theranos

redefining healthcare

BioMonitoring and Informatics System

Our immediate goal is to become the standard for improving the risk/benefit safety profile and efficacy of every therapy.

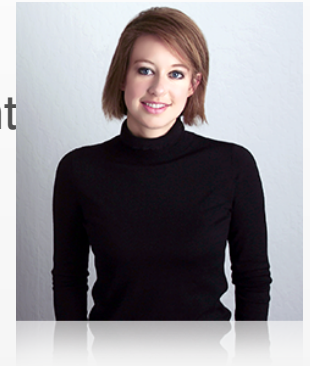
This System is designed to address these trends by monitoring real-time patient responses to therapy throughout the development cycle.

Meeting Agenda

- Theranos History
- Why Theranos?
- The Theranos Solution
- Theranos Applications for Cephalon Phase III TREANDA
- Discussion and Next Steps

Company History

Founded in 2003 by Elizabeth Holmes



- Stanford Electrical and Chemical Engineering Student
- Developed several novel biosensor systems through her work at Genome Institute Singapore and in collaboration with Genencor International

Patent, Medical Device for Analyte Monitoring and Drug Release

Operating in Palo Alto, California

100+ Employees

- IT / Bio-Informatics Experts
- Fluidic Design Experts
- Assay Development Experts

Over 39 patents pending across all aspects of the Theranos system

Actionable Information Systems for Compound Optimization

Why Theranos?

Allows* sponsors *and* sites *in "real-time" to:

- **View simultaneous PK/PD.**
- **Monitor drugs, their metabolites andrelevant biomarkers in whole blood at any testing frequency.**

  In a clinic or hospital setting or with ambulatory patients.
- **Generate longitudinal time series profiles.**

  When profiled in panels and trended over time, biomarkers can be used to trace disease progression, activity, and safety of a therapy.
- **Map efficacy and safety on an *individual level* versus population based.**
- **Integrate data into a centralized data repository.**

  All information is compiled and stored in one central repository.

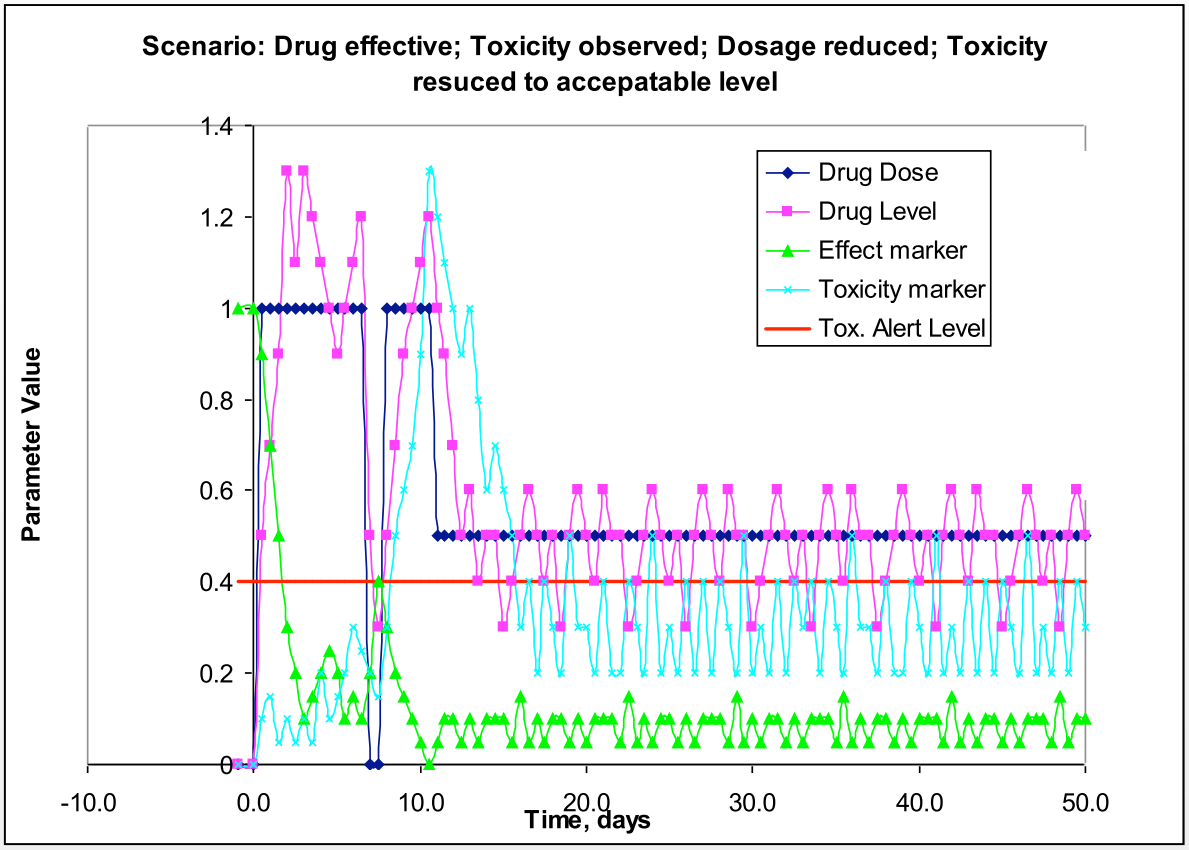
Why Theranos?

Allows* sponsors *and* patients *in "real-time" to:

- **Improve compliance through centralized home health portal.**
- **Develop precise and actionable data.**

  System provides window into "moving picture" of disease progression and individual patient response.
- **Optimize compounds to achieve better patient outcomes and improve the profile of existing drugs.**
  - Achieve the broadest patient application.
  - New indications, patient sub-populations.
  - Ameliorate safety concerns.
- **Improve ROI.**

Why Theranos?



Convergence of Healthcare Trends

Move towards the development and success of targeted therapies.

- Expand towards individualized medicine.

Focus on successfully bringing drugs to market faster and with better labeling.

- FDA is placing higher burdens on making good go/no go decisions
- Ensure understanding of safety profile .

Improve the diligence by which safety is managed after a drug hits the market.

Increase post-marketing requirements.

Improve patient compliance through remote data capture and transmission.

