

Subject: RE: Q140229/S001 Telecon
Date: Thursday, April 23, 2015 at 9:27:57 AM Pacific Daylight Time
From: Shukla, Sunita
To: Chen, Flavia
CC: Koenig, Barbara, Nussbaum, Robert, Q140229-S001@docs.fda.gov

Dear Ms. Chen,

Thank you for your email. As you stated in your email below, as long as you are not returning any results (including NGS results or results from Genelex) to parents, then your study will not require an IDE. Plus contact me if you plan to change your protocol/information reported to parents. Thank you, Sunita

Sunita Shukla, MPH, Ph.D.
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From: Chen, Flavia [mailto:Flavia.Chen@ucsf.edu]
Sent: Wednesday, April 22, 2015 6:29 PM
To: Shukla, Sunita
Cc: Koenig, Barbara; Nussbaum, Robert
Subject: Re: Q140229/S001 Telecon

Dear Dr. Shukla:

After closely reviewing FDA's Q140229/S001 feedback, we have decided not to pursue the Pgx return of results to parent-consented primary immunodeficiency patients at this time. We will not return any results to the parents, but will rather study their hypothetical interest in receiving such information.

As we understand our protocol will no longer require IDE approval, we request to cancel our upcoming May 1st teleconference.

We are grateful for your diligence and guidance during our IDE pre-submission process.

With best regards,
Flavia

From: <Shukla>, "Shukla, Sunita" <Sunita.Shukla@fda.hhs.gov>
Date: Thursday, April 9, 2015 at 9:00 AM

To: Flavia Chen <flavia.chen@ucsf.edu>, Robert Nussbaum <Robert.Nussbaum@ucsf.edu>
Cc: Barbara Koenig <Barbara.Koenig@ucsf.edu>
Subject: RE: Q140229/S001 Telecon

Dear Ms. Chen,

Thank you, we are confirmed for 5/1/15 (Friday) from 10-11 AM ET. We look forward to receiving your agenda no later than noon 4/30/15. Thank you, Sunita

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From: Chen, Flavia [<mailto:Flavia.Chen@ucsf.edu>]
Sent: Thursday, April 09, 2015 9:56 AM
To: Shukla, Sunita; Nussbaum, Robert
Cc: Koenig, Barbara
Subject: Re: Q140229/S001 Telecon

Dear Dr. Shukla,

10-11 AM ET on May 1st works from our standpoint.

We will provide an agenda of discussion items by 12 noon ET on April 30th at the latest, unless you request an earlier deadline.

Kindly call: 800-445-4613
Passcode: 5877963#

With best regards,
Flavia

From: <Shukla>, "Shukla, Sunita" <Sunita.Shukla@fda.hhs.gov>
Date: Thursday, April 9, 2015 at 6:40 AM
To: Flavia Chen <flavia.chen@ucsf.edu>, Robert Nussbaum <Robert.Nussbaum@ucsf.edu>
Cc: Barbara Koenig <Barbara.Koenig@ucsf.edu>
Subject: RE: Q140229/S001 Telecon

Yes, sorry, I meant AM. I May 1st doesn't work, I can look at other dates/times as well.

Sunita Shukla, MPH, Ph.D.

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From: Chen, Flavia [<mailto:Flavia.Chen@ucsf.edu>]
Sent: Thursday, April 09, 2015 9:40 AM
To: Shukla, Sunita; Nussbaum, Robert
Cc: Koenig, Barbara
Subject: Re: Q140229/S001 Telecon

Dear Dr. Shukla,

Kindly reconfirm the proposed teleconference time on May 1st. Is 10-11 AM or PM Eastern Time?

Unfortunately the first two proposed dates/times conflict with our schedules.

