the event of this action, nor am I, or the court reporting firm with which I am affiliated, under a contract as defined in Civil Rule 28(D).

IN WITNESS WHEREOF, I have hereunto set my hand and seal of office at Dayton, Ohio, on this 31st day of March, 2023.



KATHY S. WYSONG, RPR
NOTARY PUBLIC, STATE OF OHIO
My commission expires 12-25-2023

Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

March 31, 2023

To: Paul J. Linden

Case Name: Premier Research International LLC v. Medpace, Inc.

Veritext Reference Number: 5842655

Witness: Sean Russell Deposition Date: 3/30/2023

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 5842655
CASE NAME: Premier Research International LLC v. Medpace, Inc.
DATE OF DEPOSITION: 3/30/2023
WITNESS' NAME: Sean Russell

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have made no changes to the testimony as transcribed by the court reporter.

_____ _____

Date Sean Russell

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal

this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 5842655
CASE NAME: Premier Research International LLC v. Medpace, Inc.
DATE OF DEPOSITION: 3/30/2023
WITNESS' NAME: Sean Russell

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

_____ _____
Date Sean Russell

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;

They have listed all of their corrections in the appended Errata Sheet;

They signed the foregoing Sworn Statement; and

Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

ERRATA SHEET

VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 5842655

PAGE/LINE(S) / CHANGE /REASON

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Date Sean Russell

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____

DAY OF _____, 20_____ .

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Notary Public

_____

Commission Expiration Date

s

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of U.S. Application Serial No. 88/490,775
Mark: BUILT FOR BIOTECH

PREMIER RESEARCH INTERNATIONAL LLC Opposer, vs. MEDPACE, INC., Applicant.	)	Opposition No.: 91251921

DECLARATION OF SEAN RUSSELL

Pursuant to 28 U.S.C. § 1746, I, Sean Russell, hereby state and aver as follows:

1. I am of legal age and competent to testify in this matter. I submit this declaration in connection with the above-referenced opposition proceedings.

2. I am currently the Chief Commercial Officer for Premier Research International LLC ("Premier Research"). I have been involved with the marketing of Premier Research for over 11 years and have been Chief Commercial Officer for over 5 years. As the Chief Commercial Officer, I am very familiar with Premier Research's history, service offerings, branding, marketing and promotional materials, target customers, channels of trade, and competitors.

Premier Research International LLC

3. Premier Research is a clinical research organization ("CRO") founded in 1989 and headquartered in Morrisville, North Carolina.

Exhibit
0001

4. Premier Research has two offices and over 1,100 employees across the United States. It has operations in over 84 countries.

5. Premier Research provides clinical research, product development, and consulting services throughout the United States primarily to small and mid-size biotech companies, but also to small and mid-size pharmaceutical companies, medical device companies, diagnostic companies, and digital therapeutic companies. Premier Research provides the expertise, support, test development assistance, and research management for companies looking to test new pharmaceuticals or other medical products.

6. Premier Research markets and promotes its services in a variety of ways. For example, it attends industry trade shows and conferences every year. At those trade shows Premier Research sets up a booth where employees can talk to potential customers and industry experts. The company's booth is usually centrally located and can be visited or seen by anyone walking around the conference hall. Premier Research displays a variety of advertising and promotional materials at its booth to market its specific services, including its focus on servicing biotech clients. Employees of Premier Research, as well as its competitors, walk around at these industry events to see what competitors, clients, or innovators in the industry are marketing and discussing.

7. Additionally, Premier Research conducts direct outreach to clients by advertising on third-party industry news sites, calling clients, distributing marketing material and posting on social media.

8. Premier Research also advertises its services on its website located at premier-research.com. This website offers an abundance of information on CROs, and Premier Research's focus on assisting biotech companies. Premier Research prominently promotes the BUILT FOR

BIOTECH mark on its website. Exhibit A is a true and correct copy of the website at <premier-research.com>.

9. Premier Research competes directly with all CROs but particularly with other mid-size CROs, including Medpace. In fact, Medpace and Premier have been competing for clients since at least as early as 2009. *See* Exhibit B, a true and correct copy of an article published by Pivotal Financial Consulting, LLC and listing Premier Research and Medpace as midsize clinical research organizations and produced as PREMIER00885-889.

10. Medpace and Premier Research attend many of the same conferences and even share clients. Attached as Exhibit C is a true and correct copy of a webpage from Upstate Clinical Research Associate's website listing both Medpace and Premier Research as companies that assist in developing their clinical trials. This document was produced as PREMIER00936-937.

11. Once a customer is interested in hiring a CRO, it will initiate a bidding process to solicit proposals from multiple CROs. The customer will then cut it down to three companies for final consideration. The CROs left will then present their proposal directly to the company, usually in person (or virtually during COVID). This presentation is called a "bid defense."

12. Generally, the identity of other companies participating in a bid defense is kept confidential, although it is not uncommon for us to learn of the companies through a careless comment or email exchange.

13. When Premier Research learns of a competitor's identity, we make a note of that for opposition research.

14. Based on reports from Premier Research's representatives, I am aware of over 30 times since 2017 when Medpace and Premier Research directly competed in bid defenses for

potential customers, although the number is likely much higher, and we are simply unable to confirm due to the confidential nature of the bidding process.

15. Over the last 30 years, Premier Research has grown steadily and today, is one of the top mid-size CROs.

BEGIN CONFIDENTIAL- ATTORNEYS EYES ONLY

16. In 2017, Premier Research's revenues totaled over $159,000,000, with those revenues up to over $600,000,000 by 2021.

17. To promote its clinical research services, Premier Research spends approximately $4,000,000 a year on its advertising and marketing expenditures, which includes expenditures offered in connection with its BUILT FOR BIOTECH mark.

STOP CONFIDENTIAL- ATTORNEYS EYES ONLY

The BUILT FOR BIOTECH Brand

18. Premier is always looking for ways to separate itself from its competitors, including by focusing its advertising to its primary customers, small to medium sized biotech companies.

19. In summer 2016, Premier Research was put up for sale by its owners and as part of the sale, the marketing department created presentation materials to assist in promoting the company to potential buyers.

20. Originally the mark "Made for Biotech" was used on promotional materials, but the alliteration Built for Biotech is more advantageous for marketing purposes, so I initiated the adoption of the mark BUILT FOR BIOTECH. BUILT FOR BIOTECH was used in presentations to potential buyers of the company starting in fall 2016.

21. The mark "BUILT FOR BIOTECH" is a coined term created by myself.

22. Given the success of the BUILT FOR BIOTECH mark in the sales promotions, the company began using the mark in a consumer facing way starting at least as early as November 30, 2017. Attached hereto as Exhibit D is the document produced as AEO PREMIER01104-1174, which is a true and correct copy of a bid defense slide deck presented to a customer on November 30, 2017, utilizing the BUILT FOR BIOTECH mark.

23. Since its adoption, Premier Research has invested substantial amounts of money and time into advertising and marketing its BUILT FOR BIOTECH brand.

24. Starting in 2017, BUILT FOR BIOTECH has consistently been used in bid defense and other customer presentations. *See* Exhibit D (AEO PREMIER 1104-1174) and Exhibit E, a true and correct copy of a slide deck used in a bid defense on January 17, 2019 (AEO PREMIER1175-1269). Exhibits D and E are representative samples of what has probably been hundreds of bid defense PowerPoints using the BUILT FOR BIOTECH mark since 2017.

25. Premier Research has also consistently used its BUILT FOR BIOTECH mark at industry trade shows and conferences since 2018 including, but not limited to, (i) the DIA 2018 Annual Meeting hosted by the Drug Information Association in Boston, Massachusetts on June 24 – 28, 2018, (ii) the 2019 ASCO Annual Meeting hosted by the American Society of Clinical Oncology in Chicago, Illinois on May 31 – June 4, 2019, and (iii) the 2019 BIO International Convention hosted by the Biotechnology Innovation Organization in Philadelphia, Pennsylvania on June 3 – 6, 2019.

26. At trade shows, Premier Research uses BUILT FOR BIOTECH on its marketing and promotional materials, including on company banners, lanyards, and flyers promoting the Premier Research booth. For example, Premier Research uses BUILT FOR BIOTECH on its physical booth materials including on the large banner located atop the booth to direct interested

parties to Premier Research. Attached as Exhibit F (and produced as PREMIER00862-65) are true and correct copies of photographs taken of Premier Research's booths at trade shows from 2018-2019. Exhibit F demonstrates extensive use of BUILT FOR BIOTECH.

27. Given the size of the physical booth materials, the large banners can be seen by individuals throughout the conference center, not just those that visit the Premier Research booth. Because of the expense of creating such large physical promotional materials, Premier Research uses the same materials at almost all of its trade shows and conferences. As such, the materials shown in Exhibit G have been consistently used since 2018 at the majority of trade shows and conferences attended by Premier Research.

28. Not only is BUILT FOR BIOTECH used on the physical banners and walls of the booths, but the mark is also used on marketing materials distributed at conferences and trade shows. Attached as Exhibit H is a true and correct copy of a printers' proofs for a flyer distributed by Premier Research at the 2019 MAGI conference, produced as PREMIER00772-773. This conference took place from May 5-8, 2019, in Boston, Massachusetts. My understanding is that Premier Research used this exact printers' proof for its flyer distributed at this conference. This flyer is emblematic of the types of promotional material Premier Research distributed in 2018 and 2019 at its trade shows and conferences.

29. Another example of this marketing material is attached as Exhibit I, produced as PREMIER00786 which is a true and correct copy of a one-sheeter distributed by Premier Research in 2019 prominently featuring the BUILT FOR BIOTECH mark.

30. Premier Research further advertises its services via social media including on Twitter, Facebook, and LinkedIn. Since summer 2017, Premier Research has consistently posted images displaying the BUILT FOR BIOTECH mark and used the hashtag #BuiltforBiotech on its

posts to further promote the brand. *See* Exhibit J, comprised of true and correct copies of social media posts from the official Premier Research social media pages, produced as PREMIER 00680-688, 00765-769.

31. Premier Research also advertises its services on third-party industry publications including Fierce Biotech. Premier Research, like many companies in the biotech space, will "sponsor" the news publication for a week. During that period, the sponsor is featured in a display ad at the top of the Fierce Biotech's email distributions. In early 2019, Premier Research sponsored the site and promoted its services using its BUILT FOR BIOTECH mark. Attached as Exhibit K, are true and correct copies of two Fierce Biotech newsletters from May 2019 and June 2019 sponsored by Premier Research, produced as PREMIER00749-760. My understanding is that numerous employees at Medpace are on Fierce Biotech's email distribution list.

32. Up until December 2022, I was not aware of any third-party use of the BUILT FOR BIOTECH mark other than by Medpace.

33. I recently became aware of a third-party, Vial, who was using "Built for Biotech." We promptly sent a cease and desist letter to Vial who has now stopped all use.

Medpace's Use and Application of BUILT FOR BIOTECH

34. Around June 2019, I was informed by our advertising agency, Lumentus, that our competitor, Medpace, was using Premier Research's trademark BUILT FOR BIOTECH on its website.

35. It is my recollection that I then contacted our internal legal team and asked them to investigate further. I was later informed that Medpace had filed a trademark application with the USPTO for the BUILT FOR BIOTECH mark.

36. Given the importance of the Built for Biotech mark, Premier Research filed an opposition against Medpace's trademark application for Built for Biotech and filed its own application for BUILT FOR BIOTECH.

37. Following the filing of the opposition proceeding, it is my understanding that Medpace has stopped all use of Built for Biotech. Medpace has removed the mark from its website. We have not seen Medpace using the mark in the marketplace over the last few years.

Harm If Applicant's Application Registers

38. I understand that Medpace has applied to register the mark BUILT FOR BIOTECH in the United States, and that its application covers the same, or nearly the same, services as those Premier Research offers under its BUILT FOR BIOTECH mark, namely, consulting and management in the field of clinical trials.

39. If Medpace's application for Built for Biotech is permitted to register, Premier Research will suffer harm to not only sales of its services, but also the goodwill we have worked hard to establish in the United States among consumers. Having a third party offer its services under the Built for Biotech brand in the United States will cause consumers to think the company is associated or affiliated with Premier Research while Premier Research has no control over the quality of the services offered by Medpace.

SIGNATURE PAGE TO FOLLOW

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 31 day of January, 2023

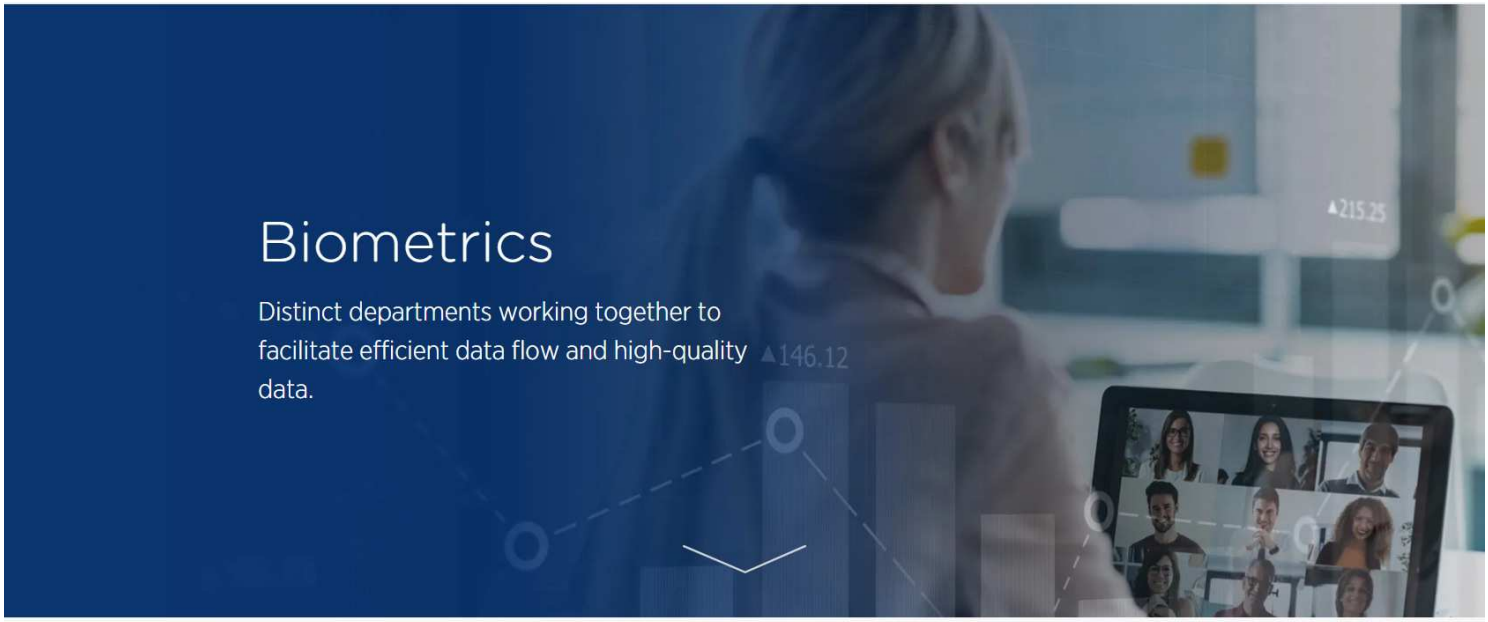
Sean Russell

EXHIBIT A
Part 1

screenshot-premier-research.com-2021.05.06-15_53_25
https://premier-research.com/our-capabilities/product-development-consulting/biometrics/
06.05.2021

premier research

SEARCH REQUEST INFORMATION



Biometrics

Distinct departments working together to facilitate efficient data flow and high-quality data.

for streamlined execution

When you begin with the end in mind, you can incorporate efficiencies throughout your project development program. That's why the Premier Research Biometrics group sets standards for each project at the outset, tailoring them to your desired outcomes and bolstering them with our scientific expertise and extensive experience.

A cross-functional team of dedicated leads from Premier Interactive Response Technology (IRT), biostatistics, and medical writing will work with you to:

- Design a protocol that represents and analyzes your outcome measures in a manner consistent with your objectives
- Plan your randomization, drug supply, and endpoint collection to assure quality, efficiency, and compliance
- Design and execute your analysis for conclusive results
- Summarize your results for clear, concise conclusions

Working with our integrated team trained in Premier's advanced systems and capabilities, including the Premier One Ecosystem, you'll benefit from:

- Broad and deep scientific expertise in our fields
- Collaborative interactions with our experts that set you up for success
- Comprehensive knowledge of our processes and procedures and how they work together, which means just one set of standard operating procedures (SOPs) for your clinical data
- Understanding our project implementation systems, so there's no learning curve for dealing with a new vendor or new procedures
- Clear structure and accountability for project teams, with the Biometrics group leading the way throughout the project life cycle

Combining knowledge and experience with integrated processes to ensure improved data quality at every step, Premier's Biometrics group makes it easier for you to focus on what matters.

- Expert scientific knowledge applied to the design of your study and its implementation
- Experience in Phase 1 to 4 trials in a broad range of therapeutic areas — with specialization in analgesia, dermatology, central nervous system disorders, and oncology
- Full service as well as standalone projects
- Management team with over 14 years of industry experience
- Staff in Europe and the U.S.
- Global systems and SOPs

PODCAST

Statistical considerations in the wake of COVID-19

COVID-19 has dramatically changed the way we conduct clinical trials and left

PREMIER PERSPECTIVE

Advantages of ePROs

In these unprecedented times, when gathering data remotely is the method of choice, it's worth making use of ePRO data in your clinical studies to help maintain the integrity of your clinical trials

many sponsors without answers when it comes to the future of their studies. Recognizing the issues is one thing, but figuring out where we go from here demands a new way of looking at some common challenges.

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Premier Biometrics Experts

Shari Medendorp
SVP, Biometrics

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Emily Stube
Senior Director, Medical Writing

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Biometrics Services

Premier Research's biometrics service offerings include biostatistics, Interactive Response Technology (IRT), and medical writing.

Biostatistics

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Premier IRT

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Medical Writing

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Check out our resource center

Our experts have developed an extensive library of white papers, case studies, blogposts, and other informative resources.

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https://premier-research.com/our-capabilities/clinical-research-and-development/biostatistics/
07.05.2021

Biostatistics

Advance your study with expert study design, optimized submission strategy, and comprehensive publication plans.

Delivering superior statistical services to define your success

Premier Research's Biostatistics Department offers full programming and data analysis to deliver laser-focused insights at every stage of your trial and, ultimately, assure regulatory compliance. Our veteran biostatistics professionals work closely with you, pairing technical expertise with an average of 11 years of industry experience to rigorously transform your data into insights. They understand your data must be clean and comprehensive and be analyzed and presented flawlessly in order to support trial success. Premier offers:

- International staff who optimize regulatory-compliant and cost-effective methods of collecting, analyzing, and presenting both interim and final analysis results
- Comprehensive clinical development planning from protocol design and sample size calculation through clinical study report (CSR) writing and review
- Direct integration of biostatistics activities throughout the full project plan, including database design and setup and report development
- Advanced knowledge of Clinical Data Interchange Standards Consortium (CDISC) standards and requirements to ensure new drug application (NDA) submission-ready data
- Extensive proficiency in data and safety monitoring board (DSMB) output, interim analysis, and investigational new drug (IND) safety updates
- Deep and varied regulatory filing experience spanning dermatology, a variety of rare/orphan diseases, oncology, central nervous system, gastrointestinal, and acute otitis media

SERVICES INCLUDE

- Study design and protocol development
- Sample size estimation
- Statistical analysis plans
- DSMB and interim analyses
- DSMB participation
- Adaptive study designs
- CDISC-compliant datasets and documentation
- Cross-functional review of data
- Statistical tables, listings, and figures
- CSR review
- Integrated summaries (ISS/ISE) for regulatory submission
- Exploratory analyses
  - Manuscripts
  - Publications
  - Marketing support

cdisc Clear Data. Clear Impact. Proud Member

DEDICATED LEADERSHIP THROUGHOUT YOUR STUDY | SPECIALIZED EXPERTISE FOR COMPLEX PROJECTS | THE STRENGTH OF EXPERIENCE

Our statistics teams have worked on hundreds of individual studies, across Phases 1-4, many of which have been included in NDA filings. We have also planned and programmed the integrated analyses for many of these NDA filings (ISS/ISE work). Core service offerings include:

- Statistical analysis plans
- Statistical programming including rigorous quality control
- Table, listing, and graph generation
- CDISC dataset generation and documentation
- Regulatory statistical strategy, integrated analysis and data submission, and follow-up support

We have experience entering the ISS/ISE process at every stage imaginable — from Phase 1 through Phase 3, where we have analyzed each individual study throughout the development cycle, to integrating an entire program of studies that have already been completed prior to our involvement.

PREMIER PERSPECTIVE

Statistical considerations for FDA COVID-19 guidance

general actions required to ensure the operational integrity and scientific robustness of clinical trials going forward.

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WHITE PAPER

Adaptive trial designs in early oncology

increase in adaptive trial designs that seek to limit the number of patients exposed to ineffective doses or treatments while accelerating the timeline to the detection of efficacy signals.

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Premier Biostatistics Experts

Shari Medendorp
SVP, Biometrics

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Vice President, Statistical Consulting

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Ready to get started? So are we. Drop us a line to learn more about how we can help.

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PUBLIC VERSION (REDACTED)

Biostatistics is part of a wide range of integrated biometrics offerings that include IRT, medical writing, and study design. Follow the links below to learn more about how clients have benefited from our specialized expertise.

IRT

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Medical Writing

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Check out our resource center

Our experts have developed an extensive library of white papers, case studies, blogposts, and other informative resources.

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EXHIBIT A
Part 2

PUBLIC VERSION (REDACTED)

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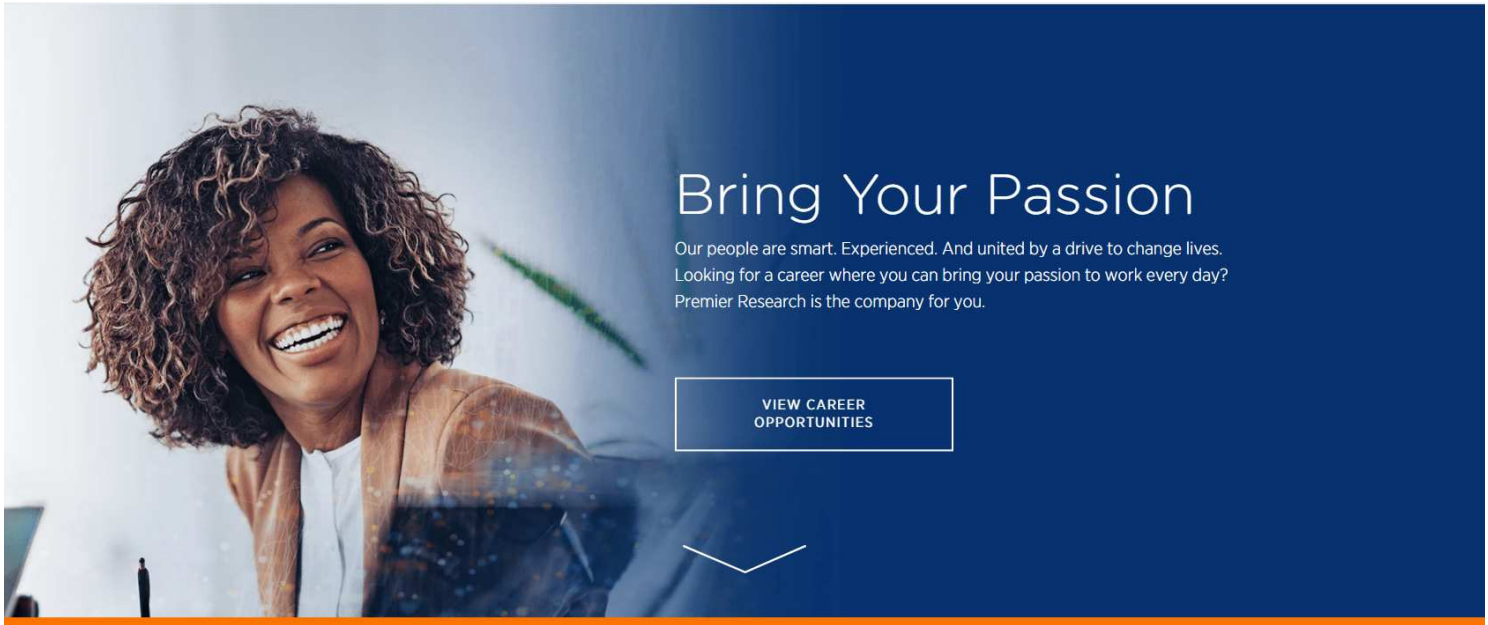
https://premier-research.com/our-company/careers/
07.05.2021

premier research

SEARCH REQUEST INFORMATION



Bring Your Passion

Our people are smart. Experienced. And united by a drive to change lives. Looking for a career where you can bring your passion to work every day? Premier Research is the company for you.

VIEW CAREER OPPORTUNITIES

We are science-minded. And heart-centered.

We are a clinical research company dedicated to helping biotech, specialty pharma, and device innovators bring life-changing therapies to patients. We're highly trained experts continuously pushing forward the development of novel therapeutics to address unmet needs. And we're a diverse team of passionate individuals in 84 countries that follows the "One Team" approach – because we know when our people are recognized across the board, the sponsors we work with can see the difference.

The excitement of a career where every day is different. And every task matters.

CLINICAL RESEARCH AND DEVELOPMENT

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MEDICAL DEVICE

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PREMIER ONE ECOSYSTEM

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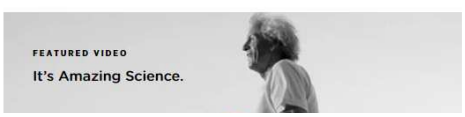
MAKE AN IMPACT | MEET OUR LEADERS

Follow your passion

Big dreams and open minds help make a life-saving difference to patients with few or no other options. That's what we do.



PREMIER000447

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Every day. See how.

Are you ready to make a difference?

We're looking for talented people who are inspired to transform an industry.

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Biostatistics	10 Open Roles
Business Development	4 Open Roles
Clinical Monitoring	15 Open Roles
Clinical Operations	5 Open Roles
Commercial Operations	1 Open Role
Corporate Administration	1 Open Role
Data Management	10 Open Roles
Finance	6 Open Roles
Functional Services	26 Open Roles
Human Resources	3 Open Roles
Information Technology	1 Open Role
Interactive Response Technologies (IRT)	1 Open Role
Medical Management	4 Open Roles
Medical Writing	6 Open Roles
Oncology Franchise	1 Open Role
Project Management	24 Open Roles
Regulatory Affairs	1 Open Role
Regulatory Professionals	11 Open Roles
Resource Planning and Management	4 Open Roles
Strategic Development	1 Open Role
Study Start Up	18 Open Roles

Can't find what you're looking for?

We're always looking for great candidates. Submit a general application or sign up for Premier job alerts here.

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APPLY TO PREMIER NOW

RECEIVE OUR JOB ALERTS

Contact us

Contact Premier Talent Acquisition directly at the following email or submit your information through our secure online application system. Premier Research is an equal opportunity employer.

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Check out our culture

Connect with us through our social channels and learn more about our culture. On Facebook, you'll see Premier Research community and social events from around the globe.

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https://premier-research.com/learnings-insights/therapeutic-and-special-population-expertise/gene-and-cell-therapy-clinical-trial-experience/
13.05.2021

Cell & Gene Therapy Expertise

The science is stunningly complex, and the regulatory terrain is constantly evolving. Having supported 60 cell and gene therapy trials in the past five years spanning oncology, hematology, metabolic disorders, and more, we know what it takes to succeed.

Supporting the evolving science of cell and gene therapy

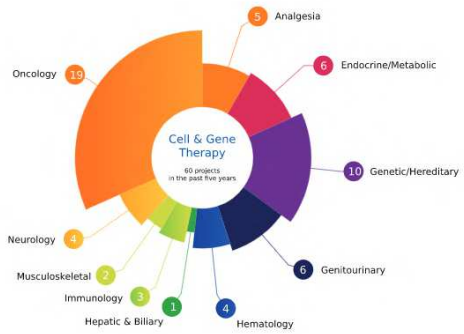
Even measured against the vast scientific mystery that defines the biotech industry, cell and gene therapy poses extraordinary challenges. To achieve operational excellence in these trials, you must understand — and overcome — obstacles ranging from start-up regulations and site selection to patient recruitment and retention. And given the limited data on the long-term effects of these therapies, participants in cell and gene therapy trials may be monitored for a long-term follow-up period, which may be as long as 15 years.

For projects of this scale, you need a partner that can deliver from start to finish. That's where Premier Research comes in.

We combine deep therapeutic expertise in oncology, rare disease, and pediatric research with other key areas, such as collaborative monitoring processes and technology. Together these allow us to deliver high-quality outcomes and an unwavering commitment to developers of next-generation therapies that makes us truly Built for Biotech℠.

Why choose Premier?

- 60 cell and gene therapy studies conducted in the past five years
- Significant experience in viral vectors
- Significant experience in both oncology and non-oncology



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Understanding how cell and gene therapy products are regulated — and how to navigate regional or national regulatory differences — can help you develop an efficient product development plan to bring your treatment to patients in need.

LEARN MORE

To understand and mitigate the risk of delayed adverse events, participants in gene and cell therapy trials may be monitored for a long-term follow-up period. Learn what's needed and how to determine if your product requires LTFU studies.

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Premier Gene & Cell Therapy Experts

Hanna Wide
Executive Director, Cell & Gene Therapy

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April Marquick
Senior Regulatory Start-Up Manager, Cell & Gene Therapy

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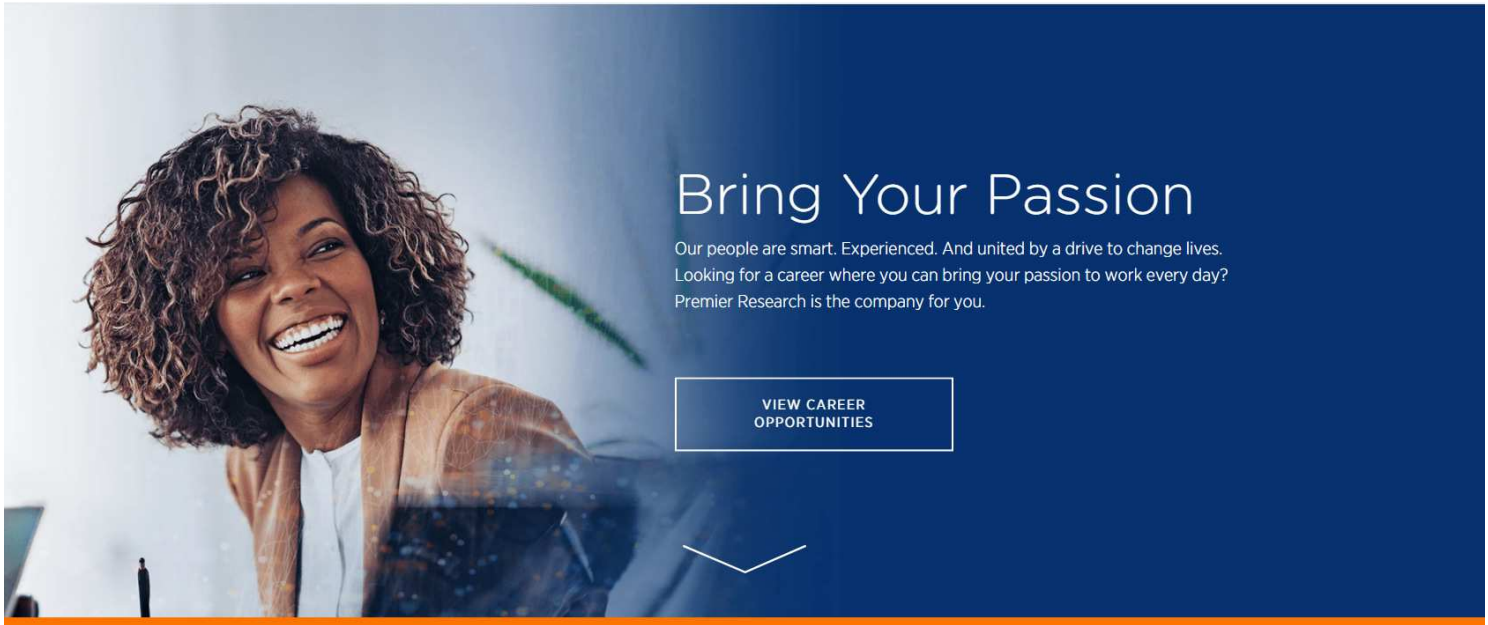
SEARCH REQUEST INFORMATION



Bring Your Passion

Our people are smart. Experienced. And united by a drive to change lives. Looking for a career where you can bring your passion to work every day? Premier Research is the company for you.

VIEW CAREER OPPORTUNITIES

We are science-minded. And heart-centered.

We are a clinical research company dedicated to helping biotech, specialty pharma, and device innovators bring life-changing therapies to patients. We're highly trained experts continuously pushing forward the development of novel therapeutics to address unmet needs. And we're a diverse team of passionate individuals in 84 countries that follows the "One Team" approach – because we know when our people are recognized across the board, the sponsors we work with can see the difference.