Actionable Blood Test Data

Central Lab Issue	*Theranos Solution*
Degraded Sample Result	• Sample Integrity (no packaging) • Real-time sample analysis has greater sensitivity (<1pg/mL and high mg/mL simultaneously)
Extended wait time for results (typical 4-7 days)	• 40 to 50 minute result turn-around time • Wireless, Ethernet or Analog transmissions • Time oriented database – true temporal queries and clean time
Missing Data (lost sample)	• Sample collected and analyzed at point-of-care • No longer need to coordinate pick up with central lab • More evaluable data
Logistics and Patient Burden	•Clinic or ambulatory setting
Patient Compliance	•Optimize patient compliance by leveraging power of wireless communication and data transmissions from home or clinic setting
Single, static result	• Complete longitudinal time-series • Integrated link to adaptive clinical trial management system
Does not contribute to database development	"Mechanism maps": Trends in panels of proteins over time to see change in rate of a panel, which we can then correlate with a clinical endpoint and map in the context of the full pathophysiology of the disease

Paradigm Shift:
Leveraging Real-Time Informatics

Getting an Early Read on Rate of Change of Protein Panels

Theranos Regulatory Guidance

IDE – Investigational Device Exemption
Non-Significant Risk Device

- U.S. – IRB Approval; Patient Informed Consent
- Global – In vitro-diagnostic device initiative- MHRA, EMEA-Ethics Committee Approval

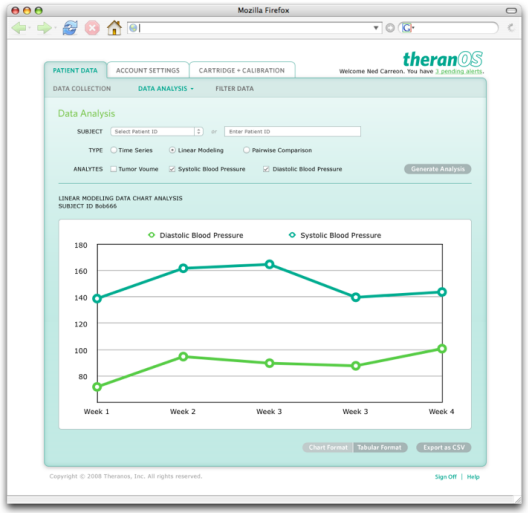
Validated System

- GLP Compliant, GMP, SOP's, study validation process/plan/report

Data Collection Process

- HIPPA and HL7 Compliant
- 21 CRF Part 11

Integrated Product Suite



Reader

The command center for remote patient care.

Cartridge

Loaded with Chemi-luminescence immuno-assays able to test 3 to 6 different assays.

TheranOS

Provides ready access to data input, output and reports by healthcare providers, companies and/or patients.

Reader

The Reader is the command center for remote patient care, wirelessly controlling and transmitting blood tests.

Graphical user interfaces serves as next-generation patient eDiary and compliance tool.

Communication portal between patient and healthcare provider/clinical coordinators.

- Capable of extracting in vitro assay data from any combination of therapeutic analyte-specific Cartridges
- Processing time is 35-50 minutes
- Training new users is fast and easy

On-board Touch Screen enables real-time transmission link to TheranOS Web portal.

Hardware is customizable for investigator site, pre-clinical or ICU environments.

Cartridge

The system's Chemiluminescence platfor
provides the capability to measure both
high-sensitivity and low-sensitivity
analytes on the same Cartridge with
a total CV of <10% with the assay CV <5%

Cartridges are standardized by lot; no
kit-to-kit variations.

Automated micro-fluidic disposable
Cartridge allows for rapid removal of
sample interference and reagent addition for increased sensitivity.

Modular Cartridge design allows for customization of assays
specific to the protocol requirements.

Assay Library Q1-08*

Cytokine Markers	*Cardiovascular Markers*	*Metabolic Markers*
GCSF	BNP	Adiponectin
iCAM-1	CKMB	GIP
IL-1 through IL-8	LTB4	GLP-1
IL-10, IL-12	Fibrin D-Dimer	GLP-2
CRP	LPS-Binding Protein	Glucagon
IL-15	Myoglobin	Insulin and Pro-Insulin
TGFß	Procalcitonin	Leptin
TNFə	Protein C	Peptide YY and NPY
TNFß	Troponin-I	Glucose
Oncology Markers	*Apoptosis Markers*	*Other Markers*
EGFR	M30	Cystatin-C
PIGF	M65	IgE - Free and Total
PSA	Nucleosomal DNA	Progesteron
sVEGF R2	*Bone Markers*	Prothombrin
VEGF	Osteoclast Panel	sCD14
FLT-3	Osteoblast Panel	Troponin-T
kit	Osteocalcin	ə-Glutathione S-Transferal

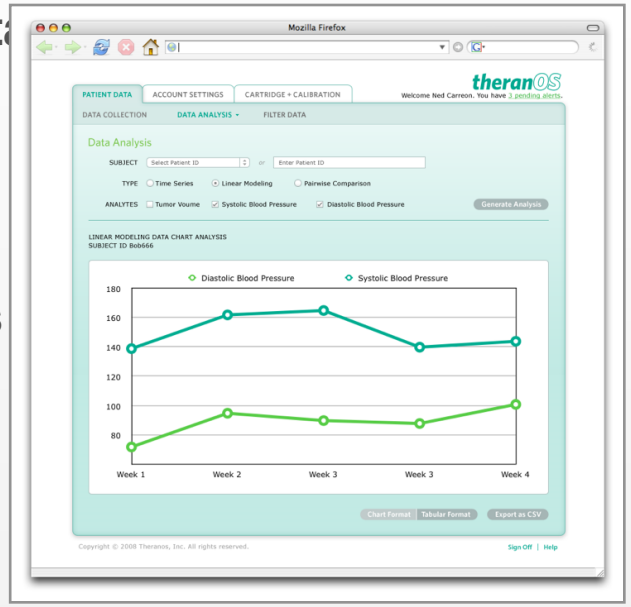
(Green highlight: 2 months development time)

TheranOS Web Portal

Provides ready access to data input, data output and data reports by healthcare providers, companies and/or patients.

Patient "consumer health" portals are industrially designed to engage patients in the therapy process and increase compliance.

