

Issue #1: Theranos was never contacted by Eric or other authors. They can find no email to a senior executive. They are accusing the authors of the study of making false claims to the media.

Dr. Schadt did attempt to contact Theranos executives via LinkedIn, as he did not have their direct contact details and thought a LinkedIn message would go to the email address attached to the account (as part of the inmail service). See attached for screenshots of Dr. Schadt's message to the COO and President of Theranos, Sunny Balwani. He sent an identical email via LinkedIn inmail to Patrick O'Neill, Chief Creative Officer of Theranos. Dr. Schadt believes he also sent an email to Elizabeth Holmes as well, but is still trying to locate that email (it would be essentially identical to the email attached below).

Note: we are providing screenshots taken directly from Dr. Schadt's LinkedIn account (rather than just copying the text of the messages) to help demonstrate authenticity.

The screenshot shows a LinkedIn interface. At the top, there's a navigation bar with 'in' logo, 'RecruiterLife', and tabs for 'Projects', 'Clipboard', 'Jobs', 'Reports', and 'More'. Below this is a search bar with the text 'Search for people by skill, employer, and more...'. The main content area is titled 'Archived Messages' and shows a message from 'Eric Schadt' to 'Sunny Balwani' dated 'December 14, 2015, 9:42 AM'. The message status is 'Pending'. The message body contains three paragraphs of text discussing a study comparing Theranos, Labcorp, and Quest. The first paragraph describes the study's purpose and methods. The second paragraph discusses the comparison of results. The third paragraph mentions the inclusion of actual methods in the paper. The message is signed 'Eric Schadt' with the email 'Eric.schadt@gmail.com'. On the right side, there's a sidebar titled 'ABOUT THIS PERSON' for 'Sunny Balwani', President & COO at Theranos, with buttons for '+ Project', '+ Contact info', and a note 'No email address available'. At the bottom of the message area is a 'VIEW LESS' button.

Study comparing Theranos to Labcorp and Quest
Eric Schadt
December 14, 2015, 9:42 AM

To: Sunny Balwani
Status: Pending

My group completed a study this past summer comparing different tests run at Theranos, Labcorp and Quest. We were interested in running these tests to assess wellness in individuals as part of a broader wellness study. We were excited about Theranos as one option to get closer to DTC-based testing to enable people to better understand and track their health. Our study consisted of 60 healthy adults that were given 22 common clinical lab tests, with blood drawn nearly simultaneously for testing at Theranos (finger prick), labcorp and quest (both venipuncture). The tests for each sample were run in triplicate at labcorp and quest, and we carried out two separate finger sticks on each person at two different Walgreens locations over the course of a few hours.

We then directly compared the test results among the three labs. Interestingly, there was as much variation for almost all tests between labcorp and quest as there was between Theranos and the other two labs. I think the paper we have written is generally favorable for Theranos, although there are a few issues, but overall it demonstrates good comparability.

What we would like to include in the paper are the actual methods that were used to perform the tests at Theranos. We are unsure whether your proprietary microfluidics processing of the samples were used, or something more standard. I think given the negative press Theranos is getting at present, that our study may put Theranos in a better light, and will make our paper more solid to have the actual methods given. I note we had carried out this study before all of the media coverage around Theranos, so our motivation really was one of wanting to be sure the tests we applied in our wellness studies were accurate.

Eric Schadt
Eric.schadt@gmail.com

VIEW LESS

ABOUT THIS PERSON
Sunny Balwani
President & COO at Theranos

+ Project

No email address available

+ Contact info

Add a note or task...

Issue #2: Eric did not disclose that he is on scientific advisory board of NuMedii, a potential competitor to Theranos. Dr. Dudley did not disclose the extent of his involvement -- that he owns more than 5 percent of NuMedii and is entitled to royalties.

We strongly disagree that NuMedii is competitive with Theranos' business.
Comments from Dr. Dudley:

“NuMedii is, and has always been, focused on pharmaceutical drug discovery. Even more narrowly, they are focused on drug repurposing. See their tagline on their [website](#): ‘*Translating Big Data into New Medicines for Drug Repositioning*’. NuMedii has never had plans, nor has plans now, to participate in the clinical blood testing business.”

Compare the missions of each company:

- On the Theranos website: *“Our [Theranos] mission is to make actionable information accessible to everyone at the time it matters.”*
- On the NuMedii website: *“NuMedii discovers and de-risks effective new drugs by translating Life Sciences Big Data into therapies with a higher probability of therapeutic success”*

Compare the primary customers of each company:

- The primary customer of Theranos is physicians and patients. The product of Theranos is blood testing services and data.
- The primary customer of NuMedii is pharmaceutical companies and biotechs. The product of NuMedii is therapeutic compounds.

