

Message

From: Kingshuk Das [REDACTED]
Sent: 3/13/2016 4:23:40 AM
To: Tina Lin [tlin@theranos.com]
CC: Kingshuk Das [kdas@theranos.com]; Michele Carbone [REDACTED]; David Zifkin [dzifkin@bsflp.com]; Sunny Balwani [sbalwani@theranos.com]; Heather King [hking@theranos.com]; Daniel Young [dyoung@theranos.com]
Subject: Re: Updated corrected reports summary

Thanks, Tina--yes, you mentioned the Advia vs. XPT comparisons...was hoping it covered more than patient distributions, but certainly not expecting it. Unfortunately, it's not possible to extract bias from that type of comparison, since it's nowhere near a method comparison. Since QCs were not illuminating, the last chance we have is to comb through the periods in question to see if there are any preanalytical factors that may account for such huge shifts--most likely identifiable scenario would be spikes in specialty clinic testing (depending on the type of clinic, renal/dialysis centers would be most likely culprit, perhaps endocrine as well) during those periods. However, I believe Daniel already checked, and didn't note anything significant along those lines.

It's worth one more look, as I think we're out of other options--let me know.

Otherwise, I don't see another way at this point to narrow the range of affected accessions here.

Thanks again,

king

On Sat, Mar 12, 2016 at 3:00 AM, Tina Lin <tlin@theranos.com> wrote:

King,

As we noted over the phone, the only way we were able to extract any possible meaningful bias was to compare the monthly means of each of the ADVIAs versus the XPT for the trouble months (I double checked just now that medians are the same as the means for both).

For example:

ADVIA 2 was flagged high for calcium in January 2015.

Calcium mean on XPT that month was 9.65

Calcium mean on ADVIA 2 that month was 10.33

I corrected all ADVIA 2 results by 10.33-9.65, or 0.68

Anything that fell from normal to low were then flagged, since you had excluded the high<->normal shift as not having clinical impact.

Does this approach work for you? And did you get a chance to speak with Michele regarding whether this approach makes sense? It would be best if you and Michele could sync up to confirm. I believe by now I've described in detail the two methodologies to choose from, but do let me know if I can provide anything else.

Thanks for your time,

Tina

From: Kingshuk Das [REDACTED]
Sent: Friday, March 11, 2016 8:05 PM
To: Kingshuk Das <kdas@theranos.com>
Cc: Tina Lin <tlin@theranos.com>; Michele Carbone <[REDACTED]>; David Zifkin <dzifkin@bsflfp.com>; Sunny Balwani <sbalwani@theranos.com>; Heather King <hking@theranos.com>; Daniel Young <dyoung@theranos.com>

Subject: Re: Updated corrected reports summary

Sorry it took until this evening, but here goes:

I had a chance to touch base with Tina and Daniel the other day to get details on the updated patient impact assessments, and I've decided to take a more conservative approach. I agree with everyone, the periods of significantly shifted patient distributions definitely need to be addressed via corrected/voided reports, however we should not filter by multiple analytes affected, but rather analyte by analyte, as that is how they would have clinical impact...i.e., if a period had shifted distributions for Na, then it should be addressed, regardless of concurrent distributions in total protein or calcium, etc...since clinicians would indeed be triggered by single analyte findings.

The issue appears to be the difficulty in ascertaining any sort of bias for these distributions, as the concurrent QCs are not helpful, and distribution deviations on their own won't truly quantify bias. If there are other indicators of bias during those periods, perhaps correction factors can be derived--although that seems difficult to nail down since the QCs were not helpful, so all the reports would need voiding--even those reported as "normal," as a subset of those will be "false negatives" that are difficult to identify without bias/correction factor estimates.

Tina, let me know if we have any sense of possible bias/correction factors for those periods--and if not, please prepare to void the problematic periods for each analyte as identified by Michele--I think you've already pulled the accessions.

Thanks everyone,

king

On Fri, Mar 11, 2016 at 12:03 PM, Kingshuk Das <kdas@theranos.com> wrote:

Will send an email mid-afternoon, so we can finalize summaries ASAP

From: Kingshuk Das
Sent: Friday, March 11, 2016 11:38 AM
To: Tina Lin

Cc: [REDACTED]; Michele Carbone; David Zifkin; Sunny Balwani; Heather King; Daniel Young
Subject: RE: Updated corrected reports summary

Haven't yet, sorry--I'm busy jumping through exit proceedings hoops here at UCLA all day, waiting in line after another, to get signatures, etc. State gov't is expert @ bureaucracy.