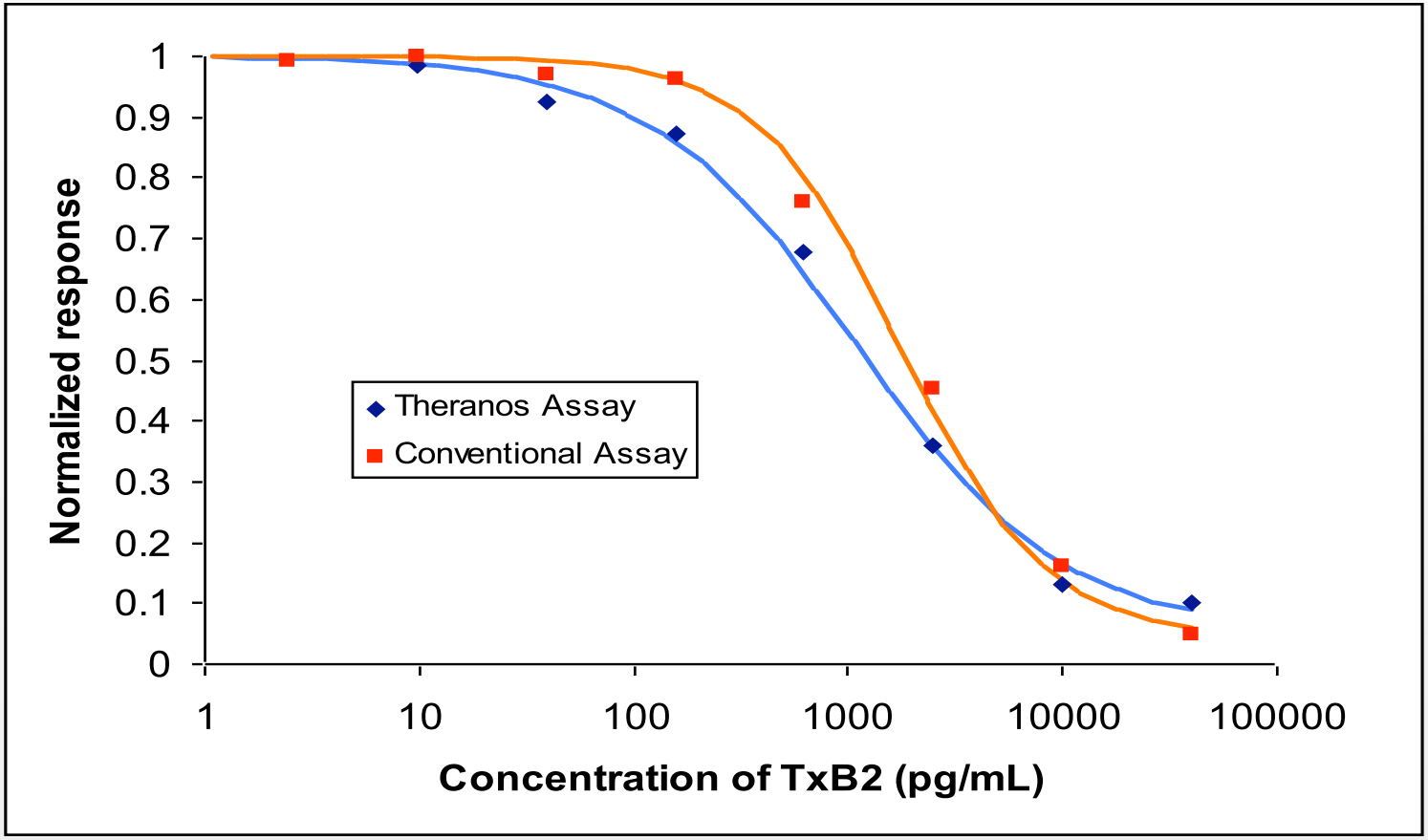
- Inverted search function – customizable to disease state



Provides ready access to data input, data output and data reports by healthcare providers, companies and/or patients.

Query capability into the data which can be represented in a variety of ways including reports, graphs and other visualizations including 3D surfaces.

Theranos System Validation Tests



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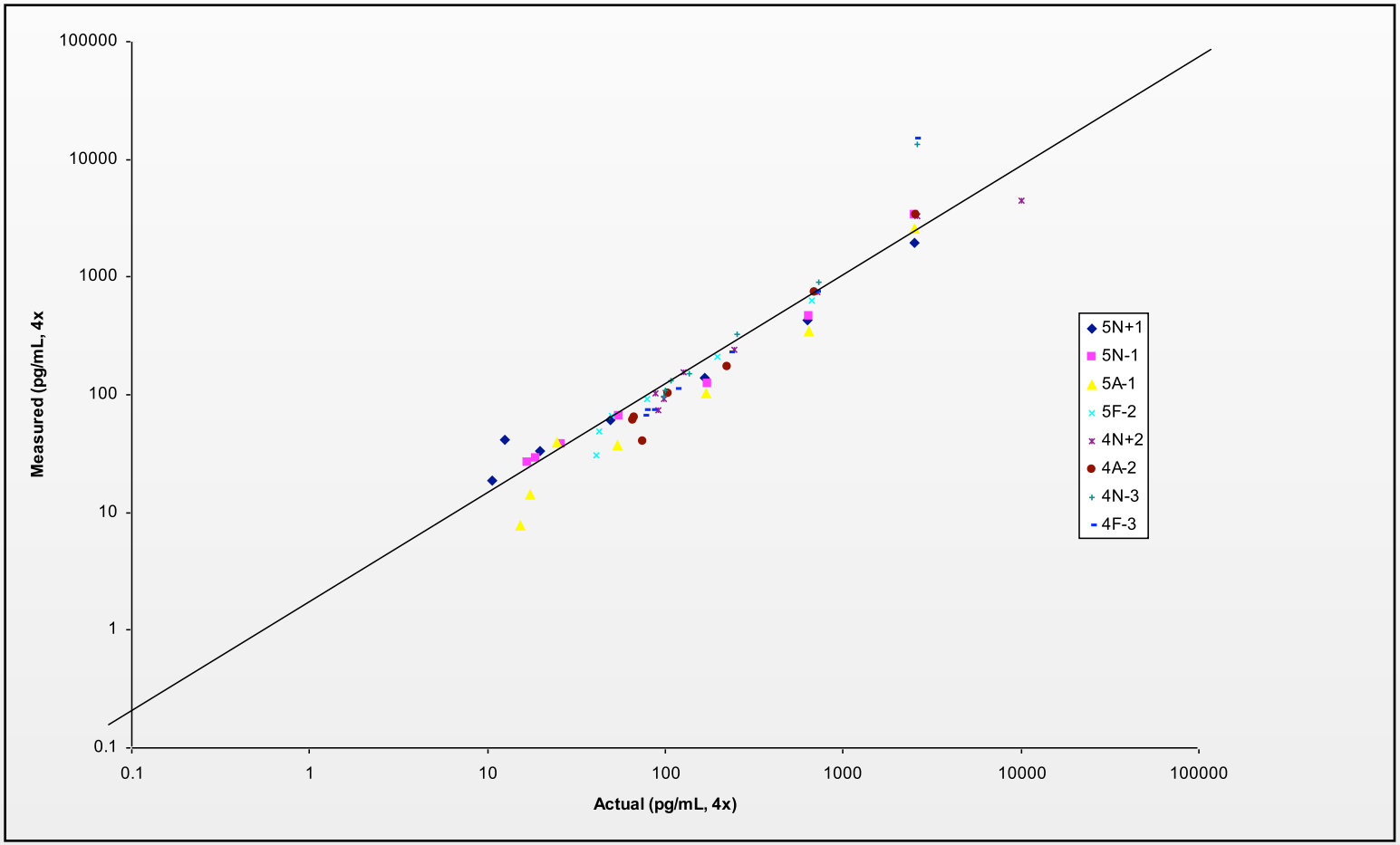

