



**COPD Biomarkers Qualification Workshop
January 27th & 28th, 2010
Bethesda North Marriott Hotel & Conference Center
Bethesda, MD**

Day One: Wednesday, January 27th, 2010

Breakfast: 7:00-8:00am

Introductions

8:00-8:05am	COPD Foundation	John W. Walsh
8:05-8:15am	NHLBI Co-Chair	James Kiley
8:15-8:25am	FDA Co-Chair	Badrul Chowdhury

Session 1: Background

8:25-8:35am	FDA Biomarker Qualification Process	Federico Goodsaid
8:35-8:45am	FDA PRO Tool Qualification Process	Laurie Burke
8:45-9:15am	Redefining COPD as a Multi-component Disease: emerging knowledge of the pathophysiology of COPD	Thomas Croxton

Break: 9:15-9:30am

Session 1: PROs Overview- Symptoms and Health Status Questionnaires

(Each topic will include a 20 minute presentation followed by 40 minutes of discussion time.)

Chair: Paul Jones

9:30-10:30am	EXACT PRO	Nancy Leidy
10:30-11:30am	SGRQ, SGRQ-C, CAT, EQ-5D	Paul Jones

**Session 2: Candidate Biomarkers for Use as Intermediates in Drug Development in COPD-
linking phase II endpoints to phase III outcomes**

Chair: Ruth Tal-Singer

Part 1: Biochemical Biomarkers

(Each topic will include a 10 minute presentation followed by 20 minutes of discussion time.)

11:30-12:00pm Desmosine/isodesmosine in blood Alasdair Gaw
and urine

12:00-12:30pm Exhaled Breath Biomarkers Ruth Tal-Singer

Lunch: 12:30pm-1:30pm

Part 1: Biochemical Biomarkers (Continued)

(Each topic will include a 20 minute presentation followed by 40 minutes of discussion time.)

1:30-2:30pm Blood Biomarkers-stable disease David Lomas

2:30-3:30pm Blood Biomarkers-COPD exacerbation Chris Brightling & Jorgen Vestbo

Break: 3:30pm-3:45pm

3:45-4:45pm Sputum Biomarkers Rob Stockley & Iain Kilty

Summary & Outcomes of Day 1

4:45-6:30pm Discussion Panel Leonardo Fabbri

Dinner: 6:30pm-8:00pm

