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From: Carolyn Balkenhol[/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=CBALKENHOL]
Sent: Tue 3/3/2009 2:51:18 AM (UTC)
Subject: Follow up
Theranos Evaluation Summary_GSK Biomarker Lab.pdf
Theranos Systems Pharmaceutical Introduction.pdf

Aiden,

It sounds like the call went great today. I apologize for not having some of these materials to you in advance of the call, but I was finalizing some updates to our overview document and wanted to be sure to give you the latest information. Elizabeth asked me to forward you this GSK report, as well, for your review. She's hoping that there might be a time for another call next week, so you can discuss GSK-specific applications of Theranos Systems.

Please let me know if you have any difficulty with these transmissions and if there's a good slot for you and your team next week.

Thanks so much.
Carolyn

Excerpts from GSK Metabolic Study Report

Nelson Rhodes, Director GSK Metabolic Biomarker Laboratory
Surekha Gangakhedkar, Theranos Assay Systems Lead

Background information:
The Theranos system was evaluated at GSK to profile active GLP-1 and C-peptide values and these data were compare to "gold standard" ELISAs using frozen human plasma from study XXXXXXX. The key project objectives (found in the attached statement of work) were:

- To assess the performance of the Theranos System in measuring a multiplex for GLP-1 and c-peptide values (the "Cartridge Analytes") as compares to the current gold standard ELISAs (which are not multiplexed).
  - Specifically, the study will assess Theranos' capabilities to detect points that the reference assays failed to accurately detect by running samples with C-peptide values in a standard range (ng/mL) and GLP-1 values between 0-3.2 pM
- To assess the functionality, specificity, reproducibility, accuracy, and precision of the Theranos System.
- Assess the Theranos data reporting and transfer functions

Thirty plasma samples (assayed in duplicate) were chosen based on historical GSK data for total GLP-1 levels from subjects given a mixed meal and two finger prick blood draws were performed. Five Theranos machines were used with active GLP-1 and C-peptide cartridges that required 20µL of plasma. MesoScale Discovery's (MSD) active and total GLP-1, Linco (Millipore) active GLP-1, and Linco (Millipore) C-peptide ELISAs were run as comparator assays.

GSK Metabolic Biomarker Lab comments:

- Data show good correlation
  - $r^2 = 0.90$ for GLP-1 (MSD vs. Theranos)
  - $r^2 = 0.96$ for C-peptide (Linco vs. Theranos)
- Inter-instrument precision (RLU average %CV = 11)
- Machines worked well
- Touch-screen interface was easy to use
- Cartridges were pretty straight forward (easy to handle and load)
- Assays took approximately 1 hour and 15 minutes per cartridge

Overall conclusions:
- The Theranos system eliminates the need for a lab and provided quality data
- The Metabolic Biomarker Lab has a favorable impression of the technology/system and recommends GSK clinical groups to work with Theranos

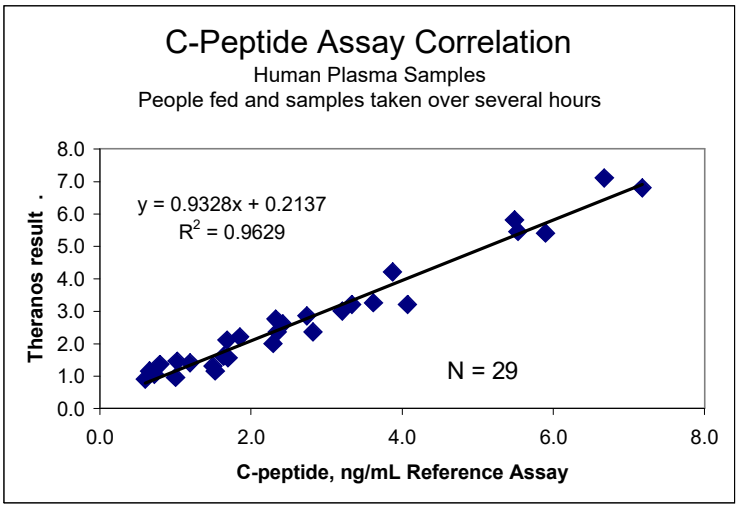
Data:

