# AGA CGIT Registry Update

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The American Gastroenterological Association (AGA) serves over 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology

The mission of the AGA is to advance the science and practice of gastroenterology

#### AGA works to:

- Foster scientific discovery and the application of new knowledge to improve care of patients with digestive disease; and
- Define optimal clinical practice and help gastroenterologists provide high-quality, high-value care.



# AGA as a neutral objective body to support evidence generation

- AGA staff and members have a unique blend of clinical, research, regulatory and payment knowledge
- AGA reputation as an unbiased body can help companies gather the data that can be trusted by payors and regulatory agencies
- The data can support the approval, coverage, reimbursement and adoption of new technologies, therapies and procedures GI, nutrition, and hepatology devices, therapeutics, and diagnostics.

#### **AGA Centers**

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AGA has three specialized centers unique to medical associations:

- Center for GI Innovation and Technology (est. 2010)
- Center for Gut Microbiome Research and Education (est. 2012)
- Center for Diagnostics and Therapeutics (est. 2014)

## **Center for GI Innovation and Technology**

#### **Mission**

To support innovation and the development of technologies and procedures to improve the health and outcomes of patients with digestive disorders.

#### **Objectives**

- 1. Establish AGA as the professional home for GI innovators.
- 2. Provide objective guidance, insight and recommendations to the medical community, device industry, investment community, payers and regulatory bodies that support the development, availability, assessment, coverage and adoption of new technologies and procedures for patients with digestive disorders.
- Foster collaboration amongst all relevant stakeholders that develop and
  assess technologies and procedures, and raise awareness of the literature and
  registry requirements for approval, adoption, coverage and reimbursement of
  new procedures.

## What Types of Issues Does the CGIT Advise?

- Is the data sufficient and robust enough to support specialized or wide-spread uptake and adoption of a technology, procedure, diagnostic or therapeutic?
- We leverage our strong relationships with governmental agencies, commercial payers, industry, and researchers, and combine this with our powerful depth of member expertise to identify data gaps and determine unmet needs.
- We develop projects and identify pathways to address the needs of the various stakeholders with the goal of quality, value-based care, e.g., observational registries

# AGA guides through all stages of post FDA approval evidence generation

- Gap analysis of evidence needed for reimbursement
- Protocol Development and Power Analysis
- Study execution and publication

- 1. Identifying PI, DSMB members
- 2. IRB approval, Site Selection
- 3. Training and Site Activation (EDC)
- 4. Study Implementation
- 5. Study Oversight and Safety
- 6. Study Close-out
- Ancillary Studies Submission, Review, and Approval
- 8. QA
- 9. Analysis
- 10. Publications and publications Policy

# Registry Oversight Subcommittee



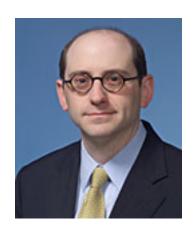
Ashish Atreja, MD, MPH (Chair)



Uri Ladabaum, MD



Jason Dominitz, MD MHS



Joel Rubinstein, MD, Msc

# STAR Registry: Update TheStreet



### American Gastroenterological Association And EndoGastric Solutions Establish Registry For GERD Procedures



#### #PR Newswire

BETHESDA, Md., March, 20, 2014 /PRNewswire-USNewswire/ -- The American Gastroenterological Association (AGA) Center for GI Innovation and Technology today announced a partnership with EndoGastric Solutions® to develop a registry comparing surgery to an incisionless procedure to treat gastroesophageal reflux disease (GERD).

- Surgery Versus Transoral
   Incisionless
   Fundoplication: Anti-Reflux
   Registry
- First real-world data
   observing patient outcomes
   following traditional
   laparoscopic surgery and TIF
- 10 sites enrolled, 7 live

# STAR: Prospective Observational Casecontrol registry comparing LNF and TIF

- Effectiveness (primary outcome, 75% reduction in GERD HRQL, secondary outcome, 50% reduction)
- Durability (3 years)
- Side effect profile (PAGI- SYM)
- Cost (Episodes of care, complications)

https://clinicaltrials.gov/ct2/show/NCT02211105

# STAR Registry PI's and Co-PI's



Brian Fennerty, MD AGA



W Scott Melvin, MD President, SAGES (2012-2013)

### Fecal Microbiota Transplantation National Registry

An initiative of the **AGA Center for Gut Microbiome Research and Education** Supported by a grant from the **National Institute of Allergy and Infectious Diseases** 

Goal: Collect clinical data from FMT recipients and donors to

- 1. Assess **short- and long-term safety** of FMT;
- 2. Gather information on the practice of FMT in the U.S. and **assess its effectiveness**;
- 3. Promote **scientific investigation** of FMT; and
- 4. Aid physicians and clinical trial sponsors in **satisfying regulatory requirements**.

#### **Target Enrollment**

• 4,000 FMT recipients from 75 IRB-approved sites

#### **Data Collection**

- Baseline characteristics of FMT recipients and stool donors
- Minimum annual follow-up post-FMT: clinical outcomes up to 2 years;
   patient-reported outcomes up to 10 years



### **FMT National Registry Steering Committee**



#### **Principal Investigators**

Colleen R. Kelly, MD, Brown University Loren A. Laine, MD, AGAF, Yale University Gary D. Wu, MD, University of Pennsylvania

#### **Co-Investigators**

Ashish Atreja, MD, MPH, Mount Sinai Hospital James D. Lewis, MD, MSCE, AGAF, University of Pennsylvania

#### **Partnering Societies and Their Co-Investigator Liaisons**



Thomas A. Moore, MD Infectious Disease Consultants of Kansas



David T. Rubin, MD, AGAF University of Chicago



Stacy A. Kahn, MD University of Chicago

## Questions?

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https://www.gastro.org/corporate-relations/center-for-gi-innovation-and-technology