The excitement of a career where every day is different. And every task matters.

CLINICAL RESEARCH AND DEVELOPMENT

LEARN MORE

MEDICAL DEVICE

LEARN MORE

PREMIER ONE ECOSYSTEM

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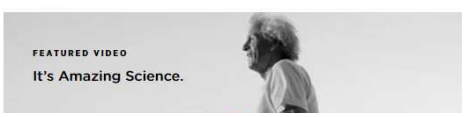
MAKE AN IMPACT | MEET OUR LEADERS

Follow your passion

Big dreams and open minds help make a life-saving difference to patients with few or no other options. That's what we do.



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Every day. See how.

Are you ready to make a difference?

We're looking for talented people who are inspired to transform an industry.

By Location

All Locations

Search All Jobs ...

By Department

Biostatistics	10 Open Roles
Business Development	4 Open Roles
Clinical Monitoring	15 Open Roles
Clinical Operations	5 Open Roles
Commercial Operations	1 Open Role
Corporate Administration	1 Open Role
Data Management	10 Open Roles
Finance	6 Open Roles
Functional Services	26 Open Roles
Human Resources	3 Open Roles
Information Technology	1 Open Role
Interactive Response Technologies (IRT)	1 Open Role
Medical Management	4 Open Roles
Medical Writing	6 Open Roles
Oncology Franchise	1 Open Role
Project Management	24 Open Roles
Regulatory Affairs	1 Open Role
Regulatory Professionals	11 Open Roles
Resource Planning and Management	4 Open Roles
Strategic Development	1 Open Role
Study Start Up	18 Open Roles

Can't find what you're looking for?

We're always looking for great candidates. Submit a general application or sign up for Premier job alerts here.

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Contact us

Contact Premier Talent Acquisition directly at the following email or submit your information through our secure online application system. Premier Research is an equal opportunity employer.

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Check out our culture

Connect with us through our social channels and learn more about our culture. On Facebook, you'll see Premier Research community and social events from around the globe.

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https://premier-research.com/learnings-insights/therapeutic-and-special-population-expertise/gene-and-cell-therapy-clinical-trial-experience/
13.05.2021

Cell & Gene Therapy Expertise

The science is stunningly complex, and the regulatory terrain is constantly evolving. Having supported 60 cell and gene therapy trials in the past five years spanning oncology, hematology, metabolic disorders, and more, we know what it takes to succeed.

Supporting the evolving science of cell and gene therapy

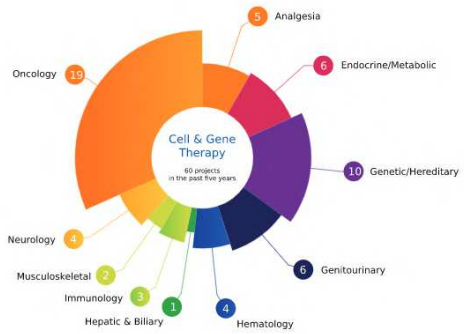
Even measured against the vast scientific mystery that defines the biotech industry, cell and gene therapy poses extraordinary challenges. To achieve operational excellence in these trials, you must understand — and overcome — obstacles ranging from start-up regulations and site selection to patient recruitment and retention. And given the limited data on the long-term effects of these therapies, participants in cell and gene therapy trials may be monitored for a long-term follow-up period, which may be as long as 15 years.

For projects of this scale, you need a partner that can deliver from start to finish. That's where Premier Research comes in.

We combine deep therapeutic expertise in oncology, rare disease, and pediatric research with other key areas, such as collaborative monitoring processes and technology. Together these allow us to deliver high-quality outcomes and an unwavering commitment to developers of next-generation therapies that makes us truly Built for Biotech℠.

Why choose Premier?

- 60 cell and gene therapy studies conducted in the past five years
- Significant experience in viral vectors
- Significant experience in both oncology and non-oncology



Click image to enlarge

Understanding how cell and gene therapy products are regulated — and how to navigate regional or national regulatory differences — can help you develop an efficient product development plan to bring your treatment to patients in need.

LEARN MORE

To understand and mitigate the risk of delayed adverse events, participants in gene and cell therapy trials may be monitored for a long-term follow-up period. Learn what's needed and how to determine if your product requires LTFU studies.

LEARN MORE

Premier Gene & Cell Therapy Experts

Hanna Wide
Executive Director, Cell & Gene Therapy

MORE

April Marquick
Senior Regulatory Start-Up Manager, Cell & Gene Therapy

MORE

Featured Resources

PREMIER INSIGHT

Delivering the Global Expertise Required to Coordinate a Pediatric Gene Therapy Trial

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WHITE PAPER

Operationalizing Gene Therapy Trials

LEARN MORE

WEBINAR

Oncology Trials in the Time of COVID-19: Expert Insights

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SEARCH REQUEST INFORMATION

A focus on end-to-end clinical research and development

Expert guidance, every step along the way

We've unified the disciplines that underpin successful clinical research and development, from dedicated rapid study start-up staff to Premier-trained project managers and fast-track application expertise. With so much at stake – livelihoods, expectant investors, and most important, the patients who entrust to us their health and safety – there is no room for shortcuts.

Our experienced research professionals are capable of managing even the most complex clinical research studies from Phase 1 to Phase 4. Our therapeutically focused teams have the knowledge and experience necessary to effectively manage situations as they arise, and our approach is firmly grounded in comprehensive project management principles and well-defined processes.

Service Areas:

- Study Design
- Study Start-Up
- Project Management
- Biostatistics
- Data Management
- Premier IRT
- Safety & Pharmacovigilance
- Medical Writing
- Quality Management & QA
- Biometrics
- Functional Service Provider
- Combination Products

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Related Capabilities

Adding value at every step in the process, we provide expertise in product development consulting, medical devices, and technology applications to ensure data integrity, process efficiency, and timely analytics and reporting.

PRODUCT DEVELOPMENT CONSULTING

LEARN MORE

MEDICAL DEVICE

LEARN MORE

PREMIER ONE ECOSYSTEM

LEARN MORE

Therapeutic Focus

There's no substitute for experience. And we have a lot of it. See what we've been busy doing for the past five years.

EXPLORE THERAPEUTIC EXPERTISE

Check out our resource center

Our experts have developed an extensive library of white papers, case studies, blogposts, and other informative resources.

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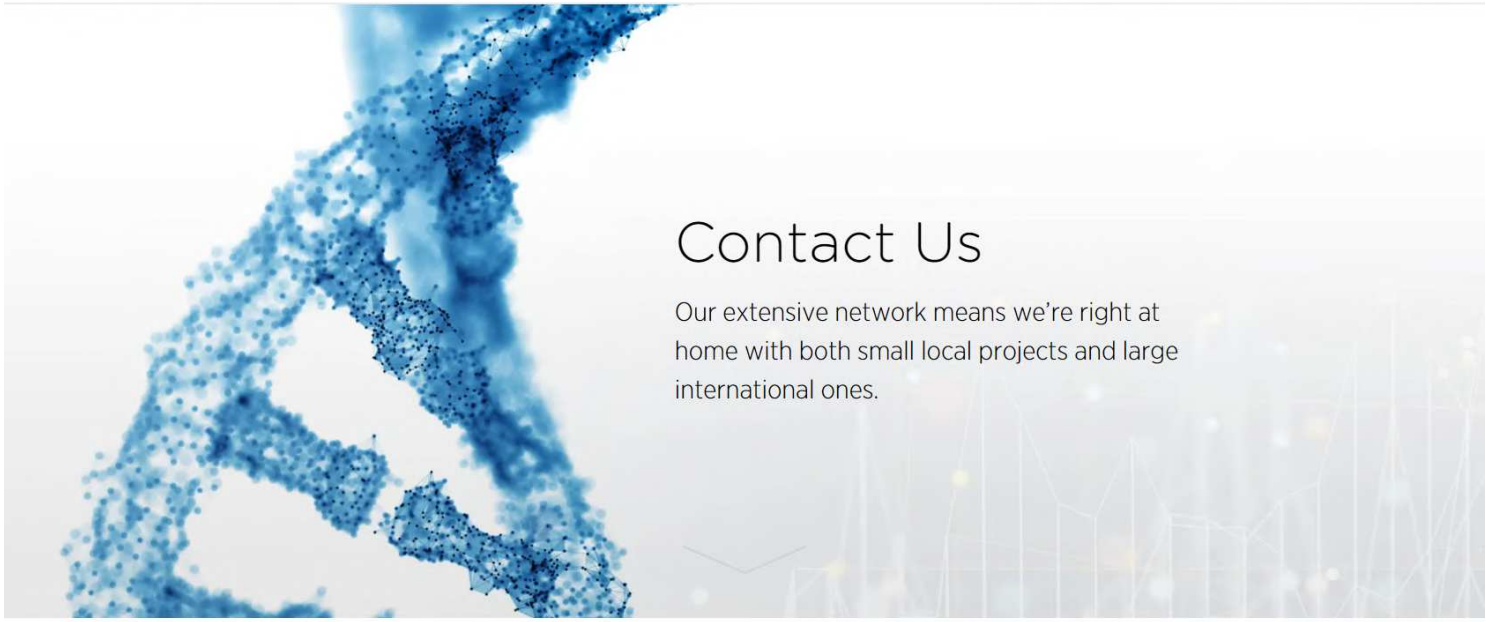
SEARCH REQUEST INFORMATION



Contact Us

Our extensive network means we're right at home with both small local projects and large international ones.

Submit Request

Submit a request to gain an understanding of how Premier Research can help you achieve your goals.

First Name *

Last Name *

Email Address *

Phone Number

How can we help? *

Country *

Tell us more *

CONTACT US

By submitting your information to us through this webform, your business details will be added to our database. In accordance with our Privacy Notice, we may then contact you with marketing information about Premier Research that might be of interest to you. We will never sell your details to third parties. You can unsubscribe from marketing communications at any time.

Biometric Application Support

Click here for the Biometric Application Support form.

North America

3800 Paramount Parkway Suite 400
Morrisville, NC 27560

Tel: +1 919 627 9100
Directions

Europe

250 South Oak Way
Green Park
Reading, Berkshire, RG2 6UG

Tel: + 44 118 936 4000
Directions

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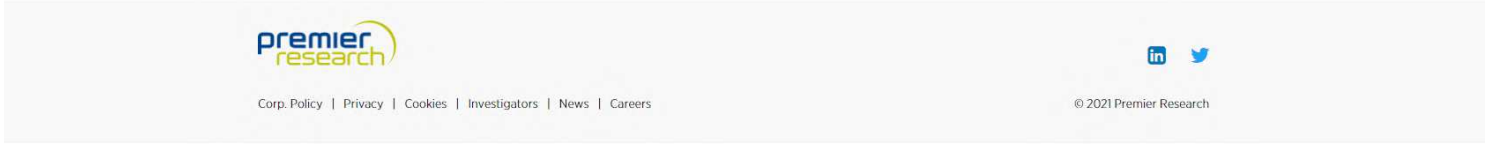

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Updates on COVID-19

Click Here for the Latest Updates and Information Regarding the COVID-19 (Coronavirus) Outbreak

Corporate Responsibility

Covid-19 Task Force: Keenly Focused on the Impact to Our Patients, Sponsors, and Employees

Premier Research takes its corporate responsibility very seriously. In view of the global impact of COVID-19, we have assigned a task force to ensure business continuity is maintained. The task force is closely monitoring the changing global situation to ensure the health and welfare of our staff, patients enrolled in projects, and investigative sites and staff. Our customers' projects are of the utmost importance to us, and we understand the business impact this might have on our sponsors.

While this crisis, either in fact or in perception, threatens the proper execution of our clinical protocols, we want to ensure that the integrity of our trials doesn't get compromised. This will entail:

- Maintaining the safety of patients currently enrolled in our trials
- Minimizing unreasonable cancellation or delay of patient follow-up visits
- Continuing patient enrollment along with our new priorities
- Working with our vendors so that patients continue to have trial medication and study materials
- Understanding and addressing institutional challenges related to the conduct of the trial

In addition to our ongoing site outreach and incident monitoring, we are looking at having backup plans in place to review data remotely should that become necessary.

We continue to remain in full control of our sponsors' projects and proactively working to mitigate any potential risks. In addition to the sites, we are also working with the vendors to ensure we have up-to-date information on any impact they may have on overall operations.

If you have any project-specific questions or concerns, please contact your project manager or one of our sales associates, who are working in concert with our Covid-19 Task Force.

Global Code of Conduct

Our global mission is to improve productivity in clinical development. Our commitment is to execute with quality every time, everywhere, in everything we do.

Our values are driven by the knowledge that what we do every day affects the business outcomes of the customers we serve, the lives and well-being of the patients we support, the physicians and providers we work with, the investors who support us, and the colleagues that share our mission. We therefore commit to:

- Alignment with the goals of our customers
- A culture of achievement
- A fundamental belief in teamwork, accountability, and transparency
- Compliance with industry regulations and business ethics
- Support and understanding of patient communities and the challenges they face

Our Commitment to Our Customers

Our philosophy embraces high-touch customer service, a belief that is core to our corporate foundation and culture. In 2016, we designed "Built for Biotech," an operating model that delivers outcome-focused insights for sponsors. This model enables us to offer a combination of industry acumen, global compliance, and therapeutic expertise and ensures that innovative ideas aren't hindered by short-term thinking or limited resources.

Our Commitment to Our Talent

We're a science-minded culture dedicated to helping transform the latest life-changing discoveries into reality. Because what we do is profoundly connected to saving and improving lives, we never forget the huge responsibility we carry. Every day is different, and every project is special. Whether it's the importance of addressing unmet needs in rare disease or pediatrics, the thrill of working on state-of-the-art medicines, or working with the smartest and most collaborative people in the industry. It's hard work and we are invested in the success of our employees. We believe that when our colleagues are inspired and nurtured, they do their best work. That's why we developed The Academy, Premier Research's training program to support professional and career development, emphasize our cultural anchors, and promote our commitment to continuous learning.
We also believe that the best work gets done when a diverse team searches for solutions that address the needs of a varied populace and we are committed to increasing diversity within our ranks.

Our Commitment to Patients

Patients and their advocates are at the heart of everything we do, so we created a support network called Patient and Stakeholder Engagement (PASE) that integrates the input of all relevant stakeholders in the development of patient-centered drugs and devices. We work with sponsors to understand each disease's burden and patient treatment goals, gaining vital insight into effective recruitment and retention strategies. Patients and families factor heavily in trial design. And, importantly, we build relationships with patient communities and key opinion leaders.

Our Commitment to Social Responsibility

Premier Research supports many programs and activities that contribute to the unmet societal and charitable needs of people with rare diseases across our global community. These include Rare Disease Day, Alex's Lemonade Stand Foundation, Make-A-Wish Foundation, March of Dimes, back-to-school initiatives, men's and women's health programs, and charity runs.

Our Commitment to the Environment

We are continuously improving our environmental management system by reviewing internal processes to ensure Premier Research is consistently achieving environmental objectives.

Our environmental policy has been incorporated throughout the company and applied to our supply chain by adopting the following measures:

- Ensure the awareness and compliance of all Premier Research staff through induction training, annual updates and continuous development. This aims to encourage staff to continue to work in an environmentally responsible manner, promoting the efficient use of materials and resources provided by Premier Research, in particular those which are non-renewable.
- Ensure that our suppliers and/or service providers have, as a minimum, an Environmental policy in place that ensure they are continuously striving to operate more efficiently and with reduced fuel emissions.
- Reduce our Carbon footprint and waste through re-use and recycling and by purchasing recycled, recyclable or re-furbished products and materials where these alternatives are available, economical and suitable
- Ensure that our processes are operating within the minimum, achievable environmental impact by integrating the consideration of environmental concerns into all of our decisions and processes.
- Minimize the potential environmental impact of our products and services where possible by:

Reusable and Hazardous Materials

- Striving to minimize the use of paper in the office, e.g., by introducing electronic signatures, we cut down on printing hard copies for handwritten signatures.
- Purchasing recycled and recyclable paper products.
- Reusing and recycling all waste where possible (appropriate bins are provided).
- Replacing hazardous materials and products such as cleaning products, with suitable substitutions and ensuring that employees are aware of the processes that are in place to protect human health and the environment when these materials are used, stored and disposed of.

Energy

- Installation of passive infra-red detectors that switch off lights in common areas when no one is present.
- Making use of efficient luminaires where possible, e.g., L.E.D. light bulbs.
- Triggered heating and air-conditioning systems for use during office hours only.
- Installation of local thermostats to create comfort zones, eliminating wasted energy for unoccupied spaces.
- Purchasing of energy efficient products.

Travel

- Limiting the need for unnecessary travel.
- Requiring senior management approval for non-billable travel.
- Booking non-stop flights reducing carbon emissions at take offs and landings.
- Utilizing IATA (International Air Transport Association) member airlines who invest in carbon offset programs.
- Encourage hybrid and electric car rentals.
- Encourage train and bus travel where practical.

In pursuit of continual improvement we actively encourage everyone within Premier Research to play a part in our corporate responsibility, by taking action to reduce our environmental impact.

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https://premier-research.com/our-capabilities/clinical-research-and-development/data-management/
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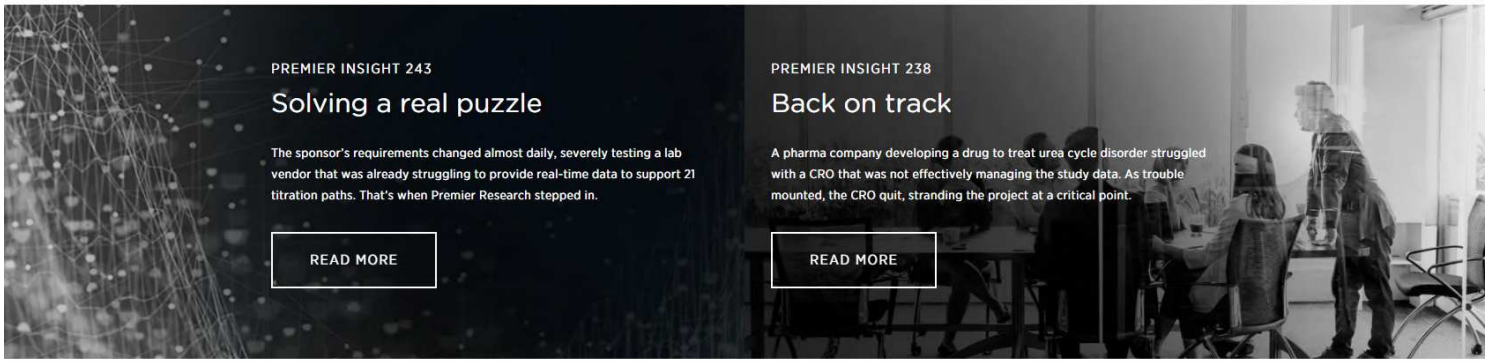
SEARCH REQUEST INFORMATION

Clinical Trial Data Management

In the real world of research, study timelines change, staffing needs shift, unusual database formats need reconciliation, and data noise is a steady distraction. That's where we come in.

We've learned a lot of lessons about clinical trial data management along the way, completing projects in all major therapeutic areas across multiple study phases. We strive to quickly address any issue that arises, providing clean, robust data to guide your drug through its development life cycle.

Our data managers are seasoned in information technology and pharmaceutical research data analysis. Many hold advanced degrees in math, science, or computer science, and all provide a full complement of services including database design, development, and validation; development of case report forms; data cleaning; medical coding; and handling of serious adverse events.



PREMIER INSIGHT 243

Solving a real puzzle

The sponsor's requirements changed almost daily, severely testing a lab vendor that was already struggling to provide real-time data to support 21 titration paths. That's when Premier Research stepped in.

READ MORE

PREMIER INSIGHT 238

Back on track

A pharma company developing a drug to treat urea cycle disorder struggled with a CRO that was not effectively managing the study data. As trouble mounted, the CRO quit, stranding the project at a critical point.

READ MORE

Data management is part of a wide range of service offerings that include regulatory consulting, project management, and pharmacovigilance. Follow the links below to learn more about how clients gain from our specialized expertise.

Regulatory Consulting | Project Management | Safety and PV

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Check out our resource center

Our experts have developed an extensive library of white papers, case studies, blogposts, and other informative resources.

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GLOBAL COMPLIANCE

Premier Research Names Ellen Teplitzky Chief Compliance Officer and SVP of Legal Affairs

April 8, 2021

MORRISVILLE, N.C., April 8, 2021 Premier Research, the clinical research company that's Built for Biotech℠, today announced the appointment of Ellen Teplitzky as Chief Compliance Officer and Senior Vice President, Legal Affairs.

Since joining Premier Research six years ago, Ms. Teplitzky has been instrumental in streamlining the customer contracting process and managing requirements associated with the European Union's General Data Protection Regulation (GDPR) among other successes. In her new role, she will be responsible for establishing standards and implementing procedures that ensure the highest level of global compliance for Premier's biotech and specialty pharma sponsors.

"From day one six years ago, Ellen has supported our customers in so many ways by continuously monitoring changes in the legal and regulatory landscape and proactively seeking out and implementing effective solutions," said Premier Research Chief Commercial Offer Sean Russell. "Now she has stepped up to direct our global compliance efforts just as this function has become more critical than ever to our sponsors and regulators."

Ms. Teplitzky began her legal career in private practice and transitioned into government service. She earned a Master of Law with a specialty designation in law and development, awarded with merit from the University of London. She also holds a bachelor's in history from Emory College, and a J.D. from the Emory University School of Law.

About Premier Research

Premier Research, a clinical research company, is dedicated to helping biotech, specialty pharma, and device innovators transform life-changing ideas and breakthrough science into new medical treatments.

As a global company, Premier Research specializes in the use of innovative technologies for smart study design and trial management to deliver clean, conclusive data to sponsors.

Whether it's developing product lifecycle strategies, reducing clinical development cycle times, securing access to patients, navigating global regulations, maximizing the impact of limited rare disease data, or providing expertise in specific therapeutic areas, Premier Research is committed to helping its customers answer the unmet needs of patients across a broad range of medical conditions.

Tags:

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https://premier-research.com/epremier-ctms-the-central-organizing-principle-for-successful-studies/
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CLINICAL RESEARCH: PHASE 1 - PHASE 4

ePremier CTMS: The Central Organizing Principle for Successful Studies

By Premier Research | April 7, 2021

Across the industry, most trials don't have access to real-time results...which leads to delays. 95% of those delays last longer than a month.

Addressing this challenge means tackling the underlying problems of data being held in disparate places, and failure to predict and address risk. Our Premier One Ecosystem captures all the data related to your trial and brings it together in our ePremier Integration hub, used by our highly trained clinical data scientists for seamless study management, near-real-time data analysis and rapid, informed actions.

The ePremier CTMS is part of this system-agnostic data integration platform. Watch this video to learn how this powerful application brings together all your study data so that your Premier project team can provide you with deeper insights, automate administrative tasks, and generate critical reports. Premier Research. Built for Biotech℠

RECENT POSTS

FUNCTIONAL SERVICE PROVIDER (FSP)

The Emerging Biotech's Guide to Creating Scalable Infrastructure With a Functional Service Provider

By Cheryl Silva
April 27, 2021

CLINICAL RESEARCH: PHASE 1 - PHASE 4

5 Key Takeaways: Insights on Alternative Designs to the Traditional 3+3 Design in Phase 1 Dose Escalation Studies

By Abie Ekangaki
April 8, 2021

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Setting a Real-World Strategy in an Evolving Clinical Research Environment

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SEARCH REQUEST INFORMATION

Events

Look for Premier Research at these upcoming events.

Webinar

Market Application and Life-Cycle Management: The Road to Commercial Success

Wednesday, May 19, 2021 | 11am EDT (NA) / 4pm BST (UK) / 4pm CEST (EU-Central)

Dermatology Webinar Series

Looking Ahead to the Future of Dermatology Research

On-Demand

Case Study

Premier One Ecosystem

On-Demand

Webinar

The Importance of Site Selection and Dosing Strategies in Early-Phase Oncology Studies

On-Demand

ATTENDING AN UPCOMING EVENT?

CLICK HERE TO SCHEDULE A CONVERSATION WITH ONE OF OUR THOUGHT LEADERS.

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https://premier-research.com/frequently-asked-questions-drug-development/
07.05.2021

Frequently Asked Questions for Drug & Product Development

By Premier Research | February 4, 2020

0-9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

0-9

What is the 21st Century Cures Act?

Legislation designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

A

What is an active pharmaceutical ingredient (API)?

Any substance or mixture of substances that is intended to be used in the manufacture of a drug product and that becomes an active ingredient of the drug product when used in the production of the drug.

What is adaptive design?

A clinical trial study design that may be more flexible by utilizing results accumulated during a trial to modify the trial's course in accordance with pre-specified rules.

What is an adverse drug reaction (ADR)?

Any harmful or unintended response to a medicinal product related to any dose.

What is an adverse event (AE)?

Any untoward medical occurrence associated with the use of a medicinal product in humans, whether or not it is considered drug related.

What is the Association of American Cancer Institutes (AACI)?

An association of 100 of the top academic and independent cancer research centers in North America.

B

What are basket studies?

A more recent development for oncology clinical trials, also known as bucket studies, these studies include patients who have a certain genetic mutation in common regardless of the site or origin of cancer in the body.

C

What is a case report form (CRF)?

A paper or electronic questionnaire used in the context of a clinical trial to collect data from study participants.

What is the Center for Biologics Evaluation and Research (CBER)?

The branch of the U.S. Food and Drug Administration (FDA) that is responsible for regulating biological products for human use under applicable federal laws.

What is the Center for Cancer Research (CCR)?

The largest division of the intramural research program of the National Cancer Institute (NCI), this center comprises approximately 250 basic and clinical research groups.

What is the Center for Devices and Radiological Health (CDRH)?

The branch of the FDA that is responsible for premarket approval of all medical devices, as well as oversight of the manufacturing, performance, and safety of these devices.

What is the Center for Drug Evaluation and Research (CDER)?

The branch of the FDA that is responsible for monitoring the safety and efficacy of over-the-counter and prescription drugs, including biologics and generics.

RECENT POSTS

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April 27, 2021

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5 Key Takeaways: Insights on Alternative Designs to the Traditional 3+3 Design in Phase 1 Dose Escalation Studies

By Abie Ekangaki
April 8, 2021

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FEATURED PODCAST

PREMIER VOICES #14

Setting a Real-World Strategy in an Evolving Clinical Research Environment

LISTEN NOW

What is the Centers for Medicare & Medicaid Services (CMS)?

A federal agency within the U.S. Department of Health and Human Services (DHHS) that administers Medicare and works with state governments to administer Medicaid and the Children's Health Insurance Program (CHIP). CMS is also responsible for ensuring health insurance portability standards, long-term care facility quality standards, and clinical laboratory quality standards under the Clinical Laboratory Improvement Amendments (CLIA).

What is a centralized clinical trials office (CCTO) or clinical trials office (CTO)?

A central office that provides infrastructure and operational support for researchers, sponsors, and patients involved in the conduct of clinical trials.

What is the Clinical and Translational Science Award (CTSA) Program?

A program designed to develop innovative solutions that improve the efficiency, quality, and impact of the process for translating laboratory, clinic, and community observations into interventions that improve the health of individuals and the public.

What is the Clinical Data Acquisition Standards Harmonization (CDASH) guidance?

Part of the clinical data interchange standards consortium (CDISC) initiative, this is a set of best practices for developing case report forms.

What is clinical data management (CDM)?

A critical process in clinical research, which leads to generation of high-quality, reliable, and statistically sound data from clinical trials.

What is a clinical data management system (CDMS)?

A tool used in clinical research to manage the data generated in a clinical trial.

What is the Clinical Data Update System (CDUS)?

The main repository of clinical trial data for the NCI's Division of Cancer Treatment and Diagnosis (DCTD) and Division of Cancer Prevention (DCP).

What is a clinical research associate (CRA)?

This role is responsible for organizing and administering clinical trials of new or current drugs in order to assess the benefits and risks.

What is a clinical research coordinator (CRC)?

This role is responsible for conducting clinical trials according to good clinical practice guidelines.

What is a clinical study report (CSR)?

A detailed document that integrates the clinical and statistical description, presentations, analyses, and all background information related to a clinical study.

What is a clinical trial management system (CTMS)?

A software system used by the biopharmaceutical industry to manage clinical trials in clinical research.

What is the Clinical Trials Reporting Program (CTRP)?

A comprehensive database that includes information on all NCI-supported clinical trials.

What is the Code of Federal Regulations (CFR)?

A system of general and permanent rules and regulations published in the Federal Register by the U.S. federal government.

What is a cohort study?

A longitudinal study that is designed to follow a group of subjects over time.

What are the Common Terminology Criteria for Adverse Events (CTCAE)?

Also called common toxicity criteria, this is a set of criteria developed by the NCI to standardize the classification of adverse effects of drugs used in cancer therapy.

What is a contract manufacturing organization (CMO)?

Also called a contract development and manufacturing organization (CDMO), this is a company that provides drug development and manufacturing services to other companies in the pharmaceutical industry on a contract basis.

What is a contract research organization (CRO)?

A company that provides clinical trial support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

What is a Corrective and Preventive Action (CAPA) system?

A system to collect information, analyze information, identify, and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.

D

D

What is a data and safety monitoring board (DSMB)?

Also known as a data monitoring committee (DMC) or data and safety monitoring committee (DSMC), this is an independent group of experts who monitor study conduct and safety on an ongoing basis throughout a clinical trial.

What is a data manager (DM)?

In the context of a clinical trial, this role is responsible for ensuring that all data is collected, managed, and reported accurately.

What is a data monitoring committee (DMC)?

Also known as a data and safety monitoring board (DSMB) or data and safety monitoring committee (DSMC), this is an independent group of experts who monitor study conduct and safety on an ongoing basis throughout a clinical trial.

What is the Department of Health and Human Services (HHS)?

Also known as the Health Department, this department of the U.S. federal government is responsible for protecting the health of all Americans and providing essential human services.

E

What is an electronic case report form (eCRF)?

An electronic questionnaire used in clinical trial research to collect data from each study participant.

What is electronic data capture (EDC)?

The use of systems to collect clinical trial data in electronic form as opposed to paper form.

What is an electronic health record (EHR)?

A digital version of a patient's health records, including information from all clinicians, laboratories, and health care institutions involved in the patients' care.

What is an electronic medical record (EMR)?

A digital version of a patient's medical and treatment history, usually from one health care practice.

What is an electronic patient-reported outcome (ePRO)?

Any patient-reported outcome that is collected by electronic methods.

What is an electronic trial master file (eTMF)?

A trial master file that is in digital format and contains the essential data from a clinical trial.

What is an ethics committee (EC)?

An independent body that is responsible for ensuring that medical experimentation and research on human subjects is conducted in an ethical manner in accordance with national and international law.

What is the European Medical Device Regulation (EU MDR)?

A European Union (EU) regulation which ensures high standards of quality and safety for medical devices being produced in or supplied into Europe.

F

What is Fast Track (FT) designation?

A process designed to facilitate the development and expedite the review of drugs to treat serious conditions and to address an unmet medical need.

What is Federalwide Assurance (FWA)?

Documentation of an institution's assurance of compliance with U.S. federal regulations for the protection of human subjects in research.

What is Findable, Accessible, Interoperable, Reusable (FAIR)?

A set of guiding principles for scientific data management which were designed to enhance the ability of data or tools from non-cooperating resources to integrate or work together with minimal effort.

What is the Food and Drug Administration (FDA)?

A federal agency responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, as well as by ensuring the safety of the food supply, cosmetics, and radiation-emitting products.

G

What is a general clinical research center (GCRC)?

Also known as a clinical research center, this is any designated medical facility used to conduct clinical research.

What is the General Data Protection Regulation (GDPR)?

A regulation in EU law on data protection and privacy for all individual citizens of the EU and the European Economic Area (EEA).

What is good clinical practice (GCP)?

An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

What is good documentation practice (GDP or GDocP)?

A term used in the pharmaceutical and medical device industries to describe standards and guidelines used to record raw data entries in a legible, traceable, and reproducible manner.

H

What is the Health Insurance Portability and Accountability Act (HIPAA)?

A law enacted in August 1996 which mandates industry-wide standards for improving the portability and continuity of health insurance coverage and ensuring the privacy, protection, and confidential handling of protected health information.

I

What is an in-house clinical research associate (IHCRA)?

This office-based role is responsible for supporting clinical research associates who are in the field.

What is an independent ethics committee (IEC)?

Also known as an institutional review board, this is a committee charged with protecting the rights and safety of clinical trial participants by reviewing all relevant study materials.

What is an informed consent form (ICF)?

A document containing information that allows individuals to make an informed decision about whether or not to participate in a clinical trial.

What is an institutional review board (IRB)?

Also known as an independent ethics committee, this is a committee charged with protecting the rights and safety of clinical trial participants by reviewing all relevant study materials.

What is intention-to-treat (ITT) analysis?

A technique used in randomized controlled trials where the results of the study are analyzed based on a participant's initial treatment assignment and not the treatment eventually received.

What is an interactive response system (IRS)?

A standard industry term for interactive voice response (IVR) and interactive web response (IWR) systems that allow detection of voice, text, and web for gathering data related to clinical research.

What is the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)?