Study design

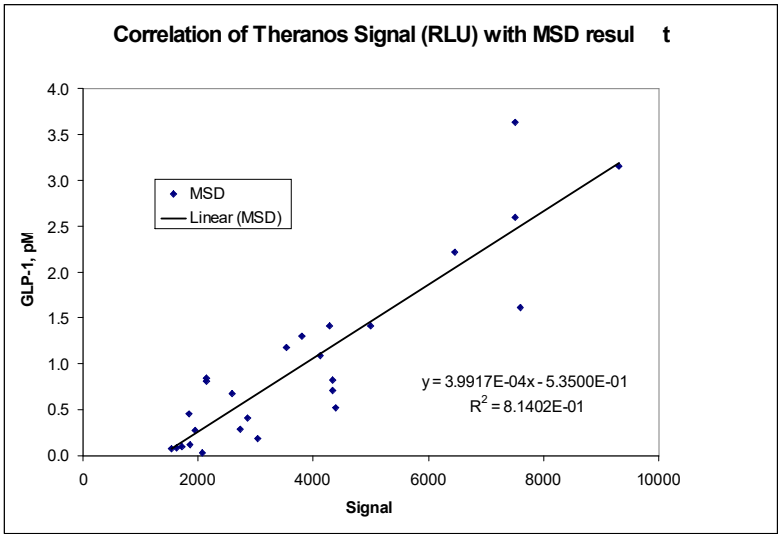
- Human subjects
- Food “challenge”
- Measure GLP-1 and C-Peptide multiplex over 5 time points
  - Linco Assay
  - MSD Assay
  - Theranos Assay

C-Peptide Assay

Averaged results

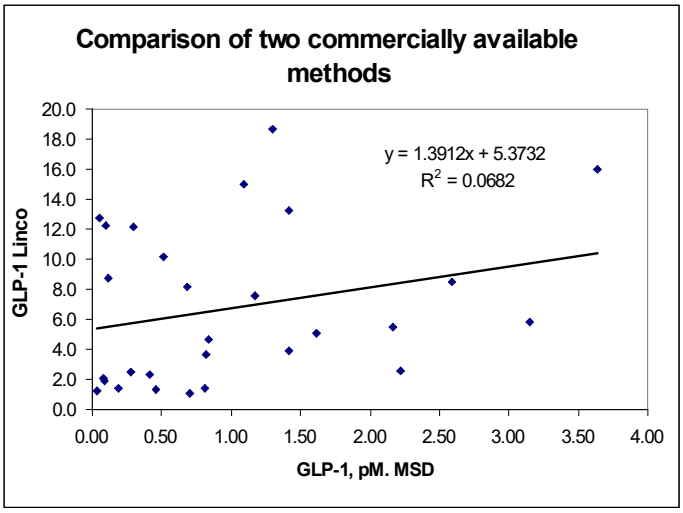


Calibration to GSK matrix



Theranos Confidential

Lack of correlation of predicate methods



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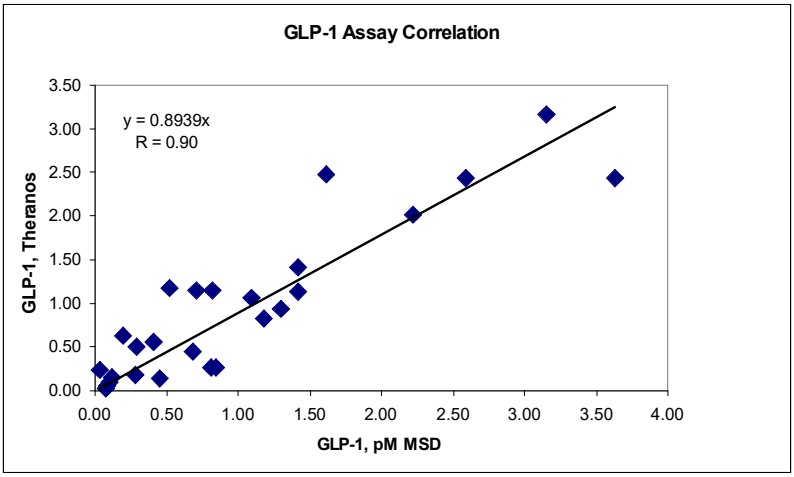
Assay correlation



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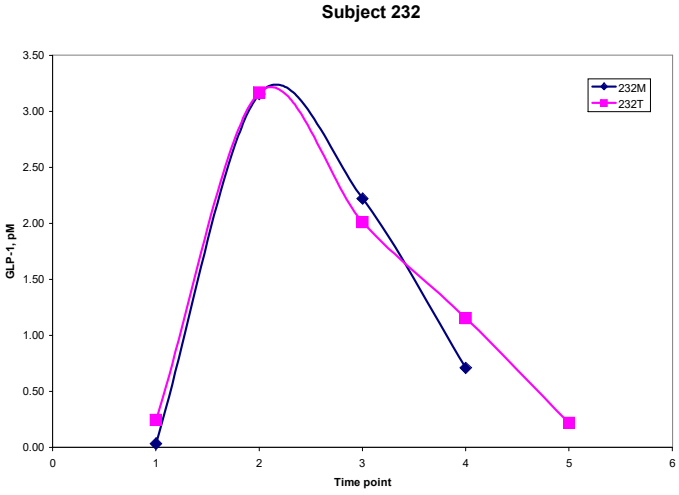
Subject 232



