



# MEET THE ROME FOUNDATION

2021-2022

**Three Decades of Service to  
Patients in the Field of Disorders  
of Gut-Brain Interaction**

# WELCOME FROM OUR PRESIDENT AND COO

## Dear Rome Foundation Members, Friends, and Sponsors

It is with great pleasure that we review the Rome Foundation's activities over the past year and discuss our current and future initiatives. This year we provide a detailed summary of all programs and activities in the 2021 edition of the Meet the Rome Foundation. In this letter we take the opportunity to summarize our key current and future programs. These include:

- Global Epidemiology Study publication, ongoing analysis and symposium
- Rome Foundation Research Initiative (RFRI) activities
- Innovative educational programs for Gastroenterologists, primary care APPs and other Allied health providers
- Communication program
- Upgraded website and social media activities
- Research and Rome Fellowship awardees

### **Global Epidemiology Study publication and ongoing analysis.**

Under Ami Sperber MD MSPH's directorship, we have completed the Global Epidemiology Study, an eight-year project. The first overview of this exciting work now appears in the January edition of *Gastroenterology*<sup>1</sup>. There is currently an oversight committee to review research applications to analyze additional studies from the research participants. We have decided to update the medical community with a series of online CME programs to review the findings over eight weekly sessions beginning in early March. For further information, click here <https://romefoundation.clickfunnels.com/optin16131391518981613139726156>

### **Rome Foundation Research Initiative (RFRI) activities.**

Magnus Simren, MD, PhD is the research director of the RFRI, with Drs. Tack and Drossman on the executive committee. We are now entering our 3rd year and have several exciting projects underway, including a sponsored bloating and diet study with Danone Nutricia Pharmaceuticals and the ROBOT and DOMINO projects. We have over 80 investigators internationally who are available for research studies. We would also like to welcome Takeda Pharmaceuticals as a gold sponsor joining Ironwood pharmaceuticals our diamond sponsor. For full information, please go to our annual report: Click here <https://theromefoundation.org/research-institute-rome-foundation/>.

### **Innovative educational programs for Gastroenterologists, primary care, and allied health providers.**

The unfortunate experience with COVID-19 has led us to make changes to meet our educational needs by adapting to more online programs. We have upgraded our website to accommodate more online CME programs (see below), and last October, we converted our regional on-site CME programs to be entirely online. Still, when we can, we will return to on-site educational activities to capture the full learning experience with small groups and interactive sessions. So moving forward, we plan to combine online and on-site programs to maximize the learning experience.

### **Communication program.**

Our communication program, a collaboration between the Rome Foundation and DrossmanCare <https://romedross.video/Collaboration>, has been highly successful in many ways. Through a series of recent publications<sup>2-5</sup>, producing a "tips and techniques" study guide for providers <https://romedross.video/2YphMDd>, and our current work on Rome Foundation Working Team on Communication soon to be published, we continue to provide educational resources. One key finding of the Working Team was that an evidence review showed that effective communication skills and training lead to improved patient and doctor satisfaction, adherence to treatment, improved outcomes, and reduced cost. Our educational videos are expanding now with three programs: Communication 101, Communication 202 and just launched, Communication 101.5; each has its role in teaching methods and techniques to improve the patient-provider relationship. In the last few months, Drs. Drossman and Johannah Ruddy, our executive director, published a book, "Gut Feelings: Disorders of Gut-Brain Interaction and the Patient-Doctor Relationship" for patients and providers<sup>6</sup> <https://romedross.video/GutFeelingsWebsite>. Later this year, we expect to resume our on-site workshops and train the trainer programs.

### **Upgraded website and social media activities.**

We are pleased to announce that our website has been completely renovated for easier navigation <https://theromefoundation.org/> and to offer more online education programs. Welcome to



"Rome Campus," which includes CME programs and other educational programs in a consolidated web page. <https://theromefoundation.org/welcome-to-the-rome-campus/>. To increase learning offerings for providers and patients, we now have over 20 blogs by our Rome Foundation Board and 60 patient Q&A videos [http://romedross.video/RomeQ\\_A](http://romedross.video/RomeQ_A). Each video is 8-15 minutes long, packed with information, and they keep coming! Our social media followers have more than doubled in a year to almost 800 facebook and 2,200 twitter followers.

**Research and Rome Fellowship awardees.** We are pleased to announce that awardees for 2020 and 2021 Rome Awards include:

- Professor Alexander C. Ford, MBChB, MD, FRCP- 2020 Rome/Torsoli Excellence in DGBI Awardee
- Carlo DiLorenzo, MD- 2021 Rome/Torsoli Excellence in DGBI Awardee

In addition the Rome Foundation Fellowship (RFF) is given to clinicians or scientists who have established themselves in their area of work and have committed time to activities with the Rome Foundation. For 2020 the clinical awardees are Albena Halpert MD, Brooks Cash MD, and the awardee in academic medicine is Shin Fukudo MD.

We want to thank you for your support of the Rome Foundation and look forward to future collaborations.

Sincerely Yours,



**Douglas A. Drossman MD**  
President Emeritus and COO  
Rome Foundation



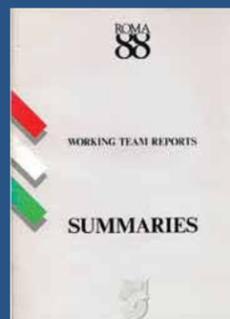
**Jan Tack MD, PhD**  
President  
Rome Foundation

1. Sperber AD, Bangdiwala SI, Drossman DA, et al. Worldwide Prevalence and Burden of Functional Gastrointestinal Disorders, Results of Rome Foundation Global Study. *Gastroenterology* 2021;160:99-114 e3.
2. Drossman DA, Ruddy J. Improving Patient-Provider Relationships to Improve Health Care. *Clin Gastroenterol Hepatol* 2020;18:1417-1426.
3. Black CJ, Drossman DA, Talley NJ, et al. Functional gastrointestinal disorders: advances in understanding and management. *Lancet* 2020;396:1664-1674.
4. Ruddy J. From Pretending to Truly Being OK: A Journey From Illness to Health With Postinfection Irritable Bowel Syndrome: The Patient's Perspective. *Gastroenterology* 2018;155:1666-1669.
5. Drossman DA. From Pretending to Truly Being OK: A Journey From Illness to Health With Postinfection Irritable Bowel Syndrome: The Provider's Perspective. *Gastroenterology* 2018;155:1664-1665.
6. Drossman DA, Ruddy J. *Gut Feelings: Disorders of Gut-Brain (DGBI) Interaction and the Patient-Doctor Relationship*. Chapel Hill, NC: DrossmanCare, 2021.

# MEET THE ROME FOUNDATION



The Rome Foundation is an independent not for profit 501(c) 3 organization whose mission is to improve the lives of people with functional GI disorders, now called Disorders of Gut Brain Interaction. The foundation provides support for activities designed to create scientific data and educational information to assist in the diagnosis and treatment of disorders of DGBIs. For three decades, beginning with the first working team committee at Roma '88 (see figure 1), the Rome organization has sought to legitimize and update our knowledge of the field. This has been accomplished by bringing together scientists and clinicians from around the world to classify and critically appraise the science of gastrointestinal function and dysfunction.



This knowledge permits clinical scientists to make recommendations for diagnosis and treatment that can be applied in research and clinical practice. The Rome Foundation is committed to the continuous development, legitimization and preservation of the field of DGBI through science-based activities. We are inclusive and collaborative, patient-centered, innovative and open to new ideas.