This initiative brings together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.

What is the International Council for Harmonisation and Good Clinical Practice (ICH GCP E6 [R2])?

An amended guidance to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting, while continuing to ensure human subject protection and reliability of trial results.

What is an investigational device exemption (IDE)?

This approval allows an investigational device to be used in a clinical study for the purpose of collecting data on safety and efficacy.

What is an investigational new drug application (IND)?

An FDA program by which a biopharmaceutical company obtains permission to start human clinical trials and to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved.

What is an investigator-initiated trial (IIT)?

A clinical study initiated, developed, designed, and managed by a qualified sponsor who assumes sole responsibility for conduct and management of the study.

What is an Investigator Site File (ISF)?

A file containing the essential clinical trial documents necessary for the principal investigators

and the research team.

L

What is a local regulatory affairs associate (LRAA)?

A professional who is responsible for ensuring compliance with local government regulations.

What is long-term follow up (LTFU)?

In the context of a clinical trial, this refers to continuing monitoring to evaluate the long-term effects of a treatment or intervention.

N

What is the National Cancer Institute (NCI)?

Part of the National Institutes of Health (NIH), this agency leads, conducts, and supports cancer research across the U.S.

What is the National Institutes of Health (NIH)?

Part of the HHS, this is the largest biomedical research agency in the world.

What is the National Library of Medicine (NLM)?

Operated by the U.S. federal government, this is the world's largest biomedical library.

What is a natural history study?

A study that follows a group of people over time who have, or are at risk of developing, a specific medical condition or disease.

What is a new drug application (NDA)?

A vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.

What is a normal healthy volunteer (NHV)?

A person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention.

O

What is an observational study?

A fundamental part of epidemiological research, this is a study in which researchers observe the effect of a diagnostic test, treatment, intervention, or risk factor without trying to change or control the variable under investigation.

What is the Office for Human Research Protections (OHRP)?

An office within the HHS that is responsible for protecting the rights, welfare, and well-being of human subjects involved in research conducted or supported by HHS.

What is an Office of Clinical Trials (OCT)?

An office within an institution that is responsible for supporting the execution and management of clinical research.

What is an orphan drug?

Defined by the Orphan Drug Act (ODA), this refers to a biological product granted special status to treat a rare disease or condition upon the request of a sponsor.

P

What is a pilot study?

A small feasibility study that is usually performed to test hypotheses in preparation for a larger interventional clinical trial.

What is a platform study?

A clinical trial with a single master protocol in which multiple treatments are evaluated simultaneously.

What is a principal investigator (PI)?

The primary individual responsible for the preparation, conduct, and administration of laboratory study or clinical trial.

What is protected health information (PHI)?

Under U.S. law, this refers to all individually identifiable health information, including demographic data, health status, test results, insurance information, and any other information used to identify a patient or provide healthcare services or coverage.

What is a protocol coordinator (PC)?

In the context of a clinical trial, this role is responsible for conducting the informed consent process and ensuring compliance with the protocol.

What is a protocol review and monitoring committee (PRMC)?

A committee responsible for assessing and overseeing the scientific merit and integrity of a clinical trial.

What is a protocol review and monitoring system (PRMS)?

Mandated by the NCI for every Cancer System, this is a system used to assess the scientific merit and feasibility of all clinical trial protocols studying subjects diagnosed with, or at risk for, cancer.

Q

What is a qualifying clinical trial (QCT)?

A trial that meets the requirements set forth by the CMS for coverage of routine costs.

What is quality control (QC)?

In the context of a clinical trial, this refers to the procedures utilized to ensure the protection of human subjects and the reliability of the data generated.

R

What is a randomized controlled trial (RCT)?

An intervention study in which a group of subjects with similar characteristics are randomized to receive one of several defined interventions.

What is real-world data (RWD)?

Data relating to patient health status and/or the delivery of health care collected from a variety of sources, such as electronic health records, claims and billing activities, product and disease registries, patient-generated data, data gathered from other sources (e.g., mobile devices).

What is real-world evidence (RWE)?

Clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data. RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective).

What is a registry?

A data collection tool typically used to better understand long-term trends in a specific population, such as patients with a particular disease or exposure to a certain treatment.

S

What is a scientific review board (SRB)?

Also called a scientific review committee or scientific review panel, this is a group of clinicians, researchers, and other experts that evaluates the detailed plan of a clinical trial for scientific quality and appropriate study design.

What is a scientific review committee (SRC)?

Also called a scientific review board or scientific review panel, this is a group of clinicians, researchers, and other experts that evaluates the detailed plan of a clinical trial for scientific quality and appropriate study design.

What is a serious adverse event (SAE)?

An untoward medical occurrence associated with the use of a medicinal product in humans which is life-threatening or results in death, initial or prolonged hospitalization, disability or permanent damage, or a congenital anomaly or birth defect.

What is a site management organization (SMO)?

Also known as a trial management organization, this is an organization that provides clinical trial-related support services to a biopharmaceutical company, medical device company, contract research organization, or clinical site.

What is source document review or source data review (SDR)?

This refers to the review of source documentation to check quality, review compliance with the protocol, and ensure critical processes and source documentation are adequate.

What is source document verification (SDV)?

A verification of the conformity of the data presented in case report forms or other data collection systems with source data. This is conducted to ensure that the data collected are reliable and allow reconstruction and evaluation of the trial.

What are Specialized Programs of Research Excellence (SPOREs)?

Cancer research grants focused on a specific organ site or on a group of highly related cancers.

SPOREs are designed to support rapid, efficient translation of basic scientific findings and to determine the biological basis for observations made in individuals with cancer or in populations at risk for cancer.

What is a standard operating procedure (SOP)?

Detailed, written instructions to record routine operations, processes, and practices followed within a business organization to ensure uniformity and compliance with institutional, federal, and state guidances.

What is a study coordinator (SC)?

This role is responsible for supporting the management and coordination of a clinical research study.

What is the Study Data Tabulation Model (SDTM)?

This defines a standard structure for study data tabulations that are to be submitted as part of an application to a regulatory authority such as the FDA.

What is a subject visit template (SVT)?

A template designed to ensure that adequate and complete documentation of a study visit is captured.

What is a suspected unexpected serious adverse reaction (SUSAR)?

A term that refers to an adverse event that occurs in a study participant and which is assessed by the sponsor or study investigator as being unexpected, serious, and likely to have a causal relationship with the study drug.

T

What is a trial management organization (TMO)?

Also known as a site management organization, this is an organization that provides clinical trial-related support services to a biopharmaceutical company, medical device company, contract research organization, or clinical site.

What is a trial master file (TMF)?

The collection of essential documents which allows the conduct of a clinical trial to be reconstructed and evaluated.

U

What are umbrella studies?

Studies designed to test the impact of different drugs on different mutations in a single type of cancer.

What is an unanticipated adverse device effect (UADE)?

Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that adverse effect was not previously identified in the investigational device exemption. This term may also be used for any other unanticipated serious problem associated with a device relative to the rights, safety, or welfare of study participants.

What is an unexpected adverse drug reaction (UADR)?

An adverse reaction for which the nature or severity is not consistent with information in the relevant source documents.

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Global Compliance & GCP

Have you taken the most effective regulatory pathway?

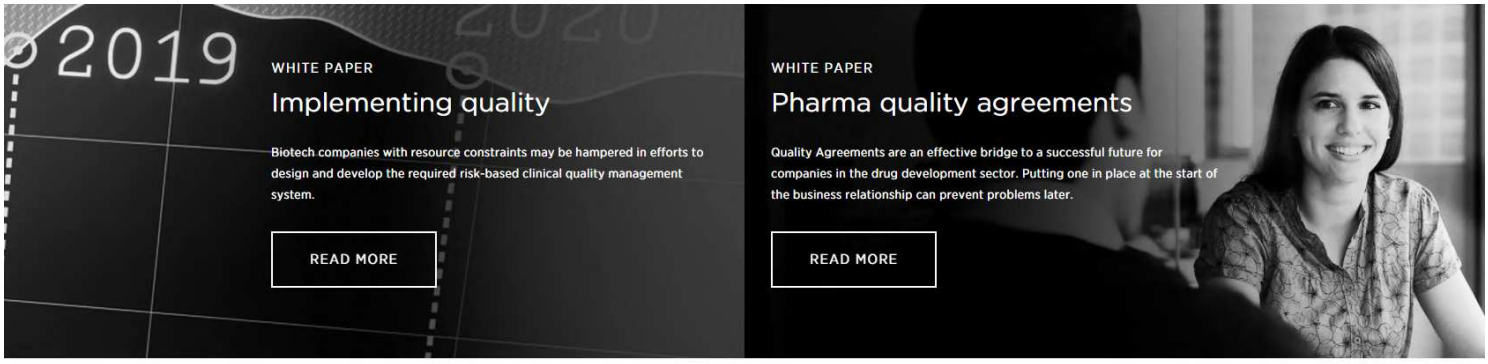
regulatory risks

We'll equip you to stay compliant – and safe

Today's regulatory environment has the potential to reform clinical monitoring and trial management and shift focus to standards of quality and safety for medical devices while helping accelerate product development and bring new innovations and advances to patients who need them faster and more efficiently. We're highly focused on protecting patient data and staying current with the new regulatory guidance that governs this rapidly changing industry.

We constantly monitor a regulatory intelligence database to manage the compliance issues facing the industry, and our study start-up professionals and regulatory strategists share this insight with clients to ensure their access to robust data within the scope of evolving global compliance rules.

Whether it's FDA regulations, investigational new drug (IND) applications, good clinical practice (ICH GCP standards), or other regulatory and compliance hurdles, we can lead you to the best opportunity for successful medical device and product development outcomes.



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Global compliance is part of a wide range of service offerings that include regulatory consulting, project management, and study start-up. Follow the links below to learn more about how clients gain from our specialized expertise.

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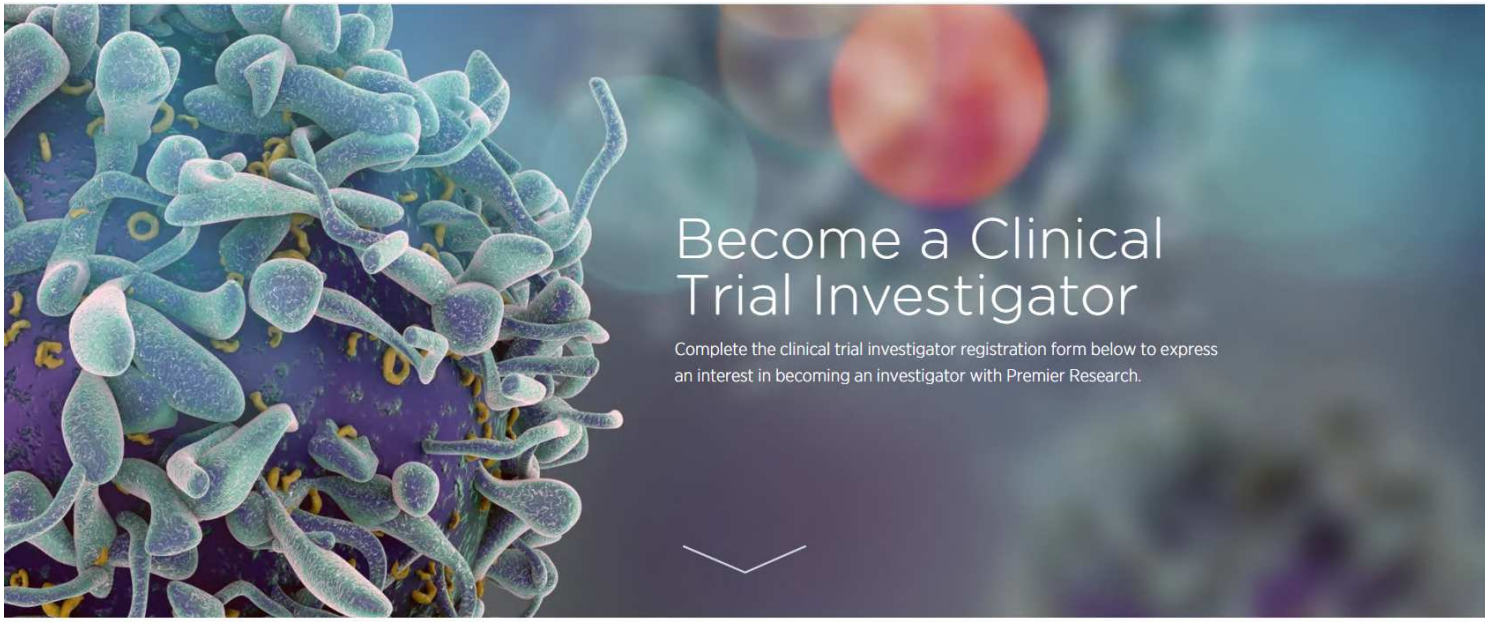

Premier is conducting clinical research in more than 84 countries around the world. Our business is growing and we are always interested in talking to physicians about opportunities to participate in our clinical trials. The first step to getting involved is to complete our registration form. Then a member of our investigator management team will contact you for additional details and will set you up on our clinical investigator database ready for matching with suitable projects.

Investigator Registration Form

1 Demographics 2 Experience 3 Institutions

Name*

Salutation | First | Middle Initial | Last | Suffix

Professional Title

Location*

Street Address

New York — City

NY — State / Province / Region

10001 — ZIP / Postal Code

United States — Country

Primary Email*

Alternate Email #1

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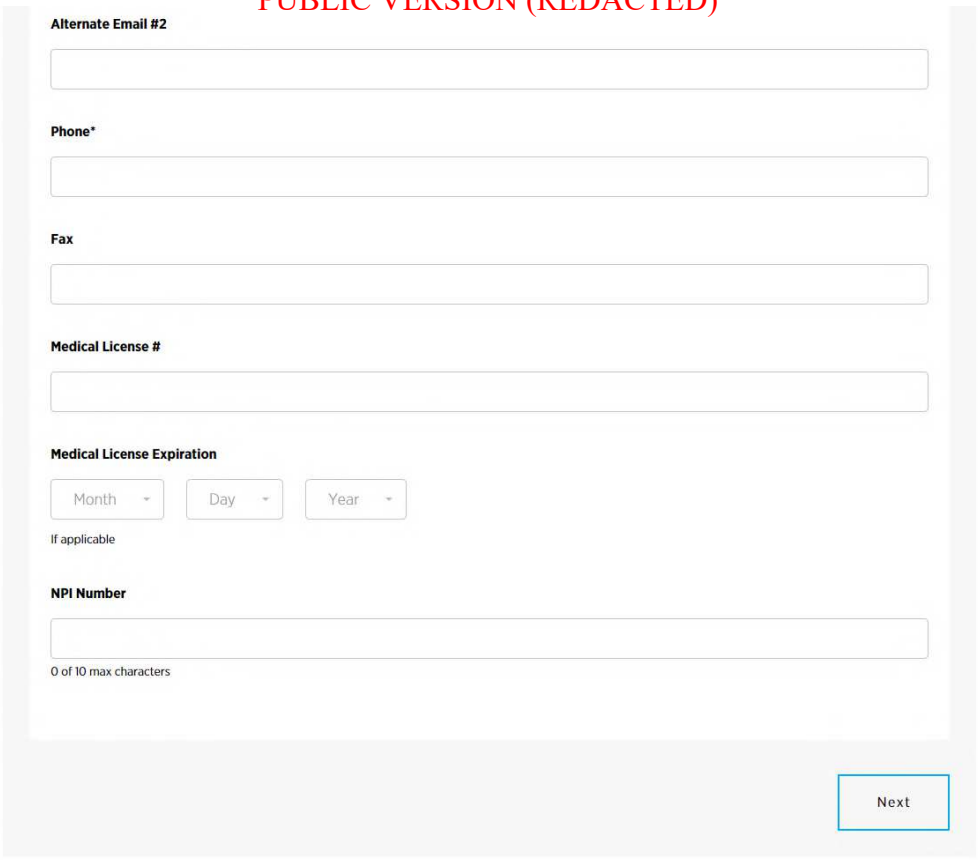

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Your next drug trial shouldn't be a study in complexity — and it doesn't have to be. The Premier IRT system simplifies clinical trial management, improves data security, and easily accommodates your specific study design requirements. Premier IRT offerings include:

- Interactive Voice Response System (IVRS): Voice-based IRT system
- Interactive Web Response System (IWRS): Web-based IRT system
- Electronic Clinical Outcome Assessment (eCOA) Solution: IVRS + IWRS + reporting device of your choice for electronic patient-reported outcomes (ePROs) and other clinical assessments

Our reliable, fully validated 21 CFR Part 11-compliant IVRS/IWRS system incorporates electronic reporting and ePRO capabilities, allowing you to automate many aspects of your trial with flexibility and confidence. That means less stress on investigators and patients alike, and it lets you focus more on science and less on administration.

The Premier IRT system, available as a full-service capability or as a standalone offering, has proven itself on trials throughout North America, Europe, South Africa, Asia, and Australia. It's backed by a strong, stable team of IRT experts experienced in all facets of interactive response and ePRO systems.

Premier IRT Benefits:

- Fully automated user registration and approval
- Subject randomization and IP dispensing, including centralized, stratified, adaptive, and biased coin algorithms
- Screening, screen failure, washout, and run-in visit tracking — even management of rescue medication
- Early termination, completion, and follow-up visit tracking, including management and dispensing of down-taper medication
- Anytime access to real-time customized reports that can be sorted, filtered, and exported
- Full-range clinical supply management functionality, including automatic reorders, expiry tracking, management of drug returns, and access to unblinded reports
- Diary collection for patients, investigators, and other caregivers through our eCOA "bring your own device" solution

Mobile ePRO/eCOA reporting at your fingertips

With our easy-to-use mobile ePRO application, patient diaries and other eCOA data can be entered on any Android or iOS device. Types of data that can be captured include:

- NPRS (0-10): e.g., Pain on a scale of 0-10
- Five Point Scales: e.g., Always, Often, Sometimes, Seldom, Never
- Yes\No Questions: e.g., Did you take any rescue meds?
- Numeric Values: e.g., How many rescue tablets did you take? How many times did you wake up last night?

Our mobile solution helps ensure compliance and is tightly integrated with our core IRT system within the ePremier Integration Hub, which brings study data and data quality processes together under one platform. Click here to learn more.

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Get more information

Ready to get started? So are we. Drop us a line to learn more about how we can help.

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Advantages of ePROs

In these unprecedented times, when gathering data remotely is the method of choice, it's worth making use of ePRO data in your clinical studies to help maintain the integrity of your clinical trials.

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The era of non-traditional data sources

Non-traditional data points, in particular real-world data (RWD) and real-world evidence (RWE), are becoming more and more important in the current research climate.

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PATIENT AND STAKEHOLDER ENGAGEMENT

"It Motivates Me Every Day": Our Premier Research Team on Why Rare Disease Research Matters

By Angi Robinson | February 19, 2021

There are as many as 7,000 distinct types of rare and genetic diseases, and an estimated 400 million people suffer from a rare disease globally. In addition, three of 10 children with a rare disease won't live to see their fifth birthday. Rare Disease Day, celebrated around the world on the last day of February, is a day of observance to raise awareness for rare disease patients and their families while also improving access to treatment and medical representation.

At Premier Research, we recognize the importance of centering the patient perspective and building deep connections with advocacy groups and other stakeholders to help answer the unmet needs of patients across a broad range of medical conditions. Because we're Built for Biotech℠, we share the passion and commitment of our sponsors when it comes to transforming life-changing ideas and breakthrough science into new medical treatments. We asked our project teams to share their stories about the importance of rare disease research – here's what they said:

"Your perfectly happy and seemingly healthy five-year-old child says they want to be a doctor when they grow up. You know your beautiful baby will soon begin to show symptoms of a rare disease and won't grow up. Few people understand what will happen, even fewer that can provide information, and there is no cure, no hope. Working in rare disease research is working to provide that hope, that information, and hopefully that cure."

Ann Marie McCann, *Associate Project Director*

"A notable moment for me that highlights the importance of rare disease research is reflected in a conversation I had with a specialist at a rare disease conference. He shared that after collecting pediatric clinical trial data, his team performed the first adult study in a particular rare indication. Given that research is typically done in adult populations, I inquired about the evident shift with him. His response was that 20 years ago, children suffering from rare diseases typically did not survive childhood. Now there are enough rare disease patients who have matured into adulthood to allow further research into the adult implications of the condition to be collected and assessed. I found this amazing and profound, and felt quite proud that the work we do in this area makes an astonishing difference, not only to the children but to their families as well."

Anthony Poynton, *Senior Director, Program Delivery, Rare Disease & Pediatrics*

"For me, rare disease research provides hope to patients and families that are often overlooked. It gives them options and a way forward that would otherwise not have been there."

Hanna Wide, *Executive Director, Gene and Cell Therapy*

"Rare disease research teaches us to understand the fundamentals of human physiology and pathophysiology, which are often applicable to prevent more common diseases and disorders."

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Pawel Skowronski, *M.D. Associate Project Director*

"I have been working on rare disease projects for more than13 years. Rare disease studies are very often complex and demanding, but the working atmosphere and level of engagement created among the different teams–sponsor, investigational staff, vendors, and Premier Research–in connection with families is unique. I'm incredibly proud to be able to support these patients and their families in their journey. It motivates me every day."

Elena Martinez, *Senior Project Manager*

"I have two family members with a rare genetic disorder and see first hand how treating the symptoms rather than the underlying condition is not a long-term solution for the best quality of life. My hope is that the work that we do every day helps shift this treatment paradigm to support the best outcomes for all patients with rare diseases."

Jackie Brown, *Executive Director, Program Delivery, Rare Disease & Pediatrics*

"What I've learned from working with rare disease patients is to never give up – never give up on the work we are doing and never give up hope. I've learned this from my friends and colleagues who have been impacted directly by a rare disease and from the parents and patients who have shared their personal stories to support disease awareness, shared their knowledge and experiences to educate sponsors and regulators, and contributed even more by participating in clinical research. I've witnessed life-changing drugs become available in my career and it's important that we do not give up on bringing more effective treatment options to those with unmet need."

Angi Robinson, *Vice President, Specialty Areas*

Follow the stories of those for whom rare disease research matters most at https://www.rarediseaseday.org/or by following the hashtag #RareDiseaseDay. We are proud to partner with the companies that are advancing these critical life-changing therapies. For more information about our work, click here.

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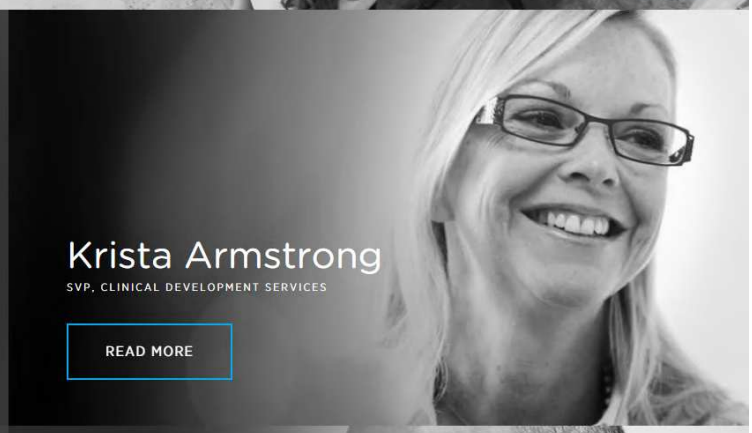

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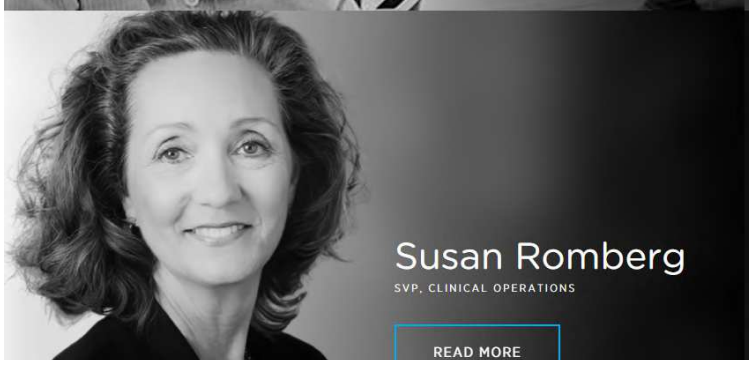

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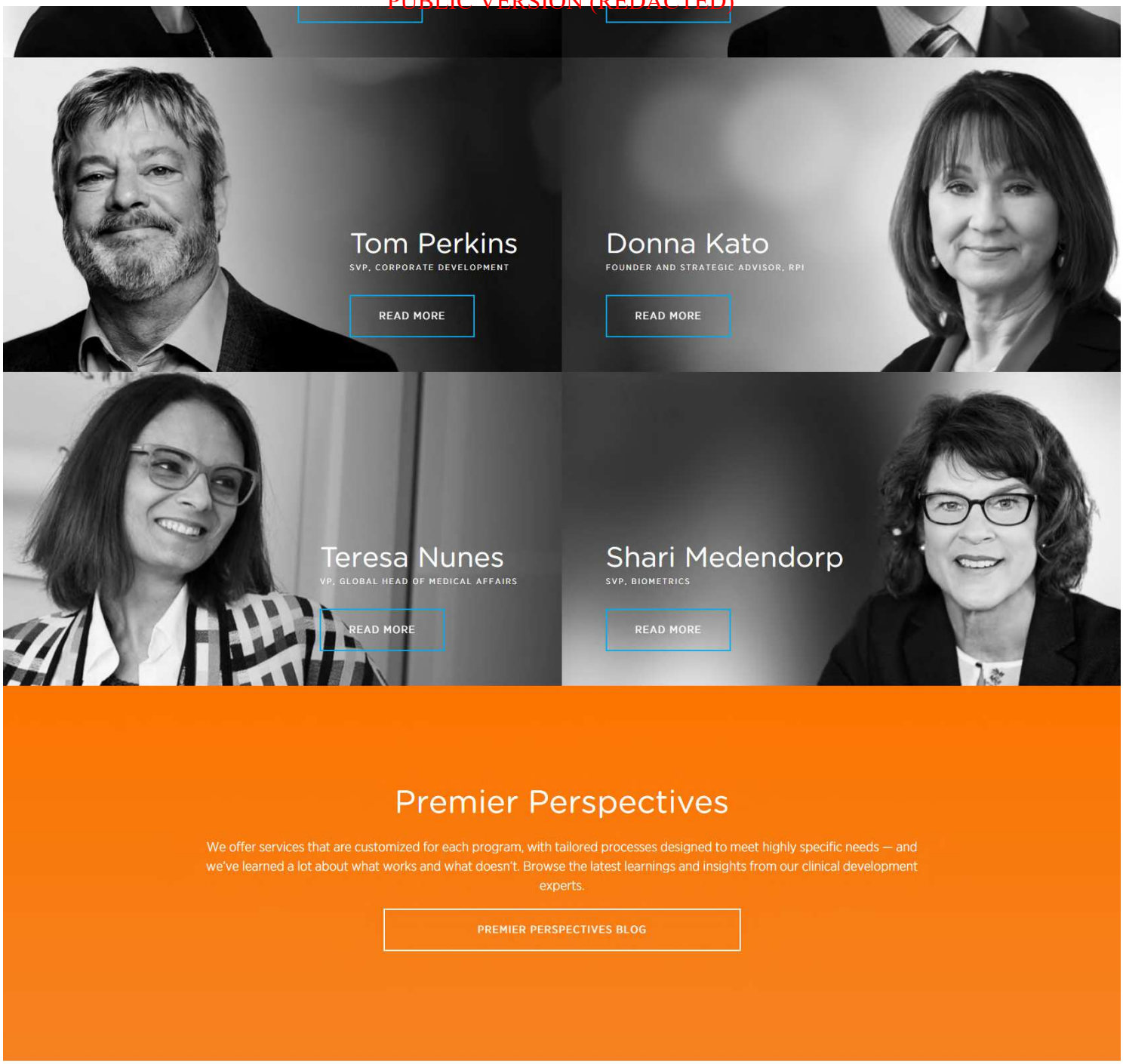

Premier Perspectives

We offer services that are customized for each program, with tailored processes designed to meet highly specific needs — and we've learned a lot about what works and what doesn't. Browse the latest learnings and insights from our clinical development experts.

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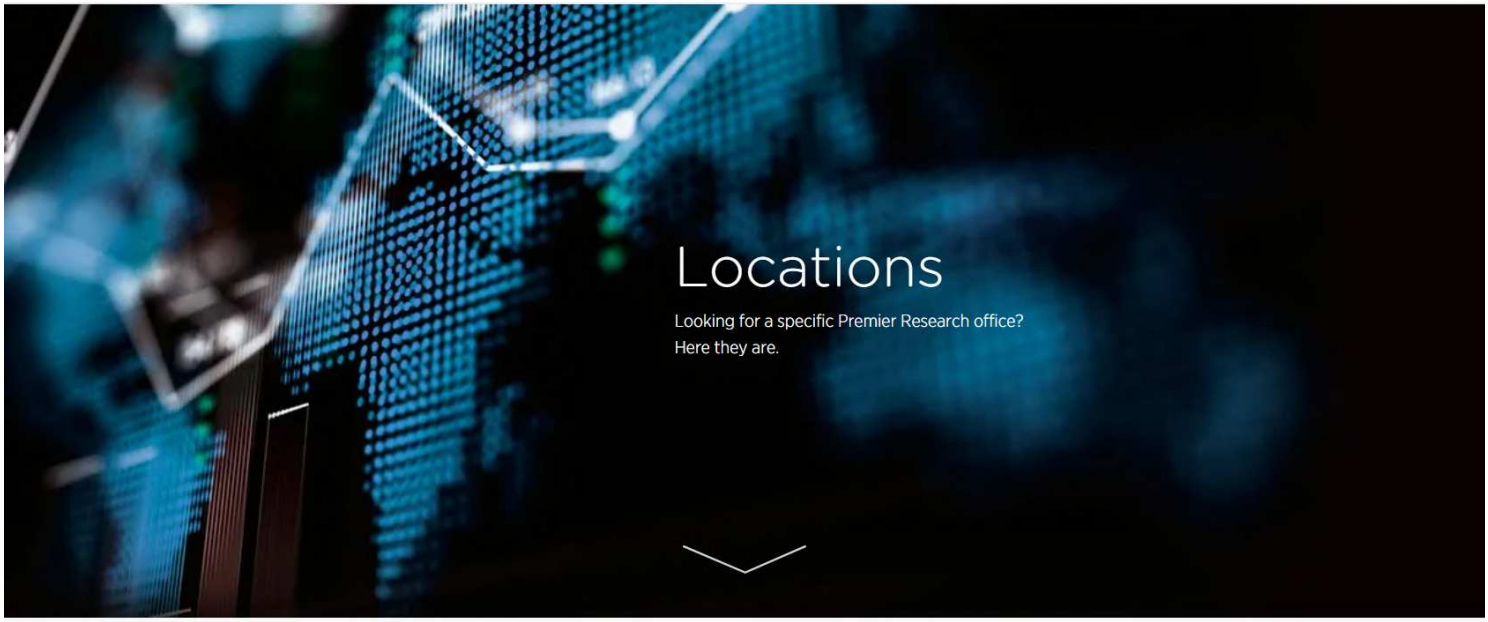

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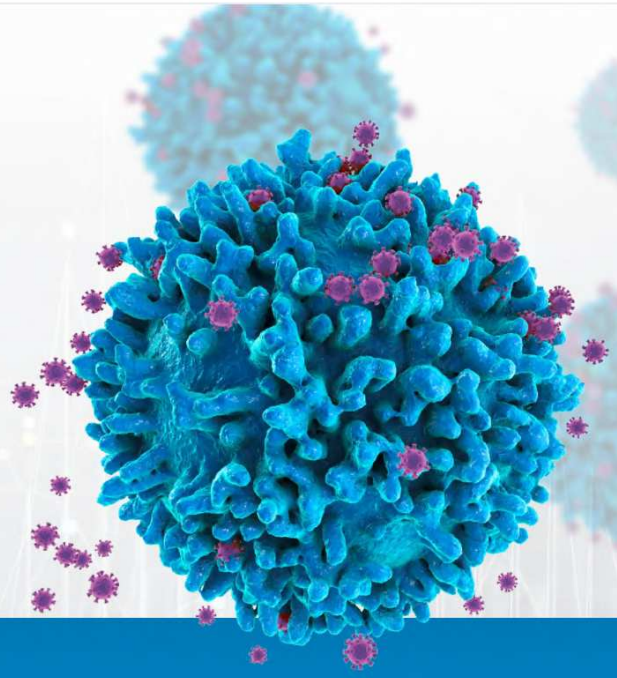