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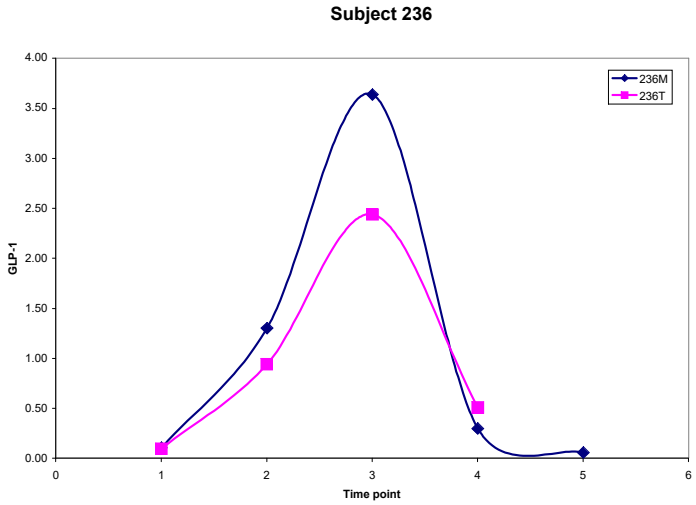

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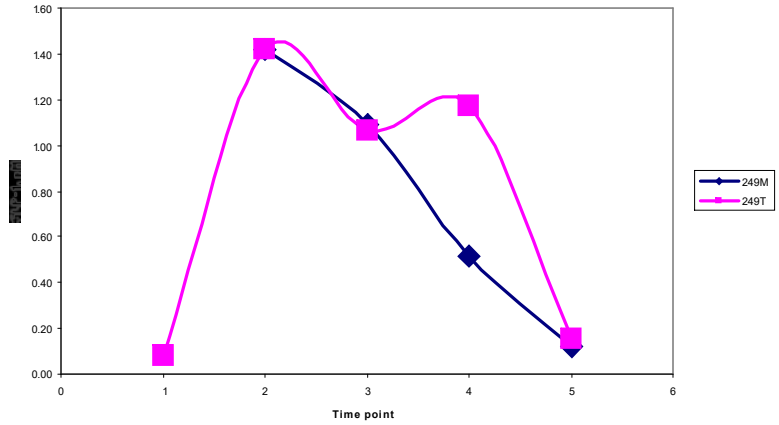

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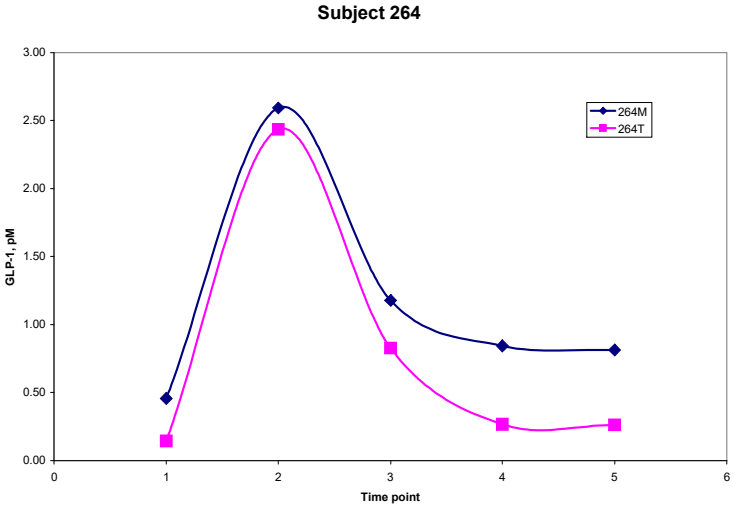

Summary Statistics GLP-1 Comparison

- Theranos LOD = 0.17 pM
- Dynamic range measured: 0-3.2 pM
- Mean = 0.9 pM (Th), 1.0 (MSD)

Theranos Systems

Introduction
Theranos is transforming patient management, individual wellness, and the economics of health care delivery.

In doing so, Theranos has showcased a new economic model for pharmaceutical companies, exponentially increasing sales and rate of growth while cutting development expenses.

As the Theranos infrastructure begins to transform the way payors and physicians approach blood testing and reimbursement, the adoption of Theranos Systems in pharmaceutical companies is powering a radical new growth model for the pharmaceutical and biotech industry.