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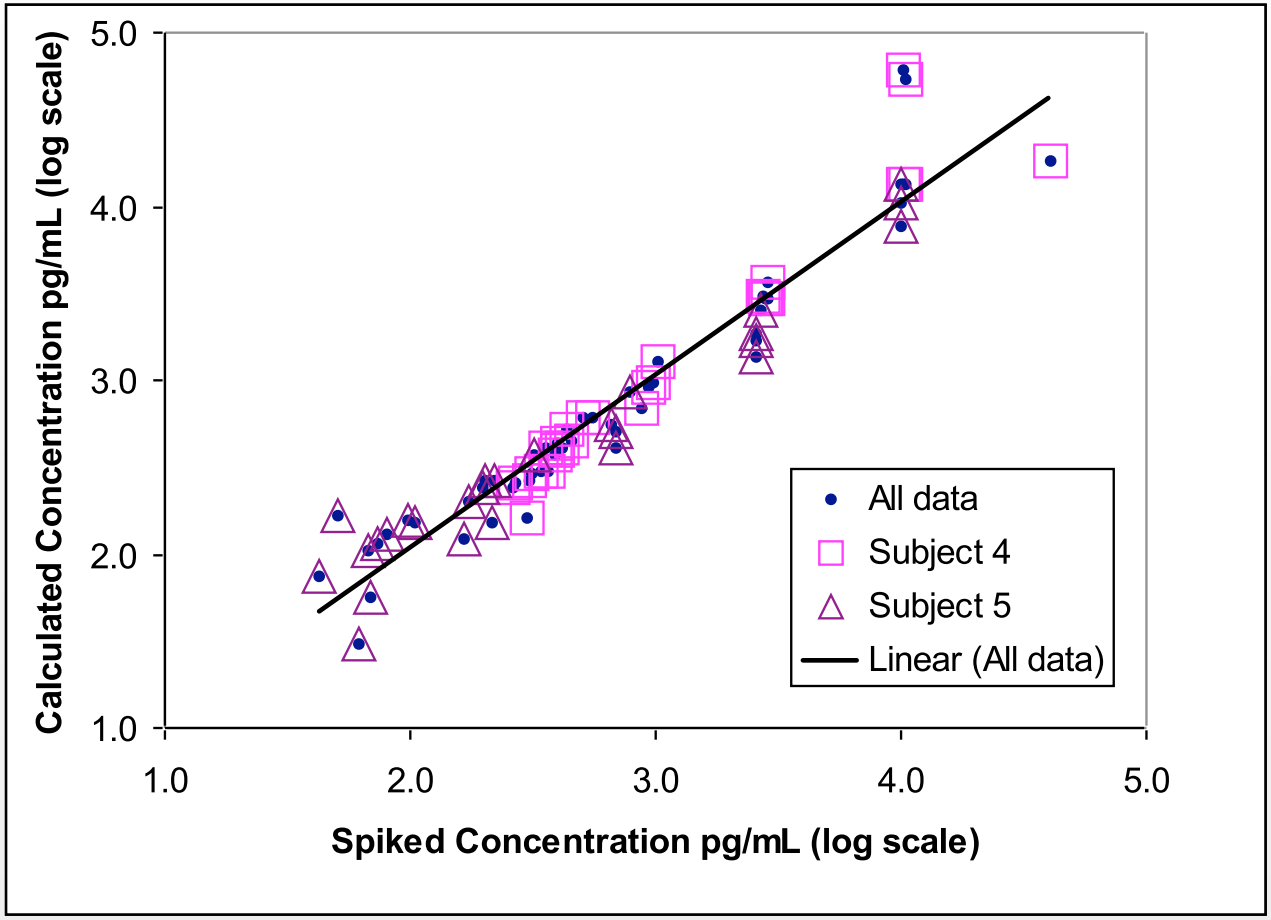

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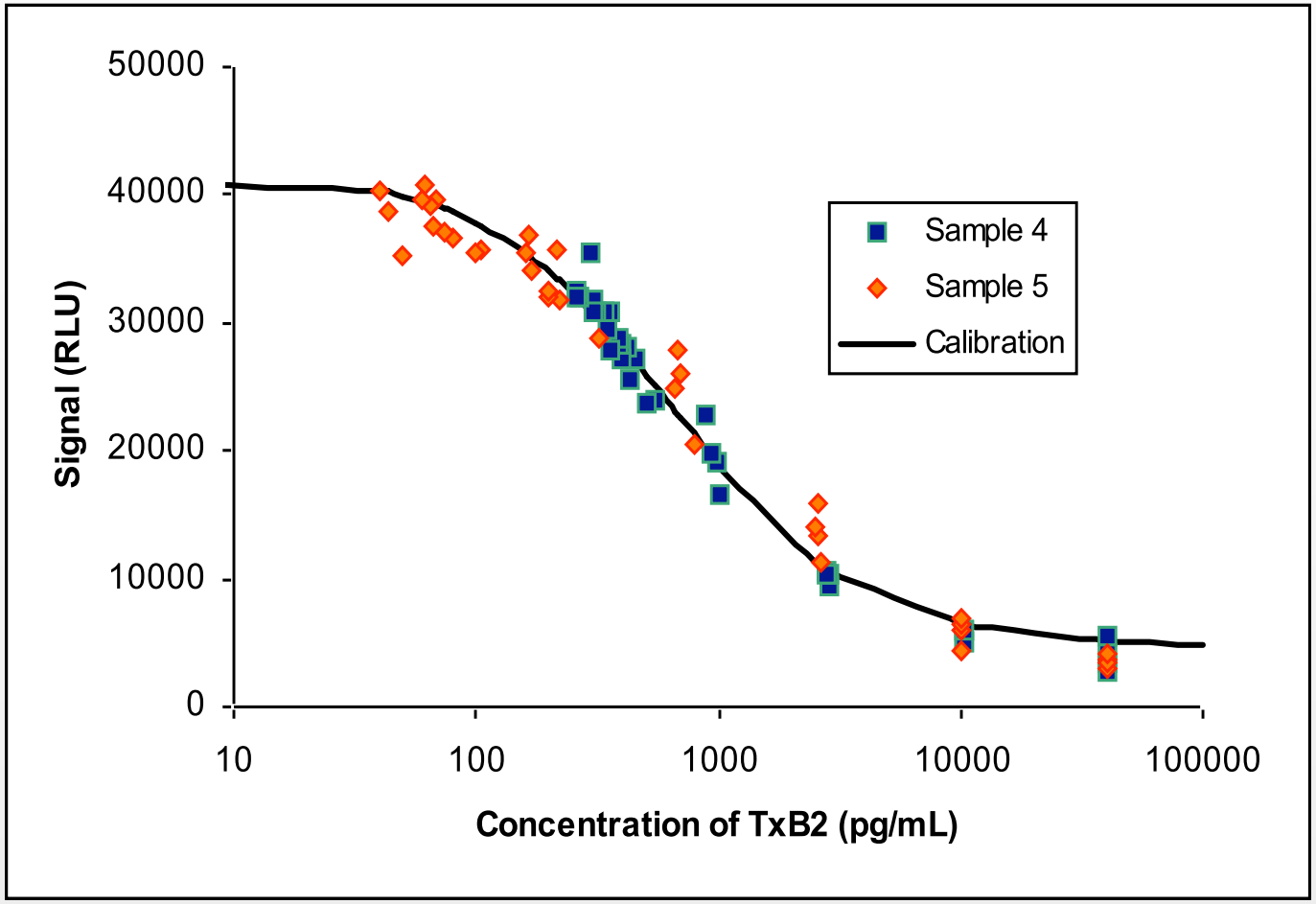

