MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
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Public workshop: Incorporating patient preferences into medical device clinical trials
May 18, 2018
Washington, DC

8:30 – 8:40	**Welcome**	**Pamela Goldberg**, President and CEO, MDIC
8:40 – 8:55	**The MDIC PCOR project: Collaborating with industry, FDA and patients to create a new method for patient-centered clinical trials**	**Stephanie Christopher**, Program Director, MDIC
8:55 – 9:40	**Keynote: Moving from P-Values to Patient values**	**Andrew Lo**, PhD, Charles E. and Susan T. Harris Professor of Finance; Director, Laboratory for Financial Engineering, MIT
9:40 – 10:40	**Keynote: A vision for partnering with patients – A conversation with the Michael J. Fox Foundation for Parkinson's Research**	**Sohini Chowdhury**, Deputy CEO, The Michael J. Fox Foundation for Parkinson's Research **Margaret Sheehan**, MJFF Patient Council **Anna Donnelley**, MJFF Patient Council
10:40-10:55	*Break*	
10:55-11:15	**Keynote: FDA - CDRH perspective on partnering with patients**	**Jeffrey Shuren**, MD, JD, Director, Center for Devices and Radiological Health (CDRH), US Food and Drug Administration
11:15 – 12:00	**MDIC PCOR Project Results: Aims 1-3**	**Annie Saha**, CDRH **Brett Hauber**, RTI Health Solutions **Shomesh Chaudhuri**, MIT
12:00 – 12:45	Lunch	
Concurrent sessions		
12:45 – 1:45	**Aim 1 – Understanding what matters to patients**	Moderator: Annie Saha • **Katrina Gwinn**, CDRH • **Anna Donnelly**, MJFF Patient Council • **Brittany Caldwell**, CDRH

	Aim 2- Designing and Conducting the Patient Preference Study	Moderator: Brett Hauber • **Heather Benz**, CDRH • **Mo Zhou**, CDRH • **Brennan Mange**, RTI • **Margaret Sheehan**, MJFF Patient Council
	Aim 3 – Designing methods for clinical trials based explicitly on patient input	Moderator: Shomesh Chaudhuri • **Martin Ho**, CDRH • **Andrew Lo**, MIT • **Kevin Kwok**, Person with Parkinson's • **Edward Karst**, Abbott
1:45 – 2:00	*Break*	
Return to large group session		
2:00 – 2:20	**Wrap-up and summary from the concurrent sessions**	• **Annie Saha** • **Shomesh Chaudhuri** • **Brett Hauber**
2:20 – 3:40	**Panel discussion: What are the implications of this patient-centered approach to clinical trials?**	• **Margaret Sheehan** • **Anna Donnelly** • **Andrew Lo** • **Brett Hauber** • **Greg Molnar,** University of Minnesota • **Lauren McLaughlin**, Michael J Fox Foundation for Parkinson's Research • **Owen Faris**, CDRH
3:40 – 4:00	**Fitting this project into MDIC's broader effort to advance the Science of Patient Input**	**Barry Liden**, Edwards LifeSciences