With best regards,
Flavia

From: <Shukla>, "Shukla, Sunita" <Sunita.Shukla@fda.hhs.gov>
Date: Thursday, April 9, 2015 at 6:27 AM
To: Flavia Chen <flavia.chen@ucsf.edu>, Robert Nussbaum <Robert.Nussbaum@ucsf.edu>
Cc: Barbara Koenig <Barbara.Koenig@ucsf.edu>
Subject: RE: Q140229/S001 Telecon

Dear Ms. Chen,

Thank you for your condolences. I have checked our schedules and unfortunately, there is one party that is out of the office at that time. Here are some proposed dates/times below:

Monday (4/27) 3-4 PM ET
Tues (4/29) 2-3 PM ET
Friday (5/1) 10-11 PM ET

Please let me know as soon as possible which dates/times work for you. If these do not work, I will find another time. Thank you again, Sunita

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From: Chen, Flavia [<mailto:Flavia.Chen@ucsf.edu>]
Sent: Thursday, April 09, 2015 9:11 AM
To: Shukla, Sunita; Nussbaum, Robert
Cc: Koenig, Barbara
Subject: Re: Q140229/S001 Telecon

Dear Dr. Shukla,

Please accept our condolences on the passing of your colleague.

Upon discussion with Dr. Nussbaum and Dr. Koenig, we would like to proceed with your participation. We propose a rescheduled teleconference date of Friday, April 24th from 7-8am Pacific Time (10-11am Eastern Time).

Please let us know if this date/time works in your schedules. I will write with a call-in number once we have settled on a teleconference date and time.

With best regards,
Flavia

From: <Shukla>, "Shukla, Sunita" <Sunita.Shukla@fda.hhs.gov>
Date: Wednesday, April 8, 2015 at 10:10 AM
To: Robert Nussbaum <Robert.Nussbaum@ucsf.edu>
Cc: Flavia Chen <flavia.chen@ucsf.edu>, Barbara Koenig <Barbara.Koenig@ucsf.edu>
Subject: RE: Q140229/S001 Telecon

Thank you, we truly appreciate your understanding.

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From: Nussbaum, Robert [<mailto:Robert.Nussbaum@ucsf.edu>]
Sent: Wednesday, April 08, 2015 12:50 PM
To: Shukla, Sunita
Cc: Chen, Flavia; Koenig, Barbara
Subject: Re: Q140229/S001 Telecon

I am meeting with Ms Chen and Dr. Koenig at 1 PM today. I will get back to you as soon as that meeting is over and I can discuss alternative times with them about rescheduling.

From: <Shukla>, Sunita Shukla <Sunita.Shukla@fda.hhs.gov>
Date: Wednesday, April 8, 2015 at 12:47 PM
To: Robert Nussbaum <robert.nussbaum@ucsf.edu>
Cc: "Chen, Flavia" <Flavia.Chen@ucsf.edu>, Barbara Koenig <Barbara.Koenig@ucsf.edu>, "Q140229-S001@docs.fda.gov" <Q140229-S001@docs.fda.gov>
Subject: Q140229/S001 Telecon

Dear Dr. Nussbaum,

Unfortunately, a co-worker of ours passed away this week and her funeral will be held this Friday during our scheduled teleconference time. I am wondering if we can either re-schedule the teleconference for next week or after 4/22/15. Please note that I will be out of the office next week, however if you would like to hold the telecon at that time, the other managers will be on the call. If you can have the call after 4/22/15, then I will be able to participate. Please let me know your preferences as soon as possible so that I can find a time to reschedule. I truly apologize for any inconvenience and thank you for your understanding. Please also provide a call-in number, if possible. Thank you, Sunita

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From: Shukla, Sunita
Sent: Tuesday, April 07, 2015 2:38 PM
To: 'Nussbaum, Robert'
Cc: Chen, Flavia; Koenig, Barbara; Q140229-S001@docs.fda.gov
Subject: Q140229/S001 Feedback

Dear Dr. Nussbaum,

Please find our feedback for your above referenced submission attached. Please provide an agenda of

discussion items by 4/9/15, based on this feedback, ahead of our upcoming teleconference on 4/10/15 at 11 AM-12 PM ET. Please also provide a call-in number to reach you for the teleconference as the FDA number will not be available.