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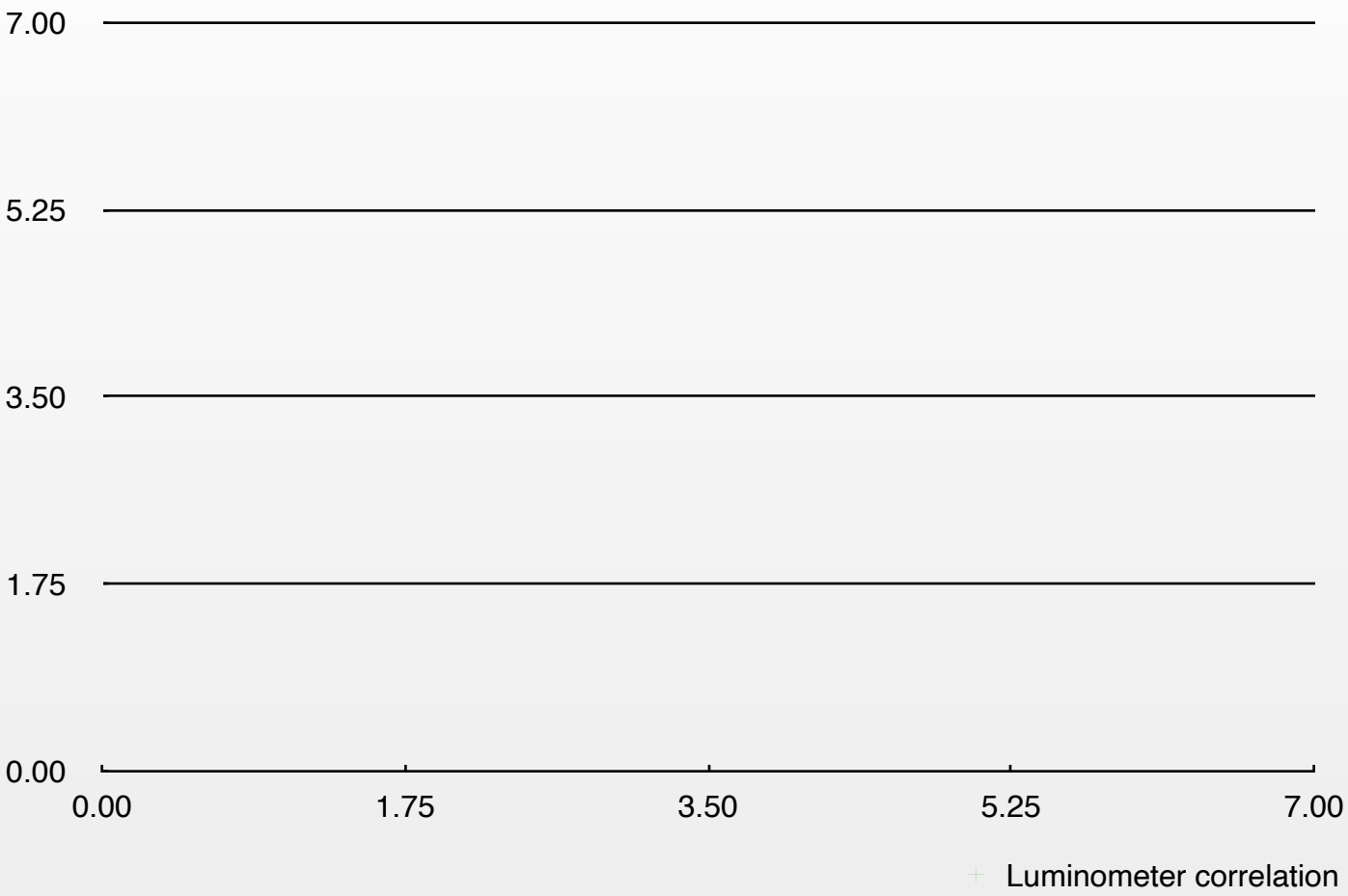
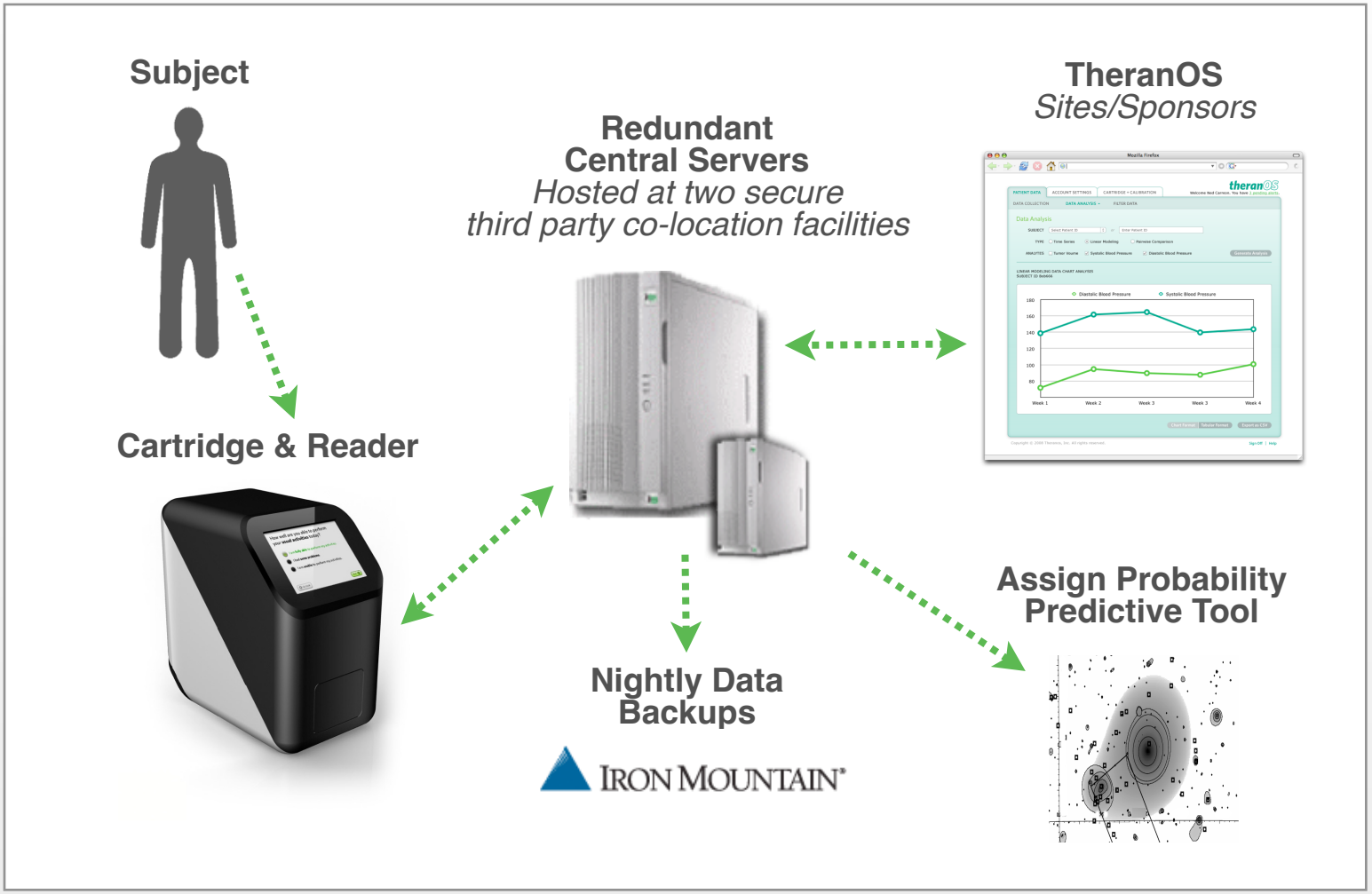