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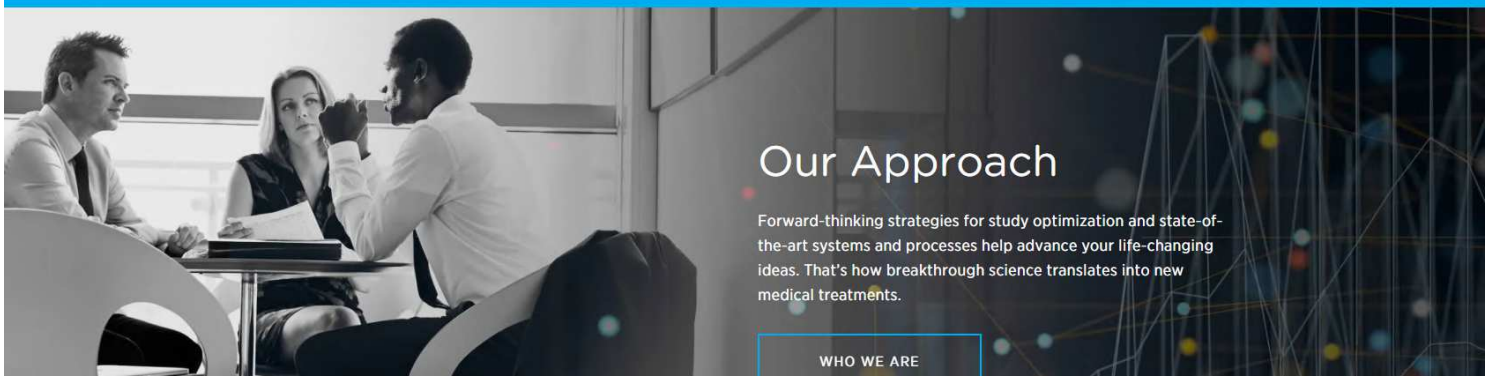

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Kristi Miller, Ph.D., Vice President, Regulatory Affairs, Regulatory Professionals, a division of Premier Research

Christopher Hendry, Senior Director, Technical Services, Regulatory Professionals, a division of Premier Research

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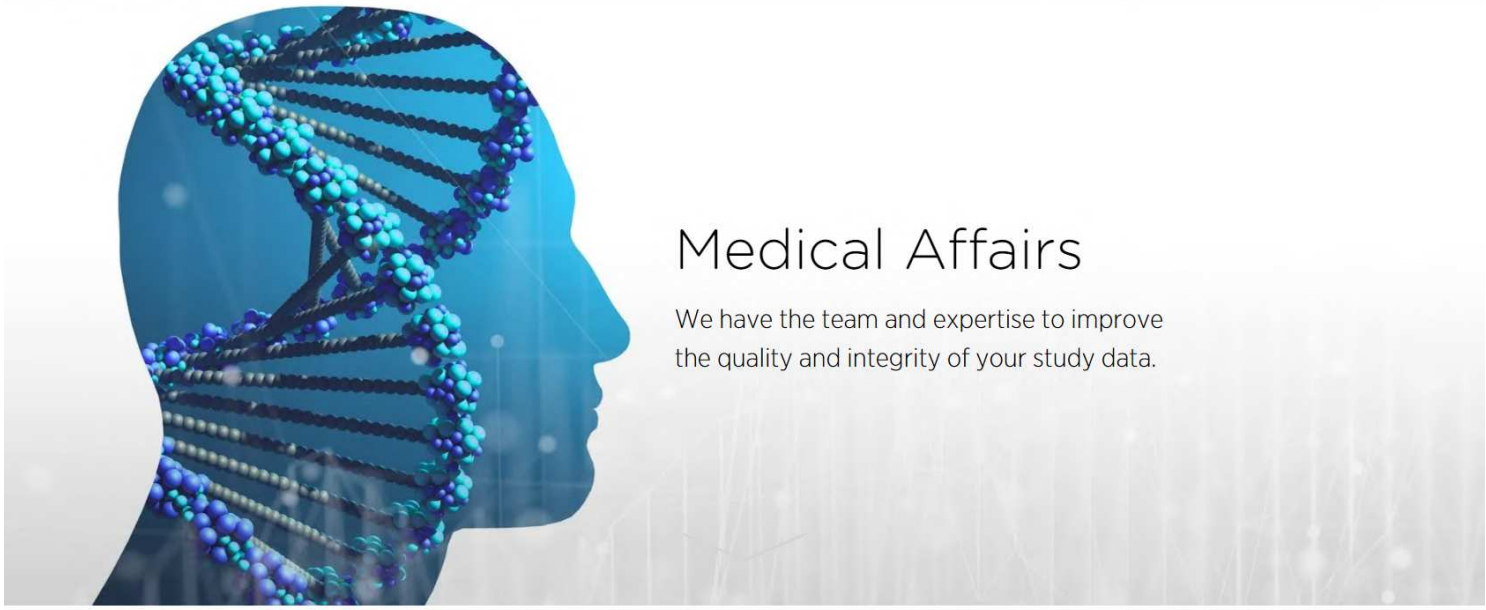

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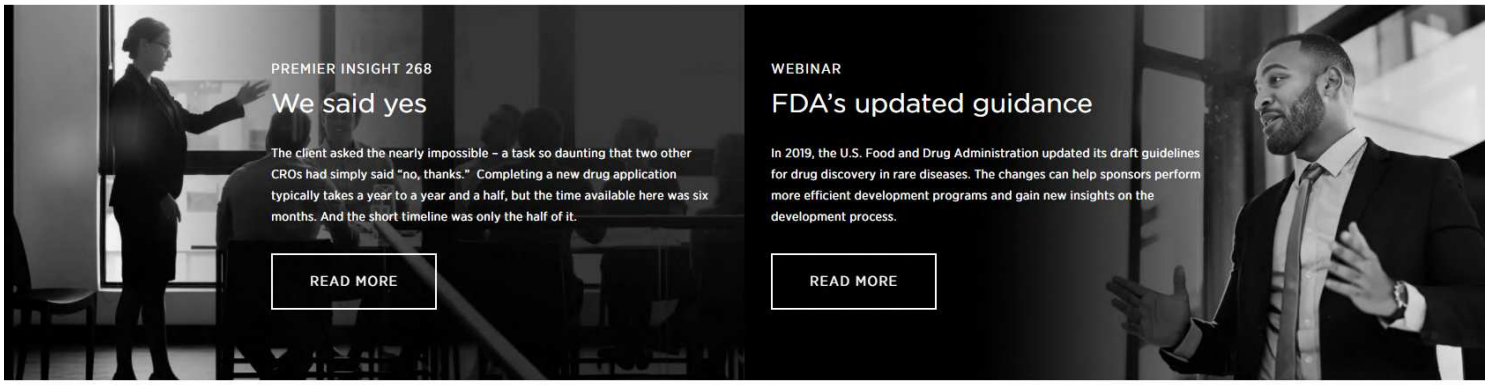

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25.04.2022

Mid-Size CRO Competitive Landscape

Last week I had a great opportunity to attend and present (on behalf of Clinipace) at Baird's Annual Healthcare Conference in New York City. As always, the conference was well run, well attended and provided the opportunity to meet with peers, customers and investors to discuss the pharma services sector. Everyone seemed to agree that increased biotech funding, mid-size CRO consolidation and the widening gulf between the large and midsize CROs has changed the sector dynamics. A frequent question was: "Which mid-size CROs does Clinipace see as their main competition?". Ironically, just yesterday, I received the same question during Veeva's annual conference in Philadelphia.

My Answer

I don't see the other mid-size CROs as Clinipace's prime competition. Realistically we are more peers than full on competitors. Naturally, we compete in many instances, but it's less often than the investor community might think. We compete with mega/large CROs and niche/regional CROs more often than our mid-size peers. When I first entered the industry with MDS Pharma Services back in 2007, the question was: "How can a CRO differentiate with so many CROs in the market?". I believe that narrative has changed in recent years in mid-size sector for the following reasons:

1. Differentiation among the mid-size CROs
2. Small pharma/biotech sponsors growth along with less mid-size CROs
3. The widening gulf between the large/mega CROs and their mid-size counterparts

Mid-Size CRO Differentiation

Today's mid-size CROs differentiate both therapeutically and geographically. I have pulled together data taken from several of the key mid-size CROs in the market today: Clinipace, Premier Research, Medpace, Synteract, Worldwide Clinical Trials, Pharm-Olam, TFS & CROM-Source. My apologies to other privately held mid-size CROs I may have omitted (I also needed to cut off my analysis as the chat below is already tough on the eyes). The schedule below lays out the key therapeutic areas for each of the aforementioned CROs.

Premier Research	Clinipace	Medpace	Synteract	Worldwide Clinical	Pharm-Olam	TFS	CROM Source
Analgesia	Oncology & Hematology	Immunology	Dermatology	Central Nervous System	Oncology & Hematology	Oncology & Hematology	Respiratory
Dermatology	Gastrointestinal	Cardiovascular	Neuro-Degenerative	Cardiovascular	Infectious Disease & Vaccine	Dermatology	Opthamology
Oncology & Hematology	Nephrology	Endocrine & Metabolic	Oncology & Hematology	Immunology	Rare & Orphan Disease	Opthamology	Oncology & Hematology
Neuroscience	Rare & Orphan Disease	Oncology & Hematology	Pediatrics	Rare & Orphan Disease		Cardiovascular	Rare Disease & Orphan
Pediatrics	Women's Health	Infectious Disease & Vaccine	Rare & Orphan Disease	Oncology & Hematology		Immunology	
Rare & Orphan Disease		Neurology & Psychiatry		Endocrine & Metabolic		Endocrine & Metabolic	
		Nephrology		Pediatrics		Central Nervous System	

The next schedule (with the purple header) summarizes the number of times a therapeutic area was listed by our mid-size CRO group. As expected Oncology & Hematology was listed by every CRO (Baird & Pharmaprojects estimate that 35% of current industry pipelines are focused on oncology - which means having some oncology expertise is a must for a mid-size global CRO). You can see that after oncology/hematology and rare/orphan disease there isn't a lot of overlap among the group (in fact 11 of the 18 therapeutic areas only came up once or twice).

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Therapeutic Expertise	# of CROs
Oncology & Hematology	8
Rare & Orphan Disease	6
Immunology	3
Cardiovascular	3
Pediatrics	3
Dermatology	3
Endocrine & Metabolic	3
Central Nervous System	2
Infectious Disease & Vaccine	2
Opthamology	2
Nephrology	2
Neuroscience	1
Respiratory	1
Neurology & Psychiatry	1
Gastrointestinal	1
Women's Health	1
Analgesia	1
Neuro-Degenerative	1
Grand Total	**44**

A bit of a similar story from a geographic standpoint, the below schedule shows that our peer group all have a physical presence in at least 2 geographic regions. However, a few items jump out. Clinipace and Medpace have made the clear decision to invest in Asia-Pac with offices in 8 countries (shameless plug but last month Clinipace welcomed its 100th employee in India). Pharm-Olam and TFS have offices in the most European countries, which is no surprise as TFS was established as a European CRO and Pharm-Olam is known for its strength in Eastern Europe. I expect more Asia-Pac expansion from this group in the future.

Mid-Size CRO Countries with Offices

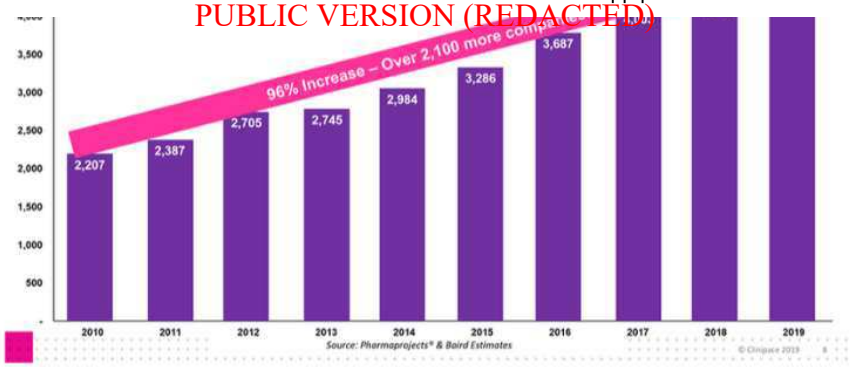
Region	Clinipace	Premier Research	Medpace	Synteract	Worldwide Clinical	Pharm-Olam	TFS	CROM Source
Africa	-	-	1	-	-	1	-	-
Asia-Pac	8	3	8	-	2	1	-	-
Europe	11	13	13	10	12	17	17	10
North/South America	4	2	2	1	3	2	1	1
Total	23	18	24	11	17	21	18	11

Notes:
1) Info taken from each company's website
2) Does not include multiple offices in a country - for example Clinipace has 2 offices in Germany. For purposes of this analysis Germany is only included once.
3) CROs may have staff, contractors or legal entities in other countries not included in this analysis.

Increase in Small Pharma/Biotech

The large amount of biotech funding in recent years isn't a new revelation (as the chart below depicts).

The increased funding has doubled the number of biotechs with active pipelines. Creating a much larger market for today's mid-size CROs over the past decade.



Small pharma/biotech had more mid-size CROs to choose from a decade ago. Which is likely many thought that the mid-size CRO would become extinct as it was harder differentiate and compete (with a small customer pool).

With more buying customers and less competition, the mid-size CRO market has proven itself as a needed segment of the CRO market and has demonstrated long-term viability.

Mega/Large CRO Revenue Growth

I consider the mid-size CRO sector to include global CROs with revenue between $100M and Medpace's $700M, including pass-through revenue (Medpace being the largest mid-size CRO on the market). Mid-size CROs quickly reacted to the new market dynamics and focused their businesses on partnering with small pharma/biotech. The sustained success of the mid-size CRO sector suggests that smaller sponsors like the more customized focus they receive from mid-size CROs (this doesn't suggest that large/mega CROs aren't great companies - they certainly are but like all service industries its hard to have processes to partner with the likes of Pfizer and a startup biotech). I should point out that several of the large CROs launched divisions focused on the biotech market in 2019. A few observations from the chart below:

1. In 2010 there were 5 mega/large CROs, due to consolidation there are now 7 in 2019
2. In 2010, the IQVIA was 39x larger than the average $100M Mid-Size CRO, in 2019 IQVIA is 104x larger
3. In 2010, the "smallest" large CRO (Icon) was about 12.6x the size of a $100M mid-size CRO, in 2019 the

smallest "large" CRO (PRA) is almost 29x a mid-size CRO

4. IQVIA is now 15x larger than the largest mid-size CRO (Medpace)

Large/Mega CRO Revenue

#	CRO	2010 (4)	#	CRO	2018 (4)
1	Quintiles	$ 3,924	1	IQVIA	$ 10,412
2	Covance	$ 2,038	2	Syneos Health	$ 4,390
3	PPD	$ 1,471	3	Labcorp (Covance)	$ 4,313
4	Parexel	$ 1,336	4	Parexel (2017) (2)	$ 2,442
5	ICON	$ 1,263	5	ICON	$ 2,596
6	INC Research (2011) (1)	$ 656	6	PRA	$ 2,872
7	PRA	$ 520	7	PPD (private) (3)	????

Notes:
1) INC Research acquired Kendle in 2011, public info for INC Research prior to 2011 isn't available.
2) Parexel was taken private in 2018, 2017 is the last year public info is available.
3) PPD is private so current revenue results are not publicly available, but PPD is widely recognized as a top 5 CRO based on revenue.
4) 2010 & 2018 figures include pass-through revenue. Revenue recognition rules were recently changed - 2010 was adjusted for comparative purposes.

Consolidation at the top of the CRO market was expected and not a surprise - especially as strategic relationships with large pharma started to commence a decade ago. The big companies got bigger and the mid-size CROs changed. INC Research (Now Syneos) and PRA jumped up in category.

Wrapping Up

Therapeutic and geographic differentiation at the mid-size CRO tier combined with more opportunities (created by an increased biotech funding and a widening gulf between large/mega and mid-size CROs) has changed the competitive landscape. Mid-size CROs (at least Clinipace) compete more with regional and large/mega CROs rather than mid-size peers. Seems odd that the mid-tier would be competing with larger CROs, but makes sense considering larger CROs cover almost all therapeutic areas, have lots of relationships and launched divisions focused on the biotech sector. The good news is that customers have shown they value the mid-tier CRO and its place in the pharma outsourcing landscape in here to stay.

Jason Monteleone is CEO of Clinipace & President at Pivotal Financial Consulting, LLC. Clinipace is a global mid-size CRO with operations in the Americas, Europe and Asia-Pac serving small and mid-size pharma and biotech sponsors. Pivotal provides Divestiture Assistance, Acquisition Advisory Services and Strategic Planning to the Pharmaceutical Outsourcing Industry. Jason can be reached at jmonteleone@clinipace.com, jmonteleone@pvtfinance.com. Follow me on Twitter @JMPivotal. Sign up for Jason's latest blogs and updates at my www.pivotalfinancialconsulting.com.

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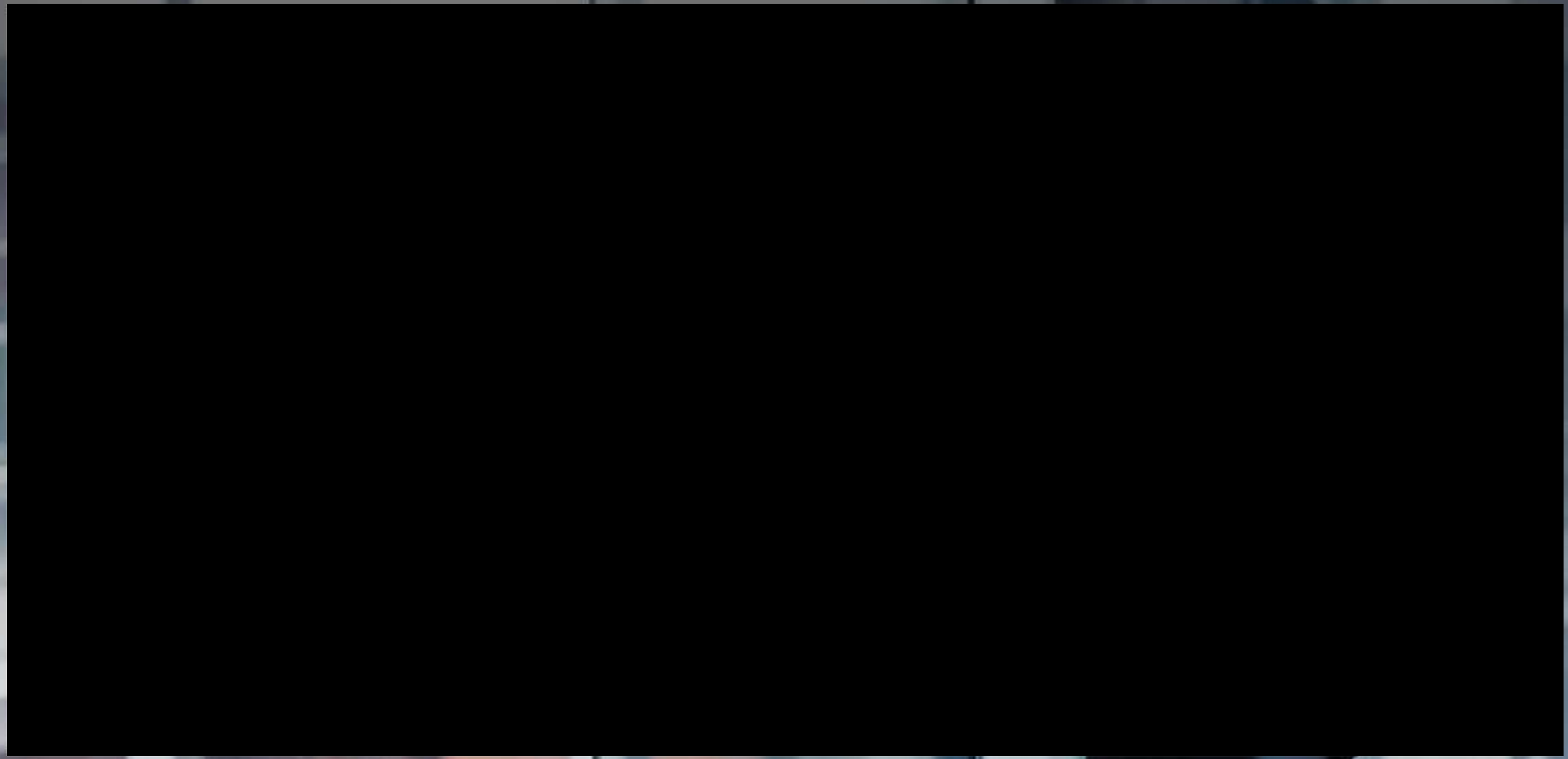