## Goals of the Rome Foundation

- Promote global recognition and legitimization of DGBIs
- Advance the scientific understanding of their pathophysiology
- Optimize clinical management for these patients
- Develop and provide educational resources to accomplish these goals

## FOR 30 YEARS THE ROME FOUNDATION HAS:

- Developed the first classification system for FGIDs (1990)
- Developed and validated questionnaires for research (1993)
- Epidemiological study of FGIDs (Rome I, 1993); First global study (2017)
- Criteria adopted by pharmaceuticals and regulatory agencies (Rome II, 2000)
- Provides a forum for interaction among industry and regulatory agencies (Advisory Council, 2002)
- Translations of questionnaires and educational products (Rome III, 2006)
- Annual research awards (2007); collaboration with AGA (2014)
- Global educational expansion: Asia, Latin America, Eastern Europe (2010)
- Expanded membership through associates program (2010)
- International symposia (Endpoints/Outcomes, IBS-Global Perspective)
- Diagnostic algorithms (2010)
- Multi-Dimensional Clinical Profile (2014)
- Rome IV launch of 6 books and online format (2016)
- Intelligent software learning application - Rome IV Interactive Clinical Decision Toolkit (2017)
- Communication 101, 101.5 and 202 and other advanced tools to enhance communication skills (2018)

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**ROME FOUNDATION**  
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RALEIGH, NC 27614

## CONTACT INFORMATION

### For Information on:

- Research Institute (RFRI)
- Global Study
- Public Relations
- Communication Program Activities
- Rome IV and Rome V
- Sponsors - Information/Opportunities
- Sponsorship of Rome Activities
- Upcoming Events/Symposia
- Website
- Financials

**Contact: Johannah Ruddy**  
jruddy@theromefoundation.org

### For Information on:

- Education Credits for Rome Campus
- Mentoring
- Tradeshow/Exhibits
- Partners Program
- Online order support

**Contact: Michelle Berry**  
mberry@theromefoundation.org

### For Information on:

- Marketing
- Bulk Orders of Rome IV Products
- International book sales
- Copyright & Licensing
- Translations

**Contact: Mark Schmitter**  
mschmitter@theromefoundation.org

### For Information on:

- Financials and Sponsors- Contract/Billing:

**Contact: Debra Wideman**  
Dwideman@theromefoundation.org

### For Information on:

- Rome V Committee Support
- Contact a Board Member

**Contact: Jennie Rambo**  
jennie@theromefoundation.org

**All other general inquiries:**  
admin@theromefoundation.org

# ETHICS POLICY

## The Rome Foundation Members Relations with the Pharmaceutical Industry Guidelines

The Rome Foundation takes ethics and conflict of interest issues very seriously, and therefore, developed specific guidelines to which its members are held. Completed disclosure forms for Rome Foundation are kept on file by Rome Foundation administration.

Members of the Rome Foundation are involved with the development of creative educational products including book chapters, journal articles, monographs, CD slide sets and other materials. Other activities include research to validate the diagnostic criteria and questionnaire development. The results of these processes are widely based and publicly recorded, and has gained the confidence of professional groups, researchers, the pharmaceutical industry and regulatory agencies around the world. Since much of the funding of the Rome process is derived from the pharmaceutical industry, it is important that the committee's work be independent of sponsor influence and that any perception of its direction by industry or conflict of interest of its members be avoided. Therefore, the members of the Rome Foundation hereby agree to the following principles:

- 1 No Rome Foundation Board Member shall be a regular employee (>50% time) of any pharmaceutical company or any group with a commercial interest in the Rome process.
- 2 The Rome Board shall not undertake projects on behalf of individual companies or commercial concerns, nor will it enter into any confidential agreements with them.
- 3 Rome Foundation Members shall declare and have on record any relationship with the pharmaceutical industry or other commercial entity that may be supporting the Rome process. These relationships must be updated biennially. In principle, members should not confine their advisory board, consulting or speaking arrangements to only one company.
- 4 No Rome Foundation Members shall represent the Rome Foundation to a regulatory agency that is adjudicating acceptance of a drug or device for functional gastrointestinal disorders by a regulatory agency.
- 5 No Rome Foundation Member shall advocate a drug for the treatment of a functional gastrointestinal disorder, nor support its application to a regulatory agency or drug funding authority in the name of the committee. Members may do so as individuals.
- 6 When consulting or lecturing, members shall ensure that it be known they are acting as individuals, not on behalf of the Rome Foundation. This applies to members' relationships to pharmaceutical companies, regulatory agencies or any other group with a vested interest in the Rome process. This does not apply when the Rome Committee is sponsoring a meeting or is invited to present at a meeting.
- 7 No pharmaceutical company or other interested commercial concern shall directly reimburse Board Members or Subcommittee Members for Rome activities.
- 8 Communications of an academic nature involving the Rome Foundation with the pharmaceutical industry shall be conducted through the Rome Advisory Council (RAC). The RAC consists of representatives of all Rome Foundation sponsors, Rome Board members and representatives of interested scientific and regulatory agencies. Representations and proposals by industry regarding the Rome process submitted to the Board shall be discussed and debated at RAC meetings. Board members may interact with industry as individuals but not on Rome matters or as Board representatives.
- 9 Industry representatives may not sit on the Rome subcommittees, nor should they be seen to have undue influence on the deliberations of any subcommittee. Representations from Industry regarding subcommittee activities should be addressed to the Board through the RAC.

# ROME FOUNDATION - PRESIDENT AND BOARD



## Jan Tack, MD, PhD, RFF President, Rome Foundation

Professor of Medicine

Head, Department of Clinical and Experimental Medicine

Head of Clinic, Department of Gastroenterology | University Hospital KU Leuven

Translational Research Center for Gastrointestinal Disorders (TARGID)

Leuven, Belgium

Professor Jan Tack is currently a Head of Clinic in the Department of Gastroenterology, a Professor in Internal Medicine and head of the Department of Clinical and Experimental medicine at the University of Leuven, and a principal researcher in TARGID (the Translational Research Center for Gastrointestinal Disorders) at the University of Leuven. He graduated summa cum laude in 1987 from the University of Leuven and specialized in internal medicine and gastroenterology at the same institution. A research fellow at the Department of Physiology at the Ohio State University, Columbus, Ohio, USA, from 1989 to 1990, he has been conducting research at Leuven University since 1990. Professor Tack's scientific interest focuses on neurogastroenterology and motility, and includes diverse topics such as the pathophysiology and management of gastrointestinal functional and motor disorders (including GERD, globus, dysphagia, FD, gastroparesis, dumping syndrome, chronic constipation, IBS and opioid-induced

bowel dysfunction), the physiology and pharmacology of the enteric nervous system, GI hormones and the control of satiation and food intake. He has published more than 600 articles and 40 book chapters on various aspects of scientific and clinical gastroenterology.

Professor Tack won several awards for Basic and Clinical Research in GI Science. Professor Tack is Editor-in-chief of the United European Gastroenterology Journal, Past-President of the European Society of Esophagology, Past-President of the International Society for Diseases of the Esophagus, and has served as co-editor for *Neurogastroenterology and Motility*, *Gastroenterology*, *Gut and Digestion*. He serves or has served as a member of the editorial board of *Gastroenterology*, *American Journal of Gastroenterology*, *Alimentary Pharmacology and Therapeutics*, *Journal of Internal Medicine*, *Bailliere's Best Practice and Research in Clinical Gastroenterology*, *Annals of Gastroenterology and Journal of Gastroenterology*.

### ADVISORY COUNCIL

Communications of an academic nature involving the Rome Foundation with the pharmaceutical industry are conducted through the Rome Advisory Council. The Advisory Council consists of representatives of all Rome Foundation sponsors, Rome Board members, the American Gastroenterological Association (AGA), the International Foundation for Functional Gastrointestinal Disorders (IFFGD) and representatives of interested scientific and regulatory agencies. Each year the Advisory Council meets to discuss present ongoing Foundation activities and topics of general interest. Members also prepare presentations of general interest to the members for discussion at these meetings.

### MEMBERS OF THE ADVISORY COUNCIL

AlfaSigma	Abbvie	Biomerica
Commonwealth Diagnostics Intl. Inc.	Danone Nutricia Research	Ironwood Pharmaceuticals
Nestle Health Science	Salix Pharmaceuticals	Sanofi
Takeda Pharmaceuticals	Yangtze River	

### ACADEMIC ADVISORY COUNCIL

American Gastroenterological Association	International Foundation for Gastrointestinal Disorders
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## ROME FOUNDATION - PRESIDENT AND BOARD CONTINUED...



### **Douglas A. Drossman, MD, RFF** **President Emeritus & Chief Operating Officer, Rome Foundation**

**Professor Emeritus of Medicine and Psychiatry**  
**UNC Center for Functional GI and Motility Disorders**  
**University of North Carolina**  
**Center for Education and Practice of Biopsychosocial Patient Care and Drossman Gastroenterology**  
**Chapel Hill, NC, USA**

Dr. Drossman received his M.D. degree at Albert Einstein College of Medicine and obtained his medical residency at the University of North Carolina School of Medicine and NYU – Bellevue Medical Center. He subspecialized in psychosocial (psychosomatic) medicine at the University of Rochester School of Medicine and in Gastroenterology at the University of North Carolina.