I'll get a note out to the group later today--my thoughts have not changed, so will convey to Michele, and we should be all tied up.

Thanks,
k

From: Tina Lin
Sent: Friday, March 11, 2016 11:23 AM
To: Kingshuk Das
Cc: [REDACTED] Michele Carbone; David Zifkin; Sunny Balwani; Heather King; Daniel Young
Subject: RE: Updated corrected reports summary

Hey King, did you get a chance to call Michele and come to a final conclusion on which of the 2 methods we will be going with, per our conversation yesterday?

We have the final counts for both methodologies, just waiting for your note.

Thanks,
Tina

From: Daniel Young
Sent: Thursday, March 10, 2016 3:05 PM
To: Kingshuk Das <kdas@theranos.com>
Cc: Tina Lin <tlin@theranos.com>; [REDACTED] Michele Carbone <[REDACTED]>; David Zifkin <dzifkin@BSFLLP.com>; Sunny Balwani <sbalwani@theranos.com>; Heather King <hking@theranos.com>
Subject: Re: Updated corrected reports summary

We will call you in 15min.
-Daniel

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On Mar 10, 2016, at 4:03 PM, Kingshuk Das <kdas@theranos.com> wrote:

Great--let me know a good time to call, and the best number

Should be able to wrap it up, just a couple more Q's

-k

From: Daniel Young

Sent: Thursday, March 10, 2016 2:58 PM

To: Kingshuk Das

Cc: Tina Lin; [REDACTED] Michele Carbone; David Zifkin; Sunny Balwani; Heather King

Subject: Re: Updated corrected reports summary

Hi King,

Tina and I are traveling back from Arizona now. But we are available to discuss as needed if you have questions as we wrap this up today. Thanks.

-Daniel

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On Mar 10, 2016, at 12:40 AM, Kingshuk Das <kdas@theranos.com> wrote:

Hi Tina,

Sorry for the delay--I agree with you, I favor being more conservative (515, not 76).

Though I do need some clarification: do the flagged accessions include "normal" values as well? My understanding is that these accessions were flagged as occurring during periods of time with unusual patient distributions (not QC data)

affecting >1 analyte (indicating possible systematic error). For most analytes, a bias leading to flag change from low-->normal or normal--> high, or high--> normal or normal --> low could be clinically significant, which is why I wanted to make sure we're including "normals," as they may be falsely low/high depending on possible bias (based on distributions). The situation is different for total protein, as we discussed before, where normal --> high, or high--> normal is fairly insignificant.

I'm not sure if I'm interpreting the excel sheet or emails correctly, so wanted to make sure.

Let's clear it up tomorrow--I'll be on-site in Newark, so should be no problem.

Thanks,
k

From: Tina Lin
Sent: Wednesday, March 09, 2016 8:49 AM
To: Kingshuk Das; [REDACTED] Daniel Young; 'Michele Carbone'; 'David Zifkin'
Cc: Sunny Balwani; Heather King
Subject: Updated corrected reports summary

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Thanks for your time yesterday, all. See attached for the updated summary for corrected reports. This is near final, pending highlighted section below. File is DRM'ed, let me know if you'd like me to un-DRM this.

Flagged accessions for 1800s are as follows:

- ADVIA 1 – April 2015 – high CO2, low Sodium – 1 accession
- ADVIA 2 – August 2014 – high Calcium, TP, Sodium – 26 accessions
- ADVIA 2 – January 2015 – high Calcium, Sodium, TP – 20 accessions
- ADVIA 3 – June 2014 – high Calcium, TP, Sodium – 36 accessions
- ADVIA 3 – November 2014 – high Calcium and TP – 515 accessions or 76 accessions, because:
 - If including low Sodium too, then 76 accessions only – the accessions in this month with only high Calcium and TP are marked as “sodium is not low” in column I
- The counts are listed in columns C or D depending on which approach you take
- ADVIA 3 – January 2015 – high Calcium, TP – 20 accessions

Summary:

- 7548 unique accessions (or 7172 unique accessions taking into account highlighted above)
- 8223 unique results (or 9101 unique results taking into account highlighted above)

King/Michele, can you advise on ADVIA 3, November 2014 above? I'm inclined to go with 515 but it's up to you.

Thanks,

Tina

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