

**From:** Victoria Sung </O=CELGENE/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=VSUNG>  
**Sent:** Tuesday, December 22, 2009 10:15 AM  
**To:** Gary Frenzel <gfrenzel@theranos.com>  
**Cc:** Surekha Gangakhedkar <surekhag@theranos.com>  
**Subject:** RE: PD marker development priority list

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Hi Gary,

Just wanted to let you know that we are still having internal discussions as to how we'd like to proceed with assay validation for the ACE-011 trial. Some of the biomarkers will be used to make clinical decisions and it's my understanding that Celgene would like to have those assays developed to GLP standards. Furthermore, we are considering following in the PK assay development footsteps and providing for some way to compare Theranos assay results with a standard assay from a lab such as ICON, who has all the assays validated already. Our translational development group (including me) doesn't really have a background in assay validation/development, so we might also be working with an external consultant to guide us.

With regard to your request for clinical material to use as "test" articles in your assay development process, we may have leftover serum from the PK portion of the first part of the renal study. If this is the case, we'll be sure to let you know; however, I was under the impression that you preferred whole blood since this is what the Theranos assay will be based on?

We have a meeting set to discuss these issues and others as soon as we return from the holidays and I will keep you posted.

Best wishes for a happy holiday!

Regards,  
Vicki

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**From:** Gary Frenzel [mailto:gfrenzel@theranos.com]  
**Sent:** Wednesday, December 02, 2009 9:40 PM  
**To:** Victoria Sung; Surekha Gangakhedkar  
**Cc:** Elizabeth Holmes  
**Subject:** RE: PD marker development priority list

Thanks Vicki, Great to talk to you today, and the list is a great help. As we discussed this morning, I would like to work closely with you during our development phase to keep you informed as they progress, as well as if you have any suggestions. When you find out what is considered the gold standard amongst your team please let us know. If you are open to our suggestions for the standard we can let you know what we have found as well. Thanks again. Gary

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**From:** Victoria Sung [mailto:VSung@celgene.com]  
**Sent:** Wed 12/2/2009 5:23 PM  
**To:** Surekha Gangakhedkar; Gary Frenzel  
**Cc:** Elizabeth Holmes  
**Subject:** PD marker development priority list

Per our conversation today, I include a list of the biomarkers arranged according to priority...I added a fourth group since I think FSH and LH are actually ranked higher than the remaining markers (please let me know if there are markers I've left out or conversely, if there are some included that you've never seen before). I will send out e-mails to the team to ask about reference assays as well as "extra" clinical samples available and will get back to you as soon as I can.

Best regards,  
Vicki

[Top priority:](#)

EPO  
HGB

FGF23

Second Tier:

BSAP  
CTX  
NTX  
TRAP5b  
PTH

Third Tier:

FSH  
LH

Final Frontier:

Osteocalcin  
NTP  
P1CP  
P1NP  
IGF-1  
Testosterone  
Dihydrotestosterone  
(DHT)  
Estrogen/estradiol  
Vit.D

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**From:** Surekha Gangakhedkar [mailto:surekhag@theranos.com]  
**Sent:** Tuesday, December 01, 2009 12:54 PM  
**To:** Victoria Sung  
**Subject:** RE: Celgene Clinical Trial - PD marker development

Hi Vicki,

Will you be available tomorrow for a conference call? Thanks for your patience.

Warm regards,  
Surekha

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**From:** Victoria Sung [mailto:VSung@celgene.com]  
**Sent:** Friday, November 20, 2009 3:44 PM  
**To:** Surekha Gangakhedkar  
**Cc:** Gary Frenzel  
**Subject:** FW: Celgene Clinical Trial - PD marker development

Hello,

Just following up with you to find out if you may have time next week for a quick phone conversation? I think the issues below can be discussed within 30 minutes or so and it would just be me calling Surekha. Once we have a better idea of

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the basics, I can arrange for a meeting with others who are involved.

