

Appointment

From: Carolyn Balkenhol [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=CBALKENHOL]
Sent: 3/30/2009 7:27:04 PM
To: Elizabeth Holmes [eholmes@theranos.com]; Marc Thibonnier [mthibonnier@theranos.com]; Seth Michelson [smichelson@theranos.com]; Tim Kemp [kemptm@theranos.com]; Stefan Hristu [shristu@theranos.com]; Gary Frenzel [gfrenzel@theranos.com]; Ian Gibbons [igibbons@theranos.com]; Daniel Young [dyoung@theranos.com]; Kelley Harrison [kharrison@theranos.com]
Subject: Copy: Schering-Plough folks here - Draft agenda attached
Start: 5/5/2009 3:00:00 PM
End: 5/6/2009
Show Time As: Busy

Required Attendees: Elizabeth Holmes; Marc Thibonnier; Seth Michelson; Tim Kemp; Stefan Hristu; Gary Frenzel; Ian Gibbons; Daniel Young; Kelley Harrison

I'm sure you'll only be required during a portion of this meeting, but I wanted to let you know about it, at any rate; also, I assume they'll want a tour of the facility.

Thanks,
Carolyn

Participants from Schering-Plough:

Bart van Hoogstraten, M.D., Ph.D. - Director, Clinical; Egbert Biesheuvel; Jean-Louis Saillot; Constance Cullen - Director, Preclinical & Clinical bioanalytics; Malaz Abutarif, Ph.D., G.C.P.M, M.B.A. - Principal Scientist - PK PD and PM group; Robert Fick, M.D. - Senior Group Director - Experimental Pathology & Pharmacology; Mark Watson, M.D., Ph.D. - Director for ECREM; Ferdous Gheyas, Ph.D. - Associate Director, Statistics

Schering-Plough requested agenda items:

1. Assay validation process
2. Quality oversight in place
3. Timing for validations
4. Process for development of proprietary assays such as those for drug levels or anti-drug antibodies
5. Multiplexing process - how are multiplexed assays validated?
6. Computer system validation - how is result integrity ensured?
7. Protection of patient confidentiality - how do we ensure that HIPA requirements will be met?
8. Incurred sample reanalysis

**Meeting at Theranos Headquarters
3200 Hillview Avenue, Palo Alto, California
5 May 2009
8:00 a.m. – 5:00 p.m.**

- 8:00 a.m. Light breakfast and introductions
- 8:30 a.m. Background on Theranos, Inc.
- 8:45 a.m. Theranos Point-of-Care Systems – questions from Schering-Plough
1. Assay development and validation
 - Development process (including proprietary drug level and antibodies assays)
 - Multiplexing process
 - Validation process
 - Validation program timing
 - Incurred sample reanalysis
 2. Quality
 - Confidentiality & HIPAA compliance
 3. Software validation – ensuring result integrity
- 10:45a Break
- 11:00 a.m. Theranos Operating System
1. Data Integration
 2. Modeling and Simulation
- 12:15 p.m. Lunch
- 1:00 p.m. Theranos Case Studies
1. Accelerating study timelines
 2. Rapid label optimization and expansion pre-approval and in post-marketing studies
- 2:30 p.m. Customized analytical system for Schering-Plough
1. Inflammation and Rheumatoid Arthritis System
 2. TRA System
- 3:45 p.m. Break
- 4:00 p.m. Tour
- 4:30 p.m. Discussion and action items

Schering-Plough Participants

Malaz Abutarif, Ph.D., G.C.P.M, M.B.A. – Principal Scientist - PK PD and PM group
Egbert Biesheuvel
Constance Cullen – Director, Preclinical & Clinical bioanalytics
Robert Fick, M.D. – Senior Group Director - Experimental Pathology & Pharmacology
Ferdous Gheyas, Ph.D. – Associate Director, Statistics
Jim McLeod – by phone?
Jean-Louis Saillot
Mark Watson, M.D., Ph.D. – Director for ECREM
Bart van Hoogstraten, M.D., Ph.D. – Director, Clinical

Theranos Participants

Gary Frenzel – Vice President, Assay Development
Ian Gibbons, PhD – Senior Director, Assay Development
Elizabeth Holmes – President & CEO
Tim Kemp – Theranos Fellow
Seth Michelson, MA, MS, PhD – Principal Scientist, Biomathematician
Marc Thibonnier, MD, MSc, FAHA – Chief Medical Officer
Daniel Young, PhD – Senior Modeler

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