In 2012, Dr. Drossman founded the Drossman Center for the Education and Practice of Integrated, LLC care as an entity to help train physicians in relationship centered biopsychosocial care with emphasis on communication skills and enhancing the patient doctor relationship. Some focus is on the care of difficult to diagnose and manage patients with Disorders of Gut-Brain Interaction such as IBS.

Dr. Drossman is Professor Emeritus of Medicine and Psychiatry at the University of North Carolina School of Medicine where he was on staff from 1977 through 2011. He was founder and co-director of the UNC Center for Functional Gastrointestinal and Motility Disorders (since 1993). He was founder, past chair (1989-1993) and newsletter editor of the Functional Brain-Gut Research Group of the AGA, Chair (since 1989) of the Rome Committees (Rome I, II, III and IV) and President of the Board of the Rome Foundation (since 2004), past Chair of the Functional GI American Digestive Health Foundation's Digestive Health Initiative (1999-2001) and of the Motility and Nerve-Gut Section of the AGA Council (2003-2005). He is Past-President of the American Psychosomatic Society (1997), a Fellow of the American College of Physicians, a Master of the American College of Gastroenterology, and has been on the Board of Directors and Chair of the Scientific Advisory Board of the International Foundation for Functional GI Disorders (IFFGD). He has served on three committees of the

Institute of Medicine Committee on Gulf War and Health, has been an Ad Hoc member of NIH/NCCAM Advisory board, and is on the NIH-National Commission on Digestive Diseases.

Dr. Drossman has written over 500 articles and book chapters, has edited numerous books, a GI Procedure Manual, and textbook of Functional GI disorders (Rome I, II, III Rome IV, Primary Care Book, Understanding the Irritable Gut, and The Multi-Dimensional Clinical Profile), and serves on six editorial and advisory boards in Gastroenterology, psychosomatic medicine, behavioral medicine, and patient health. He served 5-years as Associate Editor of the journal Gastroenterology and was the Gastroenterology Section Editor of the Merck Manual for 17 years. Currently he is co-senior editor of Rome V to be released in 2026 and just wrote and published with Johannah Ruddy "Gut Feelings: Disorders of Gut-Brain Interaction and the Patient-Doctor Relationship."

Dr. Drossman's research relates to the clinical, epidemiological, psychosocial and treatment aspects of gastrointestinal disorders. He has developed and validated several assessment measures (e.g., illness severity and quality of life questionnaires for IBD and IBS, a physician-patient relationship questionnaire, and an abuse severity scale) for clinical research, is involved in psychosocial outcomes research, and has also studied brain imaging in IBS and abuse. He was principal investigator on several NIH sponsored research grants with over \$15,000,000 in funding. This included a multi-center grant for treatment (antidepressant and cognitive behavioral treatment) of the functional bowel disorders. He also consults with regulatory and pharmaceutical agencies regarding the design and evaluation of treatment trials. He is a recipient of the Janssen Award for Clinical Research (1999), the American

Psychosomatic Society President's Award (2003), the AGA Joseph B. Kirsner – Fiterman Award in Clinical Research (2005) the AGA Mentors Research Scholar Award (2007), and the American Journal of Gastroenterology Lectureship (2011). He has also received several "Who's Who", "Patient Choice" and "Best Doctors" citations over the past 15 years.

Dr. Drossman's educational and clinical interests relate to the psychosocial and behavioral aspects of patient care. He has produced numerous articles and videotapes on the biopsychosocial aspects of medical care, medical interviewing and the patient-doctor relationship, and received second prize at the 1997 AMA International Film Festival. As a Charter Fellow of the American Academy of Communication in Health Care, he facilitates workshops to develop clinical skills in patient-physician communication. He received the AGA Distinguished Educator Award (2004), received the American College of Gastroenterology David Sun Lecturer

Award (2012), was identified as a "Best Gastroenterologist" in Men's Health (2007) and in Woman's Health (2008) and is featured as one of 12 gastroenterologists in a book "Best Gastroenterology Practices" (2007). With regard to the Rome Foundation, Dr. Drossman was founder and currently serves as President of the Board. He has been editor in chief of Rome I, II and III books and currently of Rome IV published in 2016. The Rome IV project consists of 6 books available in print and e-book form and by subscription.

In June 2019, and after 29 years, Dr. Drossman stepped down as President and became President Emeritus and Chief of Operations of the Rome Foundation. His activities now include creative development, educational and communication programs, fund raising and marketing. He will also remain on the Executive Committee of the Rome Foundation Research Institute.



### **Giovanni Barbara, MD, RFF** **Associate Professor** **Department of Medical and Surgical Science** **University of Bologna** **Bologna, Italy**

Giovanni Barbara graduated Summa cum Laude in Medicine at the University of Bologna, Italy. He subsequently qualified in Internal Medicine and then in Gastroenterology at the same University. He was trained partly in London, UK and completed a three years basic science post-doctoral research fellowship in neuro-immunology at McMaster University in Canada. Currently, he is involved in clinical gastroenterology diagnostic and therapeutic endoscopy, teaching and research at the Department of Digestive Diseases and Internal Medicine of the University of Bologna (AD 1088).

Professor Barbara's main research interest relate to basic and clinical aspects of functional gastrointestinal disorders, neuroimmunology and host-microbiota interactions. He has

authored numerous indexed peer-reviewed articles and reviews on these topics, published in various biomedical journals, including Gastroenterology, Gut, Journal of Clinical Investigation and Trends in Pharmacological Science. He is, or has been, a member of the Editorial Board of Gut, American Journal of Gastroenterology, Neurogastroenterology and Motility, the American Journal of Physiology and other international scientific Journals.

Professor Barbara has received numerous national and international awards including the Master Award in Gastroenterology from the American Gastroenterological Association. He is currently President of the European Society of Neurogastroenterology and Motility (ESNM).

## ROME FOUNDATION - PRESIDENT AND BOARD CONTINUED...



### **Lin Chang, MD, RFF**

**Professor of Medicine**  
**Oppenheimer Center for Neurobiology of Stress**  
**Division of Digestive Diseases**  
**David Geffen School of Medicine at University of California, Los Angeles**  
**Los Angeles, CA, USA**

Lin Chang, MD, is a Professor of Medicine in the Division of Digestive Diseases, Department of Medicine at the David Geffen School of Medicine at UCLA. She serves as the Co-Director of the Oppenheimer Center for Neurobiology of Stress and Resilience at the David Geffen School of Medicine at UCLA. This center is an interdisciplinary research and education organization, dedicated to the study of brain-body interactions in health and disease. She is also Program Director of the UCLA Gastroenterology Fellowship Program and Director of the Digestive Health and Nutrition Clinic at UCLA. Dr. Chang's clinical expertise is in functional gastrointestinal disorders, which include irritable bowel syndrome (IBS), chronic constipation and functional dyspepsia. She is a funded NIH-investigator studying brain-gut interactions underlying IBS. Specifically, her research is focused on the pathophysiology of IBS related to stress, early life adversity, sex differences, and genetic and epigenetic factors, and gut microbiome and the treatment of IBS.

Dr. Chang is the recipient of the Janssen Award in Gastroenterology for Basic or Clinical Research and the AGA Distinguished Clinician Award. She is Past-President of the American Neurogastroenterology and Motility Society (ANMS). She served on the the Rome IV Editorial Board and the Functional Bowel Disorders Committee, as well as the liaison for three Rome IV committees: 1) Childhood Functional Gastrointestinal Disorders: Neonate/Toddler; 2) Age, Gender and Women's Health and the Patient; and 3) Multi-Cultural Aspects of Functional Gastrointestinal Disorders committees. Dr. Chang is currently a member of the Rome Communications Working Team. Dr. Chang is a fellow of the American Gastroenterological Association and American College of Gastroenterology, and a member of the Society for Neuroscience. She recently served as Associate Editor of the American Journal of Gastroenterology. Dr. Chang is a member of the FDA GI Drug Advisory Committee and the NIH Clinical, Integrative, Molecular Gastroenterology (CIMG) Study Section. She has authored more than 100 original research articles, 50 review articles, and 20 book chapters on her specialty interests.



