Reg-ent | Data Access Toolkit

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. 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

1. Requests for Reg-ent data will be made to the Reg-ent Research Advisory Group utilizing the **Reg-ent Research Data Request Form**.

2. 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.

   a. 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 peer-reviewed 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.