

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

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