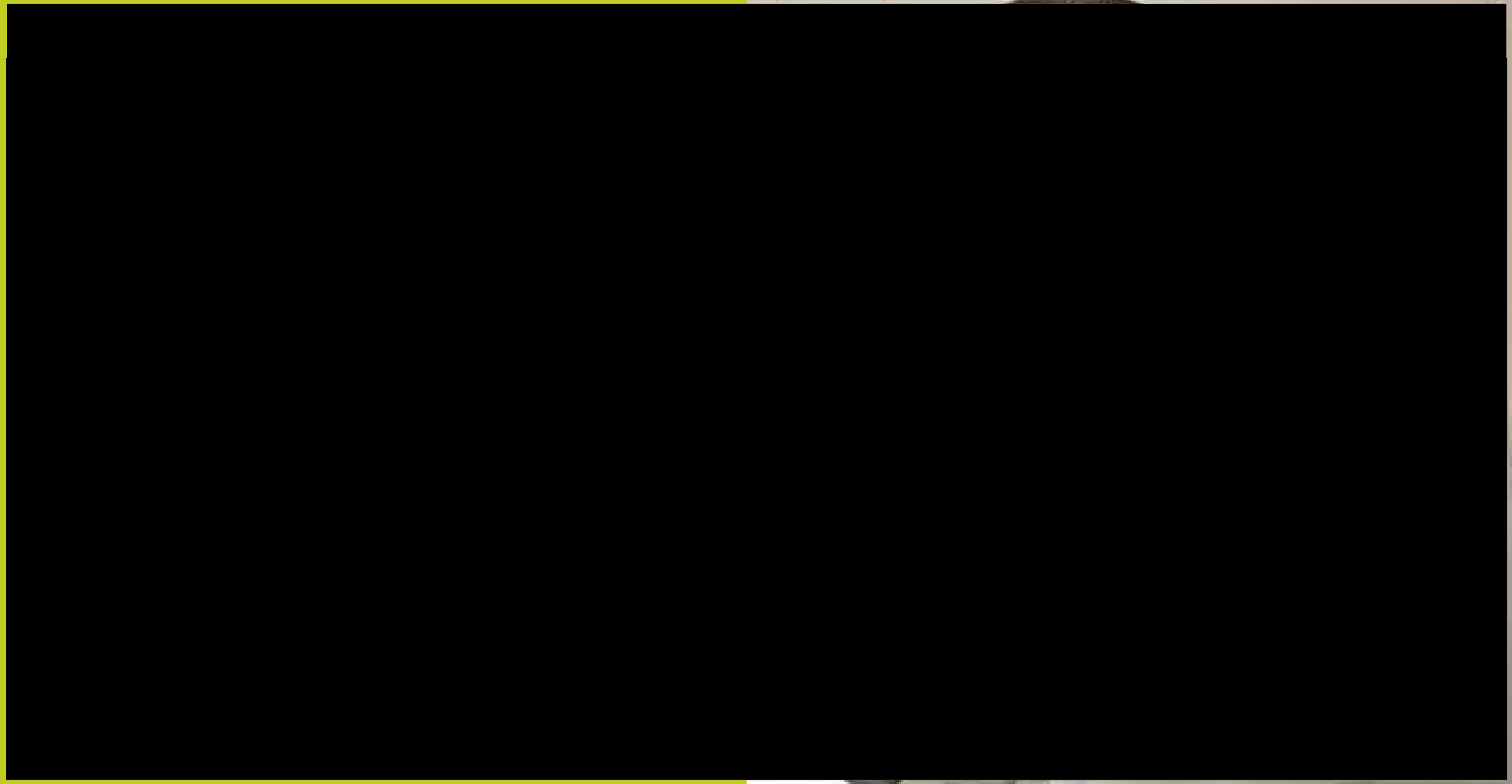

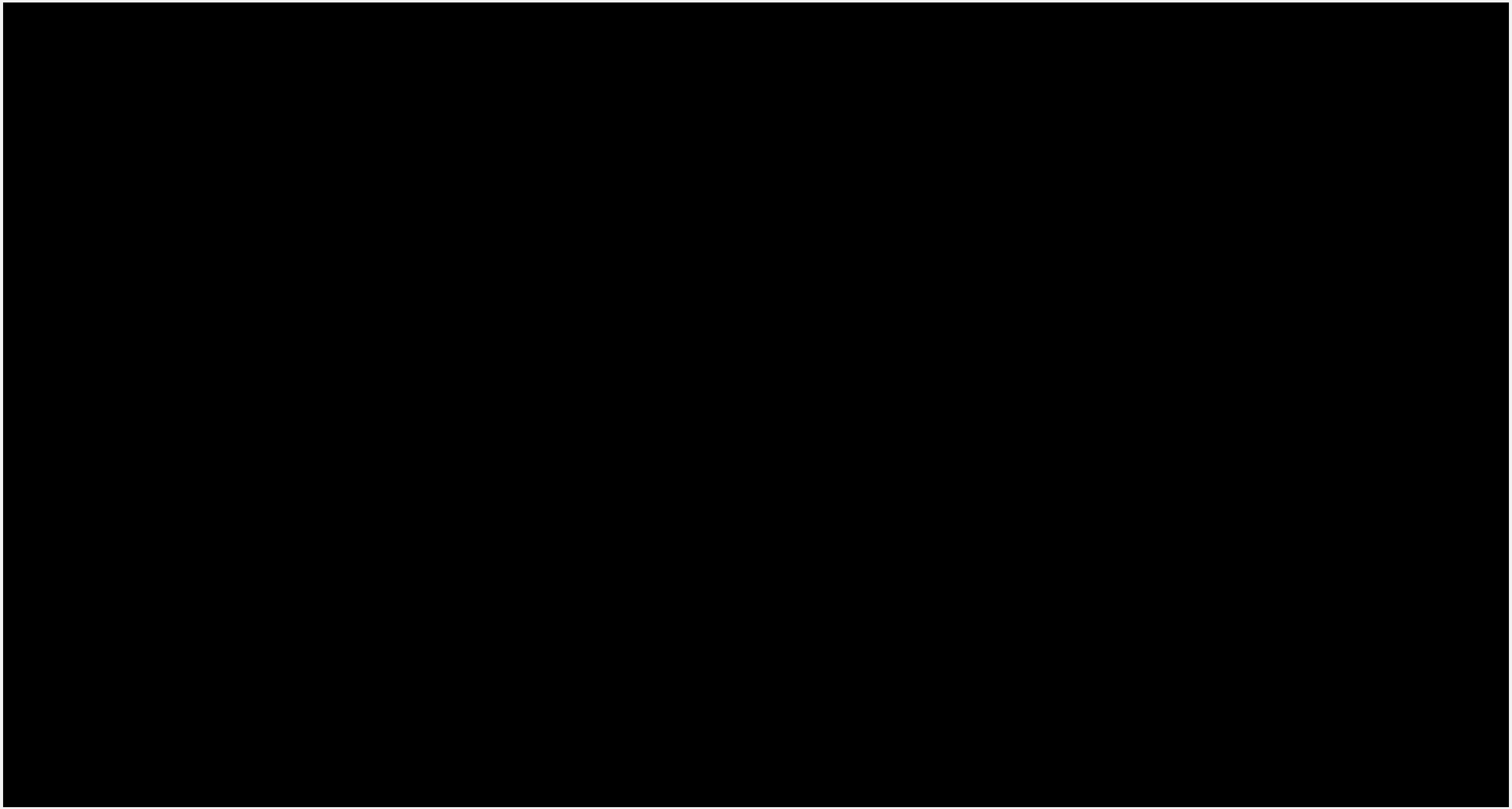

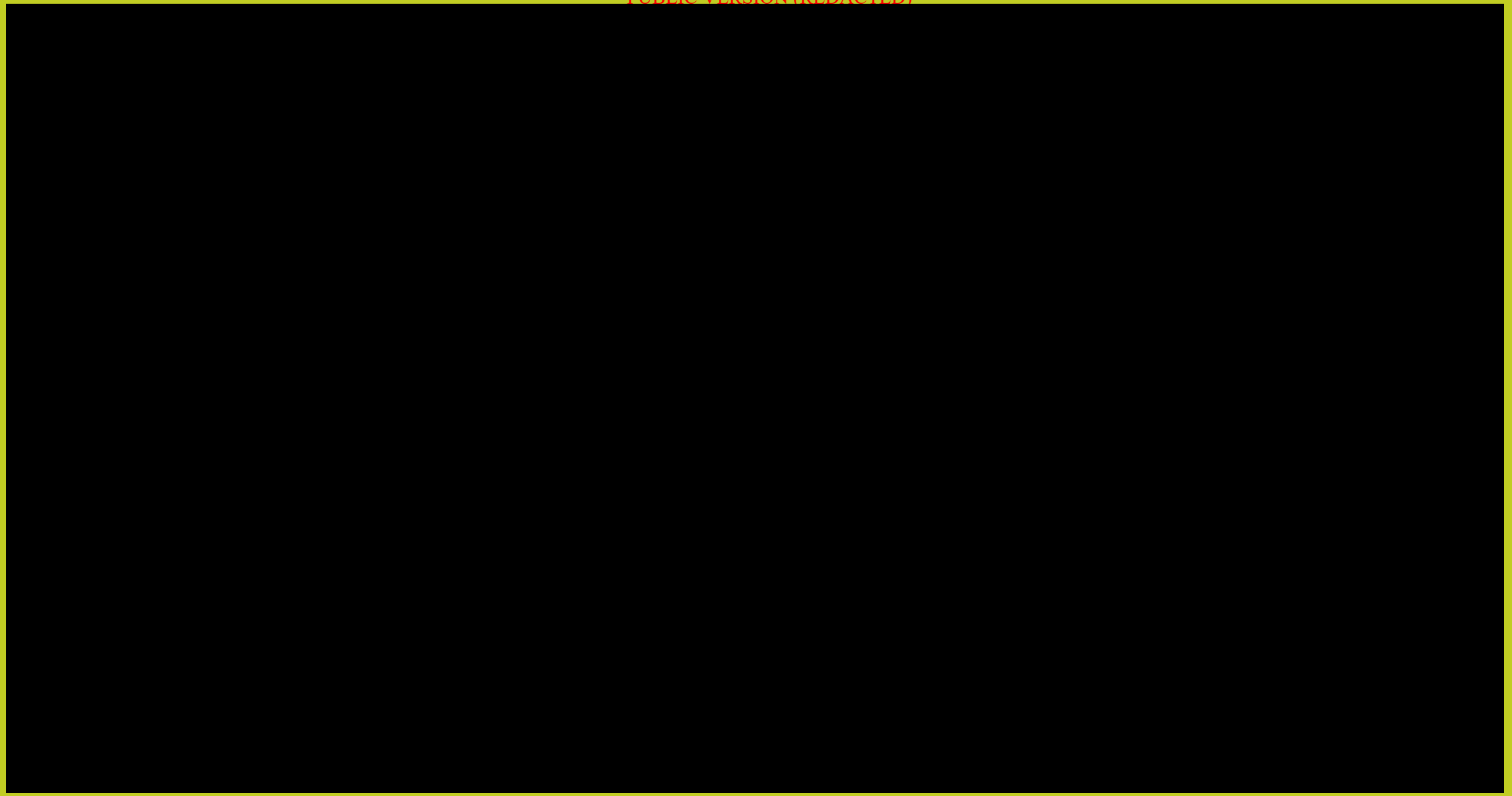

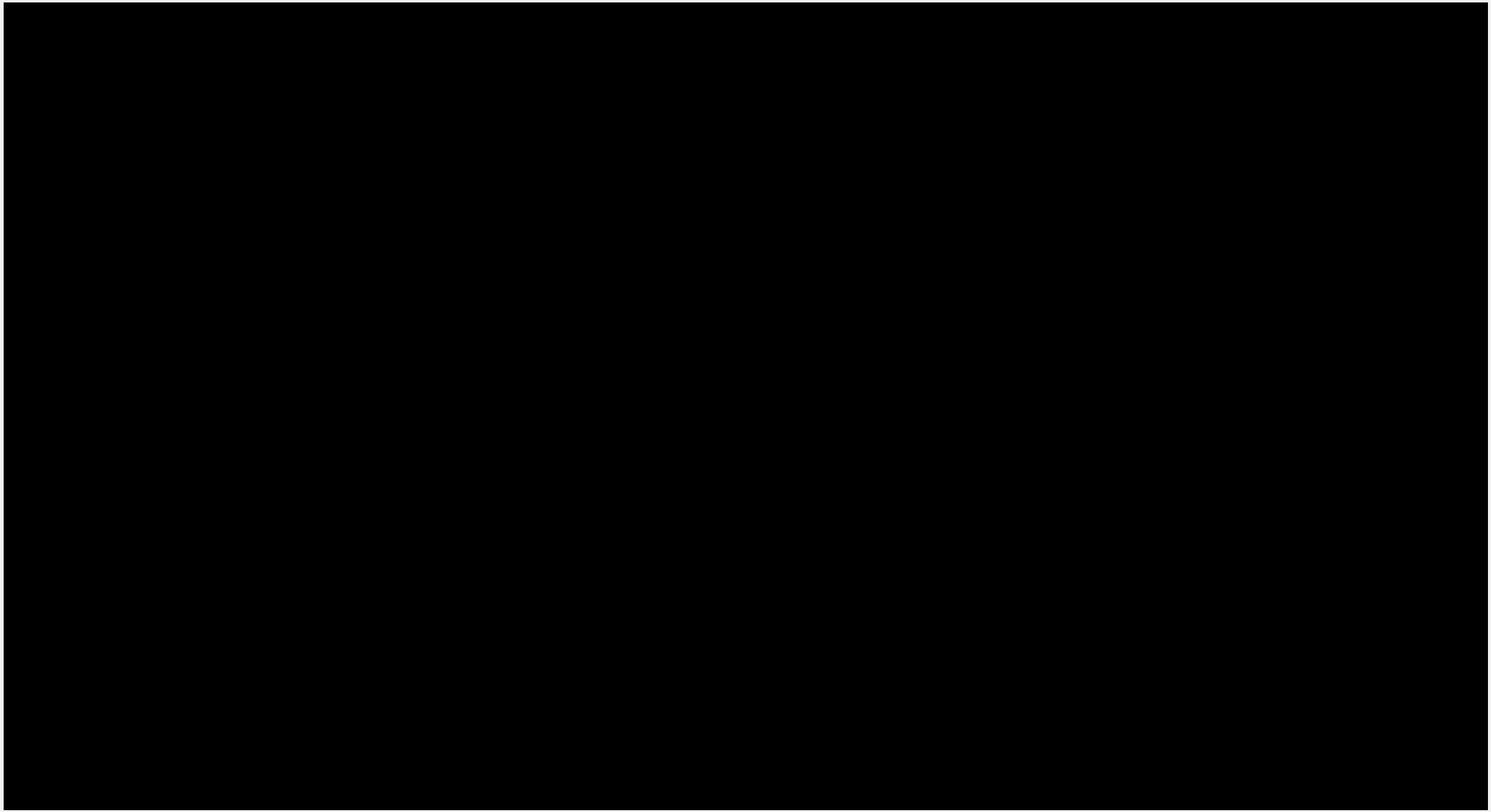

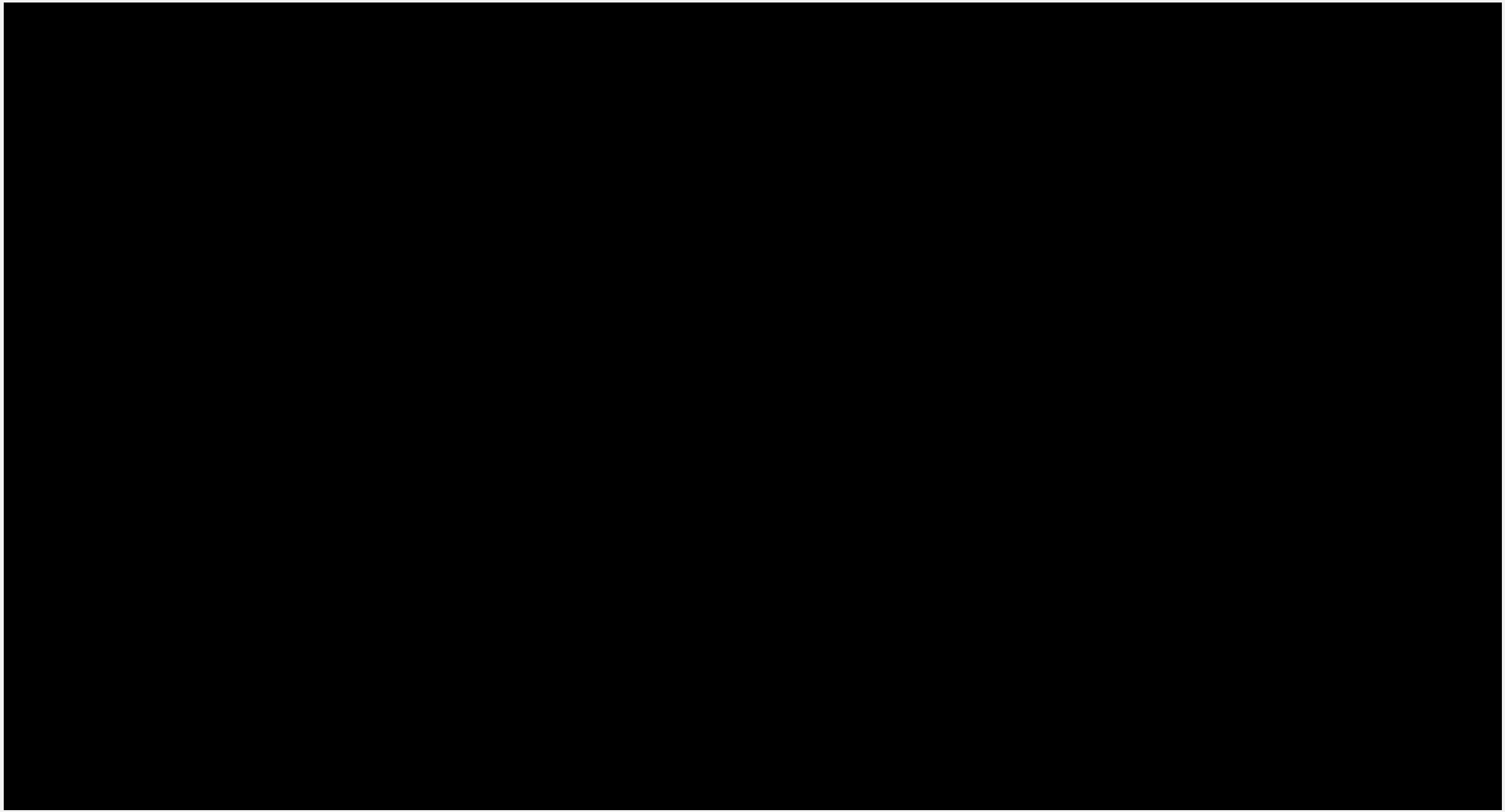

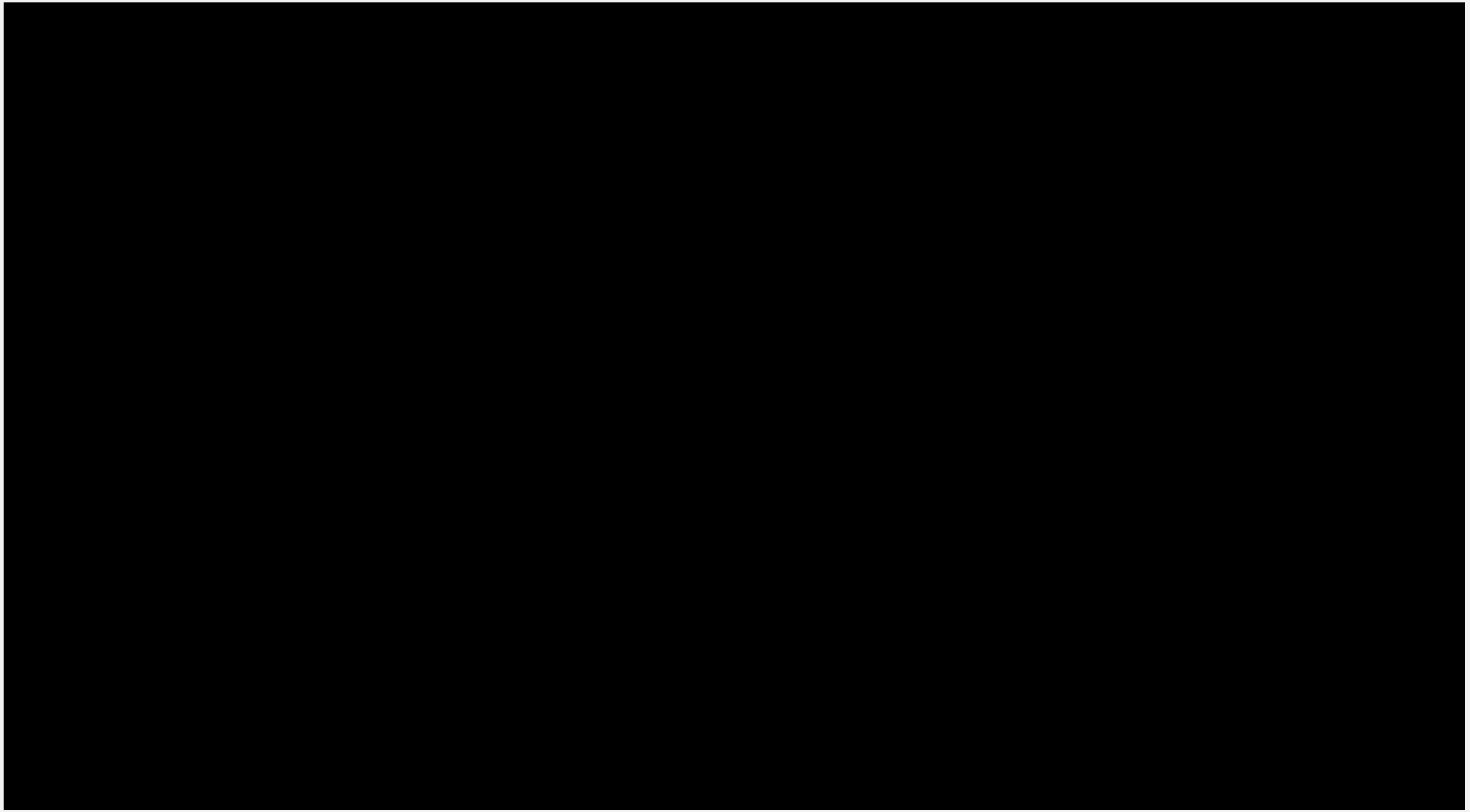

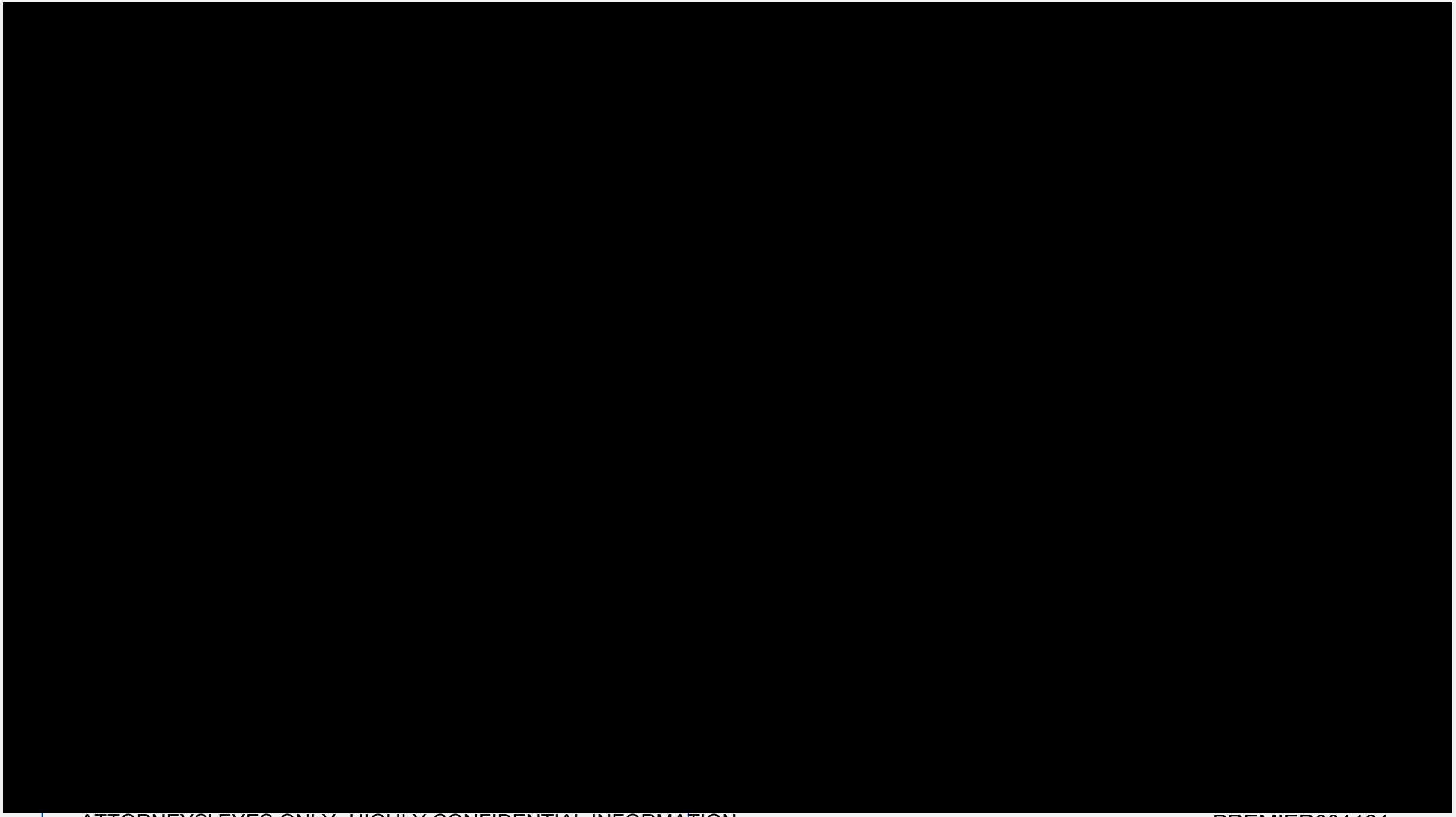

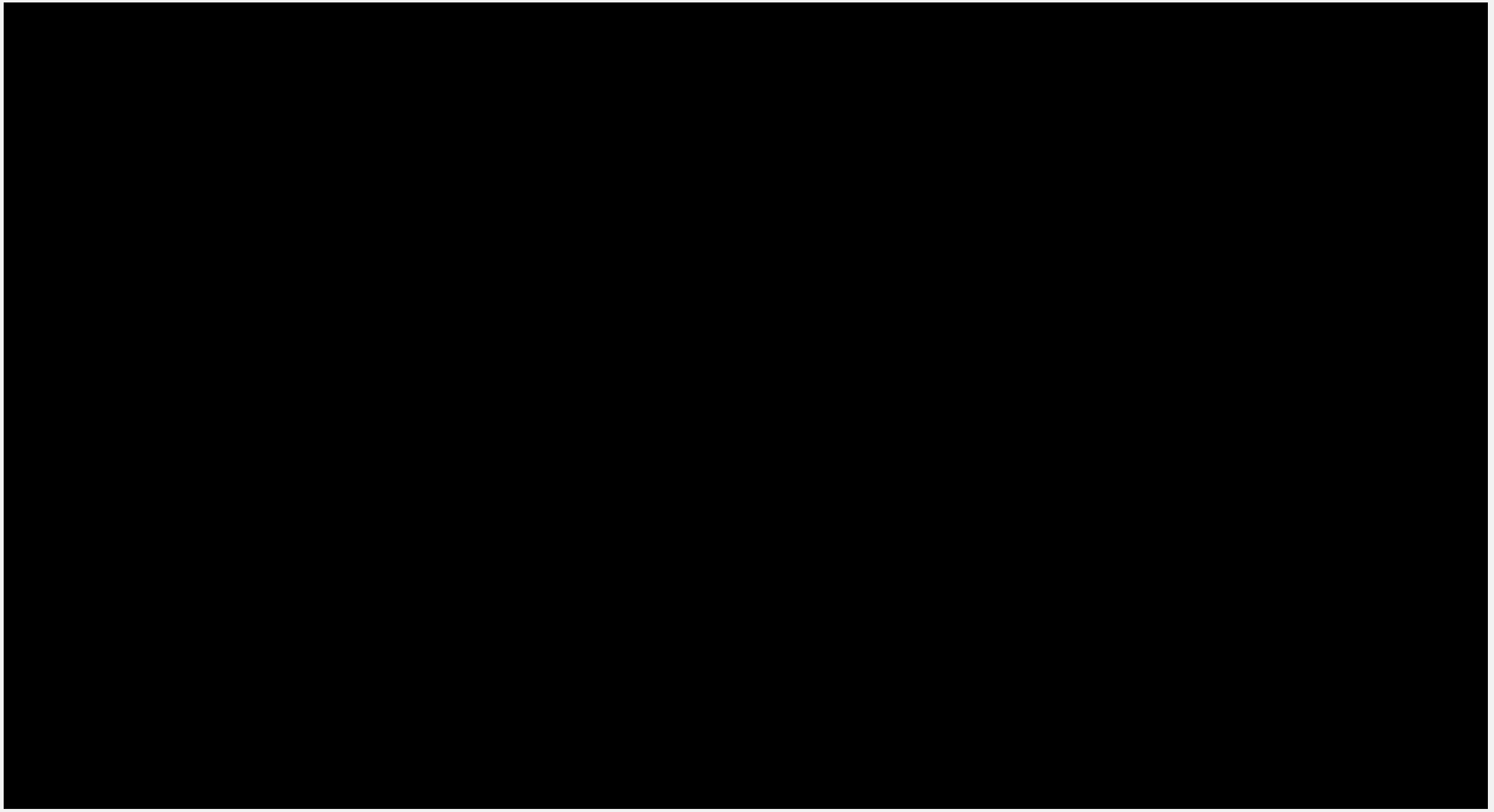

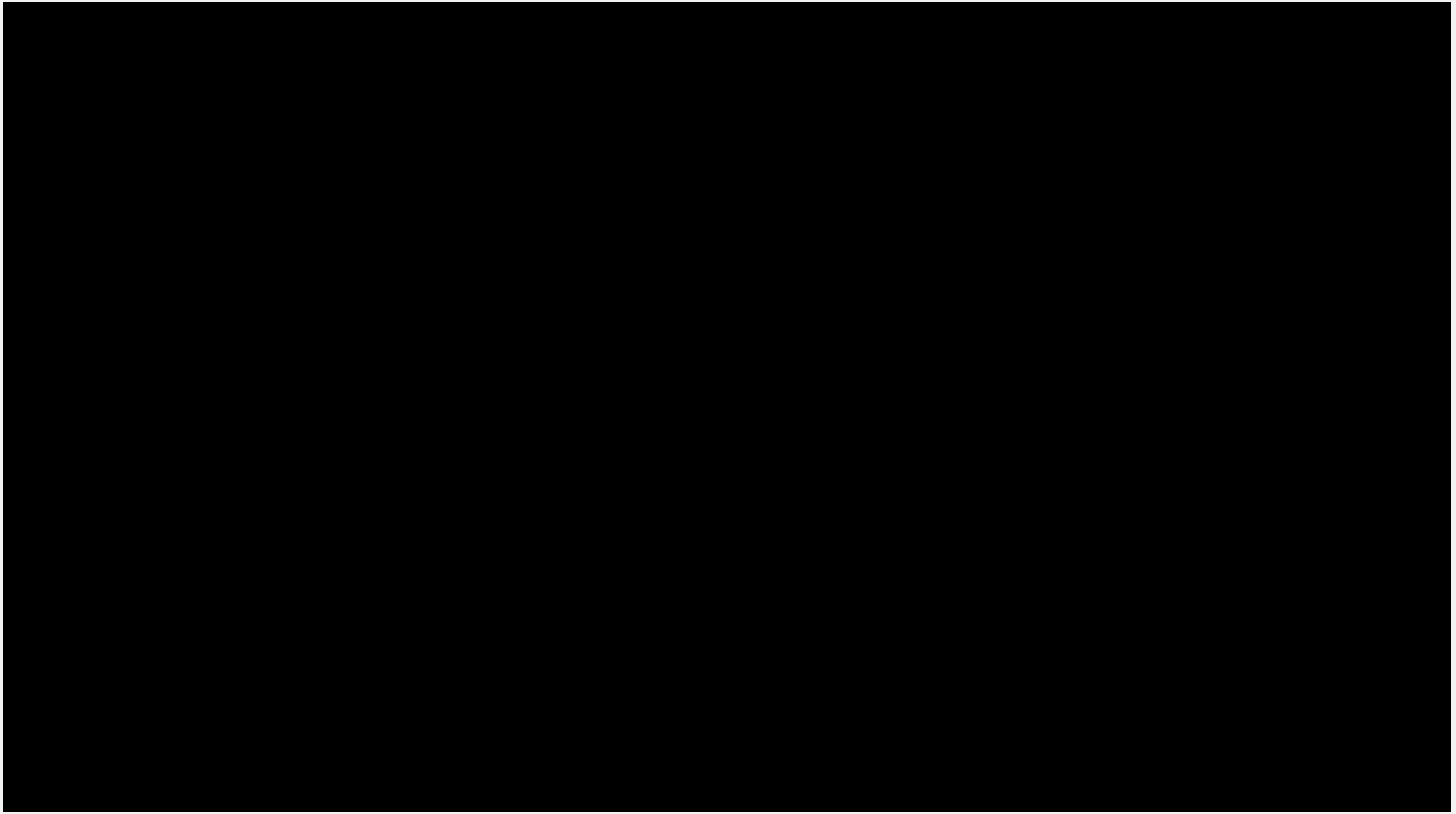

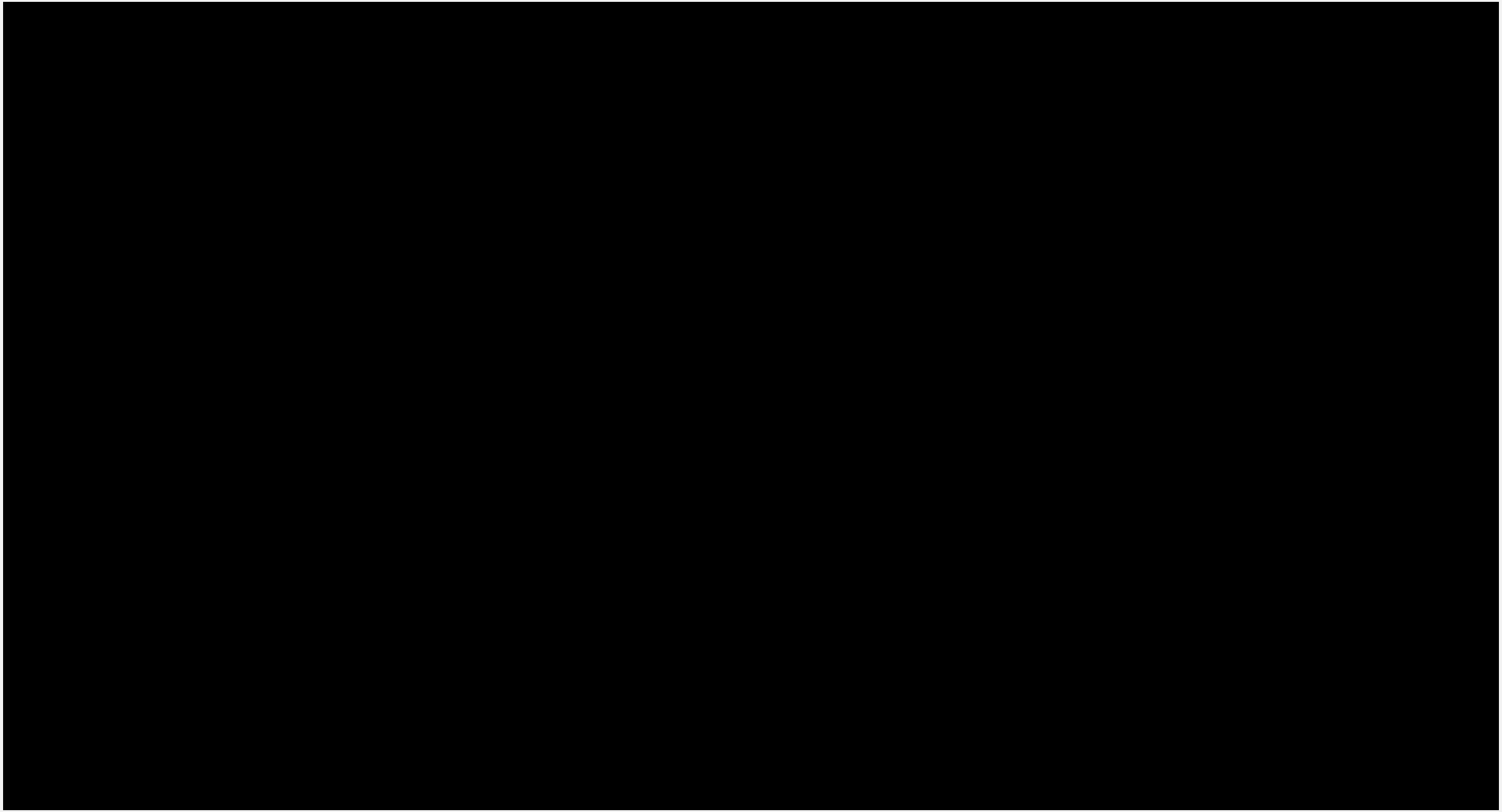

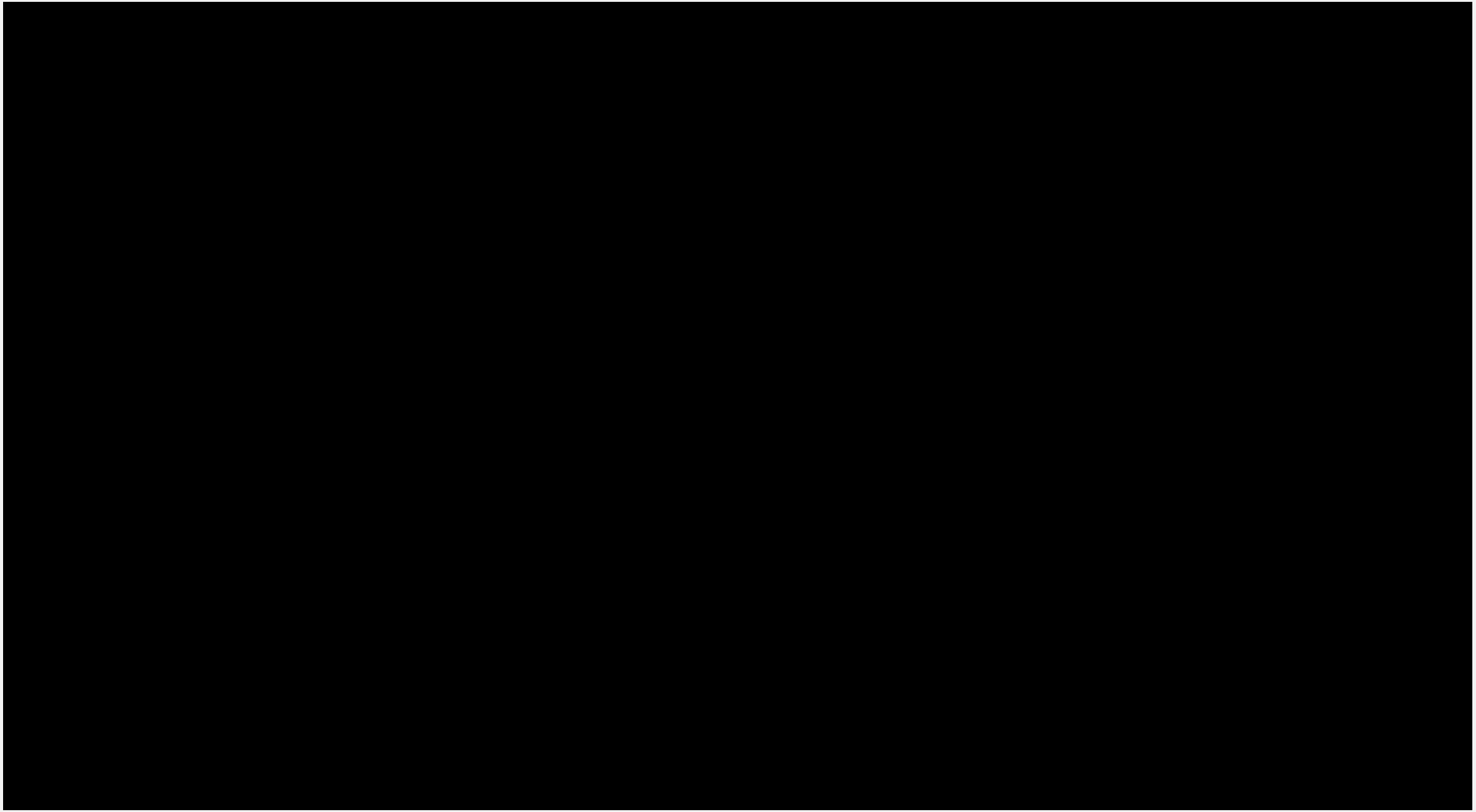