We look forward to speaking with you on 4/10/15. Thank you, Sunita

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From: Nussbaum, Robert [<mailto:Robert.Nussbaum@ucsf.edu>]
Sent: Wednesday, April 01, 2015 1:46 PM
To: Shukla, Sunita
Cc: Chen, Flavia; Koenig, Barbara
Subject: Re: Q140229/S001

Correct, to see if we can do it and for for internal use/comparison's sake . The actual Pgx result will be based on the GEnLex result.

We are also looking for evidence of a primary immune deficiency in the NGS sequencing result but that result is NOT going back to the patient.

From: <Shukla>, Sunita Shukla <Sunita.Shukla@fda.hhs.gov>
Date: Wednesday, April 1, 2015 at 10:43 AM
To: Robert Nussbaum <robert.nussbaum@ucsf.edu>
Cc: "Chen, Flavia" <Flavia.Chen@ucsf.edu>, "Q140229-S001@docs.fda.gov" <Q140229-S001@docs.fda.gov>
Subject: RE: Q140229/S001

Thank you. Just to confirm, you are collecting NGS data from dried blood spots, correct?

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From: Nussbaum, Robert [<mailto:Robert.Nussbaum@ucsf.edu>]
Sent: Wednesday, April 01, 2015 12:44 PM
To: Shukla, Sunita
Cc: Chen, Flavia
Subject: Re: Q140229/S001

This set of subjects are affected with primary immunodeficiency and will Receive pre-test counseling and be consented to

1. Allow us to go back and get their NBS
2. Give a buccal swab for confirmation of what we see in the NGS of their newborn blood spots

From: <Shukla>, Sunita Shukla <Sunita.Shukla@fda.hhs.gov>
Date: Wednesday, April 1, 2015 at 8:07 AM
To: "Chen, Flavia" <Flavia.Chen@ucsf.edu>
Cc: Robert Nussbaum <robert.nussbaum@ucsf.edu>, "Q140229-S001@docs.fda.gov" <Q140229-S001@docs.fda.gov>
Subject: RE: Q140229/S001

Thank you. Just to confirm, you will collect the buccal swabs from the same subjects as you collect the DBS samples from and then send to Genelex?

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From: Chen, Flavia [<mailto:Flavia.Chen@ucsf.edu>]
Sent: Wednesday, April 01, 2015 9:25 AM
To: Shukla, Sunita
Cc: Nussbaum, Robert; Q140229-S001@docs.fda.gov
Subject: Re: Q140229/S001

Dear Dr. Shukla,

We understand that Genelex will use buccal swabs for their DNA collection.

With best regards,
Flavia

On Mar 31, 2015, at 7:04 PM, "Shukla, Sunita" <Sunita.Shukla@fda.hhs.gov> wrote:

Dear Ms. Chen,

Could you please verify which sample type(s) Genelex will use to confirm your results (which you will obtain using dried blood spot samples)? Please let me know as soon as the information is available. Thank you, Sunita

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From: Shukla, Sunita
Sent: Tuesday, March 31, 2015 2:25 PM
To: 'Chen, Flavia'
Cc: Nussbaum, Robert; 'Q140229-S001@docs.fda.gov'
Subject: RE: Q140229/S001

Thank you for the attached validation data. I will let you know if we have any questions.

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From: Chen, Flavia [<mailto:Flavia.Chen@ucsf.edu>]
Sent: Tuesday, March 31, 2015 1:23 PM
To: Shukla, Sunita
Cc: Nussbaum, Robert; 'Q140229-S001@docs.fda.gov'
Subject: Re: Q140229/S001

Dear Dr. Shukla,

Please find attached two confidential attachments:

1. Validation summary of pharmacogenetic testing of CYP2D6 CYP2C19 CYP2C9 CYP3A4 CYP3A5 and VKORC1
2. Validation summary of pharmacogenetic testing of Panel 3 (which includes CYP2B6 and CYP1A2)

These documents and the information they contain are being submitted by UCSF PI Dr. Robert Nussbaum under the terms of a Confidential Disclosure Agreement with Genelex Corporation to add to the record file of Q140229/S001 for FDA review.