### **William D. Chey, MD, FACG, AGAF, FACP, RFF**

**Timothy T. Nostrant Collegiate Professor of Gastroenterology**  
**Professor of Nutrition Sciences**  
**Director, Digestive Disorders Nutrition & Behavioral Health Program**  
**Director, Michigan Food for Life Kitchen**  
**Director, GI Physiology Laboratory**  
**Medical Director, Michigan Bowel Control Program**  
**Division of Gastroenterology | Michigan Medicine**

Dr. Chey received his BA degree from the University of Pennsylvania and medical degree & training in internal medicine at the Emory University School of Medicine. He completed a fellowship in gastroenterology and has remained on the faculty at the University of Michigan in Ann Arbor where he is currently the Timothy T. Nostrant

Collegiate Professor of Gastroenterology. He holds a joint appointment in the Department of Nutrition Sciences.

At Michigan, he has helped to create multiple innovative clinical programs including the Digestive Disorders Nutrition & Behavioral Health Program, the Michigan Food for Life

Kitchen, and Michigan Bowel Control Program. He is also the director of the GI Physiology Laboratory at Michigan Medicine.

His research interests focus on the diagnosis & treatment of disorders of gut-brain interaction and H. pylori infection. He is a medical innovator and entrepreneur, holding several patents. Dr. Chey has authored more than 400 manuscripts, reviews, chapters & books. He served as Co-Editor-in-Chief of the American Journal of Gastroenterology (2010-2015) and founding co-Editor of Clinical & Translational Gastroenterology (2011-2014). He is current Editor-in-Chief of Current Treatment Options in Gastroenterology. He has co-authored more than 10 national and international clinical practice guidelines by the ACG, AGA, ANMS, CAG, and Rome Foundation.

Dr. Chey is a board member of the American College of Gastroenterology, Rome Foundation, GI on Demand, and the International Foundation of GI Disorders.

Dr. Chey has received multiple awards including Michigan Medicine's League of Clinical Excellence, League of Research Excellence, the Dean's Outstanding Clinician Award and the Dean's Award for Innovation & Commercialization. He is a recipient of the Distinguished Clinician Award from the American Gastroenterological Association. In 2020, he was awarded honorary membership in the Academy of Nutrition & Dietetics and the Berk-Fise Award, the highest clinical honor bestowed by the American College of Gastroenterology.



### **Xiucui Fang, MD, RFF**

**Professor of Medicine**  
**Department of Gastroenterology**  
**Peking Union Medical College Hospital**  
**Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China**

Dr. Xiucui Fang is working in the Department of gastroenterology of Peking Union Medical College Hospital (PUMC hospital), Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China.

She graduated from Sun Yat-sen University of Medical Sciences in 1984, and completed her internship and residency training program in internal medicine in PUMC Hospital. From 1987 to 1990, she completed the Master program in internal medicine and gastroenterology at Peking Union Medical College. After that, she completed her fellowship in the gastroenterology, and worked in PUMC hospital as an attending physician (from 1990), associate professor (from 1995), full professor (from 2006). She was a visiting scholar of enteric nervous system team in the Ohio State University, USA (2002-2005). Dr. Fang's research is focused on irritable bowel syndrome and enteric nervous system.

Dr. Fang was the secretary (from 2000) and the vice chair (2007-2018) of the Chinese Society of Gastrointestinal

Motility. She served as a vice editor-in-chief or editor of Chinese Journals and peer-reviewed journals. She published more than 60 original research articles and six books on Functional Gastrointestinal Disorders (FGIDs).

In 2008, Dr. Xiucui Fang, together with Dr. Meiyun Ke, translated Rome III textbook into Chinese, making Rome III the first foreign language version of Rome textbook. She then introduced the Rome criteria in the Chinese Medical Tribune with the special column, whose activities spread the Rome criteria and related knowledge of FGIDs in China. Dr. Fang joined to the Rome IV team as a member of Multi-cultural Aspects of FGIDs Committee. In 2016, she organized Chinese colleagues to translate Rome IV textbook into Chinese, she is also a coeditor-in-chief of Chinese version of MDCP (second edition), and the principal reviewer of Chinese version DGBIs for Primary Care and Non-GI Clinicians. Dr. Fang is the fellow of Rome Foundation; she also served as the member of international liaison committee.

## ROME FOUNDATION - PRESIDENT AND BOARD CONTINUED...



### Laurie Keefer, PhD, RFF

Associate Professor of Gastroenterology and Psychiatry  
Icahn School of Medicine at Mount Sinai  
New York, NY, USA

Laurie Keefer, PhD, is a clinical health psychologist specializing in gastroenterology. She received her PhD from SUNY Albany in 2003 where she studied group-based cognitive therapy for IBS, and then continued her training as a resident and fellow in health psychology at Rush University in Chicago IL. In 2006, she set up one of the first fully integrated GI Psychology programs in the country at Northwestern University, where she was on the faculty for 10 years. During this time she built an NIH funded research program focused on the development and implementation of brain-gut psychotherapies for IBS, GERD and IBD and received the first NIH funded Training Grant (T32) for GI Physiology and Psychology, focused on preparing young professionals for careers in psychogastroenterology. She has held elected leadership positions in the field, including as a member of Council for the American Neurogastroenterology and Motility Society and as a Commissioner for the American Psychological Association's Commission for the Recognition

of Specialties and Proficiencies in Professional Psychology. Dr Keefer is Director of the Gaining Resilience through Transitions [GRITTTM]-IBD Program at the Icahn School of Medicine at Mount Sinai in NYC, overseeing a multidisciplinary team of clinicians and scientists to provide early, effective psychosocial care for high risk pediatric and adult patients with Inflammatory Bowel Diseases. Her current research program focuses on resilience and the application of positive psychology interventions in this population.

Prior to joining the Rome Board, Dr Keefer served as Co-Chair of the Rome IV Centrally mediated disorders of GI Pain Committee and Member of the Rome IV Psychosocial Committee. She is the founder and Director of the Rome Foundation's GastroPsych Group, focused on supporting and connecting clinicians and scientists around the world who seek to advance science and practice at the intersection of gastroenterology and psychology.



### Brian E. Lacy, MD, PhD, FACC, RFF

Senior Associate Consultant at Mayo Clinic  
Jacksonville, FL, USA

Brian E. Lacy, Ph.D., M.D., FACC is currently Consultant and Professor of Medicine at Mayo Clinic Jacksonville. He previously worked at the Dartmouth-Hitchcock Medical Center where he was Section Chief of Gastroenterology and Hepatology and Professor of Medicine at the Geisel School of Medicine at Dartmouth.

Dr. Lacy's clinical and basic science research interests focus on disorders of gastrointestinal motility, with an emphasis on irritable bowel syndrome, achalasia, dyspepsia,

gastroparesis, acid reflux disease, constipation, intestinal pseudo-obstruction and visceral pain. He is the author of 195 peer-reviewed articles on gastrointestinal motility disorders and functional bowel disorders, in addition to multiple text book chapters. Dr. Lacy is a reviewer for a number of scientific journals, and is a member of a number of different scientific organizations, including the American College of Gastroenterology, the American Gastroenterology Association, and the American Neurogastroenterology & Motility Society. Dr. Lacy is the co-author of a book for the

general public on acid reflux disease, "Healing Heartburn", is the author of "Making Sense of IBS", a book for the general public on irritable bowel syndrome, and edited and authored the books "Curbside Consultations in IBS", "Functional and Motility Disorders of the Gastrointestinal Tract" and "Essential Disorders of the Stomach and Small Intestine" for health care providers. Dr. Lacy is the current co-Editor in Chief of the American Journal of Gastroenterology. He is the former Editor in Chief of Clinical and Translational Gastroenterology. Dr. Lacy was the co-Chairman for the Rome IV Committee on Functional Bowel Disorders. He is on the

Board of Trustees for the Rome Committee and the American College of Gastroenterology.