Return on Investment for Pharmaceutical Clients
Theranos' technology has been robustly validated over the last four years. Existing clients include AstraZeneca, BMS, Celgene, GSK, J&J Centocor, Mayo Clinic, Merck, Pfizer, and others. Theranos' direct-to-consumer home monitoring systems are currently being launched. In pharmaceutical clinical studies/programs, Theranos Systems have:

Accelerated trial timelines by an average of 18 months.
* Demonstrating meaningful dose-response and efficacy dynamics profiles in ~6 months where conventional infrastructure took two years and was still not able to generate equally predictive correlations.
* Existing customers value a six-month gain in time-to-market at $180 million to $540 million[1].

Reduced clinical operations costs by 50%.
* In addition to saving time, point-of-care ambulatory monitoring reduces the number of sites, as well as shipping, sample processing and clinical operations costs.
* Higher integrity field data and predictive models reduce the number of patients required in each clinical study by 25%.

Enabled realization of target product profiles that customers had not been able to achieve using the conventional testing and analytical infrastructure.
* Improved visibility into pathway dynamics
* Early reads on efficacy and safety dynamics
  - Established comprehensive longitudinal PK/PD profiles.
  - Characterized trends in the rate of change of key markers. (Conventional infrastructure obscures trends Theranos Systems elucidate.)
* Optimized development in ways previously not possible because of the biology complexities.
  - Enabled adaptive studies and development.
  - Salvaged assets that were about to be written off.
  - Rapidly enabled label expansion into key new patient populations and multiple indications.
  - Powered mechanistically driven cross-comparison studies for compound differentiation and reimbursement.

Enabled approval, reimbursement, and maximized use of key assets through drug-systems combinations now going onto the market together to optimize the benefit/risk profile of a drug on an *individual* patient basis. The individualized selection, treatment, monitoring and wellness counseling of subjects made possible through Theranos Systems is the foundation of a radical new growth model for pharmaceutical companies following the drug-device approach recommended by the Critical Path Initiative. The ability to comprehensively monitor blood-proteins and behavior in an at-home system enables pharmaceutical companies to overcome the clinical and economic limitations of what's currently known as 'personalized' – population-based medicine.

[1]Most recent estimates by an existing Theranos client value each day gained at 1-3 million dollars per day.

The Theranos System

Theranos Systems are Theranos' proprietary, patented technology. The systems are becoming the center of healthcare in the home, making healthcare a home necessity in the same way that personalized computers made computing a home necessity.

For point-of-care technology to develop into a true individualized medical system (IMS) and make it a staple of patient care at the individualized level, significant breakthroughs were needed over the current state-of-the-art tools in the following domains:

* Greater sensitivity, specificity, precision and accuracy of simultaneous assays
* Home protein analysis for time profiling
* Home drug analysis for exposure-response characterization
* Integration of data coming from various sources into electronic health records (EHR)
* Data modeling using Bayesian and other approaches
* Systematic, prompt feedback to the health care provider (HCP) and the patient
* Enabling early, adaptive and rapid decision making about healthcare utilization

The Theranos System was developed to address the aforementioned issues. Theranos Systems allow HCPs and patients to monitor drugs, their metabolites, and relevant biomarkers from fresh whole blood samples in real-time at any testing frequency in a clinic, hospital setting or any point of care, including the home.

Theranos Systems process finger-stick blood samples at the point of care, wirelessly transmit data to relevant health care providers/clinicians, and can provide individualized and integrated content back to consumers to assist them in modifying behavior and establishing/achieving health and wellness goals. The user interface on the device is a graphical touch-screen, which links with an individual's mobile phone in real-time, providing each user with 'smart,' customized information.

Theranos' proprietary blood-analysis technology has made it possible to measure multiplexed combinations of drugs, proteins and other analytes in the home, and in doing so, characterize trends in disease progression and regression that were previously not seen. The ability to capture more comprehensive longitudinal time-series measurements is fundamental to better characterizing a patient's response to therapy.

When deployed, the information system allows for the integration and exploitation of information in a way previously not feasible. The field units combined with the models in the information system enable accelerated clinical studies and realization of the target profiles of key assets.

In order to increase the value and coverage of marketed assets, compound-specific information characterized in clinical studies is being leveraged in the consumer environment. The information system allows for customized content to be deployed to device touch-screens and the associated mobile applications to enhance the value of a therapy.

The social networks which are rising around the mobile and home systems are proving to be powerful viral marketing channels.

Theranos Systems are comprised of three integrated technologies and services.