As for Dr. Schadt -> He was granted options in Numedii but they are not substantial to the point of meeting the threshold indicated by JCI. The policy at JCI states: “If an author currently has direct ownership of equity in a private or public company in the health care field of \$10,000 or more...” Dr. Schadt does not have direct ownership of equity in Numedii. Further, Dr. Schadt has not interacted with Numedii in more than two years.

Issue #3: The methodology of the study is flawed. Giving someone a big venous blood draw just prior to a finger prick could throw off the results of the finger prick test, leading to the improper assessment that results are either out of range or not returned at all. Theranos says collecting large venous sample before finger prick is contrary to its CLIA procedures.

We did two sets of draws and in the second set the finger stick was done first, not the venipuncture, so in that way we did attempt to account for any potential impact of venipuncture.

We emphasize that our study was the *first* to do a direct comparison between these 3 reference labs. If we had unlimited resources, we would have done larger sample sizes, added more randomization to the blood draws, done more testing over more wellness centers, spread out over time and so on. However, we think our study results are of interest, and we hope will motivate others in the scientific community to conduct additional research to validate our findings and address any limitations of our approach. This is indeed the scientific approach.

Further, if Theranos’ results are sensitive to things like venipuncture, then that should be disclosed upon testing. Theranos should be transparent about their procedures and these sensitivities. Based on the experience of our study participants in Arizona, when a patient comes in for a Theranos test, we’re not aware that Theranos representatives ask or warn the patient not to have a venipuncture test before doing a Theranos test. If this is such an important issue wouldn’t they ask people if they recently had a blood test elsewhere to ensure they were following their CLIA protocol? What if a patient went to Quest to get a blood draw for a test not offered by Theranos and then went to Theranos for additional tests? We’re not aware of any step in Theranos’ procedures (as we experienced in Arizona during our study) that addresses this type of situation.

We made a brief examination of the scientific or medical publications to look for this issue, and did not find any data published by Theranos or others on this. We would encourage Theranos or others to publish data and research on this, and have it contribute to the larger dialogue on improving precision and transparency in blood testing.

Issue #4: Study presents bias data but fails to present correlation data, an accepted methodology for comparing results of different labs.

Indeed there are multiple ways in which the data we generated could be analyzed. We did not exhaust all of the possible ways in which these data could be analyzed. However, we did carry out the analysis we thought was most relevant, following guidelines on how these data should be analyzed, consulting with experts in the field to aid in this, and providing an interpretation that is consistent with what the medical community and patients expect. The expectation for interpreting these tests is clearly that the absolute value measures are more important than correlations or relative measures.

We are making all of the data publicly available so that others, including Theranos, can reanalyze, reinterpret and even report their results of our data (hopefully in the process they make it known what methods were used to generate the data!). Our goal is to be open and transparent regarding the data we generated as well as the results derived from those data so that we may all learn together.

We further note that we had hoped the entire discussion around our study would be more about examining measurements such as we generated and what the differences among labs means, rather than quibbling about which lab is right or wrong. The purpose of our study was to provide data that could help assess how comparable the different testing labs are with respect to common blood tests many millions of Americans receive every year.

Issue #5: Study fails to use accepted reference method so no way to judge which measurements are truthful. Using discrepant results as way to judge accuracy is flawed because authors never followed up to evaluate those patients and see if perhaps they really were out of normal range.

The aim of our study was to compare lab tests in **a real world setting**, testing as they indicate people should be tested. Our aim was just to see if Theranos was comparable to existing standard reference labs, whether the tests could be considered easily “exchangeable”. Our JCI paper is very clear on this.

Our motivation to do this study was to determine whether tests provided by Theranos were comparable to standard reference lab tests, given we desired to use Theranos testing services for our wellness and disease studies, given testing at wellness clinics in Walgreens has the potential to be far more convenient for study participants and more cost effective. Our hope was that our study would help push for more transparency for all blood testing services (not just Theranos). The goal of the study was not to find which testing service was most accurate.

The goal of the study was to evaluate the consistency of results across providers for a population of real individuals being tested “in the wild” (vs. the more controlled spiked-

in samples used for technical proficiency testing). As stated before, our study design is aimed at questions around monitoring wellness and advancing precision medicine rather than trying to determine who is “right” among these companies.