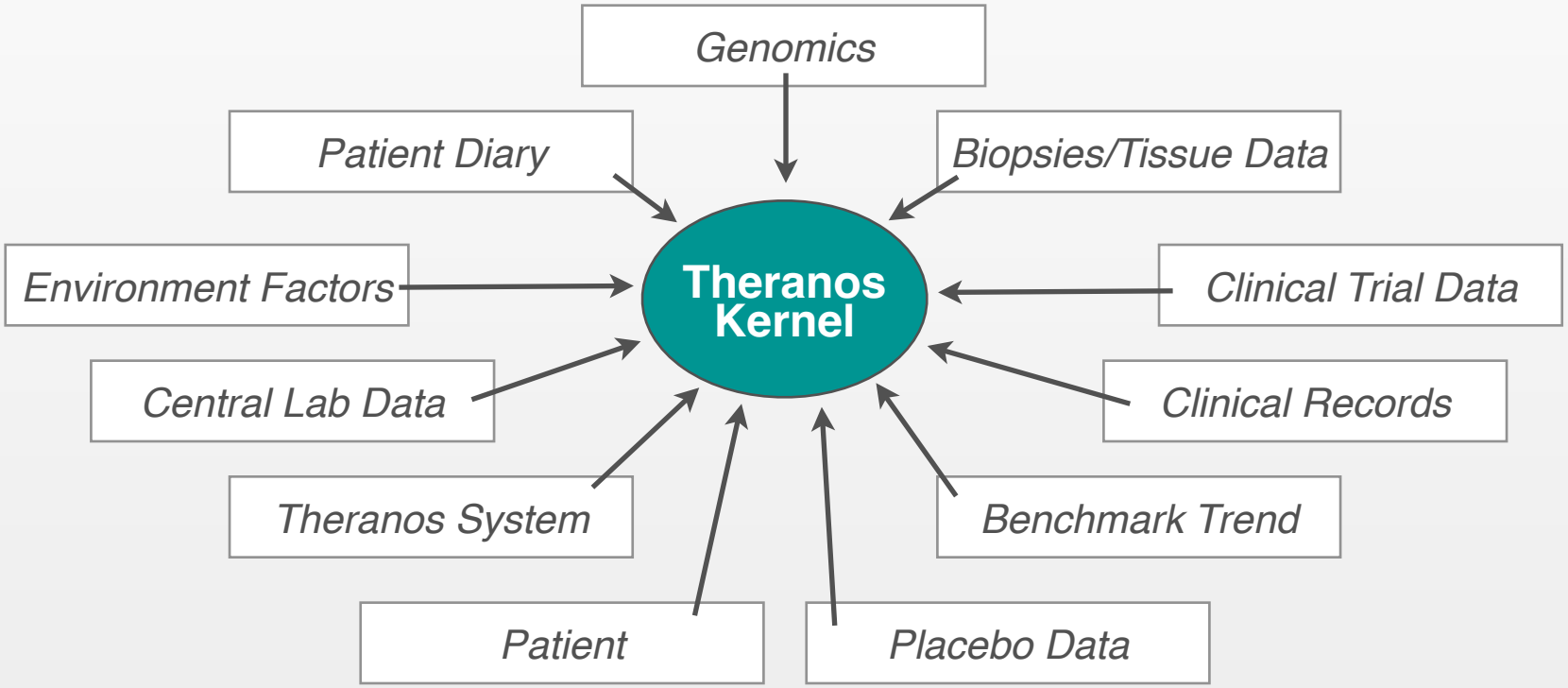
Integrated Data Infrastructure

Integrated Bioinformatics System



Centralized Data Repository

Software kernel allows convergence of many proprietary software programs through the centralization of clinical analysis features.



Simulation, Linear Regression, Bayesian

Efficacy of Drug(A) in Indication(B) = ∑ (Factor 1)(Weight (1) + Factor (2)Weight(2) + Factor(3)Weight(3) ….

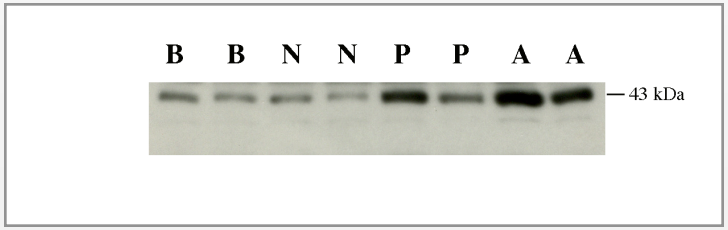
Combining Data

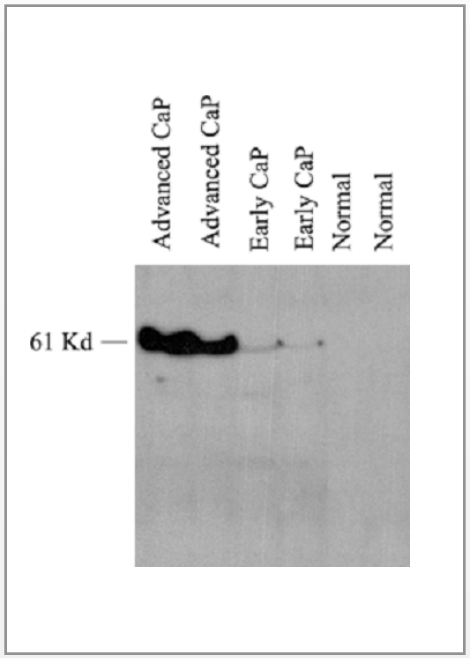
Drug, marker, and data from patient record integrated into single profile to map efficacy and safety against a threshold.

