

Charge to Workshop Speakers and Participants

Refining Processes for the Co-Development of
Genome-Based Therapeutics and Companion
Diagnostic Tests

February 27, 2013

Roundtable on Translating Genomic-Based Research for Health



Clinical Practice
Public Health

Overview

Drug Development

Diagnostic
Applications

“The purpose of the Roundtable is to explore and implement strategies for improving health through the translation of genomic and genetic research findings into medicine, public health, education and policy”

Chronology of Today's Meeting

- 2009-2012 Workshops Emphasized Clinical Utility
- Today's Workshop Targets Companion Diagnostics
 - Extension of clinical utility discussions
 - Comments from previous meetings
 - Literature
 - Roundtable meetings: members and invited guests

Framing Today's Discussion

The FDA's Companion Diagnostics process was designed to accommodate the co-development of a drug with a companion diagnostic test to allow the test to identify that subpopulation of patients most likely to respond to the drug. The clinical utility of the test is demonstrated in the phase 3 drug trial. Such a parallel path of development was designed to benefit all stakeholders.

Charge to Speakers

On the eve of the final FDA Guidance document on Companion Diagnostics (March 2013), it appears the process is problematic for many of these stakeholders

Objective

- From each speaker's (stakeholder's) perspective, address these problems, but more importantly, propose solutions that could improve the situation and return it to its original intent
- 10 minutes/10 slides

Meeting Format

- Session I: Co-Development (Broad perspective)
 - Discussion
- Session II: Challenges and Opportunities
 - Stakeholder input
 - Stakeholder presentations (Device, Pharm)
 - Discussion
 - Stakeholder presentations (Regulatory, Legal, Payers)
 - Discussion
 - Stakeholder Presentation (Laboratory and Clinical End Users)
 - Discussion
- Session III: Potential Paths Forward
 - Summarizing Stakeholder Presentations
 - Advancing Co-Development (Roundtable)