



# Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery

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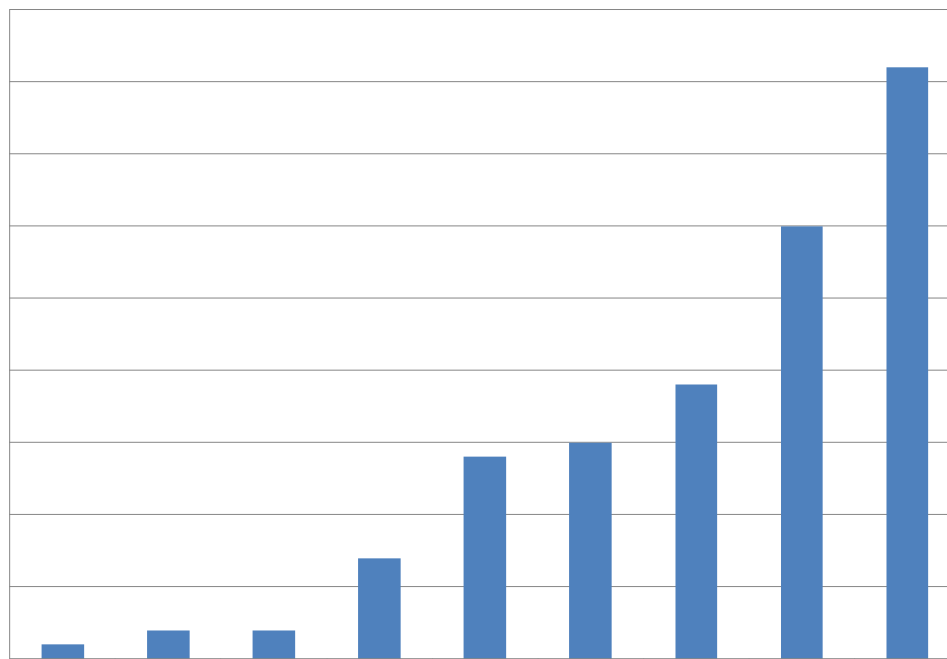
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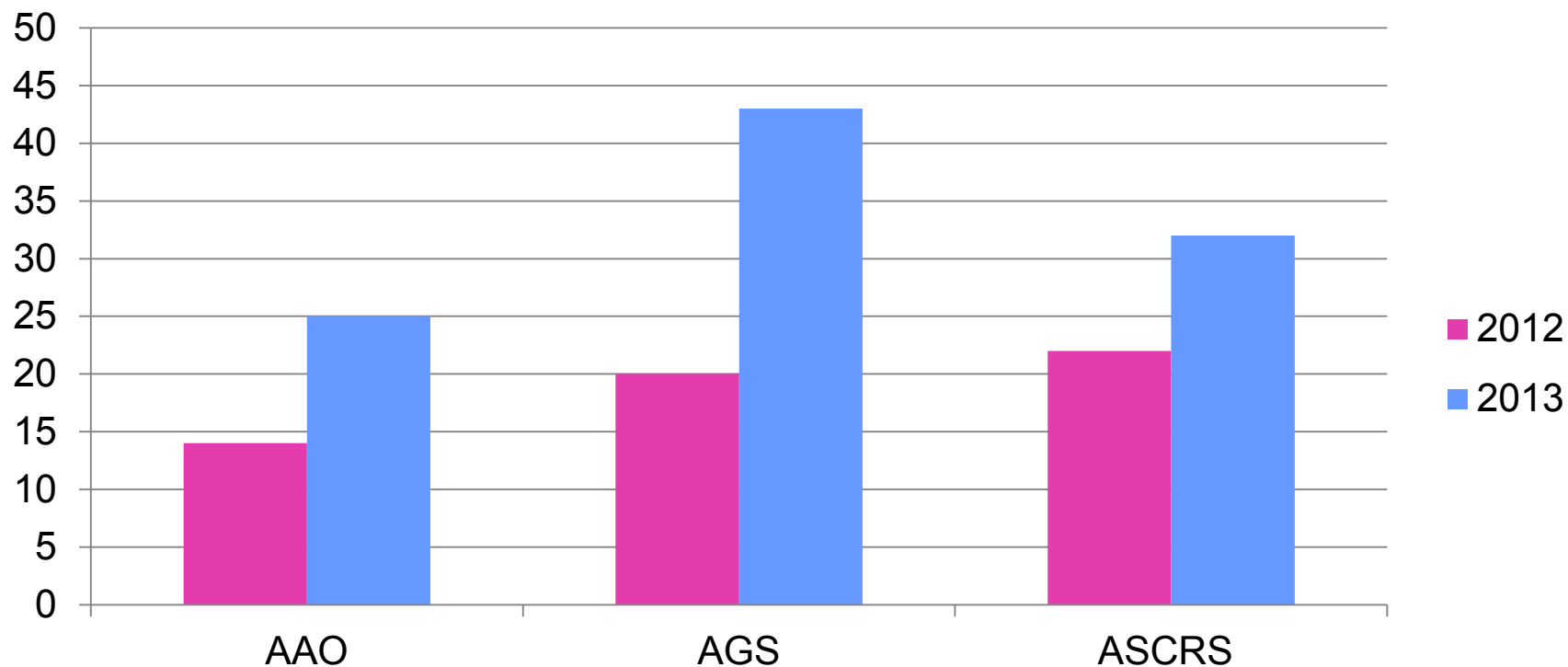
# Novel Glaucoma Surgical Devices\*: PubMed Citations



**\*Glaucoma devices not used in conventional laser, trabeculectomy or tube surgery (i.e., Ahmed, Baerveldt)**



## Novel Glaucoma Surgical Devices\*: Annual Professional Meetings\*\*



\*Glaucoma devices not used in conventional laser, trabeculectomy or tube surgery  
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\*\*Abstracts/Papers/Courses/Sessions

# Minimally Invasive Glaucoma Surgery (MIGS) Devices





# **MIGS Devices: Lack of Consensus for Clinical Trials**

- Definition of MIGS device
- Patient population
- Safety endpoints and targets
- Effectiveness endpoints and targets



# **MIGS Devices: Center for Devices and Radiological Health (CDRH)**

- Increasing number of submissions for MIGS devices
- Lack of FDA Guidance or Recognized Standard:
  - » Safety and effectiveness endpoints for the investigation are not clearly delineated
  - » Discussions with individual sponsors



## CDRH Mission

- To protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. ....We **facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways**, and assuring consumer confidence in devices marketed in the U.S.





# FDA's Goals for Today's Workshop

- To discuss the best clinical trial design for MIGS devices:
  - » Appropriate patient population
  - » Safety assessment
  - » Effectiveness assessment
- Create a foundation for development of “Leap-Frog” Guidance for MIGS Devices:
  - » Mechanism via which we can share our initial thoughts regarding the content of premarket submissions for emerging technologies
  - » Speed development and approval of future submissions



## CDRH Vision

- Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world. The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. ....



## What's your Innovation Moonshot?

