FDA Public Workshop: Biomarker-driven drug development for allergic diseases and asthma

February 22, 2024

Session 1. Regulatory Approach to Biomarkers; 8:00 AM-11:15AM

Moderator:	*David Kaslow, MD*		FDA, CBER
8:00 AM	Welcome	Peter Marks, MD, PhD	FDA, CBER
8:10	The FDA Biomarker Program	Jeff Siegel, MD	FDA, CDER
8:30	The EU Biomarker Program	Stefan Vieths, PhD	Paul Ehrlich Institut, FRG
8:50	Role of translational science in biomarker and drug development	Peter Stein, MD	FDA, CDER
9:10	Role of Omics in Biomarker Applications & Discovery	Richard Beger, PhD	FDA, NCTR
9:30	Extrapolation of a Biomarkers between age groups	Lynne Yao, MD	FDA, CDER
9:50	NIAID Support of Biomarker Research in Allergic Disease	Alkis Togias, MD	NIH, NIAID
10:10	Panel discussion/Q & A		
10:40	Break		

Session 2. Biomarkers in Respiratory Allergic Disease; 11:15 AM – 1:25 PM

Moderator:	*Gurjit Khurana Hershey, MD, PhD*		Cincinnati Children's Hospital
11:00	Allergic rhinoconjunctivitis and asthma: current clinical endpoints for efficacy	Syed H. Arshad MBBS, DM, FRCP	Southampton UK
11:25	Biomarkers and asthma endotypes	Sally Wenzel, MD	University of Pittsburgh
11:45	Component resolved testing and "IgE quality" as prognostic and predictive biomarkers	Robert Hamilton, PhD	Johns Hopkins University
12:05 PM	Break		
1:00	Host Prognostic Biomarkers for childhood asthma	Matthew Altman, MD, Mphil	Benaroya Research Institute
1:20	Cellular biomarkers for response to AIT for respiratory allergies	Mohamed H. Shamji, PhD	Imperial College
1:40	Panel discussion/Q & A		
2:10	Break		

Session 3: Biomarkers in Food Allergy; 2:30 PM to 5: 00 PM

Moderator:	*Alkis Togias, MD*		NIAID, NIH
2:30	Food allergy: risk factors and current clinical endpoints for efficacy	Pamela Guerrerio, MD, PhD	NIH, NIAID
2:50	The relationship of atopic skin disease to food allergy	Olena Goleva, PhD	National Jewish Health
3:10	Basophil Activation Test: ready for primetime?	Alexandra Santos, MD, MSc	King's College
3:30	Component resolved testing and "IgE quality" as prognostic and predictive biomarkers/"epitope"	Hugh Sampson, MD	Icahn School of Medicine
3:50	Host Prognostic Biomarkers for food allergy	Erik Wambre, PhD, MSc	Icahn School of Medicine
4:10	Cellular biomarkers for response to AIT for food allergies	Wayne Shreffler, MD, PhD	Massachusetts General Hospital
4:30	Panel discussion/Q & A		
5:00	Adjourn		