TMJ Patient RoundTable Working Groups
Steering Committee

Co-chairs:
- Terrie Cowley, TMJ Patient and President & Co-Founder, The TMJ Association, WI
- Danica Marinac-Dabic, MD, PhD, MMSc, Director, Division of Epidemiology, CDRH/FDA, MD

Members:
- Elise Berliner, PhD, Director, Technology Assessment Program at the Center for Outcomes and Evidence in the Agency for Healthcare Research and Quality, MD
- Brian Hatcher, PhD, Director of Research, Zimmer Biomet, FL
- Ning Hu, MD Medical Officer, DHHS/FDA/CDER/OMPT/CDER/OND/ODEII/DAAAP, MD
- Telba Irony, PhD, Deputy Director, Office of Biostatistics and Epidemiology, CBER/FDA, MD
- Marjorie Jenkins, MD, FACP, Director of Medical Initiatives and Policy Advancement, FDA/OWH, MD
- Michele Kaseta, TMJ Patient, MI
- Michelle Reardon, TMJ Patient, MA
- Joseph Ross, MD, MHS, Yale School of Medicine, Associate Professor of Medicine (General Medicine), Institute for Social and Policy Studies and Associate Professor of Public Health (Health Policy), New Haven, CT
- Susan Runner, DDS, MA, Branch Chief, Dental Devices, FDA/CDRH/ODE, MD
- Dave Samson, President, TMJ Concepts, CA
- Art Sedrakyan, MD, PhD, Associate Professor of Healthcare Policy and Research and Director of the Comparative Effectiveness Program of Weill Cornell Medical College, NY
- Martha Somerman, PhD, DDS, Director, NIDCR/NIH, MD
- Yelizaveta Torosyan, MD, PhD, Acting Senior Project Manager, Division of Epidemiology, CDRH/FDA, MD

Project Managers/Liaisons:
- Britt Barham, Project Leader, Duke University
- Deanne Clare, Association Administrator, The TMJ Association, WI
- Marta Steliac, Health Science Administrator, Division of Epidemiology, CDRH/FDA, MDEpiNet Project Manager, MD
## Working Group 1
**The TMJ Patient: Natural History and Assessment of Biomarkers Associated with Outcomes in TMJ Implant Patients**

### Objectives:
1. To summarize knowledge related to the overall health of the TMJ patient based on the scientific literature, and both physician and patient reported information which would broadly include pain and other health conditions.
2. To summarize existing genetic, biochemical, immunological and physiological information and mechanisms that may collectively advance our understanding of how a patient may respond to implant procedures.
3. To assess existing phenotyping data and information needed to develop device/patient phenotyping classification.

The results of this exercise will set the stage for the fulfillment of the RoundTable 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.

### Co-chairs:
- **John Kusiak**, PhD, Acting Deputy Director, NIDCR/NIH, MD
- **Christin Veasley**, Patient and Co-Founder and Director, Chronic Pain Research Alliance, RI

### Members:
- **Inna Belfer**, MD, PhD, Health Science Administrator, NIH Office of Research on Women’s Health, MD
- **Carolina Beraldo Meloto**, DDS, PhD, Postdoctoral Fellow, McGill University, Montreal, Quebec Canada
- **Allen Cowley**, PhD, TMJA Scientific Advisory Committee Chair, Medical College of Wisconsin, WI
- **Luda Diatchenko**, MD, PhD, Canada Excellence Research Chair in Human Pain Genetics, McGill University, Montreal, Quebec Canada
- **Cheryl Gray**, TMJ Patient, MA
- **Ning Hu**, MD Medical Officer, DHHS/FDA/CDER/OMPT/CDER/OND/ODEII/DAAAP, MD
- **William Maixner**, DDS, PhD, Director of the Center for Translational Pain Medicine, Anesthesiology/Center for Translational Pain Medicine, Duke University, NC
- **Dave Samson**, President, TMJ Concepts, CA
- **Lisa Schmidt**, TMJ Patient, CA
- **Yelizaveta Torosyan**, MD, PhD, Acting Senior Project Manager, Division of Epidemiology, CDRH/FDA, MD

### Women’s Health Focus:
- **Inna Belfer**, MD, PhD, Health Science Administrator, NIH Office of Research on Women’s Health, MD
- **Roger Fillingim**, PhD, Professor, Department of Community Dentistry and Behavioral Science
- **College of Dentistry, University of Florida, Gainesville, FL**
- **Mary Jenkins**, MD, FACP, OWH, FDA, MD
- **Yolanda Vallejo-Estrada**, PhD, Director, Molecular and Cellular Neuroscience Program, Integrative Biology and Infectious Diseases Branch, NIDCR/NIH, MD
- **Ning Hu**, MD Medical Officer, DHHS/FDA/CDER/OMPT/CDER/OND/ODEII/DAAAP, MD

