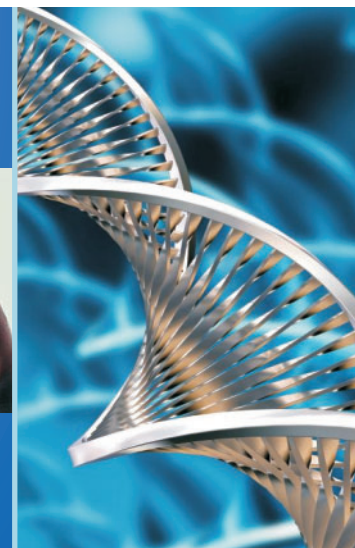


Diagnostics Briefing

Date: April 26, 2012
Time: 9:00am - 4:30pm
Fee: BayBio Members \$595
Non-Members \$695
Location: Latham & Watkins
140 Scott Drive
Menlo Park, CA 94025



Schedule

Diagnostics Role in Medicine Today 9:00 – 10:00

Diagnosis of Disease- Do you have it?
Following a Disease- What's your prognosis?
Following a Treatment- Are you cured?
Carrier- Will you pass it on to your child?

Statistical Features of Diagnostics 10:00 – 10:50

Sensitivity and Specificity
Positive and Negative Predictive Values
ROC Curves
Current Statistical Approaches to Diagnostics
Issues with Screening Tests

Break 10:50 – 11:00

Risk of Diagnostic Tests 11:00 – 11:30

False Positive and False Negative
Invasive Procedures

Types of Diagnostics 11:30 – 12:30

Blood Tests- Biomarkers
Physiologic Tests- Blood Pressure, EKG
Anatomic Tests- Xray, CAT Scan, MRI, Nuclear
Markers
Histological Tests-Biopsy, Pap Smear
DNA Tests- Genomics

Lunch 12:30 – 1:30

How Diagnostic Tests Work 1:30 – 2:30

Blood or Tissue, Microscope, Stains
Rapid Multiplexed Analyzers
Sandwich Immunoassay
PCR
SNP Chips, DNA Sequencing Machines

Break 2:30–2:40

Diagnostic Development and Approval 2:40 – 3:30

Need for "Gold Standard"
Clinical Tests
FDA Approval Pathway
Device Issues
510-K and PMA
"Home Brew", CLIA Labs

How Diagnostic Tests Are Reimbursed 3:30 – 4:00

CMS
CPT Codes

Current Issues 4:00 – 4:15

Companion Diagnostics
IVDMIA
Consumer Genomics

Q&A/Review 4:15 – 4:30

Course Description

Diagnostics Briefing is a one-day class exploring the growing role of diagnostics within the biotech industry. Participants will learn about a range of different diagnostic tests and their indications as well as the basic science behind their development, culminating in a detailed overview of the approval process for diagnostic devices. The course will also include an introduction to concepts specific to the diagnostic sector, including sensitivity, specificity, false positives and false negatives, as well as a discussion of current issues impacting the sector.

Deliverables:

A reference manual containing all of the slides used in the class, all activities, and a certificate of completion. Lunch will be served.

Refunds:

Refunds are not given. Registrants may not switch classes. If a registrant cannot attend, someone from their organization may take their place. Please contact Kerri Muir with substitute name and contact information.

Questions?

Contact Kerri Muir at 410.377.4429 x22 or Muir@BiotechPrimerInc.com

To Register:

www.BiotechPrimerInc.com and click on "Class Registration".



Instructor:

Ted McCluskey, M.D., Ph.D.

Dr. McCluskey is a biotech executive with experience in diagnostics, drug development and medical devices. In his 16-year career in the biotech industry, he has overseen the clinical development of a novel cardiovascular risk assessment diagnostic test, the international clinical development of a marketed cardiovascular product and the clinical development of 4 currently marketed products.

Originally trained in cardiology (Cleveland Clinic), he was on the faculty of the University of Cincinnati for several years. His molecular biology and clinical cardiology training were at UCSF and his MD, PhD (Pharmacology) and medical residency were at Washington University in St. Louis. His undergraduate degree was in chemistry (with research honors) from Stanford.

Dr. McCluskey started in the biotech industry at Genentech for 8 years, overseeing clinical research on cardiovascular applications for TNKase, Bosentan, CathFlo Activase and for the anti-angiogenic ophthalmic agent Lucentis. He led the clinical development for the cardiovascular application of VEGF-165 (vascular endothelial growth factor) by direct intra-coronary injection and has had extensive experience in both in-licensing and out-licensing projects. While at Genentech, he received additional training in Finance, Marketing and Management (Berkeley) and in Leadership and Strategy at an executive program at Harvard Business School. Following Genentech, Dr. McCluskey oversaw cardiovascular clinical development at Scios (a Johnson&Johnson Company) where he was responsible for the international clinical development of their lead product (Natrecor) and for VEGF-121. Most recently, he was Chief Medical Officer and Vice President of Clinical at a Stanford cardiovascular diagnostic startup – Aviiir – where he oversaw the clinical development of the Aviiir TruRisk™ Test.

Currently Dr. McCluskey is the President of Sand Hill Angels and has been on their Board of Directors for the past 4 years. He is an advisor in the Stanford SPARK drug development program and in the Stanford medical device Program in Biodesign. In addition, he is a Clinical Consultant for Biotech, Diagnostic and Medical Device companies.