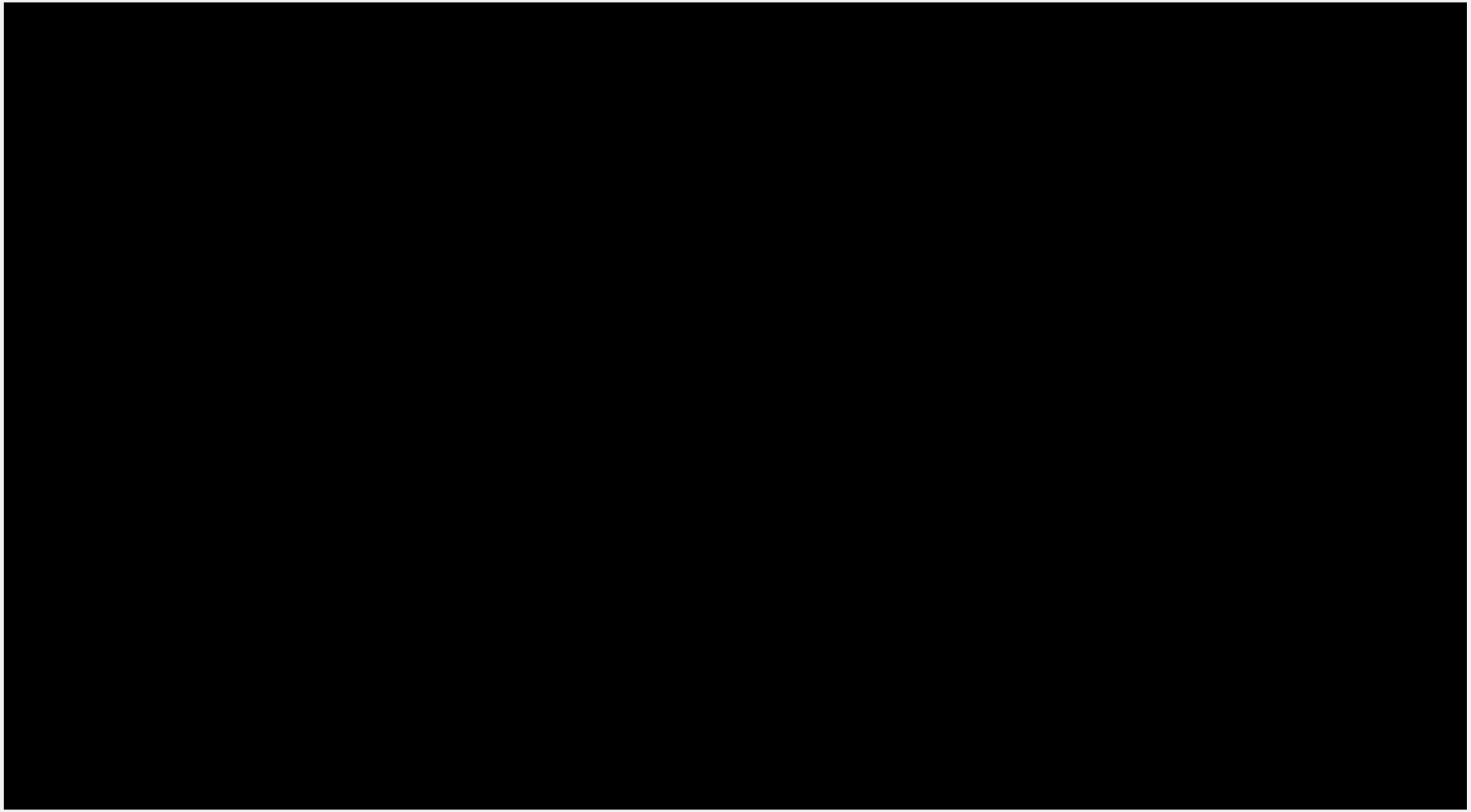

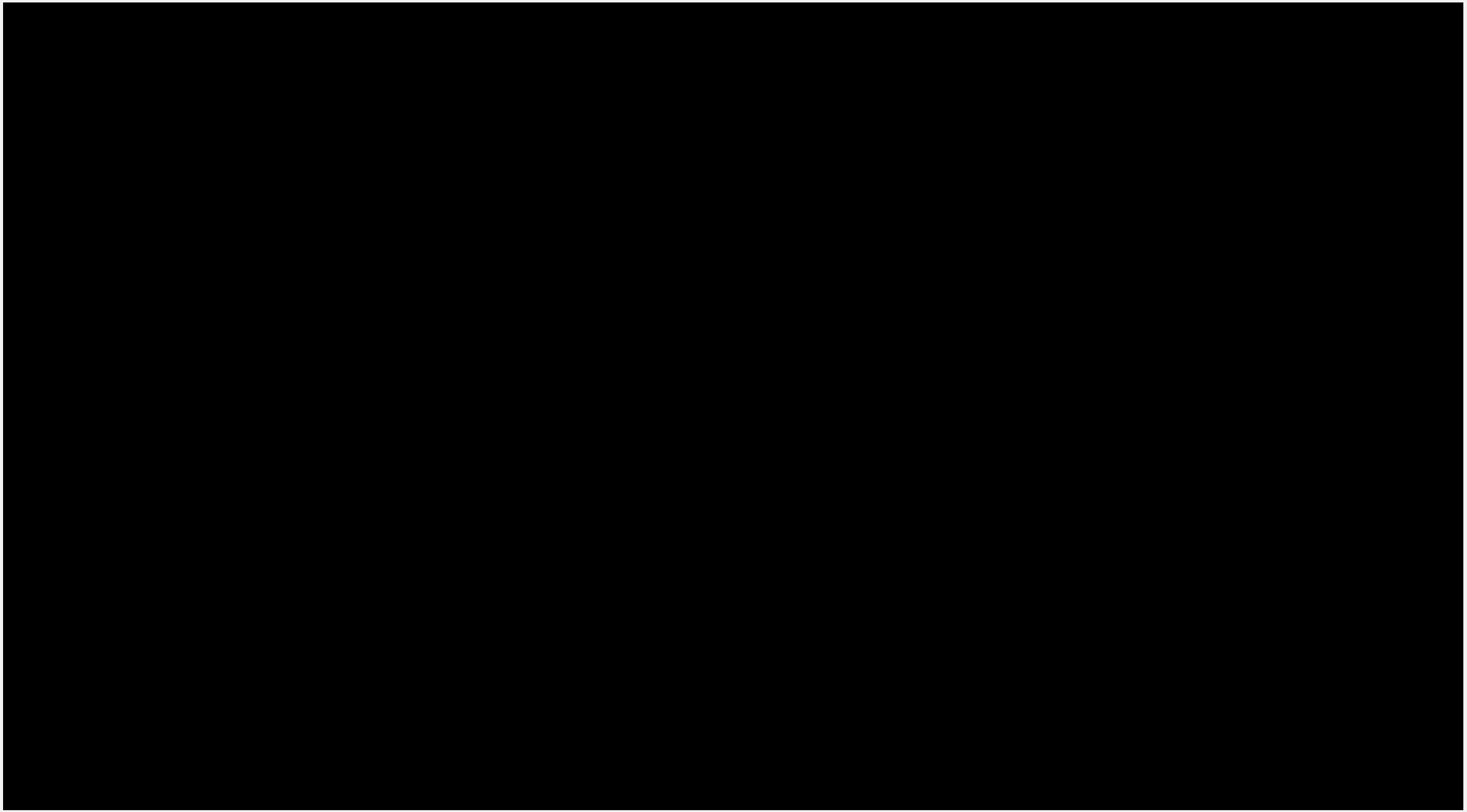

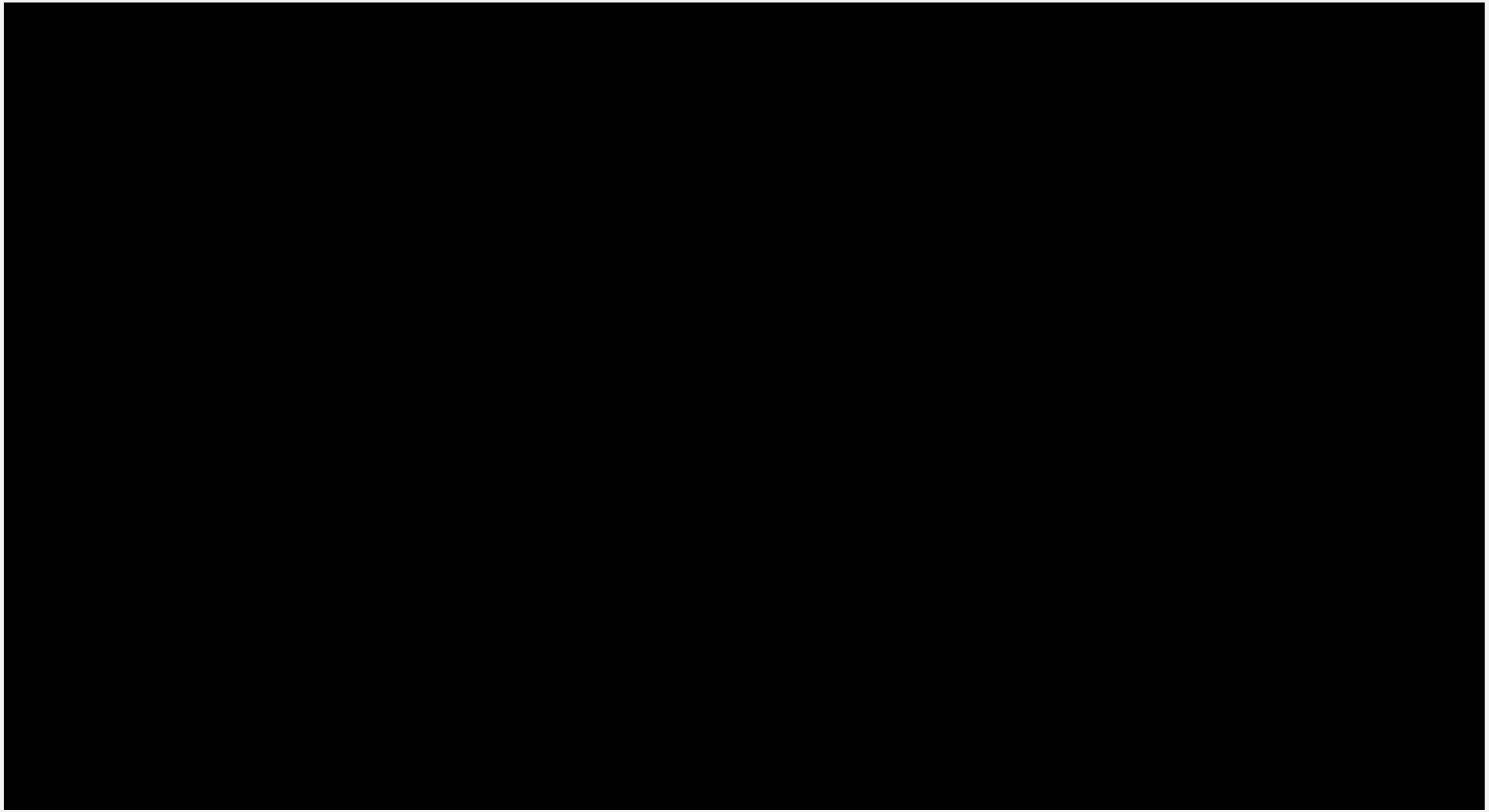

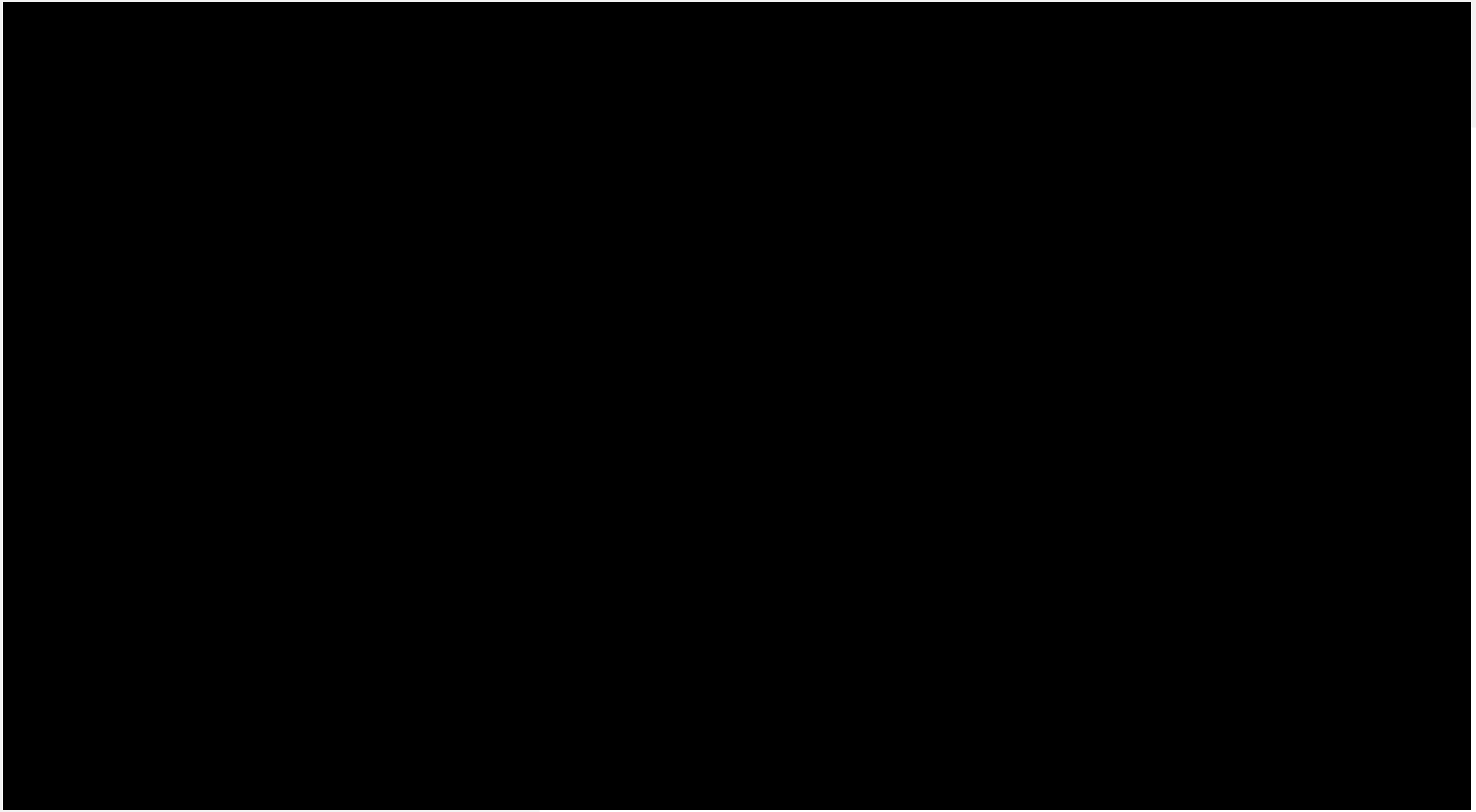

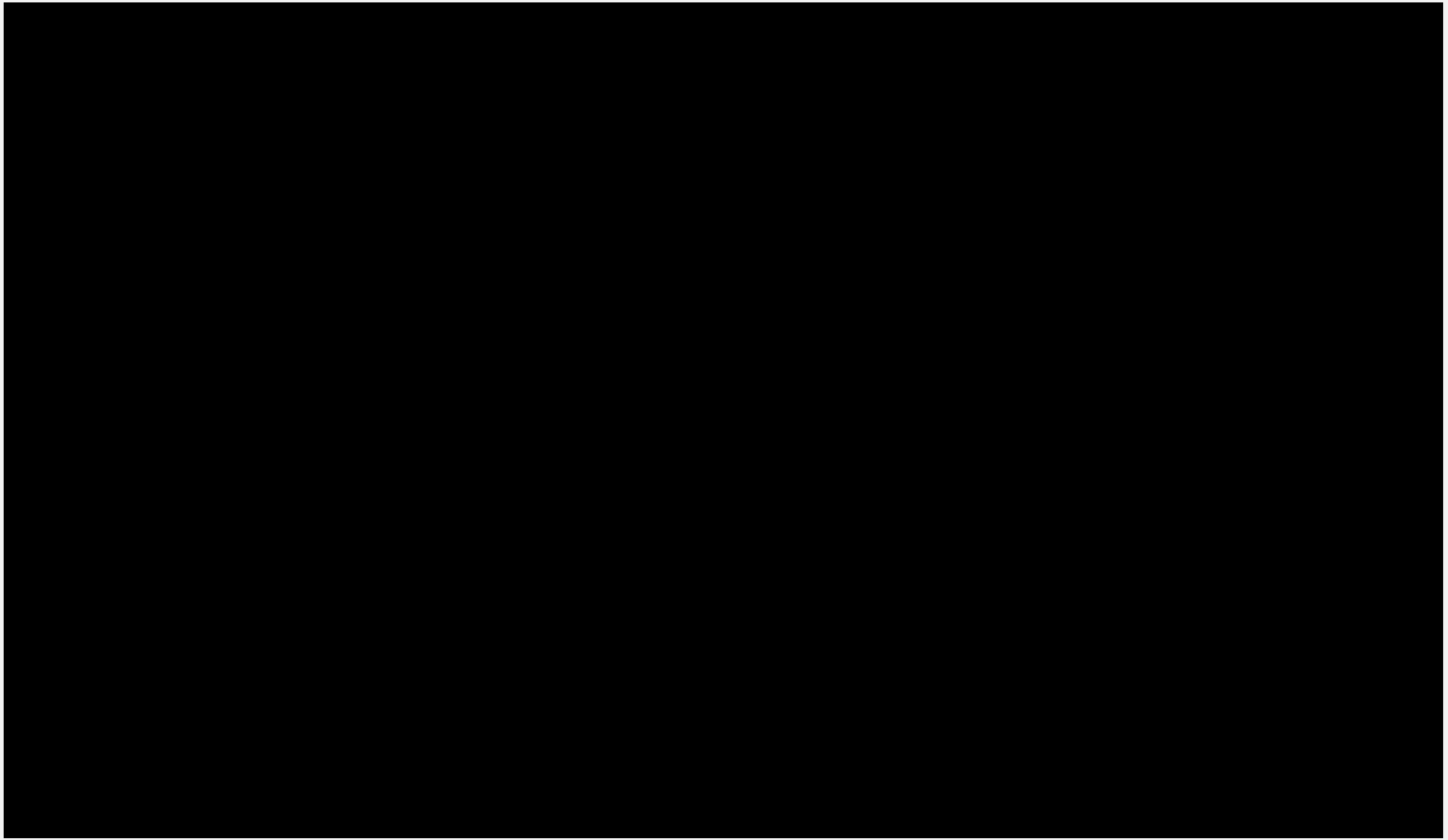

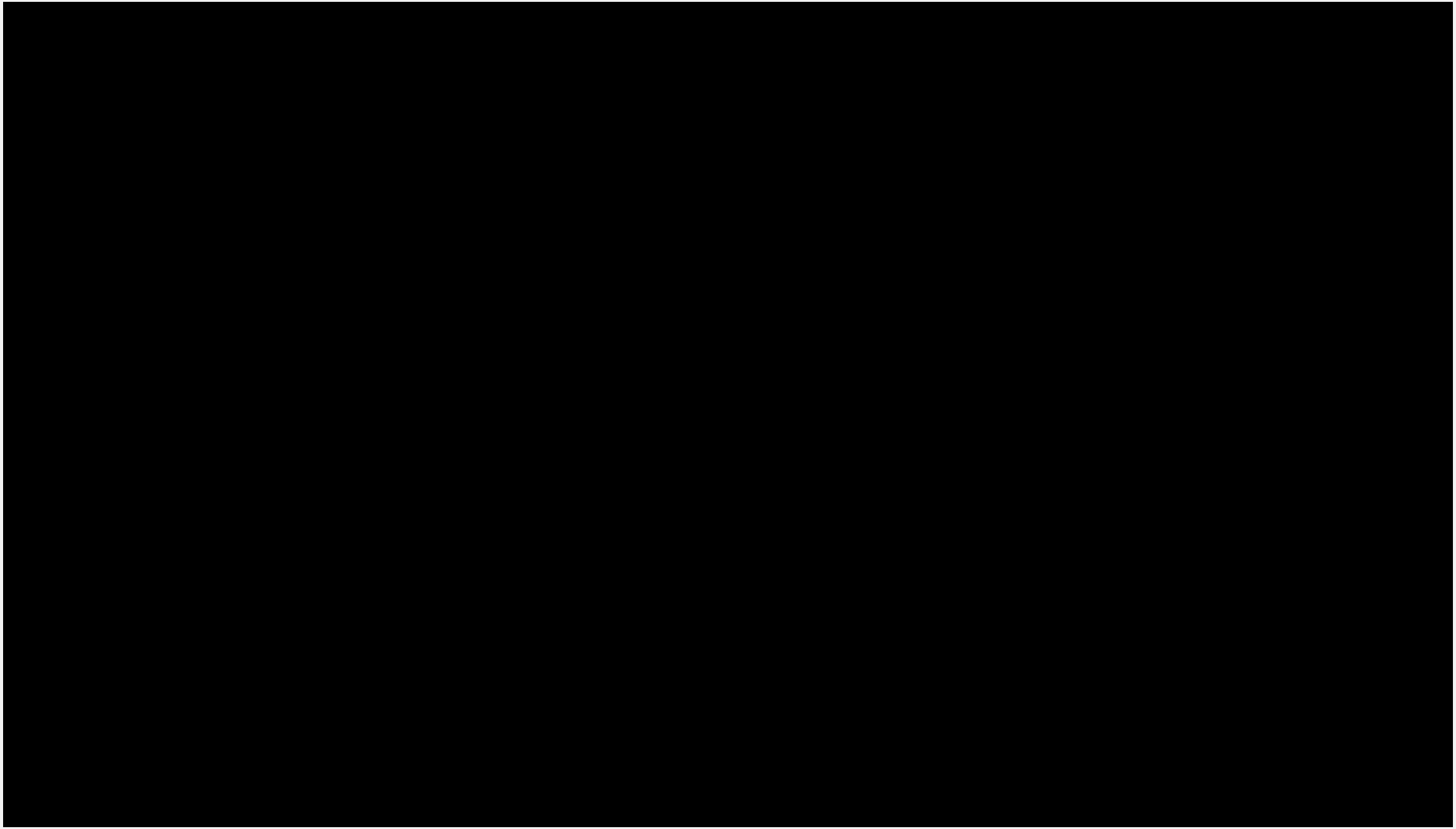

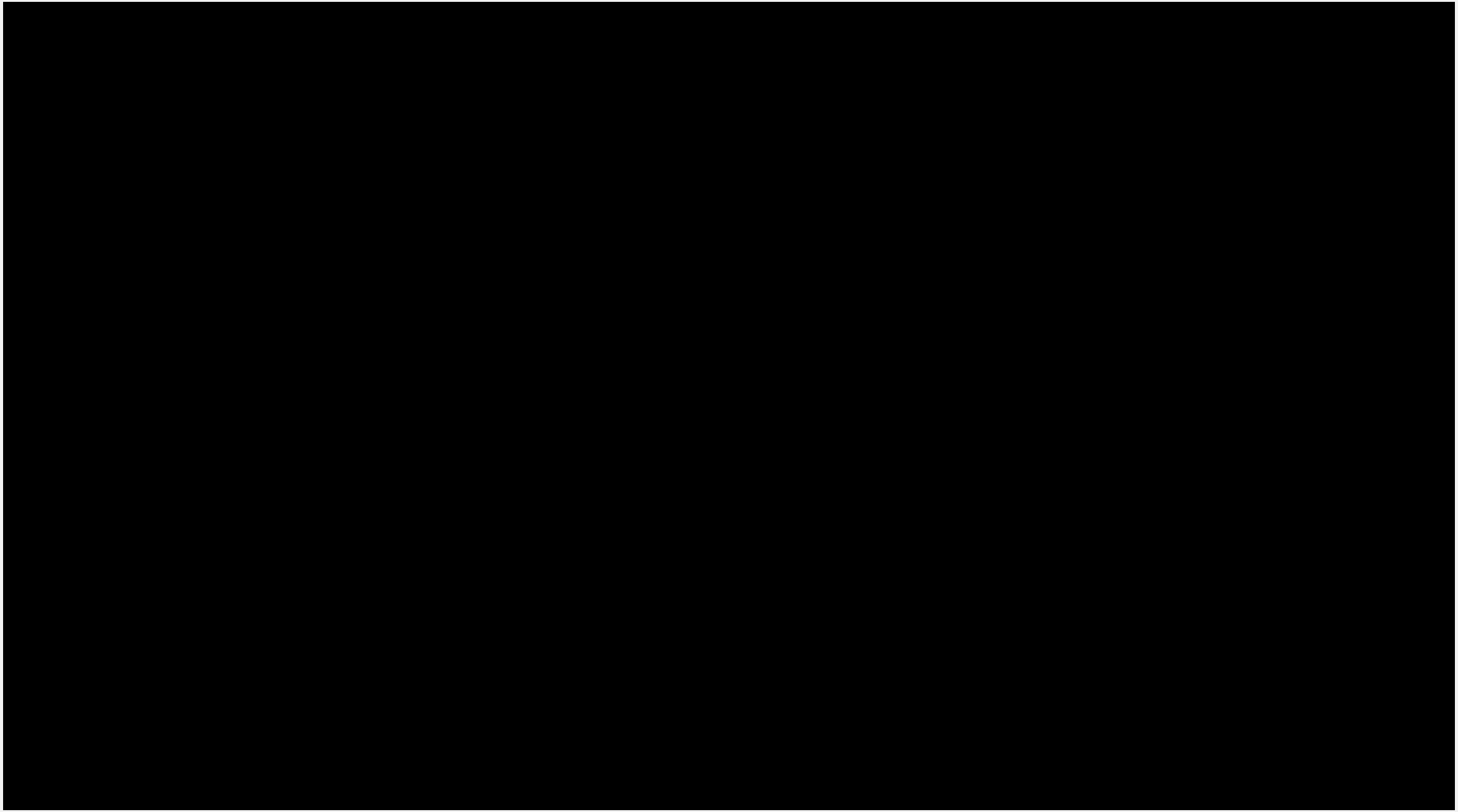

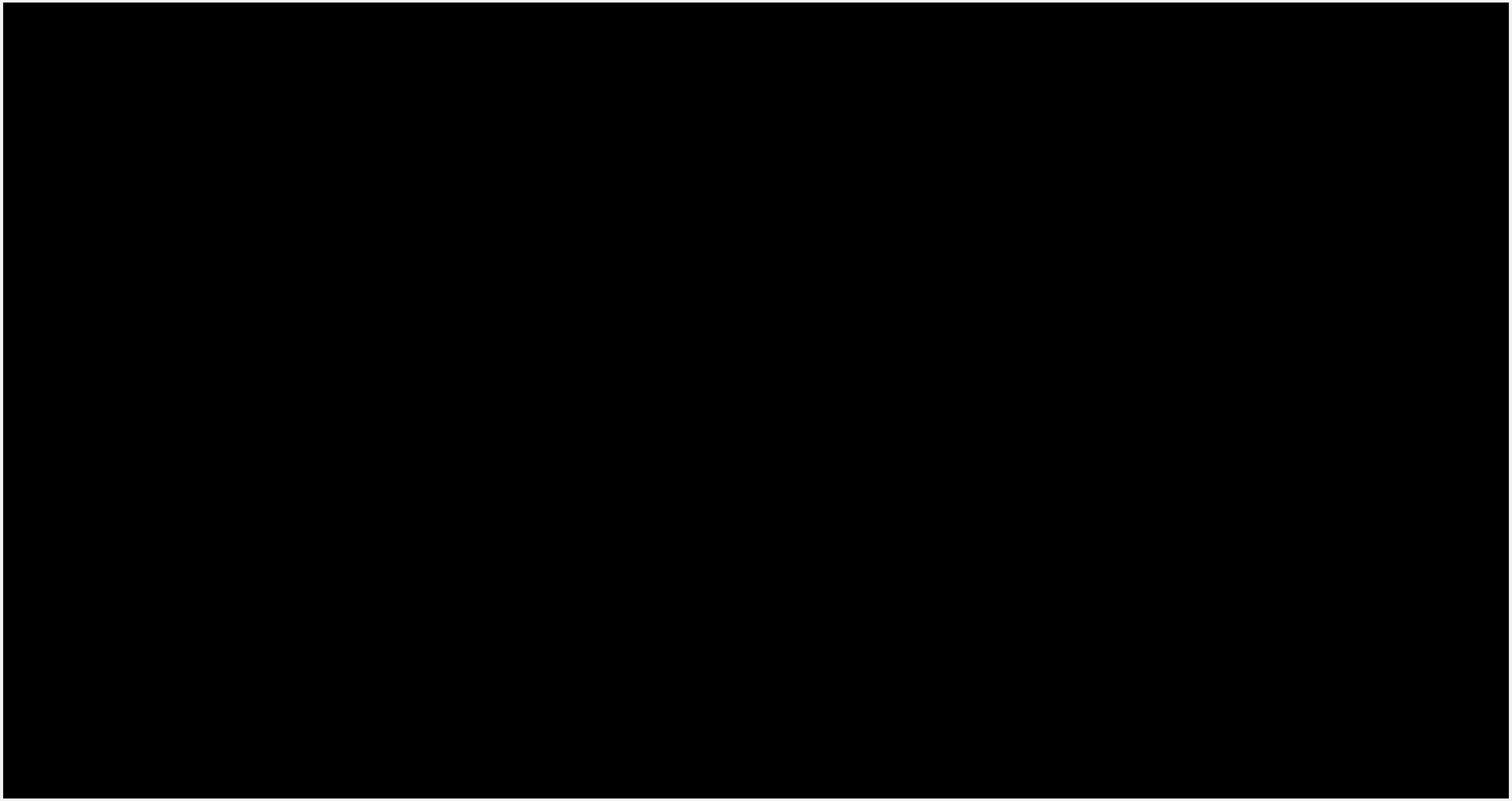

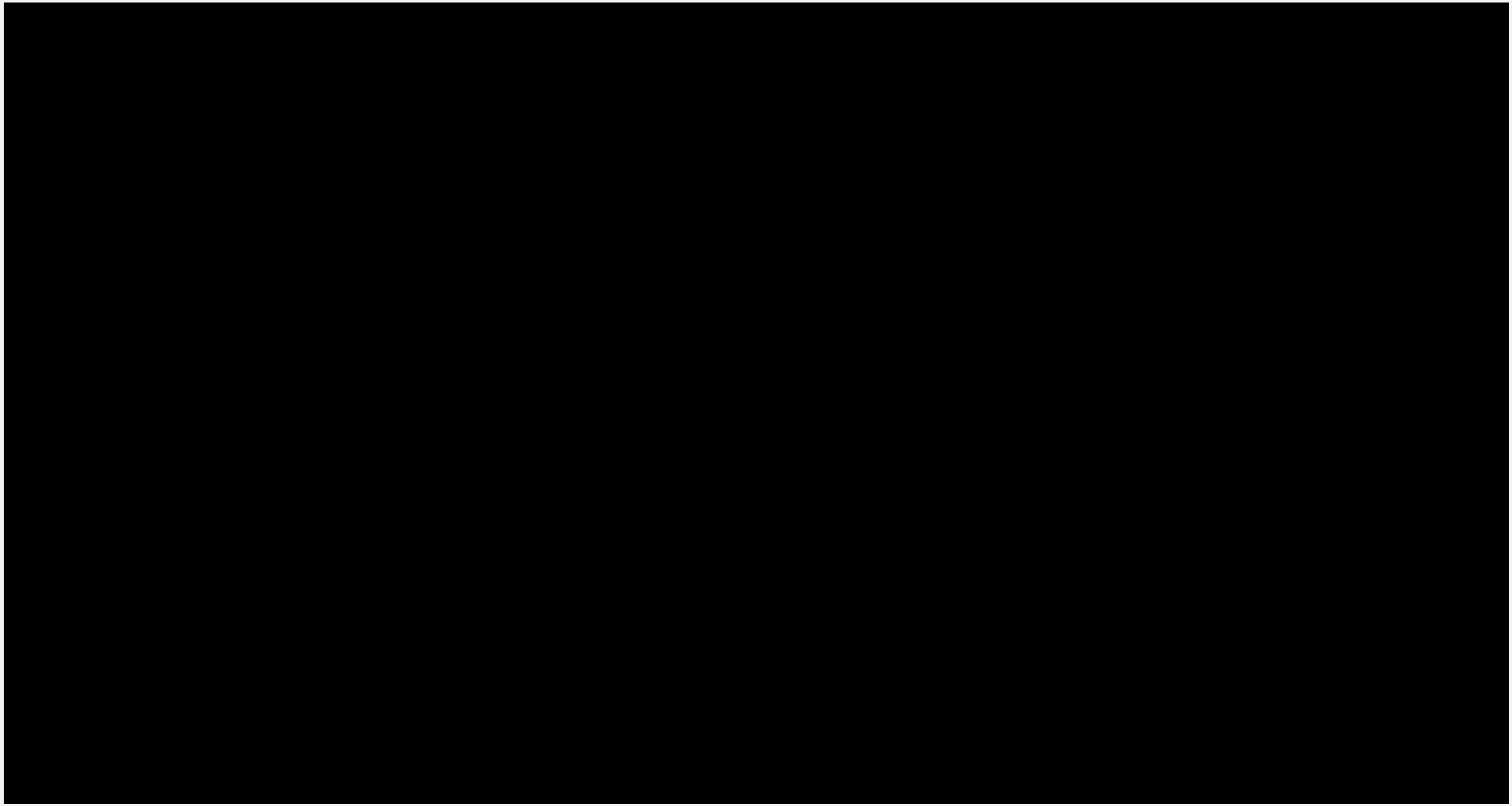

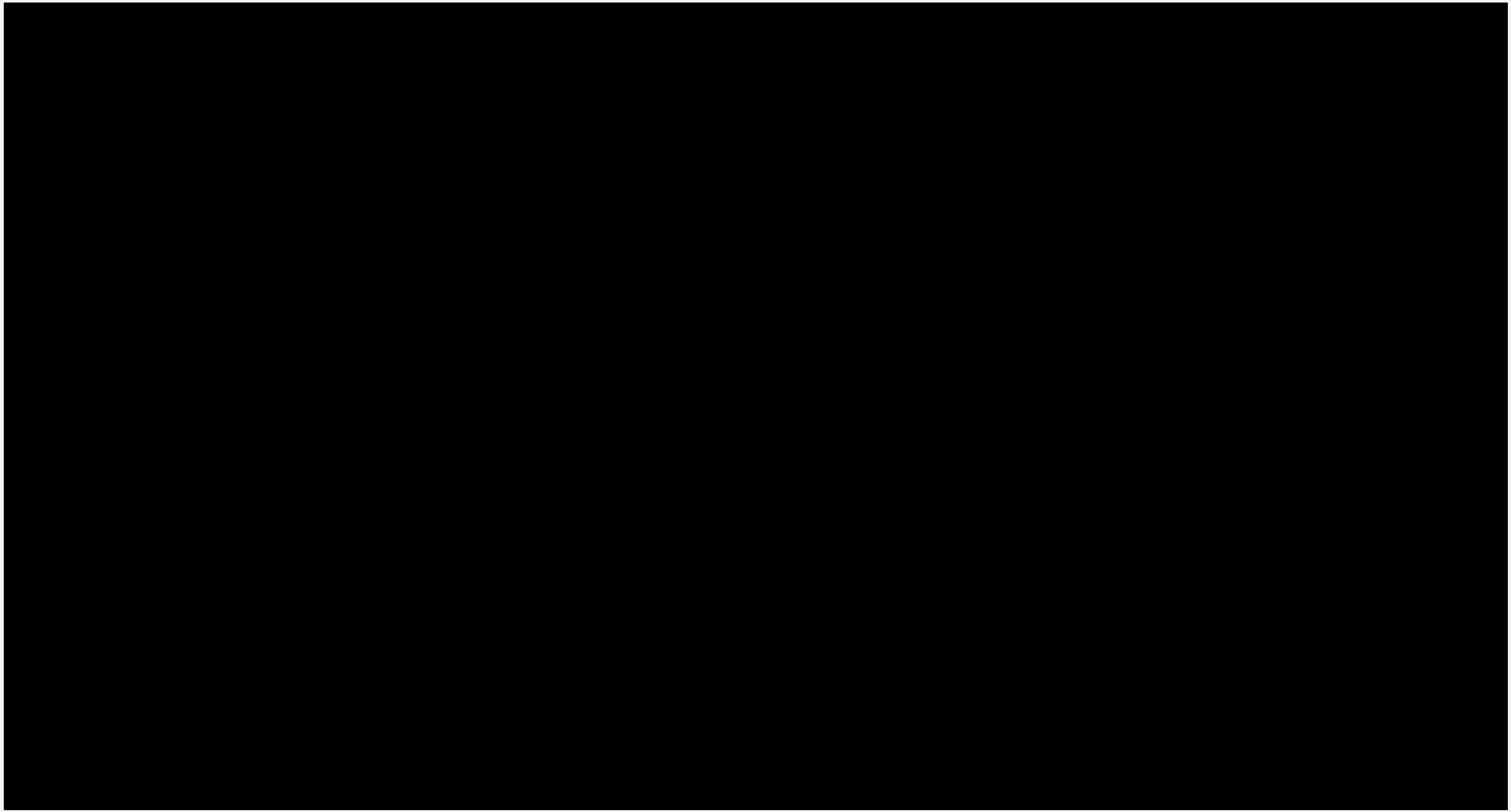

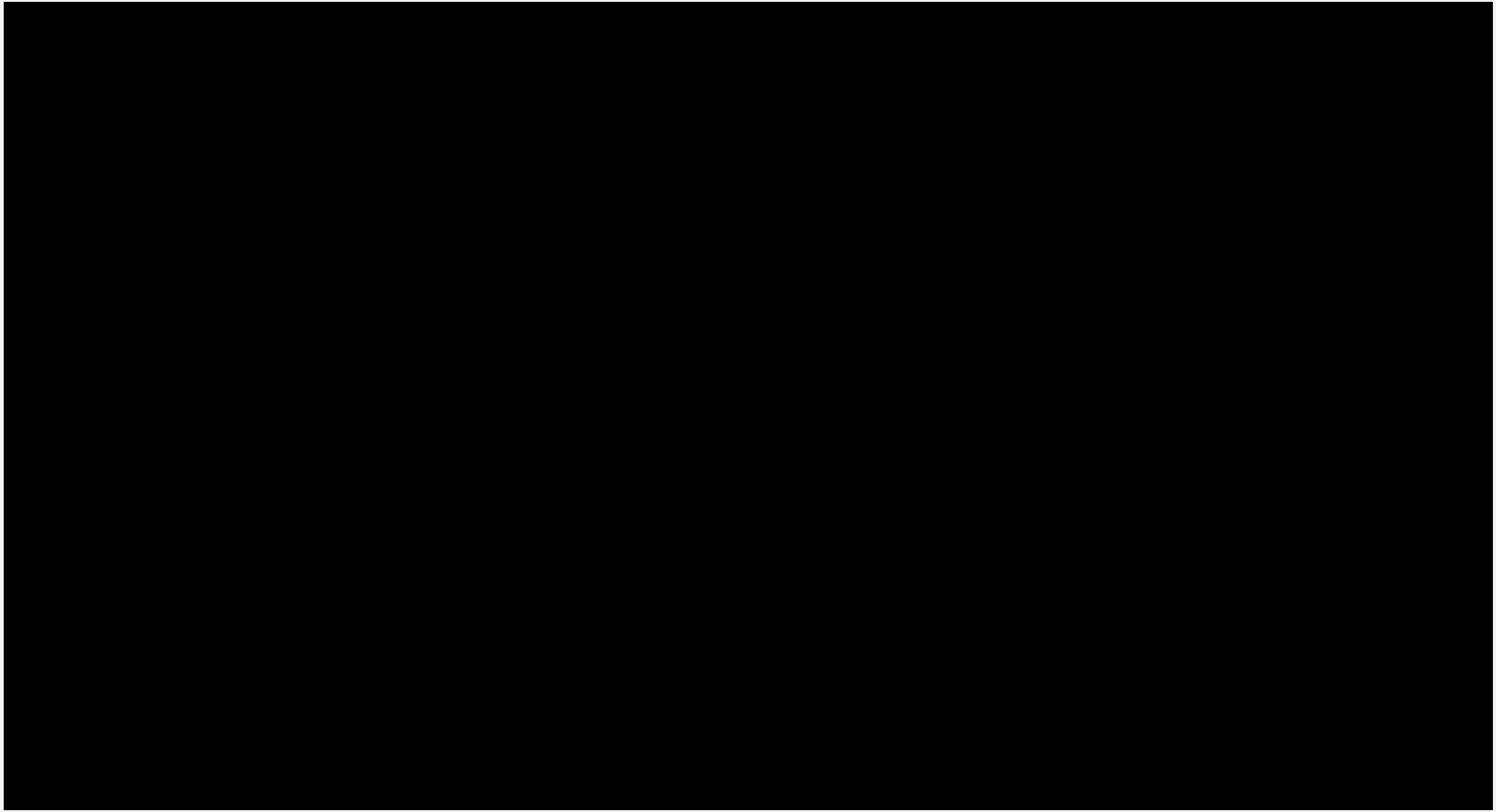