With best regards,
Flavia

From: <Shukla>, "Shukla, Sunita" <Sunita.Shukla@fda.hhs.gov>
Date: Tuesday, March 31, 2015 at 8:12 AM
To: Flavia Chen <flavia.chen@ucsf.edu>
Cc: Robert Nussbaum <Robert.Nussbaum@ucsf.edu>, "'Q140229-S001@docs.fda.gov'"
<Q140229-S001@docs.fda.gov>
Subject: RE: Q140229/S001

Dear Ms. Chen,

Unfortunately, we will not be able to provide a signed letter. However, the validation information from Genelex you are providing to FDA will be added to the record file of this pre-submission. As such, and as with all submissions reviewed by the FDA, the contents are considered confidential.

Please note that when you e-mail the validation data, you should clearly state the contents of the e-mail, state that the contents are confidential, and that the information is being submitted in collaboration with UCSF to add to the record file of Q140229/S001 for FDA review.

We look forward to receiving your data today. Thank you, Sunita

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From: Chen, Flavia [<mailto:Flavia.Chen@ucsf.edu>]
Sent: Monday, March 30, 2015 5:23 PM
To: Shukla, Sunita
Cc: Nussbaum, Robert; 'Q140229-S001@docs.fda.gov'
Subject: Re: Q140229/S001

Dear Dr. Shukla,

This afternoon I spoke with Dan Doherty and Howard Coleman at Genelex regarding sharing their validation data with the FDA. They have asked that you kindly provide an email and, at a later date, a signed letter, stating that any Genelex documentation shared with the FDA pertaining to the evaluation of Q140229/S001 will be treated as confidential and distributed on a need-to-know basis solely for work related to this project. Once Genelex has received your email statement of confidentiality, I will be permitted to forward their validation data for your review. Kindly either email me this statement, which I will then forward to Dan, or cc me on your communication to him.

Dan Doherty
Genelex Corporation
3101 Western Ave., Suite 100
Seattle, WA 98121
Dan@genelex.com

With best regards,
Flavia

From: <Shukla>, "Shukla, Sunita" <Sunita.Shukla@fda.hhs.gov>
Date: Monday, March 30, 2015 at 9:37 AM
To: Flavia Chen <flavia.chen@ucsf.edu>
Cc: Robert Nussbaum <Robert.Nussbaum@ucsf.edu>, "Q140229-S001@docs.fda.gov" <Q140229-S001@docs.fda.gov>
Subject: RE: Q140229/S001

Dear Ms. Chen,

I'm following up with you regarding the Genelex validation data for your chosen confirmation method. Please have this information to us by noon tomorrow (3/31/15) since our feedback to you is due 3-4 days prior to our upcoming teleconference on 4/10/15. Please let me know if you have any questions. Thank you, Sunita

Sunita Shukla, MPH, Ph.D.
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From: Shukla, Sunita
Sent: Friday, March 27, 2015 3:48 PM
To: 'Chen, Flavia'
Cc: Nussbaum, Robert; Q140229-S001@docs.fda.gov
Subject: RE: Q140229/S001

Dear Ms. Chen,

Thank you for your email. Please email me the validation data (such as accuracy data) from Genelex for their orthogonal test method (Sequenom Mass Array 4) you plan to use for the genetic variants included in your panel. Please provide this information to me as soon as you can. Thank you, Sunita

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From: Chen, Flavia [<mailto:Flavia.Chen@ucsf.edu>]
Sent: Wednesday, March 25, 2015 8:32 PM
To: Shukla, Sunita
Cc: Nussbaum, Robert
Subject: Q140229/S001

Dear Dr. Shukla,

In February you received our IDE pre-submission supplement to Q140229 which addressed FDA's questions regarding Genelex, the company that will orthogonally confirm our pharmacogenetic test results. We have been in contact with Genelex and have requested and received validation data under the terms of a Confidential Disclosure Agreement

(CDA) which covers their confidential trade secrets.

In preparation for our upcoming teleconference with the FDA on April 10th, 2015, are there any additional documents or agreements we should prepare, or that FDA will require, in order to discuss our IDE pre-submission?

With best regards,

Flavia Chen, MPH
Project Manager, UCSF U19