Message

From: Shams, Dahnish [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B7037E39BB6341C8850BCDC61BF9D65A-SHAMS, DAHN]
Sent: 8/6/2021 2:26:45 PM
To: Husain, Hassan [USA - EMP] [hhusain@versar.com]
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Hassan – Just closing the loop on this, we should stick with an in-vitro expertise for that last slot.

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
Center for Public Health and Environmental Assessment (CPHEA)
Office of Research and Development, U.S. EPA
O: (202) 564-2758

From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Thursday, August 5, 2021 12:42 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Roger that. I'll wait to hear from you

Hassan Husain
Senior Program Manager
Environmental Services Group
VERSAR
hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 6 Personal Privacy (PP)
www.versar.com

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Thursday, August 5, 2021 12:28 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Hassan – Can you hold off until tomorrow morning?

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
Center for Public Health and Environmental Assessment (CPHEA)
Office of Research and Development, U.S. EPA
O: (202) 564-2758

From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Thursday, August 5, 2021 11:11 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Dahnish,
Wanted to get some clarification on the email from Paul below. Should we wait for feedback from your Friday meeting or to continue pursuing experts? It also sounds like pharma might be an area we want to grab someone from as well, please advise.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

As always let me know if you have any questions or would like to discuss further.

Hassan Husain
Senior Program Manager
Environmental Services Group
VERSAR
Your Needs. Our Mission.
hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 6 Personal Privacy (PP)
www.versar.com

From: Schlosser, Paul <Schlosser.Paul@epa.gov>
Sent: Wednesday, August 4, 2021 11:35 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Is Ferguson definitely not available or just unknown right now?

I think the remaining question about the in vitro work (not sure the reviewers really discussed it) is if the sample sizes are adequate. None of them really said, "No, I wouldn't use these results because of that," and because the model uses "A1" to get human lung metabolism (the value for which comes from a pretty good study), this really just devolves to if the sample size was large enough for human liver...

So, maybe we don't need an in-vitro expert now, since we had them in the initial review. EPA/CPAD is doing a huddle on Friday, can discuss more then.

Otherwise I think the expertise we'd want is most likely to be found in pharma (including academics focused on therapeutics). This is an are I don't know well. Rusty Thomas might be able to suggest some names.

-Paul

From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Wednesday, August 4, 2021 11:05 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Dahnish,
The third pool we are referring to is the pool of potential reviewers we had identified previously but not actually contacted yet. This is outside the pool of potential reviewers we had provided previously.

Ex. 5 Deliberative Process (DP)

Let me know if you have any questions. Happy to discuss further.

Hassan Husain
Senior Program Manager
Environmental Services Group
VERSAR
Your Needs. Our Mission.
hhusain@versar.com
Direct Office: 240-252-2304
Mobile: Ex. 5 Deliberative Process (DP)
www.versar.com

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Wednesday, August 4, 2021 12:39 AM
To: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Ok thanks Tracey. Do you mind clarifying the pools you are referring to? I thought there really was only one pool from last time (i.e., the candidate reviewers) and then from that pool Versar picked the "final" reviewers who ended up on the panel. Is there another (third) pool?

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
Center for Public Health and Environmental Assessment (CPHEA)
Office of Research and Development, U.S. EPA
O: (202) 564-2758

From: Cowen, Tracey [USA - EMP] <TCowen@versar.com>
Sent: Tuesday, August 3, 2021 8:31 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Hassan Husain (versar) <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Dahnish,

Thanks for providing consent of the three selected reviewers we will distribute the review and supporting materials to them.

Ex. 5 Deliberative Process (DP)

Regarding the supplemental analysis it will be sent out as supporting information, but we just wanted to confirm that it had not been updated and the 2020 version that we sent last year will be used.

Thanks,
Tracey

Tracey L. Cowen
Environmental Scientist
Environmental Services Group

VERSAR
Your Needs. Our Mission.

Direct: 301-304-3121
Mobile: Ex. 5 Deliberative Process (DP)
Email: tcowen@versar.com
Visit us at: www.versar.com

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, August 3, 2021 4:50 PM
To: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Tracey – Thanks for the summary. Please feel free to pass on the meeting materials to the three selected reviewers from the previous panel. We have no concerns regarding their selection.

In regards to the three individuals highlighted from the broader pool of reviewers, all three individuals appear to continue to have the required expertise. However, we do want to emphasis having the right expertise mix assuming there are two reviewer slots remaining (in vitro v. PBPK modeling v. stats, etc.).

Lastly, the supplemental analysis and the Ramboll epidemiological study attachment are considered background information should not be reviewed/commented on by the experts. The focus of this review is more narrow than what reviewed last year.

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
Center for Public Health and Environmental Assessment (CPHEA)
Office of Research and Development, U.S. EPA
O: (202) 564-2758

From: Cowen, Tracey [USA - EMP] <TCowen@versar.com>
Sent: Monday, August 2, 2021 4:30 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Hassan Husain (versar) <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Dahnish and Dustin,

I am writing to provide another update and to request your consent on three selected previous peer reviewers of the revised report on physiologically based pharmacokinetic (PBPK) modeling for chloroprene (Ramboll, 2021).

Ex. 5 Deliberative Process (DP)

The four members of the pool are:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thanks,
Tracey

Tracey L. Cowen
Environmental Scientist
Environmental Services Group

VERSAR
Your Needs. Our Mission.