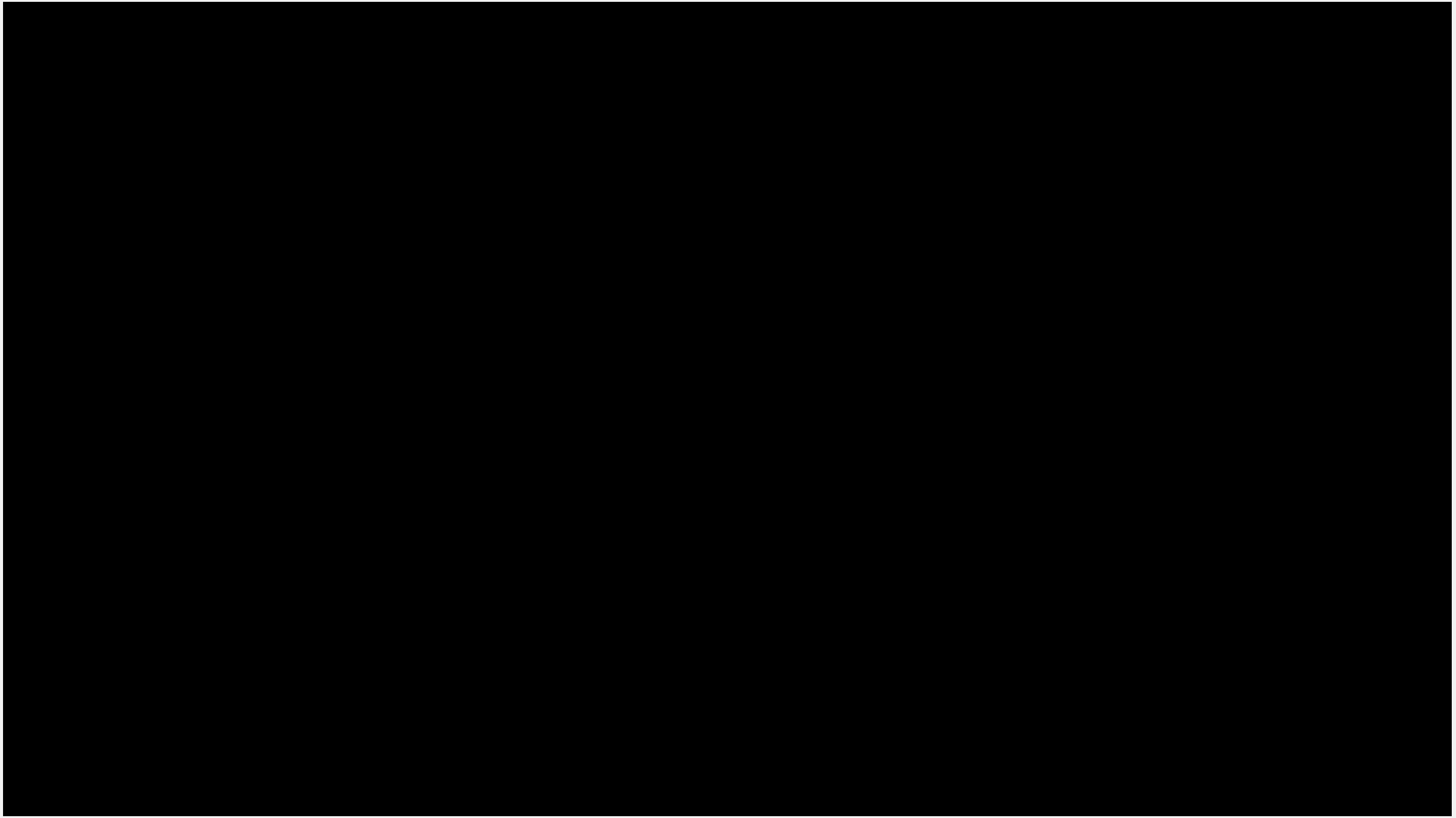

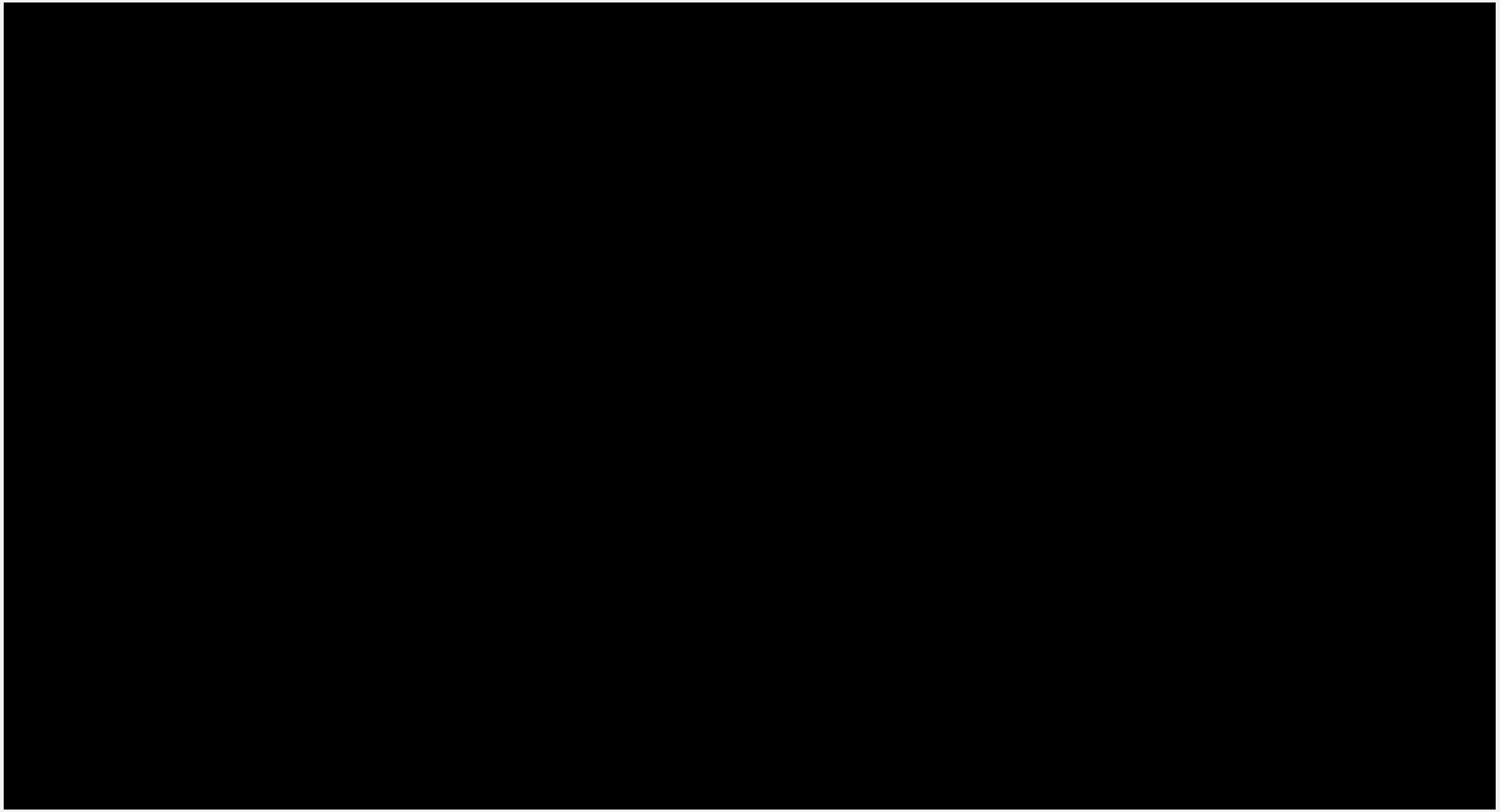

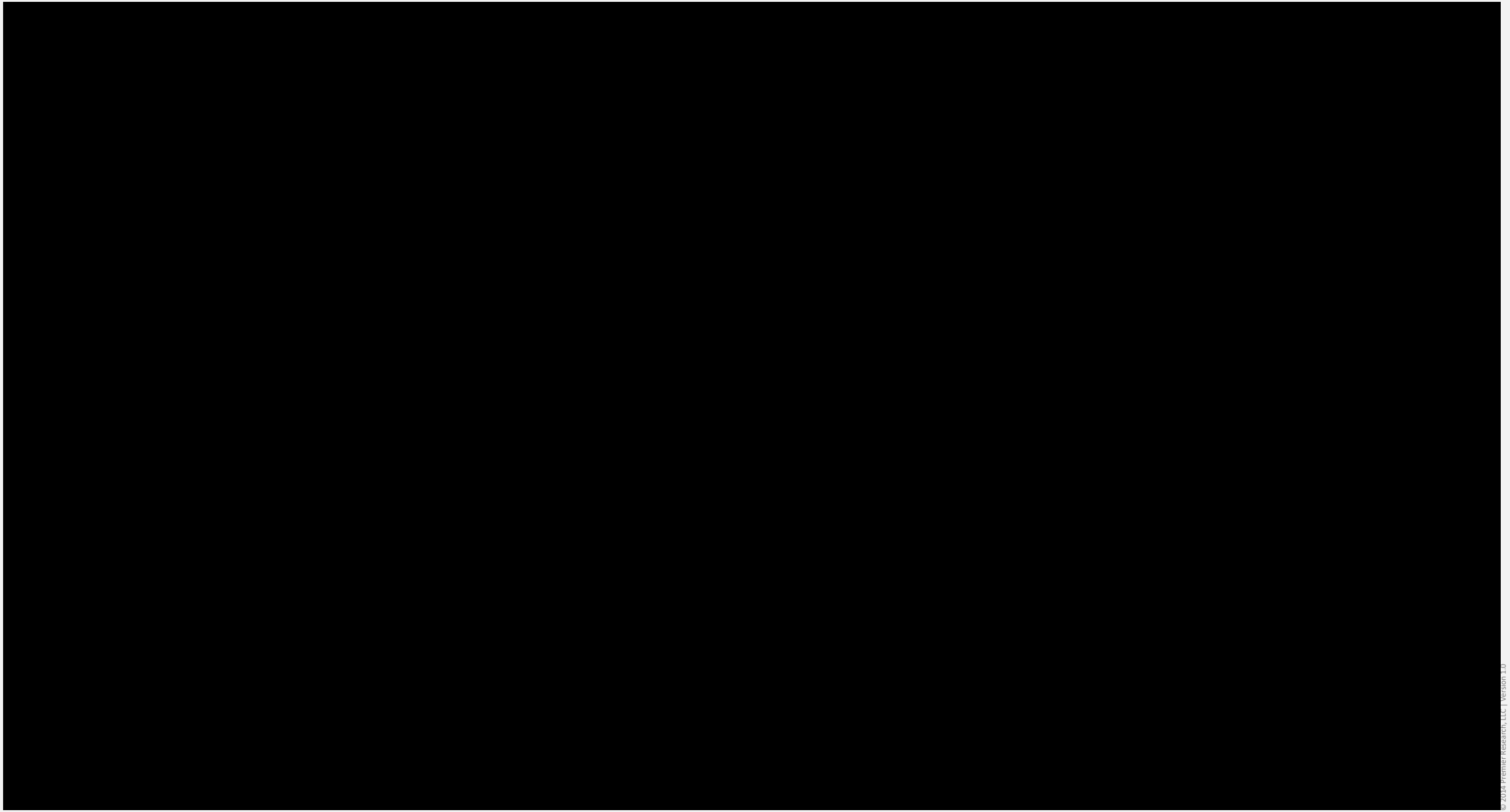

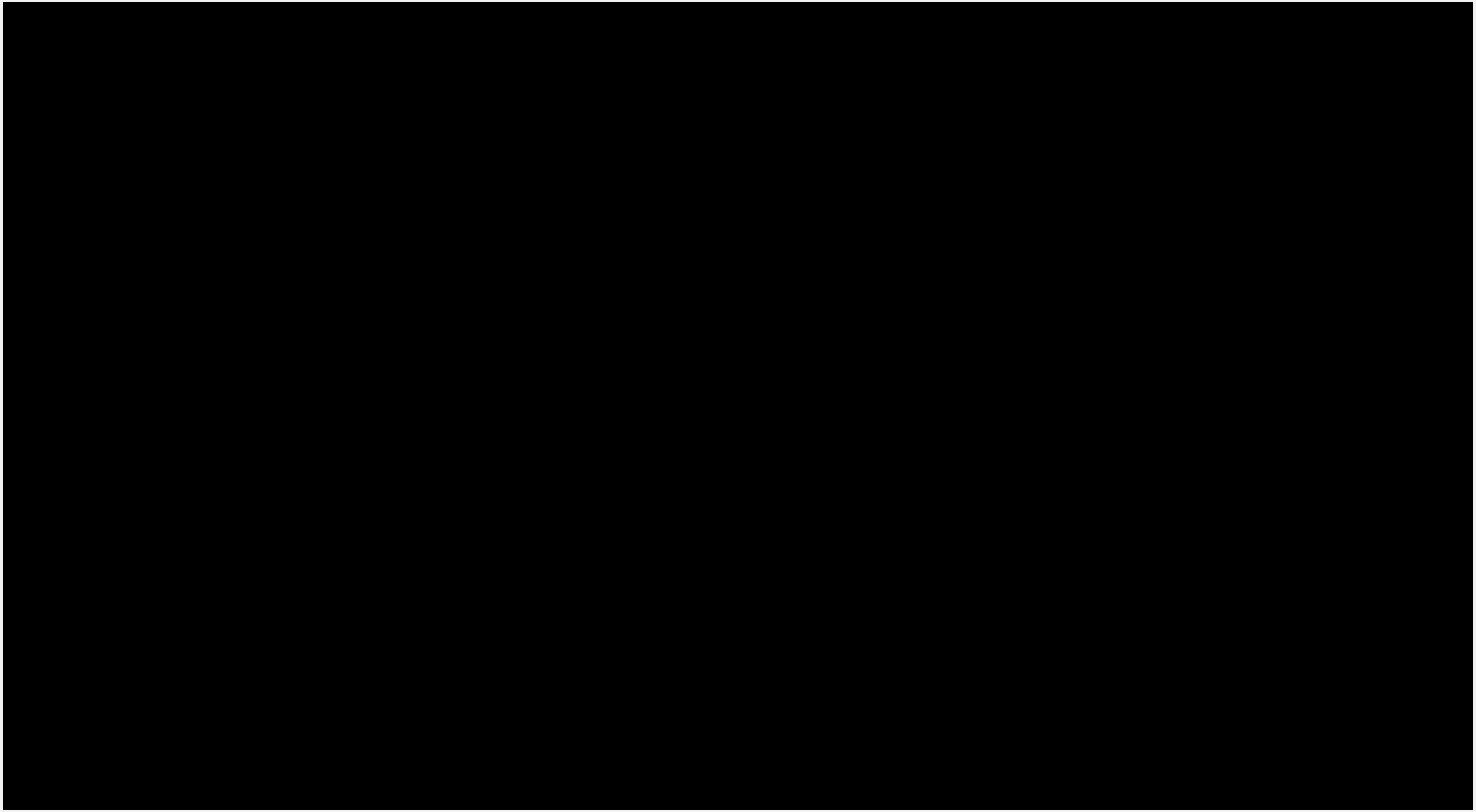

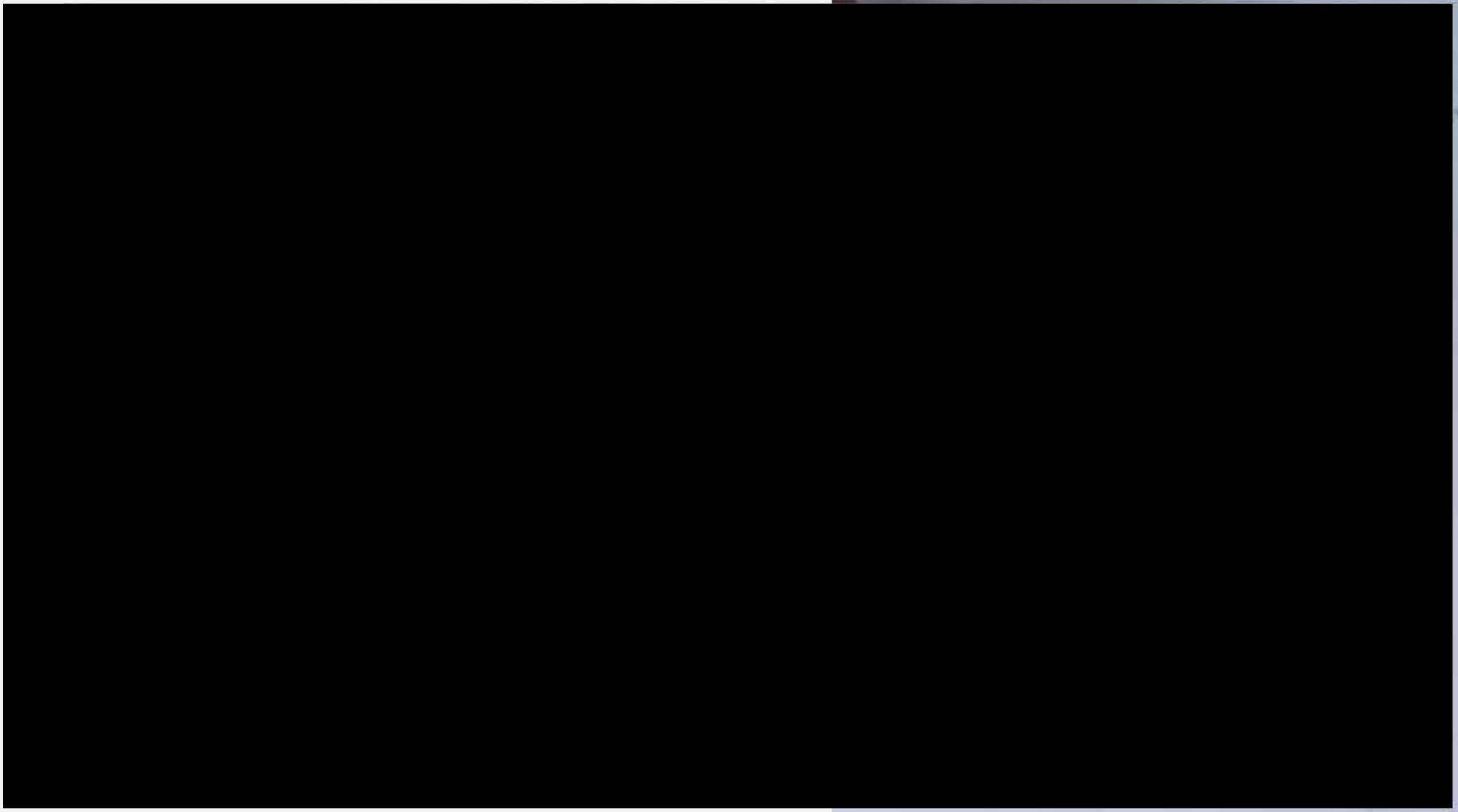

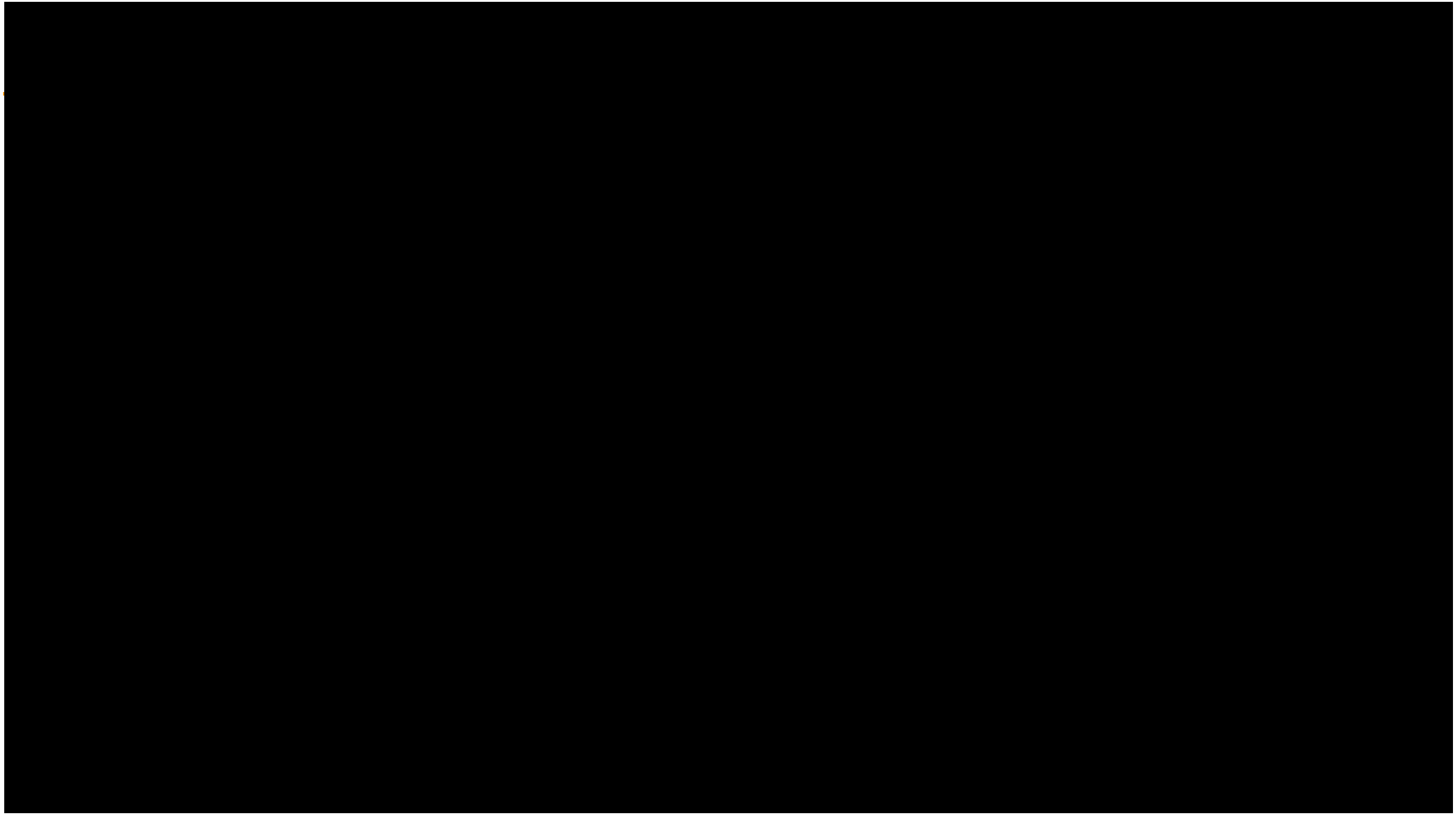

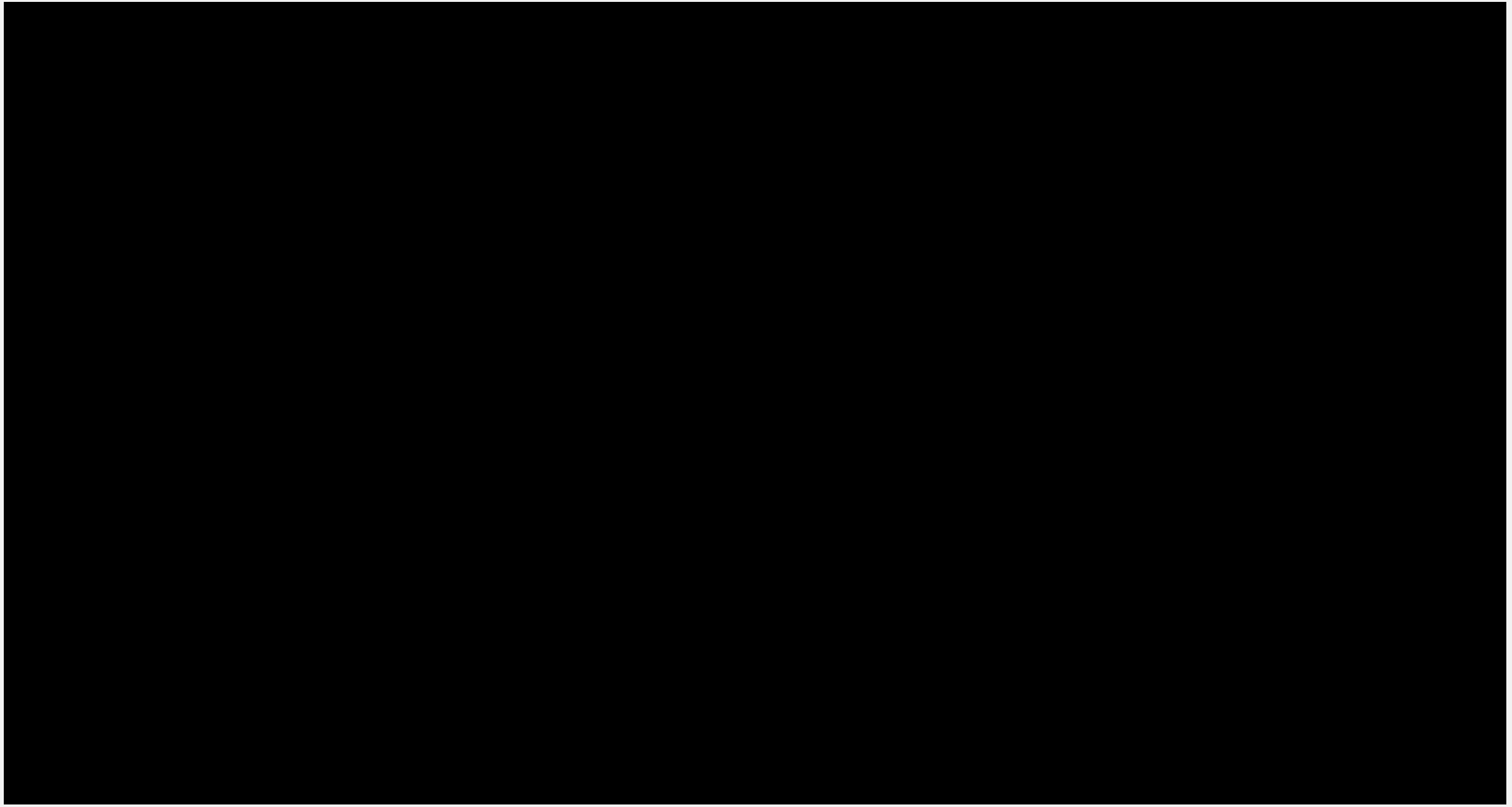

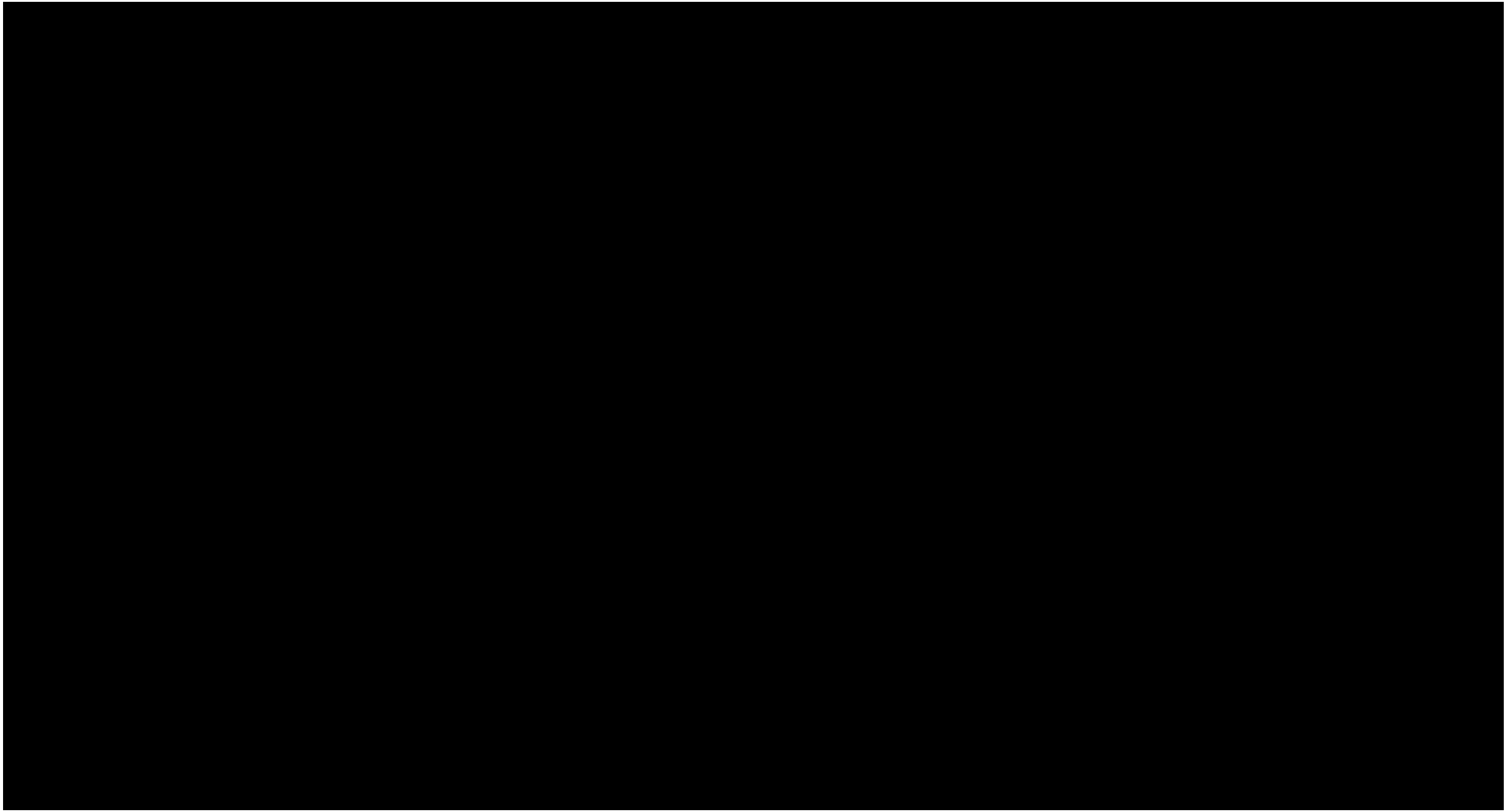

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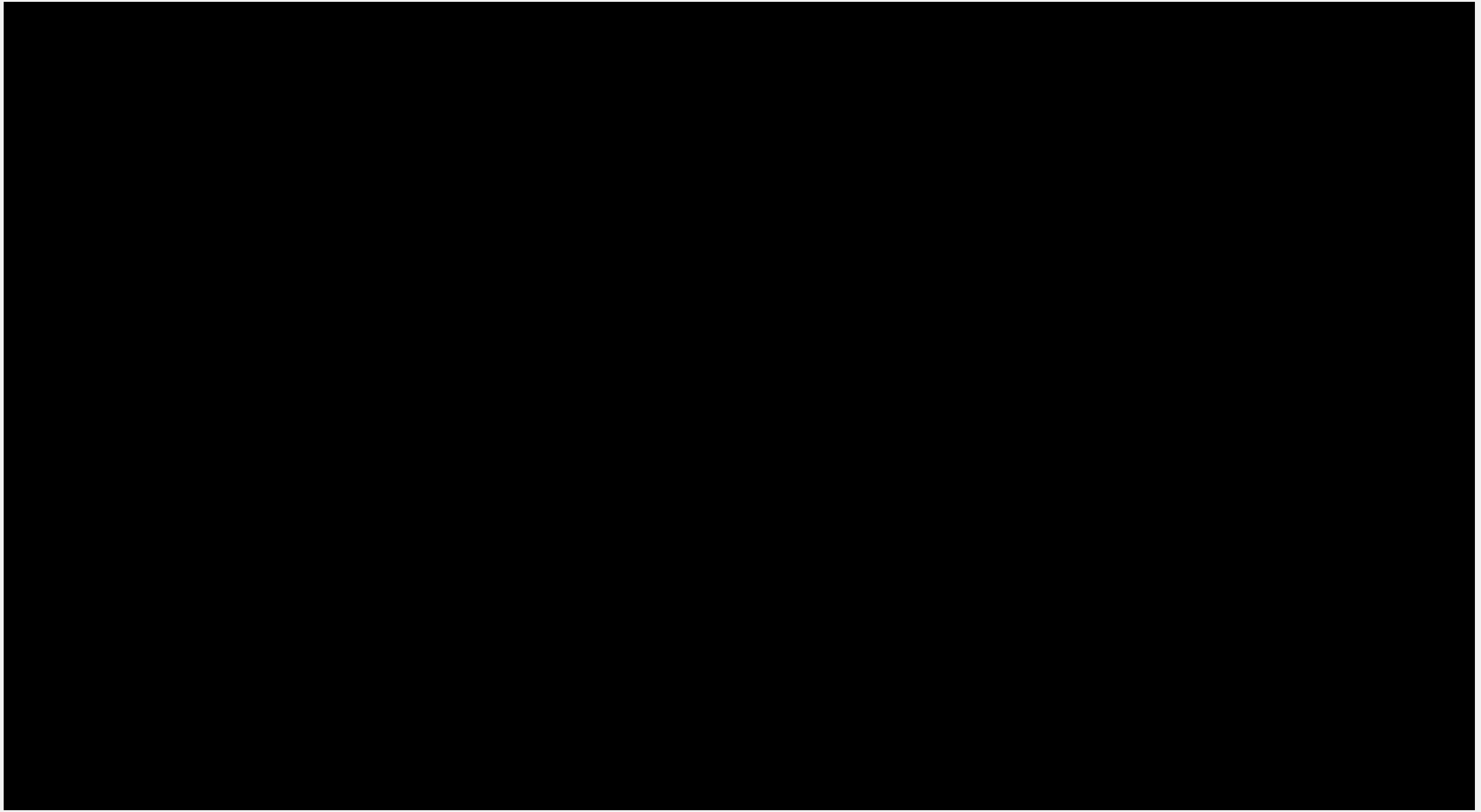

