# TMJ Implant Round Table

## Background

An estimated 35 million people in the United States have temporomandibular disorders (TMD). Their symptoms may be limited to jaw pain and jaw dysfunction (difficulty in chewing and swallowing and in speaking or making facial expressions). Traditional treatments for TMD have long focused on "fixing" the jaw joint, teeth, and related musculature, with scant evidence of their safety and efficacy. One such TMD treatment is reconstruction of the jaw joint (bone tissue of the mandible and skull) with biomaterial components. A recent FDA review of MedWatch reports found that 52% of TMJ devices were removed within the first two years after implantation due to extreme pain and other problems. It is notable that TMD primarily affects women from puberty through menopause.

Medical concerns that TMJ implant patients report most frequently are; infections, pain, sensitivity to implant materials and an array of medical conditions that emerge following implantation. Some of these include: non-malignant tumors, foreign body giant cell tumors, lymphadenopathy, widespread body pain, chronic fatigue syndrome, lupus, celiac disease, Sjogren's syndrome rashes, memory loss, confusion, flu-like symptoms, dizziness, vertigo, tinnitus, hearing loss, asthma, allergies, chemical sensitivities, intolerance to heat or cold, asthma, atypical MS, abnormal laboratory and imaging results without definitive diagnosis. Attached are two documents. Document 1 is a list of adverse reactions/conditions that we extracted from TMJ implant MedWatch reports and Document 2 is a list of adverse events that we compiled from patient reports to The TMJ Association.

The psychological impact of the hope for a better future following an implant being dashed cannot be overstated. The financial impact on the patient and their loved ones for continuous care and revision procedures is enormous leading many into bankruptcy thereby impacting society at large.

## Project Description

Indeed, there are TMJ implant patients whose quality of health and life has been improved by implants. However, those who have not had positive outcomes have not been privy to research aimed at understanding why the negative outcomes and more importantly, how to help them. Over the years, absent has been constructive dialogue among the stakeholders –device

manufacturers, Food and Drug Administration, National Institutes of Health, clinicians, basic scientists, bioengineers, patients, and patient advocates – to address the implant patients health issues pre and post implantation and compare the biological state of those with successful outcomes with those not successful.

The TMJ Implant Round Table will create a first-of-its-kind collaboration in the TMD area bringing all stakeholders together to build a body of data on implant performance, surgical outcomes, adverse events, and complications as well as provide meaningful change based upon this process.  A unique feature of this program is the patient centered approach which we are taking. Implant patients will have a vital role and discussions will address their experiences and problems. The success of this Round Table will be measured in terms of the success in bringing the best science to TMJ devices and patients. However, equally important, this transparent and respectful venue will hopefully break down the barriers that currently allow the continuation of rumors, blame, and suspicion that is detrimental to patients having had or contemplating an incredibly serious surgical treatment. What is currently shared in the darkness of chat rooms needs to be brought into the “sunshine” and addressed in fairness to all involved.