The Reg-ent clinical data registry is the first national data repository of otolaryngology-specific clinical data. Reg-ent equips otolaryngologist-head and neck surgeons with a large data repository to improve quality patient care and outcomes. After evolving from an initial phase of meeting members needs as a vehicle for public reporting to the Centers for Medicare and Medicaid (CMS) Merit-based Incentive Payment System (MIPS). Reg-ent is now fully expanded to the phase two goal of providing our members the opportunity to utilize big data from the Reg-ent de-identified patient data set for research and quality improvement projects.

Our commitment is to have high quality research projects, reviewed, prioritized and approved by the Reg-ent Research Advisory Group (RRAG) and the Executive Committee of the AAO-HNS Board of Directors, utilizing Reg-ent data sets addressing a wide variety of research projects. Only projects which fall within the AAO-HNS mission will be accepted.

AAO-HNS has partnered with OM1, a leading data analytics organization to aid in the expansion to phase two.

## **DATA ACCESS**

Reg-ent will be accepting proposals for non-commercially funded projects. When available, a data request form will be accessible from our Reg-ent Research webpage. The initial review of data request forms is completed by Research and Quality staff before completed forms are submitted to the Reg-ent Research Advisory Group (RRAG).

## SUBMISSION/APPROVAL PROCESS

- Requests for Reg-ent data will be made to the Reg-ent Research Advisory Group utilizing the Reg-ent Research Data Request Form (coming soon).
- Signed acknowledgement that Reg-ent associated research will be submitted for publication to Otolaryngology-Head and Neck Surgery or OTO Open for right of first refusal and to the AMPC for presentation at the AAO-HNS Annual Meeting is required.
  - Final publication of Reg-ent related research is subject to the standard peer-review process and final disposition is rendered by the Editor- chief of Otolaryngology-Head and Neck Surgery.
  - b. Waivers will be considered by the AAO-HNS Executive Committee following referral from the Reg-ent Executive Committee for manuscripts warranting a higher impact journal with widespread readership (e.g., JAMA, New England Journal of Medicine, Cancer, etc.) or a subspecialty journal outside of otolaryngology and for presentations outside the AAO-HNS Annual Meeting.

- **3.** If a submission is rejected by *Otolaryngology–Head and Neck Surgery* or *OTO Open*, it can be submitted to another peerreviewed journal.
- **4.** Principal Investigator (PI) must provide agreement to utilize central Institutional Review Board (IRB); if centralized IRB is not utilized, PI is responsible for institutional IRB approval which must be included at the time of proposal submission.
- 5. Applications will be accepted on a rolling basis.
- **6.** Members of the RRAG will review the applicant submission form and submit via email to the RRAG liaison for collation.
- 7. When necessary, the RRAG will correspond via email and/or conference call if there are significant concerns or discrepancies with a submission.
- 8. The RRAG Chair will provide recommendations on Reg-ent research proposals to the Reg-ent Executive Committee (REC). The AAO-HNS Executive Committee will render the final decision to the PI on REC approved proposals.

## **POST APPROVAL PROCESS**

- Research proposals (title; study type; involved committees/ institutions/investigators; progress) will be published on the Reg-ent website to avoid duplication of research efforts.
- The PI is responsible for submitting quarterly research updates, including a projected timeline to completion to the RRAG.
- Presentation of Reg-ent related research: If Reg-ent generated research is planned for presentation at an otolaryngology-specific meeting, the AAO-HNSF Annual Meeting must be given right of first refusal unless otherwise waived by the AAO-HNS Executive Committee.