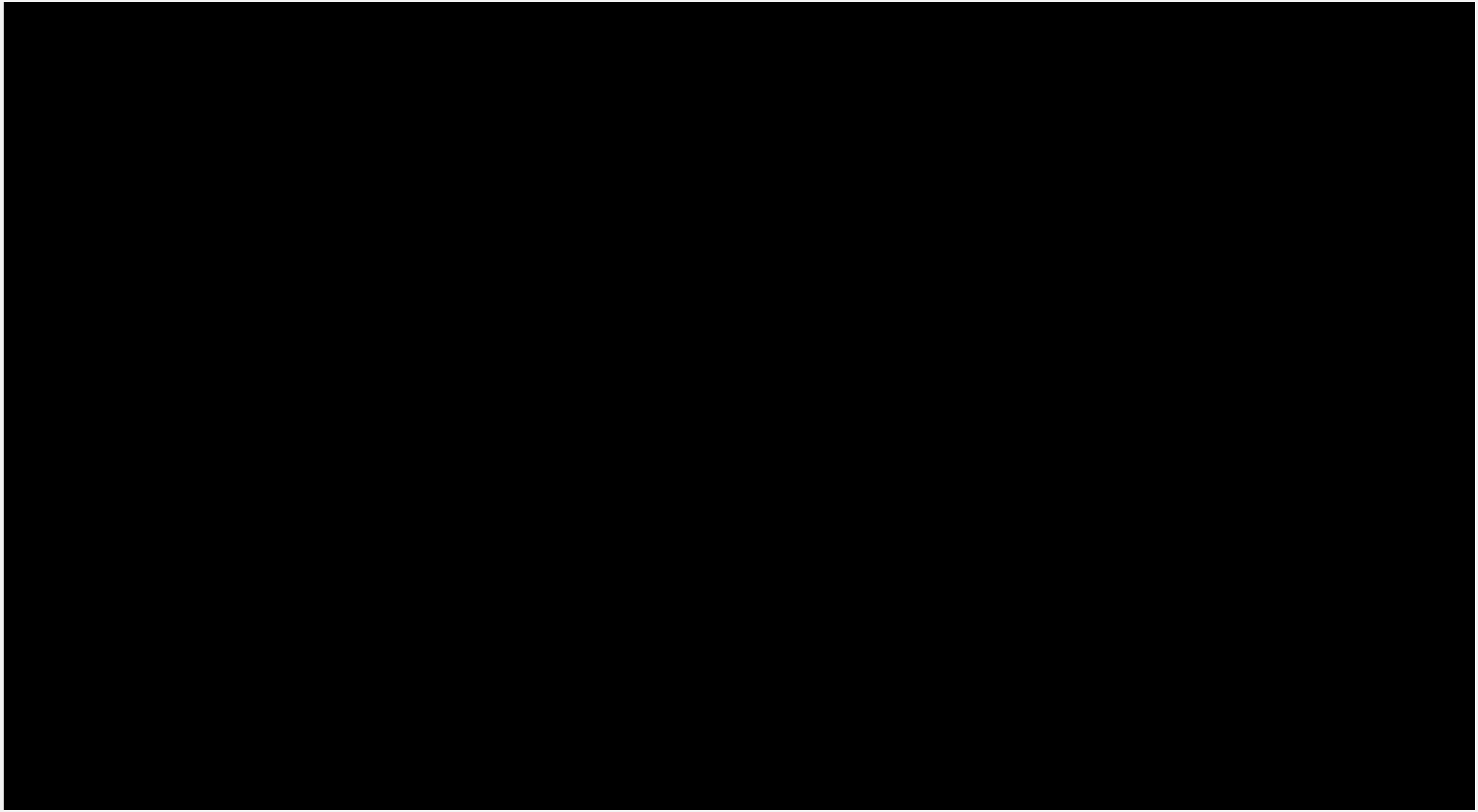

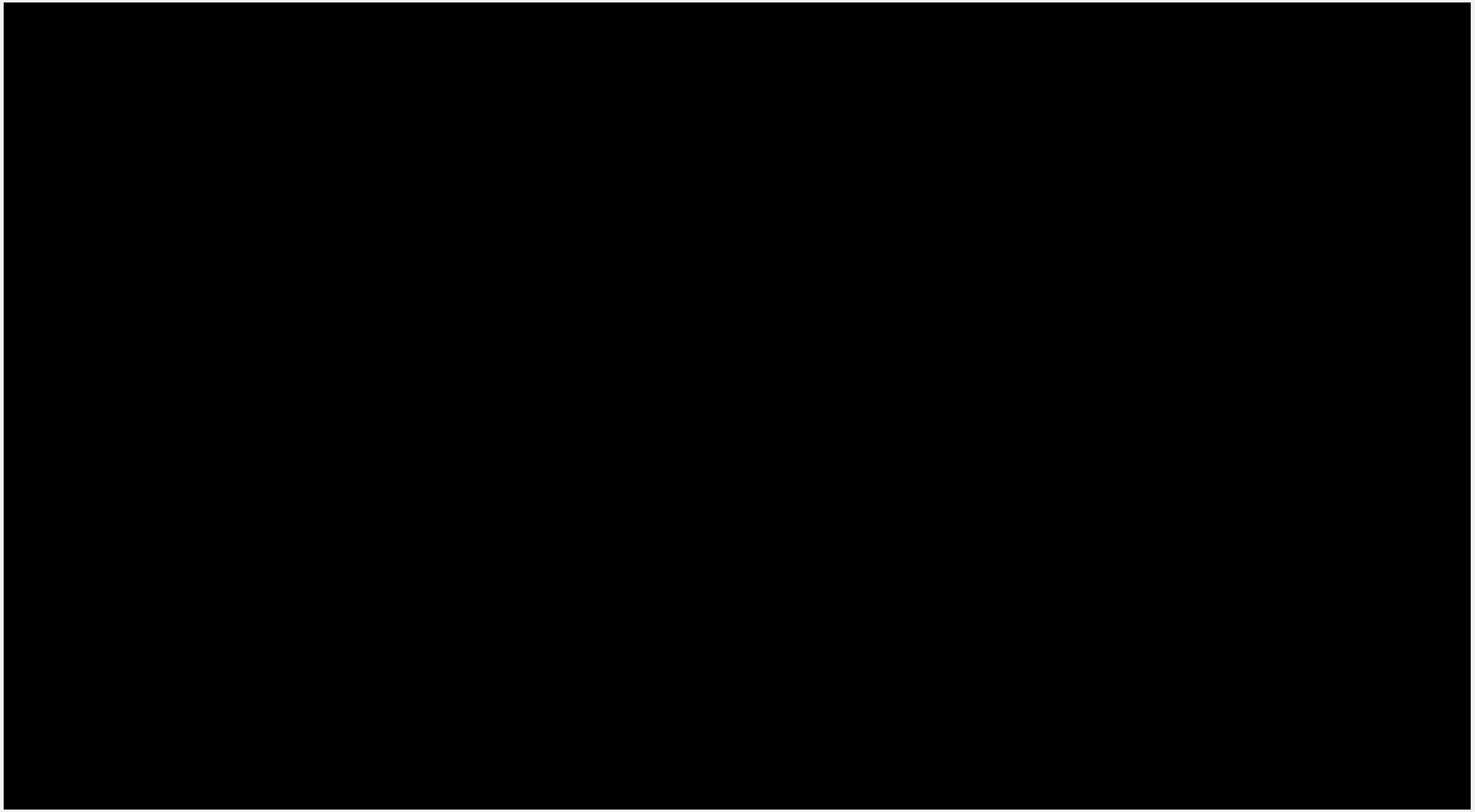

EXHIBIT E
Part 1

EXHIBIT E
Part 2

EXHIBIT F

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We know biotech:
It's 85% of our business

Built for biotech

Built for biotech

Premier Research delivers outcome-focused insight and shares your commitment to developing life-changing therapies.

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• Product development consulting
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organisms
specially
trials
grow
medicine
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innovation
bacteria
living
process
study
similarly
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targeted
life
service
clinical
material
outcome
approval
category
genetic
cells
regulatory
technique
antibodies
diseases


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There's no substitute for experience
All Therapeutic Areas
More than 1,300 studies in the past five years
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CONCLUSIVE
DATA


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DOING
WHAT WE
DO BEST
Improve
Transparency

Posted by Paul Mirek • 6/3/2019 • Boost

PUBLIC VERSION (REDACTED)

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Posted by Joy Abella • 4/12/2019 • Boost ...

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PREMIER000680

Premier Research @premierresearch · Jun 21, 2017

Smoothies are gone, one last bag left! Thanks for a great week, #DIA2017!!!

3

Premier Research @premierresearch · Nov 7, 2018

PUBLIC VERSION (REDACTED)

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June 7, 2018

EXHIBIT G
Part 2


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It's 85% of our business
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for experience
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Smart study design

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Pediatrics
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BIOTECHNO

EXHIBIT H

premier research

Built for Biotech

Who is Premier Research?

We help innovators transform life-changing ideas into reality

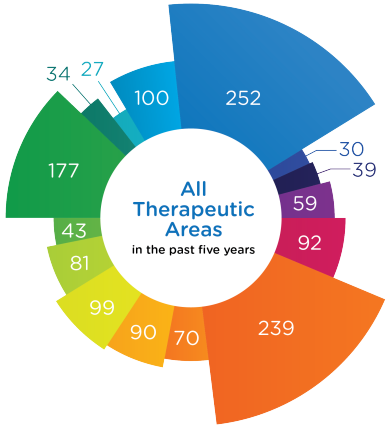
- 1,500 employees, operating in 23 offices, managing projects in 75 countries
- Broad range of clinical development services

Our market focus:

- 85% of our business is biotech and small/specialty pharma

Focusing on what we do best:

- Hematology
- Rare Disease
- Analgesia
- Strategy Development
- Neuroscience
- Pediatrics
- Dermatology
- Medical Device and Diagnostics



- Allergy/Immunology
- Analgesia
- Cardiovascular
- Dermatology
- Endocrinology/Metabolic
- Gastrointestinal
- Genitourinary
- Hematology/Oncology
- Hepatic/Biliary
- Infectious Disease
- Musculoskeletal/Orthopedics
- Neuroscience Without Pain
- Ophthalmology
- Pulmonary/Respiratory
- Women's Health

North America: **+1 919 627 9069**
Europe: **+44 118 936 4000**

info@premier-research.com
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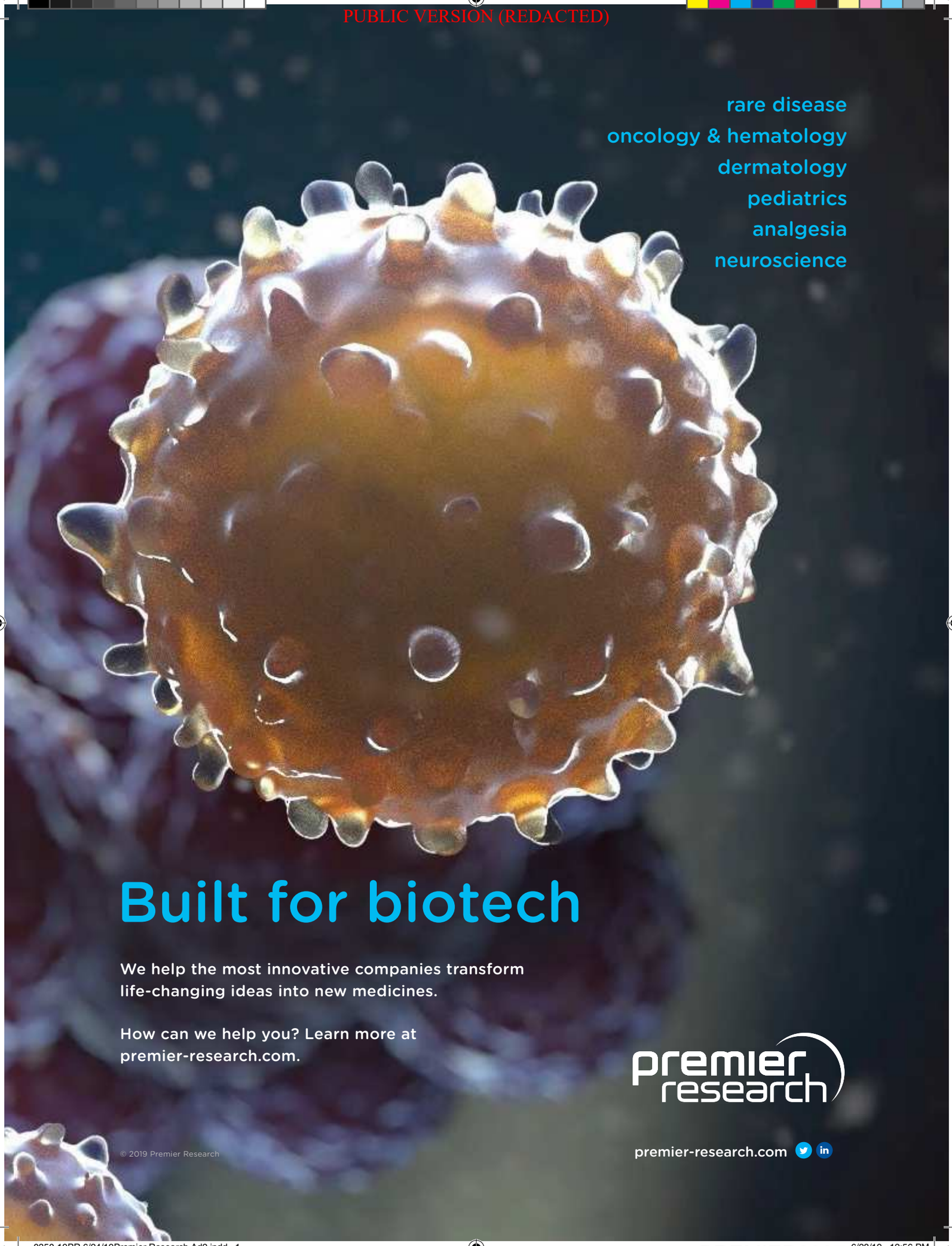
EXHIBIT I



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Posted by Joy Abella • 4/12/2019 • Boost ...

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mekana_marie · **Following**

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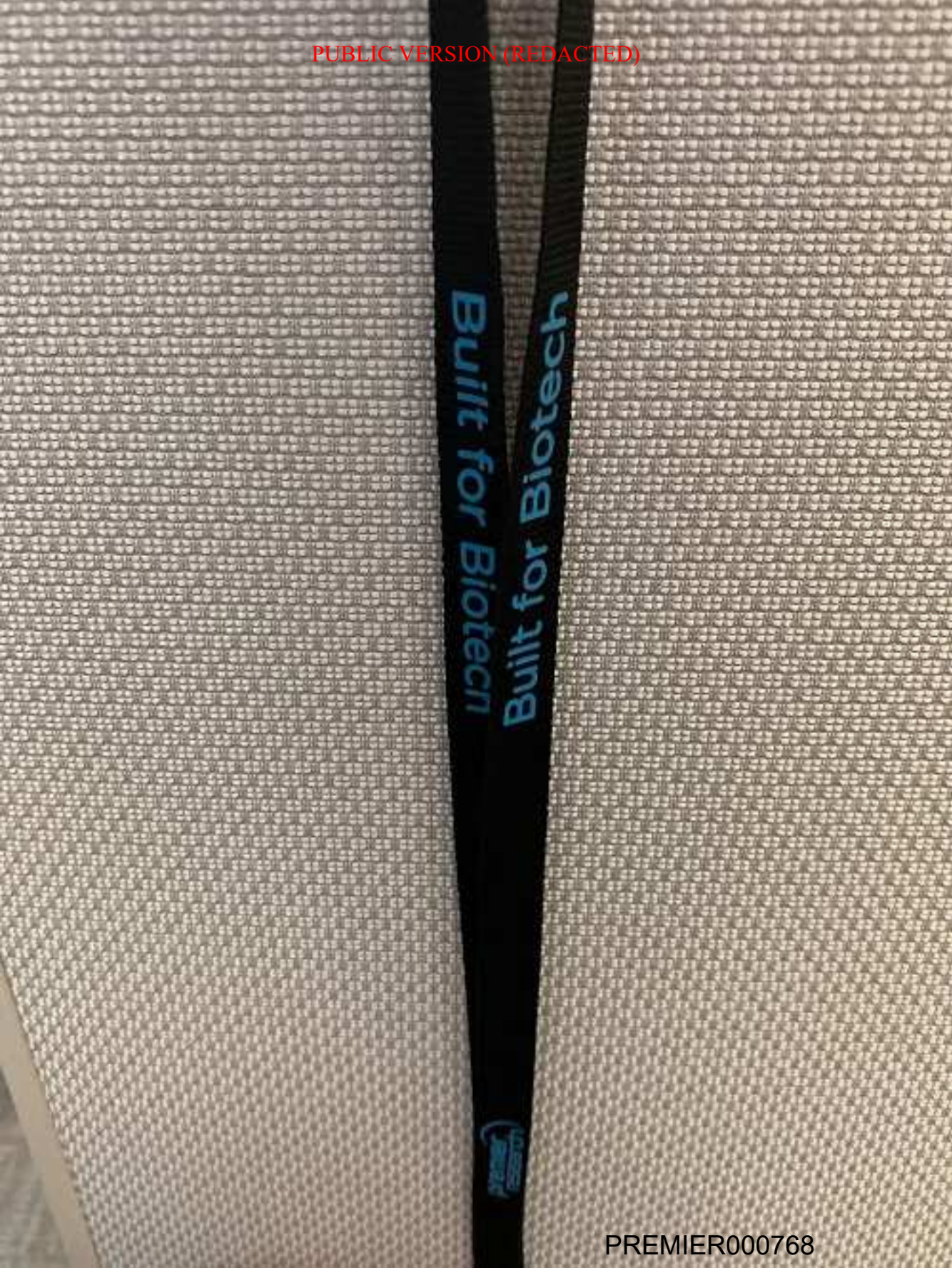

EXHIBIT K

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May 20, 2019

a. Today's Rundown

- Glioblastoma claims another pharma victim as AbbVie's ADC fails to boost survival
- Bumper day for British biotech as startups get cash haul, major research windfall
- Industry steps up interest in developing world, fueling doubling of R&D pipeline
- Schrödinger raises more cash, amassing $110M for R&D drive
- With long-term data, Med Co, Alnylam's cholesterol-fighter inclisiran poised for 2019 filing
- Philadelphia juries knock J&J with 2 multimillion-dollar verdicts in vaginal mesh cases

b. Featured Story

c. Glioblastoma claims another pharma victim as AbbVie's ADC fails to boost survival

Friday, May 17, 2019

Alongside pancreatic cancer, the aggressive brain cancer glioblastoma is one of the toughest cancers out there. Now, AbbVie is yet another biopharma learning that lesson firsthand.

d. Top Stories

e. Bumper day for British biotech as startups get cash haul, major research windfall

Monday, May 20, 2019

British biotech is often a disregarded backwater when it comes to the international view of life sciences, but today a host of positive news has shone the spotlight back onto its potential.

f. Industry steps up interest in developing world, fueling doubling of R&D pipeline

Monday, May 20, 2019

The pipeline of drugs and vaccines aimed at diseases prevalent in low- and middle-income countries has more than doubled since 2014, according to the Access to Medicine Foundation. However, the trend was driven by surging activity in noncommunicable diseases, leaving many conditions underserved by the current pipeline.

g. Schrödinger raises more cash, amassing $110M for R&D drive

Monday, May 20, 2019

Schrödinger has raised more money, bringing the total size of its recent haul up to $110 million. The computing-enabled R&D shop will use the money to advance its nascent pipeline of wholly owned drugs.

h. With long-term data, Med Co, Alnylam's cholesterol-fighter inclisiran poised for 2019 filing

Monday, May 20, 2019

The Medicines Company announced long-term data for its Alnylam-partnered inclisiran, showing that the drug consistently lowered "bad" LDL cholesterol by more than 50%. If approved, the twice-a-year injection will compete with anti-PCSK9 drugs from Amgen, Sanofi and Regeneron.

i. Philadelphia juries knock J&J with 2 multimillion-dollar verdicts in vaginal mesh cases

Monday, May 20, 2019

Johnson & Johnson was ordered by a Philadelphia jury to pay $80 million to a woman whose vaginal mesh eroded, on the heels of a $120 million verdict issued against the company's Ethicon unit last month.

j. Resources

k. [Executive Summary] Achieving a Successful Drug Product Tech Transfer

Sponsored by: Catalent

Download the executive summary to learn key considerations for a successful technology transfer for manufacturing drug products, including a case study on overcoming challenges in a process transfer for a sterile diluent.

l. [Whitepaper] Choosing the Best Sterile Dosage Form for Phase I Clinical Supply Needs

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Choosing the Best Sterile Dosage Form for Your Phase I Clinical Supply Needs.

m. [Whitepaper] Delivering oral solid dose product to Phase I Clinic in 14 weeks

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Designed with speed & flexibility,Quick to Clinic™ for Oral Solid Dose helps deliver products to Phase I Clinic in as little as 14 weeks.

n. [Whitepaper] Agile Competitive Intelligence: A 3-Step Mobile Research Strategy

Sponsored by: AlphaSense

What is agile competitive intelligence, and how can help healthcare researchers stay ahead of the curve?

o. [Paid Marketplace] Accelerating DoD's Fielding of Prototypes for Medical Countermeasures

Sponsored by: JPEO-CBRND – Medical Countermeasure Systems

MCS is currently seeking broad-based industry/academia collaboration on research and prototype work in technical areas related to developing medical countermeasures for the Joint Warfighter.

p. [Whitepaper] Now Companies Can Move Validated, Mission Critical Apps To The Cloud

Sponsored by: Outer Edge Technology

Learn how the cloud can support the performance and security requirements for validated, mission-critical applications historically designed and implemented exclusively via on-premises deployment.

q. [eBook] 2018 Weekly Compendium

Sponsored by: Biotech Primer

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r. Events

2019 BIO International Convention

June 3-6, 2019 | Philadelphia, PA

FierceBiotech Executive Breakfast at BIO 2019 – Getting Real: The Changing Tide on Real-World Evidence in Drug Development

June 5, 2019 | Philadelphia, PA

Medical Sensors Design Conference

June 25, 2019 | McEnery Convention Center | San Jose, CA

Sensors Expo & Conference

June 25-27, 2019 | McEnery Convention Center | San Jose, CA

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s. Today's Rundown

- Special Report—The top 10 pharma R&D budgets in 2018
- Sanofi's anti-CD38 combo boosts responses, extends lives in advanced multiple myeloma
- Amgen's closely watched KRAS drug, first to clinic, shrinks NSCLC, curbs colorectal tumors
- [Sponsored] How to Make the Most of Your Clinical Trial Data—All of it
- Ayala's ex-BMS drug shows promise in triple-negative breast cancer
- Astellas, Seattle Genetics' ADC banishes 12% of bladder cancers
- With FDA review nearing, Epizyme shares updated sarcoma data
- Complete response rate in Nektar melanoma trial hits 34%
- Shrinking 60% of lung cancers, Blueprint's RET drug poised for 2020 filing
- Death in Turning Point NSCLC trial overshadows 82% ORR
- GE Healthcare executive jumps ship to lead dermatology biotech LEO

t. Featured Story

u. Special Report—The top 10 pharma R&D budgets in 2018

Monday, June 3, 2019

Big Pharma companies are still, naturally, the big spenders in drug R&D, and the numbers are impressive: Last year, and for the first time, the top 15 largest companies (by sales) funneled more than $100 billion into research, and we also saw the FDA approve more drugs than ever before.

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v. Top Stories

w. Sanofi's anti-CD38 combo boosts responses, extends lives in advanced multiple myeloma

Sunday, June 2, 2019

CHICAGO—Sanofi's anti-CD38 antibody isatuximab added to the standard of care for relapsed multiple myeloma extended patients' lives and nearly doubled the number of patients for whom the standard of care worked.

x. Amgen's closely watched KRAS drug, first to clinic, shrinks NSCLC, curbs colorectal tumors

Monday, June 3, 2019

CHICAGO—It's been 30 years in the making, but the first clinical data from a KRAS inhibitor are finally here. In a small phase 1 study, Amgen's prospect, AMG 510, stopped tumor growth in the majority of patients with non-small cell lung and colorectal cancers.

y. [Sponsored] How to Make the Most of Your Clinical Trial Data—All of it

Monday, June 3, 2019

Pharma and biopharma have endless data at their disposal. Why aren't they using it? Here's how to make the most of your data for clinical success.

z. Ayala's ex-BMS drug shows promise in triple-negative breast cancer

Sunday, June 2, 2019

Israeli biotech Ayala Pharmaceuticals has just added $30 million in a Novartis-backed series B round. As preclinical results have shown, the money could be used on clinical testing of its lead drug AL101 in triple-negative breast cancer.

aa. Astellas, Seattle Genetics' ADC banishes 12% of bladder cancers

Monday, June 3, 2019

Astellas and Seattle Genetics unveiled data showing their antibody-drug conjugate shrank 44% of tumors and eliminated 12% of them in patients with advanced urothelial cancer. The treatment could become an option for patients whose cancer has worsened despite receiving chemotherapy and checkpoint inhibitors.

bb. With FDA review nearing, Epizyme shares updated sarcoma data

Monday, June 3, 2019

Epizyme has posted updated data from the phase 2 trial it hopes will secure tazemetostat approval in epithelioid sarcoma. The data feature a slight uptick in objective responses offset by rises in the rates of some adverse events.

cc. Complete response rate in Nektar melanoma trial hits 34%

Saturday, June 1, 2019

Nektar Therapeutics has posted updated data on its NKTR-214-Opdivo cocktail in first-line melanoma. The data feature four more complete responses, bringing the rate up 10 percentage points to 34%.

dd. Shrinking 60% of lung cancers, Blueprint's RET drug poised for 2020 filing

Monday, June 3, 2019

Blueprint Medicines' RET inhibitor BLU-667 shrank tumors in 60% of a difficult-to-treat group of lung cancer patients, teeing it up for a 2020 filing in patients with RET-altered non-small cell lung cancer who had already tried chemotherapy.

ee. Death in Turning Point NSCLC trial overshadows 82% ORR

Monday, June 3, 2019

A sudden, possibly drug-related death has overshadowed Turning Point Therapeutics' update on repotrectinib in non-small cell lung cancer. More than four-fifths of patients responded to the tyrosine kinase inhibitor, but shares in Turning Point fell 10% amid worries about the death.

ff. GE Healthcare executive jumps ship to lead dermatology biotech LEO

Monday, June 3, 2019

After more than a decade, LEO Pharma is getting a new chief executive as it looks to the future for a boosted pipeline and launches.

gg. Resources

hh. [Whitepaper] Agile Competitive Intelligence Strategies For Healthcare

Sponsored by: AlphaSense

What is agile competitive intelligence, and how can it help take market research to the next level?

ii. [POCKET GUIDE] Reference and Literature Management Made Easy

Sponsored by: Reprints Desk, Inc.

Get 5 quick tips for faster research and better results!

jj. [Report] Precision medicine from concept to clinic

Sponsored by: Blue Latitude Health

In this publication, Blue Latitude Health maps the journey of stakeholders impacted by the rise of precision medicine today. Download the report.

kk. [Whitepaper] Flow Chemistry: A Scale-Up Solution for Modern API Development & Manufacturing

Sponsored by: Patheon, by Thermo Fisher Scientific

Increase Safety & Flexibility with Flow Chemistry

ll. [On-Demand Webinar] Lessons Learned Implementing an End-to-End RIM Solution

Sponsored by: Veeva

IONIS shares best practices for implementing an end-to-end RIM solution in this on-demand webinar. Watch now.

mm. [Whitepaper] Site-specific, Patient-centered and Whip-smart: Enrollment Assistants Adapt to a Shifting Landscape

Sponsored by: WCG

Increasingly complex clinical trials place a tremendous burden on study sites, exacerbating already-troubling recruitment and enrollment issues. Overwhelmed, many sites may not be up to the task or have the appropriate infrastructure, creating costly delays that keep new therapies from patients.

nn. [Case Study] Clinical Supply Management

Sponsored by: Catalent

Download the case study to learn about the clinical supply management tools that helped a small sized pharma company during phase III of a multi-arm oncology study.

oo. [Video] Demand Led Services and Clinical Supply Efficiency

Sponsored by: Catalent

Watch a short video on demand led supply model. It is designed to meet the needs of patients, clinical sites, clinical team and sponsors and results in shorter lead time, less waste, less stock out risk and no booklet labels.

pp. [eBook] Strategies for Efficient Clinical Supply Management and Forecasting

Sponsored by: Catalent

Download the eBook to explore a proactive approach for clinical supply management.

qq. [Executive Summary] Achieving a Successful Drug Product Tech Transfer

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rr. [Whitepaper] Choosing the Best Sterile Dosage Form for Phase I Clinical Supply Needs

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