Direct: 301-304-3121
Mobile: Ex. 5 Deliberative Process (DP)
Email: tcowen@versar.com
Visit us at: www.versar.com

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Friday, July 23, 2021 1:14 PM
To: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: RE: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Great! Thanks for the update Tracey. Let us know when you hear back from the other reviewers.

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
Center for Public Health and Environmental Assessment (CPHEA)
Office of Research and Development, U.S. EPA
O: (202) 564-2758

From: Cowen, Tracey [USA - EMP] <TCowen@versar.com>
Sent: Friday, July 23, 2021 11:24 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul

<Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Hassan Husain (versar) <hhusain@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>
Subject: Update for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Dahnish and Dustin,

Thanks for sending the updated documents from Ramboll/ Denka.

We already have four candidates who are interested in participating in the re-review (Drs. Portier, Shao, Yang, and Zhu). Drs. Portier and Yang will both need until early September to complete their reviews due to schedule conflicts. We are hoping to hear soon from two of the reviewers (Drs. Louisse and Lumen) who are currently out-of-office. One person has declined (Dr. Benet) and one has not responded (Dr. Smith) but we're hoping to hear from him soon.

We're in the process of re-screening the four people above for COI.

We'll have another update for you early next week and may be able to get some of the reviewers started with their work, in advance of having the charge questions.

Tracey

Tracey L. Cowen
Environmental Scientist
Environmental Services Group

VERSAR

Direct: 301-304-3121
Mobile: 301-785-4094
Email: tcowen@versar.com
Visit us at: www.versar.com

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Friday, July 23, 2021 9:44 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Bottimore, David [USA - EMP] <DBottimore@versar.com>; Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: Kick Off for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

Hi Hussain/all – Attached to this email are the updated chloroprene files associated with the RFC. EPA's website is currently being upgraded so the documents aren't showing up if you Google them yet, but they will be available shortly at the URL below. Please note that there are two extra files with this submission from DPE, but both I believe are background information only and should not be directly commented on by the reviewers (e.g., the Exhibit B - Epi Data and Studies and the response to comments document). I will follow up asap if anything changes on our end.

EPA will be working to finalize the draft charge questions. However, we don't expect the final version to be complete until Paul S. returns from leave in early August.

Let me know if you have any questions or comments on this.

https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
Center for Public Health and Environmental Assessment (CPHEA)
Office of Research and Development, U.S. EPA
O: (202) 564-2758

-----Original Appointment-----
From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Monday, July 12, 2021 3:44 PM
To: Husain, Hassan [USA - EMP]; Shams, Dahnish; Kapraun, Dustin; Schlosser, Paul; Morozov, Viktor; Thayer, Kris; Bottimore, David [USA - EMP]; Cowen, Tracey [USA - EMP]; Williams, Laura [USA - EMP]; Bogen, Kenneth [USA - EMP]
Subject: Kick Off for Follow Up - External Peer Review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance
When: Monday, July 19, 2021 11:30 AM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Purpose: To kick-off the follow up peer review of a Report on (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance.

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

Or call in (audio only)
Ex. 6 Personal Privacy (PP) United States, Lynchburg
United States (Toll-free)
Phone Conference ID Ex. 6 Personal Privacy (PP)
Find a local number | Reset PIN

Learn More | Meeting options

This email and any files transmitted with it are confidential and intended solely for the named addressee. This message contains confidential information and is intended only for the person so identified. If you are not the named addressee, you should not disseminate, distribute or copy this e-mail. If you received this message by mistake, please reply to this message and then delete it, so that we can ensure such a mistake does not occur in the future.

This email and any files transmitted with it are confidential and intended solely for the named addressee. This message contains confidential information and is intended only for the person so identified. If you are not the named addressee, you should not disseminate, distribute or copy this e-mail. If you received this message by mistake, please reply to this message and then delete it, so that we can ensure such a mistake does not occur in the future.

This email and any files transmitted with it are confidential and intended solely for the named addressee. This message contains confidential information and is intended only for the person so identified. If you are not the named addressee, you should not disseminate, distribute or copy this e-mail. If you received this message by mistake, please reply to this message and then delete it, so that we can ensure such a mistake does not occur in the future.

This email and any files transmitted with it are confidential and intended solely for the named addressee. This message contains confidential information and is intended only for the person so identified. If you are not the named addressee, you should not disseminate, distribute or copy this e-mail. If you received this message by mistake, please reply to this message and then delete it, so that we can ensure such a mistake does not occur in the future.

This email and any files transmitted with it are confidential and intended solely for the named addressee. This message contains confidential information and is intended only for the person so identified. If you are not the named addressee, you should not disseminate, distribute or copy this e-mail. If you received this message by mistake, please reply to this message and then delete it, so that we can ensure such a mistake does not occur in the future.

This email and any files transmitted with it are confidential and intended solely for the named addressee. This message contains confidential information and is intended only for the person so identified. If you are not the named addressee, you should not disseminate, distribute or copy this e-mail. If you received this message by mistake, please reply to this message and then delete it, so that we can ensure such a mistake does not occur in the future.

This email and any files transmitted with it are confidential and intended solely for the named addressee. This message contains confidential information and is intended only for the person so identified. If you are not the named addressee, you should not disseminate, distribute or copy this e-mail. If you received this message by mistake, please reply to this message and then delete it, so that we can ensure such a mistake does not occur in the future.