

# 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.
3. 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
  7. Ancillary Studies - Submission, Review, and Approval
  8. QA
  9. Analysis
  10. Publications and publications Policy



# Registry Oversight Subcommittee



Ashish Atreja, MD, MPH (Chair)



Jason Dominitz, MD MHS



Uri Ladabaum, MD



Joel Rubinstein, MD, MSc





# STAR Registry: Update

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

By PR Newswire  | 03/20/14 - 12:30 PM EDT

Exclusive FREE Report: [Jim Cramer's Best Stocks for 2015.](#) 



 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 Case-control 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



AGA INSTITUTE

## 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?

Ashish Atreja, MD, MPH

Chair, Registry Subcommittee

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