Combination of multiple parameters serve as better indicators of disease progression.

Marker Panel Performance

Positive Detection Rate	PAMP mab Test	PSA Test	Combo Test
Advanced CaP	50	70	100
Early Stage CaP	50	0	50
Normal	0	0	0





Leroy Hood, Institute for Systems Biology

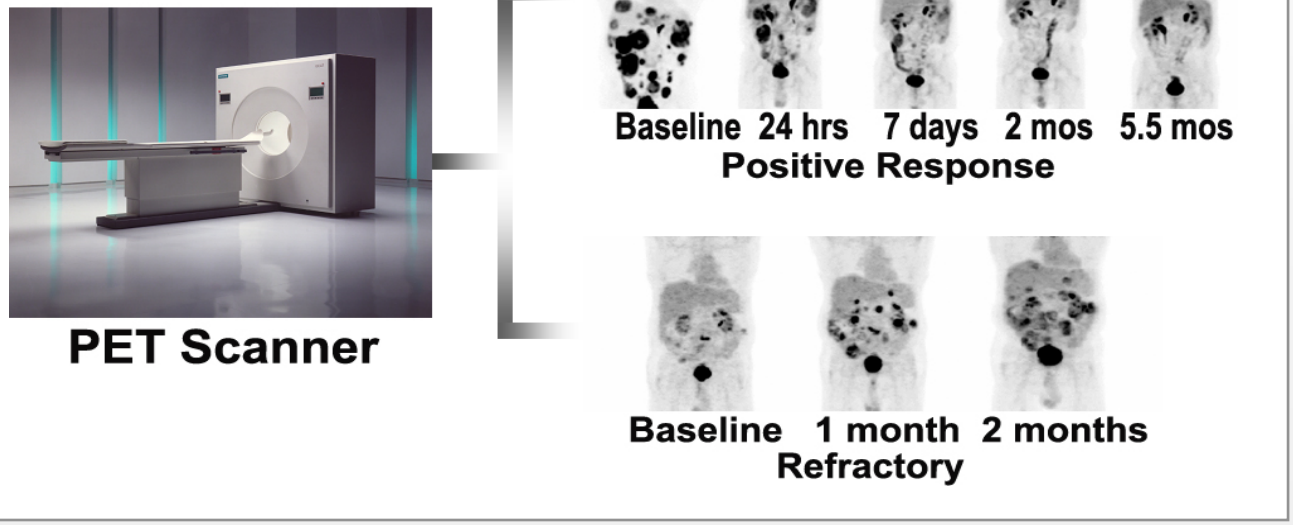
Establishing a Baseline

The TheranOS system enables the development of correlations between blood test trends, efficacy and safety.

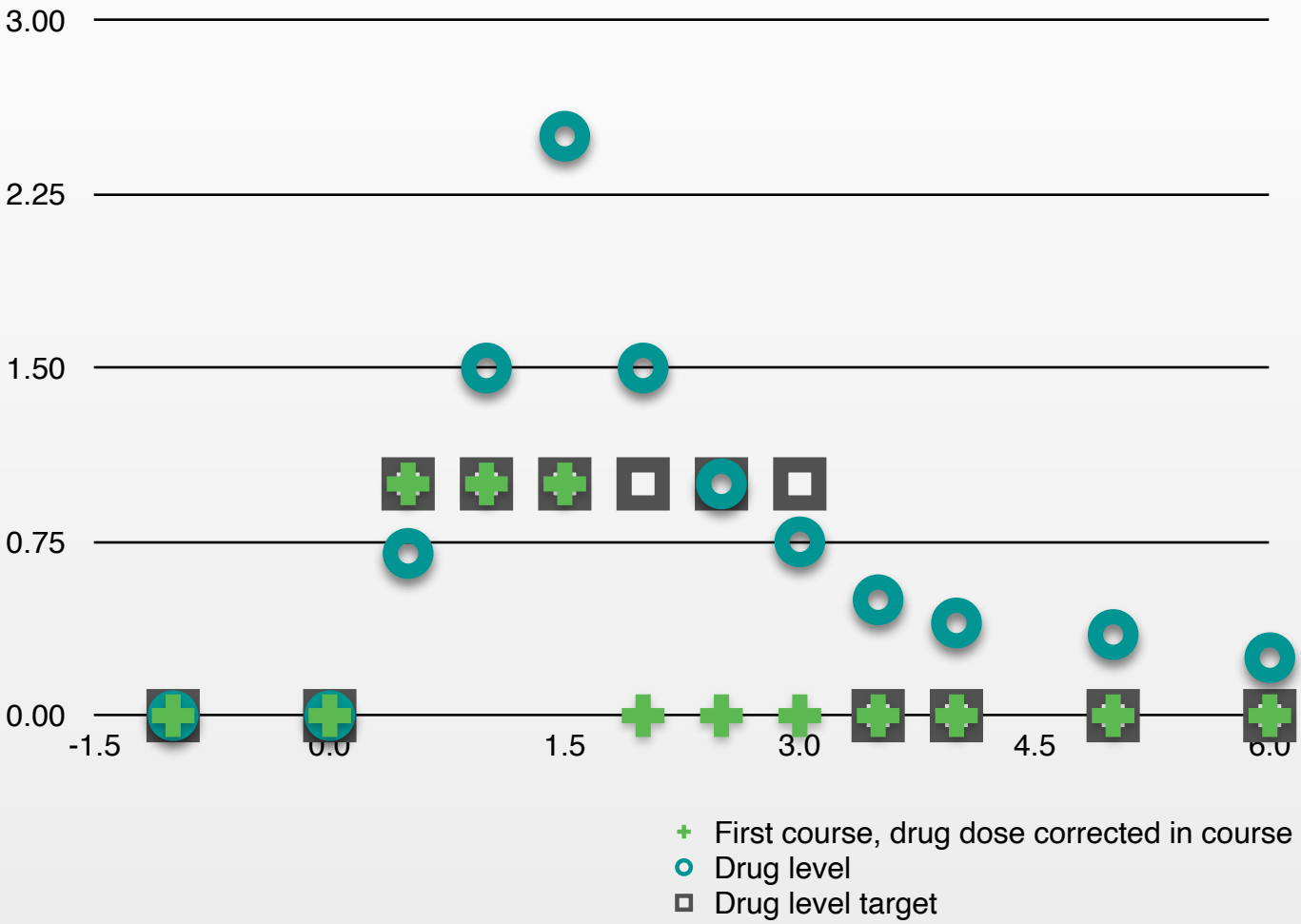
The first step is to establish baseline data within the system.

