Message

From: Sunny Balwani [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SBALWANI]
Sent: 8/29/2013 5:14:20 PM
To: Elizabeth Holmes [eholmes@theranos.com]
Subject: RE: Concerns about the launch

We will talk to him.

I assume we can use siemens chemistry for glucose and sodium? If yes then we should

As for operational, we should tell him we will limit # of samples to 50 per day for 2-4 weeks until we have addressed all staffing and training needs.

From: Elizabeth Holmes
Sent: Thursday, August 29, 2013 10:11 AM
To: Sunny Balwani
Subject: Fwd: Concerns about the launch

Begin forwarded message:

From: Adam Rosendorff <arosendorff@theranos.com>
Date: August 29, 2013, 10:06:10 AM PDT
To: Elizabeth Holmes <eholmes@theranos.com>
Cc: Daniel Young <dyoung@theranos.com>
Subject: Concerns about the launch

Hi Elizabeth

I have some medical and operational concerns about our readiness for 9/9.

1) Medical

GLUCOSE

Significant negative bias exists for glucose, 95% confidence interval for bias (negative):

Medical Decision Level:	45 mg/dL	120 mg/dL	180 mg/dL

-20% to-12% -16% to -11% -16% to -11%

N=123

This is again reflected in the reference range which is coming out as 20-97 mg/dL on the Theranos chemistries whereas on the Siemens chemistries we are establishing a de-novo reference range of 56-117 mg/dL, which compares nicely with the published range of 70-110 which means we are doing are studies properly. The recommended maximum bias is 5% Our CV% is also a little high (8%). The CLIA total allowable error (precision plus bias) is 10%, which means that our entire error budget has already been spent just on precision. I am not sure how comfortable I am applying a correction factor for glucose because criteria for diabetes for instance, have been set at a fasting blood glucose of 126 mg/dL, which is fairly standard across analyzers without post-hoc corrections. Maybe we need to work on our calibrators or chemistry?

SODIUM

I noticed that for one of the demos a few patients had sodium values in the 120s, whereas 99% of healthy patients should have sodiums between 135-145 mEq/L. The allowable bias for sodium should be 2-3 mEq/L

2) Operational

We are understaffed and not trained on the new protocols. We would need at least 2 CLSes downstairs in Normandy to do the pipetting from the BCDs/ handling of the TECAN, and 2 operators upstairs to do the QC and ADVIA operation, in addition to a "float" CLS that can fill in as needed. This means we need 5 CLSes and we only have 3. I am working with Curtis and Chinmay to finalize SOPs, and with Erez to crunch through the validation data.

I would like us to be the best that we can be. A few more weeks to sort through these medical and logistical issues, and getting the proper level of training and staffing would help us tremendously.

Regards,

Adam

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