Dr. Lacy received his doctorate in cell biology from Georgetown University in Washington, DC, and his medical degree from the University of Maryland in Baltimore. Dr. Lacy was a resident in Internal Medicine at the Dartmouth-Hitchcock Medical Center in Lebanon, NH, where he continued his training as Chief Resident and as a Fellow in Gastroenterology. He is board certified in Gastroenterology and Hepatology.



### Samuel Nurko, MD, MPH, RFF

Professor of Pediatrics  
Harvard Medical School  
Center for Motility and Functional Bowel Disorders  
Boston Children's Hospital  
Boston, Massachusetts, United States

Samuel Nurko, MD, MPH, is a Professor of Pediatrics at Harvard Medical School, and Director of the Center for Motility and Functional Bowel Disorders at Boston Children's Hospital. He was born and raised in Mexico City where he completed his medical education at the Universidad Nacional Autonoma de Mexico. He moved to the U.S. in 1981 for his pediatric residency at Boston City hospital and Massachusetts General Hospital and later completed his fellowship in pediatric gastroenterology at Boston Children's Hospital. After his fellowship, he returned to Mexico for 5 years and worked at the Hospital Infantil de Mexico, devoting his efforts to developing effective and affordable treatments for children with severe malnutrition and diarrhea. He designed new, inexpensive and culturally acceptable formulas that are still having an impact on children today. In 1993 he returned to the US to create the Center for Motility and Functional Bowel Disorders. This multidisciplinary center provides state of the art care for children, and patients travel from the US and the world to benefit from the center's innovative techniques and multidisciplinary approaches for diagnosing and treating motility and functional GI disorders. Dr. Nurko has significant experience and expertise in the physiology of gastrointestinal

motility, defecation problems and gastrointestinal pain, and in the application of gastrointestinal motility testing to understanding the pathophysiology of gastrointestinal disease in children, as well as in the design and conduct of prospective randomized trials.

Dr. Nurko has also distinguished himself during his long tenure as an academic, NIH-funded clinical researcher, teacher, expert and mentor in the field. Dr. Nurko has a long-standing interest, and dedication to patient oriented research. Dr. Nurko has written more than 230 manuscripts, reviews and book chapters. He has participated in the establishment of standards for motility procedures through the ANMS, and established training guidelines for motility procedures through NASPGHAN (North American Society for Pediatric Gastroenterology, Hepatology and Nutrition). He has participated in the establishment of international-based guidelines for the treatment of constipation in children, and was chair of the Rome IV Neonatal and Toddler Functional Gastrointestinal Disorders Committee. He was Associate Editor of the Journal of Pediatric Gastroenterology and Nutrition and founder and first chairman of the

## ROME FOUNDATION - PRESIDENT AND BOARD CONTINUED...

Neurogastroenterology Committee of NASPGHAN. He has been recipient of the Senior investigator Award from IFFGD (International Foundation for Functional and Gastrointestinal Diseases), as well as the Research Mentor Award from the AGA Council Growth, Development & Child Health. Recently he was portrayed in the Major Motion Picture "Miracles from Heaven."

Dr. Nurko has been very active in fostering education in Latin America. He has written extensively in Spanish and frequently participates in medical meetings in Latin America. He works closely with minority pre-med students. He's been formally recognized by the Hispanic community and received a diploma from Mayor Menino in honor of his service to the Latin community of Boston. He has also been recipient of the Milagros para Niños award for clinical excellence.



### Max J. Schmulson W., MD, RFF

Professor of Medicine

Facultad de Medicina

Universidad Nacional Autónoma de México (UNAM)

Laboratorio de Hígado, Páncreas y Motilidad (HIPAM)

Unidad de Investigación en Medicina Experimental

Mexico City, D.F., Mexico

Dr. Schmulson was born in Barranquilla-Colombia and received his MD degree from the Pontificia Universidad Javeriana of Santa Fe de Bogotá, where he then trained in Internal Medicine. After, he continued his Gastroenterology training in the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (INCMNSZ) in Mexico City, graduating with the award for the Best Residency-Graduation Thesis. He then worked in Los Angeles under the mentorship of Emeran Mayer in UCLA, focusing on the differences in symptoms, motility and visceral sensitivity of IBS patients according to the bowel habit predominance. Upon returning to Mexico he worked in the INCMNSZ for 6 years, and in 2005 he was appointed Full Professor of Medicine of the Universidad Nacional Autónoma de México (UNAM) and currently works in the Laboratory of Liver, Pancreas and Motility (HIPAM) of the Unit of Research in Experimental Medicine. Dr. Schmulson's research is focused on the epidemiology of FGIDs and in the immunological factors associated with IBS. He also works in Clínica Lomas Altas in Mexico City where he runs the Motility Unit and in the Gastroenterology and Endoscopy Group in the ABC Hospital. Dr. Schmulson has published more than 80 papers on peer-reviewed journals, 4 books and 48 book chapters on Functional Gastrointestinal Disorders. In 5 opportunities he has received the award "Dr. Abraham Ayala González"

and the Epidemiological Research from the Mexican Gastroenterological Association. He worked in the Latin American Consensus on IBS and coordinated the Latin American Consensus on Chronic Constipation. Dr. Schmulson previously served as Chair of the Membership Committee of the Functional Brain Gut Research Group and as Councillor as well. In 2006 he was one of the founders of the Latin American Society for Neurogastroenterology and served as the first President. He also served as Editor in Chief of the Revista de Gastroenterología de México from 2012-2014 and as Associated Editor of the American Journal of Gastroenterology from 2010-2015. He is a National Researcher (SNI-II) and a member of the National Academy of Medicine in Mexico.

Dr. Schmulson's work with the Rome Foundation includes the Spanish translation of the Rome II Modular Questionnaire and Rome III Adult Questionnaire, on the Management and Design of Treatment Trials Committee of the Rome CD Slide Set and serving as a charter member of the International Liaison Committee and as Chair from 2009 to 2013. He also served in the Multinational Working Team that released its report in 2014, in the Multi-Cultural Aspects and Design of Treatment Trials chapters of Rome IV and in the IBS Global Study Executive Committee.



### Magnus Simrén, MD, PhD, RFF

Professor of Gastroenterology

University of Gothenburg

Senior Consultant, Department of Internal Medicine

Sahlgrenska University Hospital

Gothenburg, Sweden

Dr. Magnus Simrén is working as Senior Consultant in the Department of Internal Medicine, Sahlgrenska University Hospital, Göteborg, Sweden, and is Professor in Gastroenterology at the Department of Internal Medicine & Clinical Nutrition, Institute of Medicine, Sahlgrenska Academy at the University of Gothenburg.

He graduated from medical school, University of Gothenburg in 1991, and afterwards completed his internship and fellowship in internal medicine at the County Hospital of Lidköping. From 1998 to 1999, Doctor Simrén completed his fellowship in gastroenterology at Sahlgrenska University Hospital. He defended his thesis entitled "Irritable Bowel Syndrome: Pathophysiological and clinical aspects" in 2001. He was a research fellow at the University of Leuven, Belgium, in 2002, focusing on the pathophysiology of functional dyspepsia and GERD.

Dr. Simrén is now head of the Neurogastroenterology Unit at Sahlgrenska University Hospital, and had a Senior Research position (50%) at the Swedish Research Council 2011-2016. His main research areas are the pathogenesis and pathophysiology of functional GI disorders, as well as the treatment of these disorders and the importance of brain-gut interactions. He has published more than

320 original articles and also written book chapters on GI motility diseases and functional GI disorders, and is currently supervisor for nineteen PhD students and several post-docs. Doctor Simrén has been the President of the Scandinavian Association for Gastrointestinal Motility (SAGIM), Scientific Secretary to the Swedish Society of Gastroenterology, and a served as council member for several international organizations. He is currently the chair of the United European Gastroenterology (UEG) Scientific Committee, and a member of the UEG council. He has been working as Deputy Editor and Associate Editor of Gut (2005-2009), and Clinical Editor of Neurogastroenterology and Motility (2012-2016). Doctor Simrén received the Rising Star Award from the Association of National European and Mediterranean Societies of Gastroenterology (ASNEMGE) in 2006, and has been a member of the Rome Foundation Board of Directors since 2011. From 2010-2012 he chaired the Rome Foundation Working team on "Intestinal microbiota in functional bowel disorders," and has served as a member of the Rome IV committees for Functional Bowel Disorders and Centrally Mediated Disorders of GI Pain. From 2015-2016 he was visiting research scientist at the Center for Functional GI and Motility Disorders, University of North Carolina (UNC), Chapel Hill, NC, United States, and he is now an adjunct professor at the Department of Medicine at UNC.