1. Data infrastructure (for use across an entire pharmaceutical pipeline)

An information integration and exploitation infrastructure which permits:

* Data acquisition and storage of point-of-care results in real time.
* The integration of blood parameters and patient diary data with all other physiologically relevant information into the EHR.
* A central mathematical software program to:
  - Graphically visualize, help to interpret, and analyze all data in one place
  - Link any new information into a disease management system that then maps the information onto a probability space of clinical outcomes.
* The graphical display of clinically relevant and actionable information back to the HCP and/or the patient.

A customer-specific data integration and self-learning prediction and simulation engine to:

* Centralize all information in one repository.
* Automatically import data that exist in different formats (historical data, clinical studies, literature, patient records, etc.).
* Power models of patient response and disease pathophysiologies on integrated data sets.
* Constantly evolve and become increasingly predictive as learning algorithms process data from the field and literature without requiring human intervention.

2. Predictive and dynamic, multivariate, multi-dimensional models (customized for program-specific objectives) that map disease progression and regression

Algorithms

* Built-in pattern recognition tools characterize 'responder classes' and clinical outcomes.
* Probability analysis tools systematically account for uncertainty.
* Integrate physiological models with statistical analysis tools based on Theranos' proprietary time-series analysis.

Models

* Account for all relevant pathophysiologies and compounds' mechanisms of action
* Can identify relevant circulating parameters for patient monitoring and classification
* Have increasingly predictive to power future studies and decision making
* Simulate scenarios that answer 'what-if' questions and allow users to run queries themselves
  - Patient profiles
  - Trial protocols

3. Field units (integrated point-of-care home and mobile monitoring systems that work for any combination of assays, including drug and protein analysis)

Devices – remote, portable patient care systems

* On-site, real-time, automatic processing of cartridges for blood analysis
* User interface designed for non-computer-literate subjects, allowing the patient to initiate the assays and to graphically enter a variety of relevant information, such as full patient diaries and behavioral and psychological information
* Two-way communication system from the instruments to HCP/clinicians, mobile phones, and back to patients with relevant content, messages, and health information
* Blood and environmental data is automatically (wirelessly) transmitted into models in real time.
  - Fully exploit all data (every IIT or pivotal trial increases the predictive value of the models).
  - Characterize dose-response, efficacy and safety dynamics faster and more accurately.
* Simultaneously collect relevant environmental information and comprehensive patient diary information through graphical touch-screens.

Cartridges – disposable cartridges pre-loaded with chemistries to simultaneously measure multiplexes of proteins and other analytes from ~15 µL whole blood finger-stick

* Cartridges can be customized to measure any combination of drugs and biomarkers together to map indicators/trends through comprehensive longitudinal PK/PD profiles of subject status.
* Rapid characterization of rate-of-change in key markers and trends (through more frequent monitoring than possible using central labs) yields predictive insight into clinical outcomes far earlier than more traditional radiologic and clinical end-points, resulting in earlier go/no-go decisions across multiple indications.
* Assay precision and trend generation capabilities reduce required patient numbers.
* Standardized analytical platform can be used across all sites.
  - Reduce variability of data between sites.
  - Improve quality of data by avoiding issues with analyte decay rates and sample processing.
* Drug-specific cartridges complement wellness/disease-specific cartridges that are being launched by Theranos direct to consumers and physicians.

Mobile Applications – transmission of individualized content to 'smart,' automated 'counselors' on device touch-screens and users' mobile phones to assist with behavior modification and increase compliance with therapy

* Theranos' proprietary algorithms enable the correlation of blood data to efficacy dynamics profiles, behavior, lifestyle, diet, and side-effects.
* Truly individualized content is selected to help people change their lifestyles in a sustained way, through the integrated use of the back-end algorithms, models, and data in the data infrastructure.
* Content is based on data for patient 'classes,' which recognize physiological and psychological predispositions as well as local socio-environmental influences.
* Applications link users through social networks, where success stories compound through the combination of each tailored home health system with a given therapy.

Theranos' Client Services include:

Customization

* Devices
* Cartridges
* Informatics Systems
* Web portals
* Mobile applications for specific assets

Study Planning

* Biomarker selection

Support

* 24x7 live international call center
* New Information System features for in-person training of all site and where applicable, at-home device installations and training for patients
* Maintenance of information systems and all web and mobile applications

Regulatory Filings

* Compound-specific cartridges

Distribution of the systems to consumers, physician's offices, and pharmacies

* Sale and distribution of devices and cartridges
* Reimbursement for devices and cartridges

Marketing through the creation of Theranos' product-specific mobile, device and web-based social wellness networks