### Bioengineering/Devices Focus:
- **John Bowsher**, PhD, MSc, Biomedical Engineer, ODE/FDA, MD
- **Brian Hatcher**, PhD, Director of Research, Zimmer Biomet, FL
- **Steven Kurtz**, PhD, Director of Biomedical Engineering, Exponent, Inc., PA
- **Nasrin Mirsaidi**, MSN, RN, CNOR, Physical Scientist, FDA/CDRH, MD
- **John Powers**, MD, FACP, FIDSA, Associate Clinical Professor of Medicine, George Washington University School of Medicine, MD
- **Susan Runner**, DDS, MA, Branch Chief Dental Devices, CDRH/FDA/ODE, MD
- **Lillian Shum**, PhD, Director, Division of Extramural Research, NIDCR/NIH, MD
- **Andrew Steen**, Mechanical/Biomedical Engineer, Food and Drug Administration, MD
- **Wojtek Tutak**, PhD, Lead Reviewer, Biomedical Engineer, FDA/ODE/DAGRID/DEDB, MD

### Ad Hoc Member:
- **Joel Myklebust**, PE, PhD, Deputy Director, Office of Science and Engineering Laboratories, FDA CDRH, MD
Working Group 2  
Patient-Reported Outcome Evaluation

Objectives:
1. To identify scientific literature evaluating Patient Reported Outcomes (PROs) measures in TMD/TMJ patients.
2. To specifically assess the methodological quality, the evidence related to psychometric aspects, and synthesize these assessments into an overall rating of psychometric evidence for each PRO measure by using the Consensus-based Standards Measurement Instruments (COSMIN) criteria.
3. To evaluate PROs measures of TMD/TMJ patients regarding the effects on quality of life (QoL).
4. To evaluate the safety and effectiveness of TMJ medical devices.
5. To provide recommendations whereby PRO measures can guide future decision making based upon COSMIN criteria for premarket and postmarket evaluation of TMJ medical devices.

The results of this exercise will set the stage for the fulfillment of the RoundTable goals: To develop outcome assessment and reporting tools based on patient input, and to develop evidence to incorporate patient-centered data into clinical care.

Co-chairs:
- Carolina Alvarez-Garriga, MD, DrPH, Epidemiologist, Epidemiology, OSB/CDRH/FDA, MD
- Joel Gagnier, ND, MSc, PhD, Assistant Professor, Department of Orthopaedic Surgery, Assistant Professor, Department of Epidemiology, School of Public Health, University of Michigan, MI
- Tricia Kalinowski, TMJ Patient, MN
- Michele Kaseta, TMJ Patient, MI

Members:
- Manuel Bayona, MD, MS, PhD, Staff Fellow, FDA CDRH, MD
- Inna Belfer, MD, PhD, Medical Reviewer/Clinical Analyst, Division of Anesthesia, Analgesia, and Addiction Products, CDER/ FDA, MD
- Gary Bouloux, MD, DDS, MDSc, Assistant Professor, Department of Oral Surgery, Emory University School of Medicine, Chief of Service for Oral and Maxillofacial Surgery and Director of Clinical Research at Grady Memorial Hospital, GA
- Oscar A. González, MD, DNP, Clinical Research, Biomet Microfixation, FL
- Lutricia Merritt, TMJ Patient, OH
- Karen Raphael, PhD, Professor, Oral and Maxillofacial Pathology, Radiology and Medicine, New York University, NY
- Suzanne Schrandt, JD, Director, Patient Engagement, Arthritis Foundation, DC
- Dennis Turk, PhD, Professor, Department of Anesthesiology & Pain Medicine, ACTTION, University of Washington Medicine, Dept. of Anesthesiology & Pain Medicine, Seattle, WA
- Adriana van Ineveld, TMJ Patient, Canada
- Christin Veasley, Patient and Co-Founder and Director, Chronic Pain Research Alliance, RI

Ad Hoc Members:
- Peter Bertrand, DDS, Retired, Orofacial Pain Development, National Navy Dental School, MD
- Laurie Burke, MPH LORA Group, LLC, Founder, Royal Oak, MD
- Daniel Mullins, PhD, Professor and Chair, PHSR Dept., University of Maryland, School of Pharmacy, MD
- Abbe Steel, MSc, HealthVibe, LLC, CEO, Arlington, VA
- Yolanda Vallejo-Estrada, PhD, Director, Molecular and Cellular Neuroscience Program, Integrative Biology and Infectious Diseases Branch, NIDCR/NIH, MD
Working Group 3
Education, Patient-Centered Treatment