## ROME FOUNDATION - PRESIDENT AND BOARD CONTINUED...



**Ami Sperber, MD, MSPH, RFF**  
Emeritus Professor of Medicine  
Faculty of Health Sciences  
Ben-Gurion University of the Negev  
Beer-Sheva, Israel

Dr. Ami D. Sperber is Emeritus Professor of Medicine in the Faculty of Health Sciences of Ben-Gurion University of the Negev, Israel. He was born and raised in New York City and immigrated to Israel at the age of 23. In 1981 he received his MD degree in Israel and in 1992 he completed an MSPH (Master of Science in Public Health) degree from the Department of Health Behavior and Health Education in the School of Public Health of the University of North Carolina at Chapel Hill.

In addition to patient care, Dr. Sperber has conducted extensive research on IBS including (a) the local and global epidemiology of IBS and other FGIDs, (b) co-morbidity in DGBIs, in particular sleep impairment and fibromyalgia, and (c) psychosocial aspects of DGBIs. He is the author of a book, in Hebrew, on IBS for the general public in Israel, which emphasizes the biopsychosocial approach to diagnosis and treatment and presents an empathetic description of the disorder, its diagnosis and treatment. The book was translated into English and is available as an e-book on Amazon.

Dr. Sperber has led the Rome Foundation's global initiative since its inception. In 2011 he initiated and co-chaired the first international symposium on IBS-the Global Perspective. He chaired the RF Working Team on Multinational, Cross-cultural Research, which published its final report in January 2014 and has published three papers. Dr. Sperber was chair of the Rome IV chapter committee on Cross-cultural factors in DGBIs, and head of the committee that prepared the educational slide set on the psychosocial aspects of IBS, and head of the committee that prepared a clinical algorithm on the Functional Abdominal Pain Syndrome. He is the ongoing head of the Rome Foundation Translation Project and co-chair of the Copyright and Licensing Committee. Most recently, Dr. Sperber served as chair of Rome's Global Epidemiology Study, which has recently published results of a 26-country study on the global prevalence of DGBIs.

Dr. Sperber has published on cross-cultural, multinational research and translation methodology and been invited to speak on these and other topics at meetings around the world.

## Rome Foundation Administration



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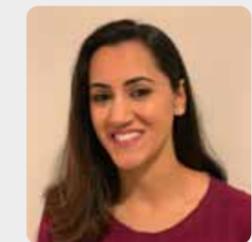
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Rome Research Institute, Research Assistant

# GLOBAL EPIDEMIOLOGY STUDY INITIATIVE

by Ami Sperber, MD



The Rome Board of Directors established a Global Committee, chaired by Dr. Ami Sperber, to coordinate all activities on the global level and to collaborate with other Rome Foundation committees such as the Education and Research committees.

Dr. Sperber has overseen multiple multi-cultural projects and working teams since 2014 within Rome Foundation.

## 1. IBS Global Perspective Conference

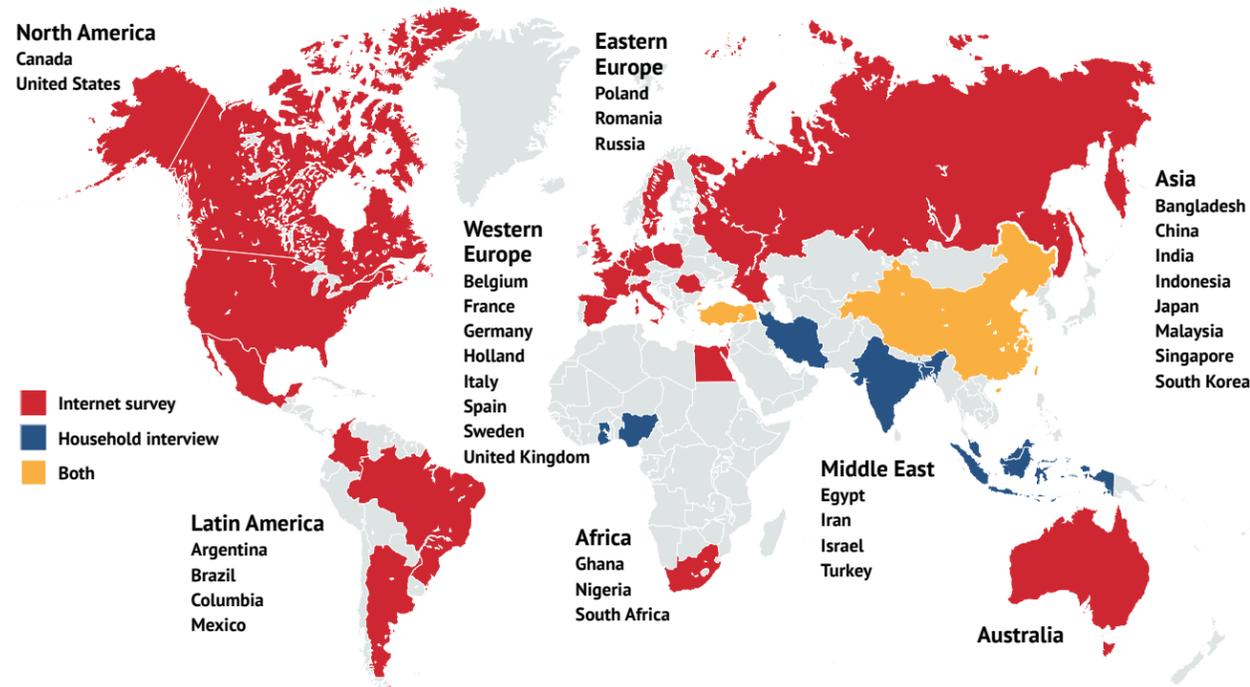
This conference, initiated by the RF and organized in collaboration with the WGO, was held in Milwaukee, WI in April 2011. It was co-chaired by Drs. Sperber and Eamonn Quigley. Over 100 participants from around the world, including gastroenterologists, psychologists, nurses, and other health care providers, attended the meeting. Among the aims of the meeting were to:

- Foster greater interest in the global aspects of IBS.
- Foster the development of cross-cultural competence in the clinical and research arenas.
- Foster international research networks and improve the quality of multinational research in IBS.
- A summary of the conference was published in the Red Section of AJG (Am J Gastroenterol 2012;107: 1602–1609). The article is online at [www.nature.com/ajg/journal/v107/n11/pdf/ajg2012106a.pdf](http://www.nature.com/ajg/journal/v107/n11/pdf/ajg2012106a.pdf).

## 2. RF Working Team on Cross-cultural, Multinational Research in FGIDs

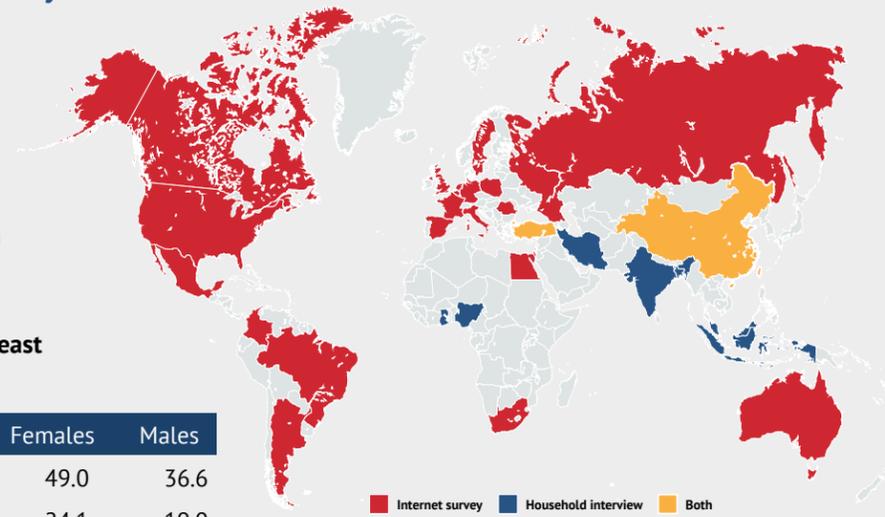
This working team, chaired by Dr. Sperber was comprised of 18 members and consultants from all around the world, completed its major task and published a final report in January 2014. This report is available for download at: [www.theromefoundation.org/working-teams-and-committees/multinational-committee/](http://www.theromefoundation.org/working-teams-and-committees/multinational-committee/).

