Theranos

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Subject: Theranos
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CC: Sriram Balasuryan
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Hi guys,
I did some more reading on the CLIA requirements, and Theranos seems to be correct that CLIA certification does mean that their tests met a certain level of accuracy.
This may or may not be sufficient to meet the FDA criteria, but I have no reason to believe it wont.
I asked GPG for two consultants: one person who developed lab tests in the past and can help evaluate the technology and another person who understands CLIA and FDA regulations to evaluate the requirements that Theranos had to meet to get CLIA certification.
I will add you to calls once they are scheduled.

On this whole Phase 2 strategy, I would stick to the view shared by the lawyers we spoke with that the FDA will want to regulate testing and will not buy into this idea of cloud data, so they will have to get the device approved by the FDA and/or they may need to get some form of CLIA clearance for those WAG locations where systems are deployed. Where you analyze this data in the cloud or in that same machine, the sample collection, and data reading occurs in the machine, and I would think this is how the FDA will look at this as well.
I would think this is not a big deal, but may be a bit of a delay for that phase only, still, they can work around these obstacles quickly and capture volume through their hub and spoke model.
In fact, I would even give an example where the FDA gave a written SPA to a drug company, but then still changed its mind – Amarin, here there is nothing in writing.
If they do get away with this cloud idea, this is upside, but in the absence of a written commitment from the FDA, I am not sure this could be a base case.

Overall, I think everything they said makes sense and I had no problems with that, and I am very much impressed with their level of preparedness and planning.
Alex