I look forward to speaking with you soon.  
Best regards,  
Vicki

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**From:** Victoria Sung  
**Sent:** Monday, November 16, 2009 2:52 PM  
**To:** Surekha Gangakhedkar; Gary Frenzel  
**Subject:** Celgene Clinical Trial - PD marker development

Hi Surekha and Gary,

Do you have time for a teleconference some time between now and Thanksgiving? This call would include me, Lea Aukerman and Sharienne Louie (Translational Development manager, reporting to Lea) from Celgene. Some of the points we'd like to discuss are:

- 1) What bone biomarkers, if any, do you already have available?
- 2) Is there biomarker assay development already underway or completed (from the list that Elizabeth and Randall agreed upon)?
- 3) How many assays per cartridge and does the Theranos system require a control channel for each assay?
- 4) The need to validate Theranos PD marker assays vs. standard assays (especially for certain markers like PTH and Vit. D, where assays vary quite a bit from lab to lab).
- 5) Realistic timelines for PD marker development and prioritization of assays

If you send me a few days/times that you're free, I can see what works best for folks here.  
Thank you and best regards,  
Vicki

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**From:** Surekha Gangakhedkar [mailto:surekhag@theranos.com]  
**Sent:** Friday, November 13, 2009 4:23 PM  
**To:** Victoria Sung; Gary Frenzel  
**Subject:** RE: Celgene Clinical Trial

Hi Vicki,

Thanks for the update. We are looking forward to discussing the details of the assays with you. Please let us know when you have more information available and we can schedule the meeting accordingly. On our side, we will try to put together similar information too.

Best regards,  
Surekha

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**From:** Victoria Sung [mailto:VSung@celgene.com]  
**Sent:** Friday, November 13, 2009 3:09 PM  
**To:** Surekha Gangakhedkar; Gary Frenzel  
**Subject:** RE: Celgene Clinical Trial

**Hi Surekha and Gary,**

**Just wanted to touch base with you again regarding the ongoing assay development that Theranos is working on for the ACE-011 project. A few of us plan to meet by TC next week to try to prioritize the list below...it is a really long list and although you have a while to work on these before the study begins, we felt that it would help tremendously to classify the biomarkers into tiers of development. We may base our prioritization on things like whether or not the assays are more challenging to develop, if they are commercially available and/or commonly run at central labs. I will set up a meeting with you before Thanksgiving to discuss the outcome of our internal discussion. Thanks for being patient with us!**

**Best regards,  
Vicki**

**From:** Elizabeth Holmes [mailto:eholmes@theranos.com]  
**Sent:** Thursday, November 12, 2009 5:58 PM  
**To:** Randall Stevens; Victor Sloan  
**Subject:** Follow up to our call

Randall,

Per our conversation, I have included the list of analytes excerpted from the protocol as discussed in our meeting in Summit.

Theranos has committed capital to develop and validate this list with the ACE-011 PK assay. Let us know if there have been any changes.

Finally, as discussed, we have added the antibody assay into the Statement of Work for the PK assay at no additional cost.

Elizabeth.

Hgb  
CTX  
Ca  
EPO  
BSAP  
TRAP5b  
VitD  
PTH  
NTX  
Osteocalcin  
FGF-23  
P1CP  
Phosphate  
Testosterone

P1NP  
IGF-1  
Dihydrotestosterone  
(DHT)  
Estrogen  
Estadiol  
FSH  
LH  
NTP

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Elizabeth Holmes  
President and CEO  
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**From:** Surekha Gangakhedkar [mailto:surekhag@theranos.com]  
**Sent:** Monday, November 09, 2009 12:48 PM  
**To:** Victoria Sung; Gary Frenzel  
**Cc:** Elizabeth Holmes  
**Subject:** RE: Celgene Clinical Trial

Hi Victoria,

It was a pleasure to meet you last week. We are also looking forward to meeting with you to further plan out the details on the PD biomarkers. I will confirm with Gary and get back to you on a suitable time for next week.

Best regards,  
Surekha

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**From:** Victoria Sung [mailto:VSung@celgene.com]  
**Sent:** Monday, November 09, 2009 12:23 PM  
**To:** Gary Frenzel; Surekha Gangakhedkar  
**Cc:** Elizabeth Holmes

**Subject:** Celgene Clinical Trial

Hi Gary and Surekha,

It was very nice to meet you last Friday and I'm sorry I had to cut short my visit. As we discussed, I will try to come up with a time slot in the next couple of weeks when the three of us, along with Lea Aukerman and Sharienne Louie (a TM Ops manager) can meet to discuss biomarker assays for the ACE-011 CKD trial. This conversation will be the first of several, and if necessary, we would be more than happy to come to Palo Alto for future discussions and you and your team are also welcome to visit our SF office. In the meantime, I will try to get some clarity and prioritization regarding the list of biomarkers. Hopefully, we can then come together and implement realistic timelines which allow you to fully validate all the assays. I think I mentioned that FPFV will likely be June 2010 but we'll have a little extra time since the first part of the study will not include biomarker sampling.

Are there particular dates and times next week that work best for the two of you? We can try to work around your schedule.

Thank you and looking forward to working with you.

Best regards,

Vicki

**Victoria Sung, Ph.D.**  
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