It has also published three scientific papers in the medical literature. Please see the section of RF Working Teams for full details on this working team.



## A global epidemiological study of functional GI disorders

- 73,076 adults surveyed (33 countries, 6 continents)
- Data collection: By Internet (24 countries, red), by household interview (7 countries, blue), or both methods (China and Turkey, green)



### Prevalence of meeting criteria for at least one of 22 functional GI disorders (%):

	All Participants	Females	Males
Internet Surveys	42.7	49.0	36.6
Household Surveys	21.6	24.1	19.0

## 3. RF Asian Working Team

The Asian working team committee was chaired by Dr. Kok-Ann Gwee from Singapore and co-chaired by Dr. William E. Whitehead.

### The working team aims were to:

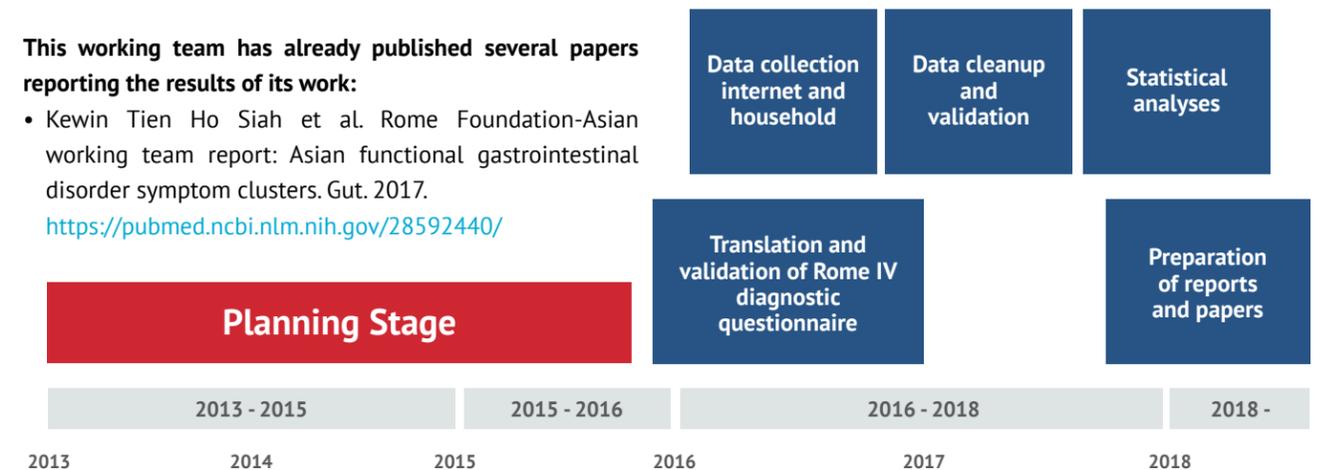
- Design a trans-Asian survey.
- Develop and validate translations of survey instruments in Asian languages.
- Carry out a survey of 200+ patients with a clinical diagnosis of IBS and 200+ with functional dyspepsia drawn from clinic sites in participating Asian countries.
- Develop and publish recommendations for Rome IV that are appropriate for Asian patients.

### This working team has already published several papers reporting the results of its work:

- Kewin Tien Ho Siah et al. Rome Foundation-Asian working team report: Asian functional gastrointestinal disorder symptom clusters. Gut. 2017. <https://pubmed.ncbi.nlm.nih.gov/28592440/>

- Lishou Xiong et al. Rome foundation Asian working team report: Real world treatment experience of Asian patients with functional bowel disorders. Journal of Clinical Gastroenterology and Hepatology. 2017. <https://pubmed.ncbi.nlm.nih.gov/28084664/>

The first global study paper was published in the January 2021 issue of Gastroenterology. Sperber AD, Bangdiwala SI, Drossman DA, Ghoshal UC, Simren M, Tack J, et al. Worldwide Prevalence and Burden of Functional Gastrointestinal Disorders, Results of Rome Foundation Global Study. Gastroenterology. 2021;160:99-114. [https://www.gastrojournal.org/article/S0016-5085\(20\)30487-X/fulltext](https://www.gastrojournal.org/article/S0016-5085(20)30487-X/fulltext)

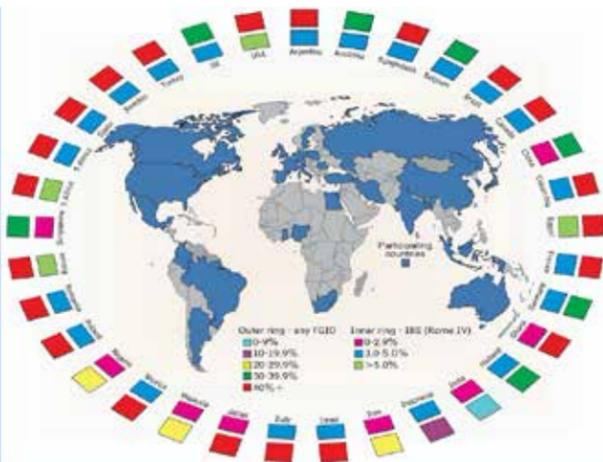


## GLOBAL EPIDEMIOLOGY STUDY INITIATIVE CONTINUED...

The data was collated by a biometry team, led by Drs. Kant Bangdiwala and Olafur Palsson. The first of many key publications is now in press in Gastroenterology, and it summarizes the prevalence of 22 Disorders of Gut-Brain Interaction across the globe and reports on their epidemiology and impact. Without the vision, persistence and motivational skills of Dr. Sperber, this would never have happened and the Rome Foundation as well as everybody working in or impacted by Disorders of Gut Brain Interaction is very grateful for this unique achievement.

Reference of the publication of the Global Epidemiology study: [https://www.gastrojournal.org/article/S0016-5085\(20\)30487-X/fulltext](https://www.gastrojournal.org/article/S0016-5085(20)30487-X/fulltext)

### Global study initial results for IBS and having any FGID, by country



Worldwide Prevalence of Functional GI Disorders

The global initiative database is now embedded in the Rome Foundation Research Institute database to allow data access and extraction for analysis, hypothesis generating and patient phenotyping for future research purposes. The full database consists of the answers to more than 170 questions by 73,076 adults from 33 countries. In each country, they closely match the composition and demographic characteristics of the adult population. The Rome Foundation Research Institute has developed a Policy and Procedures for Access to the Database, Conduct of Data Analyses, and Publications on the data. Doing so will ensure that more publications follow from this unique dataset, to further advance the scientific basis for understanding and managing Disorders of Gut-Brain Interaction. Further information on access to the database can be found on the website: <https://theromefoundation.org/research-institute-rome-foundation/rome-foundation-global-epidemiology-study/>.

## ACTIVE COMMITTEES

### International Liaison Committee

The International Liaison Committee (ILC) of the Rome Foundation aims to expand its activities globally to help improve the life of patients with functional gastrointestinal disorders of gut-brain interaction (DGBI). This is done by assisting in several ways: a) global dissemination of Rome educational materials and activities, b) setting up liaisons with regional organizations, c) motivating young researchers globally to study DGBI and mentoring them, d) increasing awareness through educational and scientific activities, and e) initiating multinational and cross cultural research and publications. Our efforts are promoted worldwide with greater attention to geographical areas where these activities are lacking and where DGBI are not sufficiently

recognized and would require proper social and health support. A new ILC initiative is a project to learn about the different diagnostic pathways and therapeutic approaches used for DGBI in different areas of the world. This will be conducted based on ad hoc surveys and the information obtained from the use of the Rome IV Interactive Clinical Decision Toolkit (GI Genuus). A second ILC initiative is to identify in any specific socio-cultural area students, fellows, and junior faculty with a potential interest in DGBI, and to advance their knowledge and commitment. It is envisaged that these initiatives will help to establish country-based educational programs for physicians and other care givers of patients with DGBI.