Objectives:
1. To collect and compile currently available best practices, clinical practice guidelines, diagnostic and treatment protocols which are currently being used to direct clinical treatments of temporomandibular disorders. This information will be identified and collected from academia, research centers, private practices, scientific societies, professional organizations, and federal agencies.
2. To assess the scientific basis of these treatment directives, as well as, the extent to which these guideline documents and treatment protocols include patient-centered preferences and guidance.

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.

Co-chairs:
- Charles Greene, DDS, Clinical Professor of Orthodontics, University of Illinois at Chicago, IL
- Michelle Reardon, TMJ Patient Representative, MA

Members:
- Andrew Bertagna, University of Illinois at Chicago, IL
- Louis Mercuri, DDS, MS, Clinical Consultant, TMJ Concepts, Visiting Professor, Rush University Medical Center, IL
- Gregory Ness, D.D.S., DP Snyder Professor of Oral Surgery, Professor-Clinical Director, Oral and Maxillofacial Surgery Residency Program, Ohio State University College of Dentistry, OH
- Ritza Reese, TMJ Patient, MD
- Kevin Reid, DMD, Orofacial Pain Dentist, Mayo Clinic, Rochester, MN

Ethics Focus:
- Charles Greene, DDS, Clinical Professor of Orthodontics, University of Illinois at Chicago, IL
- William McConagha, JD, Partner, Sidley Austin LLP, Washington DC
- Kevin Reid, DMD, Mayo Clinic, Rochester, MN

Ad Hoc Members:
- Hugo Campos, Stanford Medicine X ePatient Advisor, White House Champion of Change for Precision Medicine, Patient-centered SCAlable National Network for Effectiveness Research (pSCANNER), CA
- Daniel M. Laskin, DDS, MS, Professor and Chairman Emeritus, Virginia Commonwealth University, Oral and Maxillofacial Surgery, Richmond, VA
- Kathryn O'Callaghan, PhD, Assistant Director for Strategic Programs, Office of the Center Director, CDRH/FDA, MD
- Andrew Olson, Director of Sales and Marketing, Nexus CMF, UT
# Working Group 4
## Real-World Evidence & Patient Data

**Objectives:**

1. To assess the current availability and ability to identify, collect, and compile information related to selected aspects of TMJ patients’ therapies.
2. Develop methodologies to collect such information from sources outside of traditional clinical trials, such as prospective observational or registry studies, retrospective database studies, case reports, administrative and healthcare claims, electronic health records, registries, and social media patient networks and patient advocacy organizations.

Evaluation of data used in support of premarket approvals

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.*

**Co-chairs:**
- Open
- Michele Kaseta, TMJ Patient, MI

**Members:**
- Carolina Alvarez-Garriga, MD, DrPH, Epidemiologist, Division of Epidemiology, CDRH/FDA, MD
- Elise Berliner, PhD, Director, Technology Assessment Program at the Center for Outcomes and Evidence in the Agency for Healthcare Research and Quality, MD
- Daniel Caños, MPH, PhD, Senior Epidemiologist, Centers for Medicare & Medicaid Services/FDA, MD
- Jennifer Feldman, TMJ Patient, NY
- Anne Marie Finley, President at Biotech Policy Group, WI
- Harlan Krumholz, MD, SM, Professor of Cardiology, Yale University, CT
- Anna McCallister-Slipp, Co-founder, Galileo Analytics, Patient Advocate on FDA’s MDEpiNet’s Advisory Committee, DC
- Joseph McCain, DMD, Oral Surgeon, Miami Oral and Maxillofacial Surgery, FL
- Sharon-Lise Normand, PhD, Professor of Health Care Policy, Department of Health Care Policy at Harvard Medical School and in the Department of Biostatistics at the Harvard School of Public Health, MA
- Kim Reed, Manager Regulatory Affairs, Zimmer Biomet Microfixation, FL
- Susan Runner, DDS, MA, Branch Chief Dental Devices, CDRH/FDA/ODE, MD
- Art Sedrakyan, MD, PhD, Associate Professor of Healthcare Policy and Research and Director of the Comparative Effectiveness Program of Weill Cornell Medical College, NY
- Adriana van Ineveld, TMJ Patient, Canada