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The MDEpiNet TMJ Patient Led RoundTable

Friday, May 11, 2018

White Oak Campus, Silver Spring, MD
Great Room, Building 31, Room 1503B

Objectives

- (1) Update participants on status/results of Working Group (WG) projects
- (2) Identify gaps and next steps to achieving WG goals and establish a roadmap to achieve these goals/opportunities,
- (3) Identify data collection needs to support WG activities and establish processes for development of high quality real-world evidence with a minimal burden to patients and caregivers

8:00-8:30	Registration	Presenter/Affiliations
8:30-8:45	Welcome and Opening Remarks	FDA
8:45-9:00	Regulatory Background of TMJ Devices	Andrew Steen, FDA
9:00-9:15	Welcome and What Patients Want	Terrie Cowley, <i>The TMJ Association</i>
9:15-9:30	Opportunities	Danica Marinac-Dabic, FDA
9:30-9:45	Meeting Format and Goals for the Day	Benjamin Eloff, FDA
9:45-10:45	Working Group I Updates The TMJ Patient: Natural History and Assessment of Biomarkers Associated with Outcomes in TMJ Implant Patients	John Kusiak, NIDCR Christin Veasley, <i>The TMJ Association</i>
	Goal - To explore the multidisciplinary intersection of patient biology, anatomy, genetics, and physiology with TMJ medical devices and clinical patient-centered outcomes to better target therapies toward patients who are most likely to benefit from them.	

Open RoundTable Discussion

10:45-11:00 Break

11:00-12:00 Working Group II Updates
Patient Reported Outcome Evaluation

Carolina Alvarez-Garriga, *FDA*
Manuel Bayona, *FDA*

Goal - To develop outcome assessment and reporting tools based on patient input, and to develop evidence to incorporate patient-centered data into clinical care.

Open RoundTable Discussion

12:00-12:30 Lunch

12:30 – 1:30 **Working Group III Updates**
Education, Patient-Centered Treatment

Charles Greene, *UIC*
Michelle Reardon, *Patient Advocate*

Goal: To develop evidence-based best practices, treatment protocols and clinical practice guidelines which will include patient-centered data.

Open RoundTable Discussion

1:30 – 1:40 **Delphi and RoundTable - Delphi Process**

Danica Marinac-Dabic, *FDA*

1:40 – 1:50 Coordinated Registry Network

Art Sedrakyan, *Cornell*

1:50 – 2:50 Working Group IV Updates

Benjamin Eloff, *FDA*
Michele Kaseta, *Patient Advocate*

Goal - The results of this exercise will set the stage for the fulfillment of the RoundTable goal: to develop evidence based best practices, treatment protocols and clinical practice guidelines which will include patient-centered data.

Open RoundTable Discussion

2:50-3:00 Break

Needs and Next Steps

3:00-4:00 Needs of the Working Groups

4:00-5:00 Next Steps Needed

5:00 Closing Remarks

Terrie Cowley *The TMJ Association*
Danica Marinac-Dabic, *FDA*