- Animal and/or human data generated correlating trends in panels of proteins with endpoints such as molecular imaging serves as the foundation.
- This data can be drawn from the body of evidence on a particular therapy.

Establishing a Baseline



Establishing a Baseline



TheranOS Features

Web portal customized for researchers, patients and clinicians.

Data is extracted from any existing database and linked into a central mathematical database.

- Allows you to visually see, interpret and analyze data in one place.
- Linked to the adaptive clinical trial system.

Graphically view all the known patient information in a central database (software program) regardless of where it is stored.

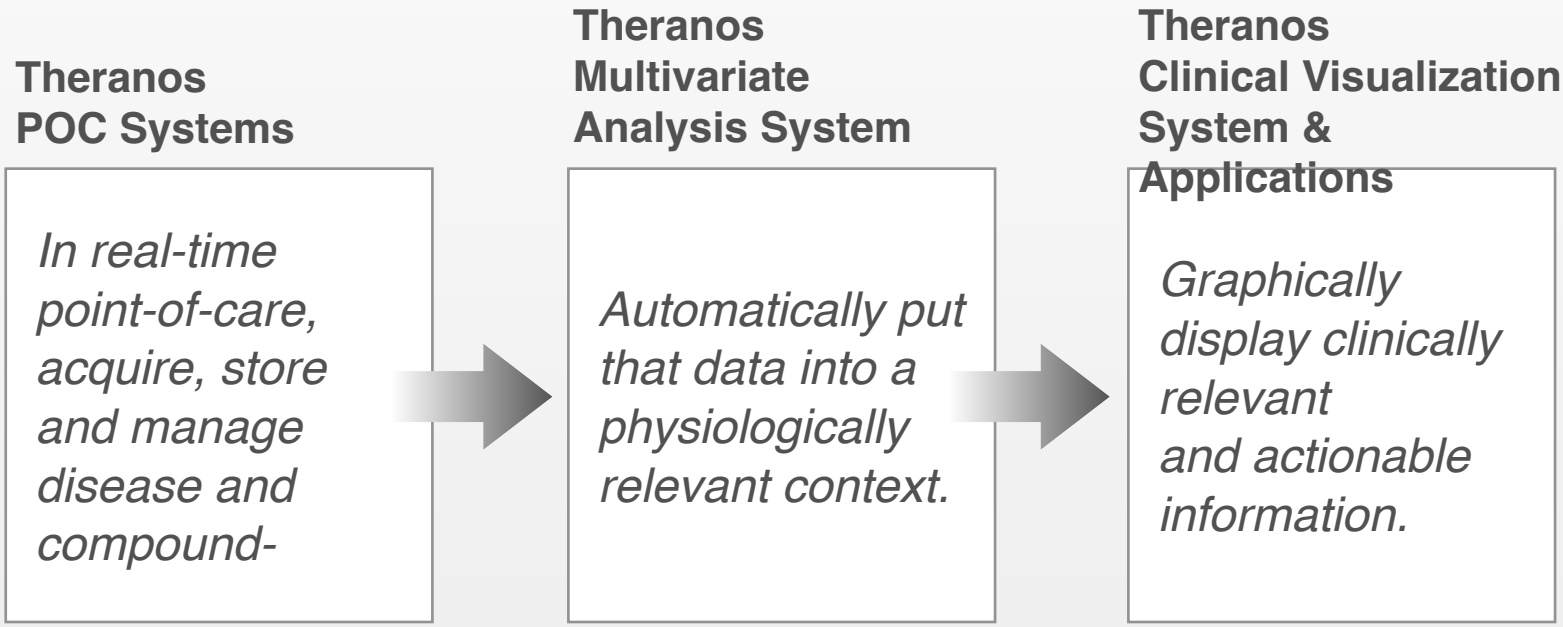
- Adds information to that repository dynamically so that the changes in proteins can be seen in the context of the full picture of disease progression (i.e. proteins linked to imaging data linked to health records).

Database is updated automatically as more data is collected.

- Serves as a trial decision making tool or system for establishing baselines against which to map future dosing schedules and or get early reads on efficacy and safety across multiple indications and populations.

Summary:

Turning Disease Specific Data into Clinically Relevant Information



Sponsor, Site and Subject Support

Structure, Training, Reporting Tools, Shipping and Supplies

Theranos Staffing Model — Team

Global Study Team Alignment

- US and European Project Managers
- US and European Project Coordinators

Cartridge and Reader (C&R) Engineering Team

- Build and configure Cartridge and Readers for each study

Data Delivery (DDE) Team

- Develop database and Web portal reports
- Develop custom data analysis reports
- Develop data transfers

Software Quality Engineering (SQE) Team

- Test Cartridge and Reader for each new study

Software Quality Test (SQT) Team

- Test standard and custom data analysis reports

Study Design Engineer (SDE)

Archive Team

- Build the document and data archive
- Validate the contents of the archive
- Produce CDs and ship to sponsor and sites

Site Training and Support

Investigator Meetings and WebEx

- Hands-on training at the IM
- Optional follow-up WebEx prior to FPI

Web-Site Learning™

- Narrated and animated modules
- Performance-oriented exercises
- Individual usage tracking
- Custom modules available

Study Support Center

- Internal dedicated experts, available 24x7

Project Management Reporting Tools

Tracking, Returns, Assignments, and Exchanges

- Proprietary System Tracks Inventory
- Scans Shipment and Receipt Information
- Reports Current Site Inventory and Credit
- Provides Inventory Status Information

Help Desk Call Log System

- Tracks Site, Client, and Subject (as required) Calls to SSC
- Reports Issues Metrics by Study, Site, Category
- Assists with Identification of Study Trends

TheranOS Analysis Reports

- Secure, Web-based access to trial-related information
- Compliance, Reader status and clinical data

Subject Training and Support

Hands-on training at the site

- Sites spend 15-30 minutes training each subject on the LogPad and how to respond to diary items
- A Training LogPad is provided to walk subjects through all questions they will answer as many times as needed

Support at home

- Theranos includes a Quick Start Guide with each Reader for subject reference and troubleshooting
- Subjects contact their site with questions, while sites are backed up by live 24x7 Theranos support

Case Study

Demonstration

Discussion and Next Steps

For more information, contact
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[redacted]@theranos.com