

NEI/FDA Workshop on Retinal Disease Clinical Trial Endpoints: AMD and Inherited Retinal Diseases

9 November 2016

Lister Hill, NIH Campus, Bethesda, Maryland

Start Time	Agenda Item	
7:00	REGISTRATION	
7:00	CONTINENTAL BREAKFAST	
7:45	INTRODUCTIONS AND OPENING REMARKS	Paul A Sieving
	STRUCTURAL ENDPOINTS—GEOGRAPHIC ATROPHY	MODERATED BY KARL CSAKY
7:50	<ul style="list-style-type: none"> • FAF IN ASSESSING GEOGRAPHIC ATROPHY AREA 	Frank G Holz
8:05	<ul style="list-style-type: none"> • OCT FOR THE ASSESSMENT OF GA AREA 	SriniVas R Sadda
8:20	<ul style="list-style-type: none"> • ALTERNATIVE ANALYSES OF GA LESIONS AND AMD SEVERITY SCALE 	Emily Chew
8:35	<ul style="list-style-type: none"> • DRUSEN VOLUME AS AN ALTERNATIVE TO GEOGRAPHIC ATROPHY FOR THE STUDY OF NON-EXUDATIVE AMD 	Philip J Rosenfeld
8:50	<ul style="list-style-type: none"> • THE REGULATORY PERSPECTIVE FOR OPHTHALMIC DEVICES 	Bradley Cunningham
9:05	<ul style="list-style-type: none"> • Q&A ON GA 	Panel of Speakers, Wiley Chambers, Malvina Eydelman
9:45	BREAK	
	STRUCTURAL ENDPOINTS WITH FUNCTIONAL ASSOCIATIONS—INHERITED RETINAL DYSTROPHIES (IRDs)	MODERATED BY JACQUE DUNCAN
10:05	<ul style="list-style-type: none"> • EZ WIDTH/AREA IN RP 	David G Birch
10:20	<ul style="list-style-type: none"> • CORRELATION BETWEEN MAIA MICROPERIMETRY AND OCT IMAGING OF ELLIPSOID ZONE IN TYPE 2 IDIOPATHIC MACULAR TELANGIECTASIA 	Glenn J Jaffe
10:35	<ul style="list-style-type: none"> • OUTCOME VARIABLES FOR STARGARDT DISEASE – THE PROGSTAR STUDY 	Hendrik PN Scholl
10:50	<ul style="list-style-type: none"> • ADAPTIVE OPTICS RETINAL IMAGING: AN OBJECTIVE, SENSITIVE OUTCOME MEASURE FOR CLINICAL TRIALS 	Jacque Duncan

11:05	<ul style="list-style-type: none"> REGULATORY PATHWAYS FOR DEVICES IN IRDS 	Angelo Green
11:20	<ul style="list-style-type: none"> Q&A ON IRDS 	Panel of Speakers, Wiley Chambers, Malvina Eydelman
11:50	LUNCH –ON YOUR OWN IN THE CAFETERIA	
	FUNCTIONAL ENDPOINTS IN GA AND IRDS MODERATED BY EMILY CHEW AND JACQUE DUNCAN	
12:50	<ul style="list-style-type: none"> VISUAL ACUITY--10-LETTER VS 15-LETTER CHANGES 	Maureen G Maguire
1:05	<ul style="list-style-type: none"> DRIVING SIMULATOR PERFORMANCE 	Cynthia Owsley
1:20	<ul style="list-style-type: none"> ROD-MEDIATED DARK ADAPTATION AS A FUNCTIONAL OUTCOME MEASURE IN THE STUDY OF AGE-RELATED MACULAR DEGENERATION 	Catherine Cukras
1:35	<ul style="list-style-type: none"> MICROPERIMETRY AND LOW LUMINANCE VISION 	Karl Csaky
1:50	<ul style="list-style-type: none"> VISUAL FIELD MODELING AND ANALYSIS (VFMA): METHODOLOGY AND SOFTWARE FOR DATA REDUCTION AND TOPOGRAPHIC DISPLAY 	Richard G Weleber
2:05	<ul style="list-style-type: none"> PREPARATION FOR PHASE 3 INHERITED RETINAL DYSTROPHY GENE THERAPY TRIAL: PRIMARY ENDPOINT SELECTION AND DEVELOPMENT 	Albert Maguire
2:20	<ul style="list-style-type: none"> TRANSFORMING CLINICAL RESEARCH: NEW ENDPOINTS AND REGULATORY RENEWAL 	José-Alain Sahel
2:35	<ul style="list-style-type: none"> QUALITY OF LIFE & FUNCTIONAL VISION ASSESSMENT: MAKING THE CASE FOR PATIENT-REPORTED OUTCOMES 	Gislin Dagnelie
2:50	<ul style="list-style-type: none"> THE REGULATORY PERSPECTIVE ON VISUAL FUNCTION <ul style="list-style-type: none"> TASK PERFORMANCE AS A MEASURE OF FUNCTION INCLUDING THE PATIENT’S VOICE IN MEDICAL PRODUCT EVALUATION 	Bernard Lepri Michelle Tarver
3:05	<ul style="list-style-type: none"> Q & A ON FUNCTIONAL ENDPOINTS 	Panel of Speakers, Wilson Bryan, Wiley Chambers, Malvina Eydelman
3:35	<ul style="list-style-type: none"> CLOSING REMARKS 	Frederick Ferris