The ILC is chaired by **Enrico Stefano Corazziari** (Italy), and other members include, **Dan Dumitrascu** (Romania), **Xiucui Fang** (China), **Carlos Francisoni** (Brazil), **Shin Fukudo** (Japan), **Uday C Ghoshal** (India), **Carolina Olano** (Uruguay), and **Ami Sperber** (Israel). **Max Schmulson** (Mexico) serves as the liaison between the ILC and the Board of Directors of the Rome Foundation.



**Enrico Stefano Corazziari, MD** | Chair  
Senior Consultant  
Department of Gastroenterology  
Clinical Institute Humanitas  
Rozzano, Milan, Italy



**Dan Dumitrascu, MD, PhD**  
2nd Medical Department  
of Internal Medicine  
University of Medicine  
and Pharmacy  
Cluj-Napoca, Romania



**Xiucui Fang, MD**  
Professor of Medicine  
Department of Gastroenterology  
Peking Union Medical College Hospital  
Chinese Academy of Medical Sciences  
and Peking Union Medical College  
Beijing, China



**Carlos Francisoni, MD**  
Hospital de Clínicas de  
Porto Alegre  
Porto Alegre, Brazil



**Shin Fukudo, MD, PhD**  
Department of Behavioral  
Medicine  
Tohoku University Graduate  
School of Medicine  
Seiryu Aoba, Japan



**Uday C. Ghoshal, MD**  
Department of Gastroenterology  
Sanjay Gandhi Postgraduate  
Institute of Medical Sciences  
(SGPGI)  
Lucknow, India



**Carolina Olano, MD, MSc**  
Universidad de la  
República de Uruguay  
Clínica de  
Gastroenterología  
Uruguay



**Max J. Schmulson W., MD**  
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Páncreas y Motilidad (HIPAM)  
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**Ami Sperber, MD, MSPHM**  
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**COMMUNICATION 101.5**

**ROME FOUNDATION**

## Rome Psychogastroenterology Group

The Rome Psychogastroenterology Group was formed by US-based GI clinical health psychologists Laurie Keefer, PhD and Sarah Kinsinger, PhD, ABPP in 2018 based on a need to connect and support an emerging, international group of professionals interested in the clinical and scientific intersection of psychology and gastroenterology. Supported by the Rome Foundation Board, our mission is to: 1) promote the use of evidence based behavioral treatments for GI disorders internationally; 2) encourage development of interdisciplinary psychosocial GI programs in gastroenterology practices through expert consultation and lectureships; 3) connect with national and international GI organizations to enhance the visibility of GI Psychology providers and encourage collaboration; and 4) expand our field into previously understudied areas of psychogastroenterology (e.g. inflammatory bowel diseases, chronic pancreatitis).

### ABOUT OUR MEMBERSHIP

Over the past 2 years, our group has expanded to almost 400 members from around the world! About 30% of our membership is within 5 years of training and are therefore a priority for us to ensure they remain connected in this specialization. About 20% of the membership is outside of the US and we are excited to focus on increasing our international reach in 2021. About 70% of our membership our doctoral level psychologists. To become a member, please register on our website at <https://romegipsych.org/register/> or email at [gastropsych@gmail.com](mailto:gastropsych@gmail.com) for more information.

### Benefits of free membership include:

- Access to a robust set of shared materials for mental health professionals, including treatment manuals, slide decks, patient and provider handouts
- A profile in the searchable Rome GastroPsych membership directory, connecting professionals and

- patients around the world.
- Access to a robust list-serv focused on professional and clinical issues in GI Psych
- Access to regional and topically-based peer consultation and support groups
- Early career program which includes special programming and an early career list-serv
  - Email Livia (International) or Meredith (US)
- Opportunities for research collaboration and mentorship



Committee Chair:  
Sarah Kinsinger, PhD



Committee Chair:  
Laurie Keefer, PhD

### OUR EDUCATIONAL MISSION

We are the first organization dedicated to training, quality improvement and promotion of research and practice in PsychoGastroenterology. A key mission of our organization is to develop and offer high quality training opportunities for multidisciplinary GI providers on the science and practice of psychological treatments for digestive disorders. Rome Psychogastroenterology is approved as a continuing education sponsor through the American Psychological Association, allowing us to offer continuing education (CE) credits to psychologists who participate in our live and on demand courses.

### We offer:

- CE workshops for mental health providers at 3 levels: Basic Skills, Intermediate Skills and Advanced Training
- A library of on-demand CE training videos
- Virtual clinical case conferences and webinars
- Consultation for clinicians, investigators and practice administrators interested in developing GI Psych programs locally
- Visiting GastroPsych scholarships

Follow us on Twitter  
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## Rome Foundation Pediatric Committee

The Rome Foundation Pediatric Committee provides the structure to foster and further develop the pediatric GI components of the Rome Foundation that will inform education, research and pediatric patient care. Since the development of the pediatric Rome criteria in 1999 there has been a major increase in their recognition and research related to it. The Rome Foundation has been supportive and instrumental in the development of pediatric criteria. It has already invested in the development of pediatric criteria, diagnostic, treatment algorithms, and relevant position papers. Using these developments as a launching point, it has become clear that it is now necessary to further expand the efforts in the pediatric field. This include education, research and therapies for pediatric DGBI allowing for both specialists as well as general practitioners, pediatricians, nurse practitioners, physician assistants to be able to recognize the disorders and provide better therapy.



Committee Chair:  
Samuel Nurko, MD, MPH, RFF



Committee Chair:  
Miguel Saps, MD

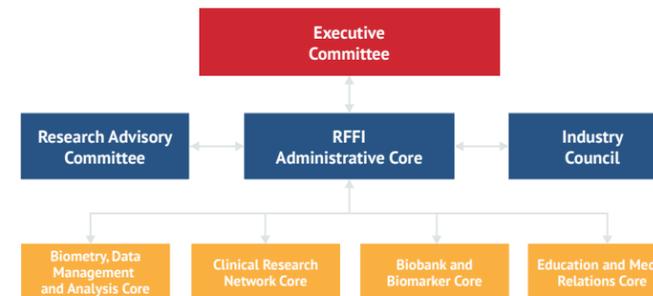


Magnus Simrén, MD, PhD  
Rome Foundation Research  
Institute Director

The Rome Foundation Research Institute (RFRI) is a subsidiary organization of the Rome Foundation. It was created in 2018 to advance the scientific understanding of Disorders of Gut-Brain Interaction. The RFRI is a semi-autonomous entity that aims to conduct and support research on DGBI, and to be a global leader in this area of knowledge. Its mission is to improve the lives of patients with DGBI through groundbreaking research. The RFRI focuses on the following objectives to:

- Develop a centralized data acquisition and research coordinating center for DGBIs.
- Serve as an international clearinghouse for investigators and industry in the development, administration, and analysis of clinical research in DGBIs.

Develop a portfolio of current and future study protocols and an accessible database of knowledge that can be adapted to address specific questions regarding DGBIs pathophysiology, impact, diagnosis, and treatment.



### RFRI studies and activities.

Over the past year, the RFRI identified a Global Research Network of leading and highly productive investigators in the DGBI domain. The RFRI also engaged in several ongoing and planned research studies. These include the development of data analysis of the Rome Foundation Global Epidemiology



Study, implementation of several clinical trials: the Domino and ROBOT studies, and a research project on bloating with Danone Pharmaceuticals. There are ongoing interactions with other companies on additional research projects. Below is a more detailed description of these studies.

### Creation of the Global Research Network.

An essential part of the mission of the RFRI is to establish an active Global Research Network of leading and highly productive investigators in the DGBI domain. These centers will coordinate their research efforts to produce compatible clinical datasets and biological samples on large numbers of DGBI patients. The centers will operate with a sufficiently uniform research methodology to make multi-center and multi-national research studies possible. To date, 91 investigators in 33 countries expressed their keen interest in joining the network (see figure 2). Many core centers will implement these aims in the ROBOT trial (see below).

The full dataset of the Global Epidemiology Study is now integrated with the RFRI. These data will be a source for data extraction and further analyses and will also be integrated with other databases the RFRI is acquiring. The investigators of the global study also form a worldwide network of FGID experts with a track record of research collaboration on a



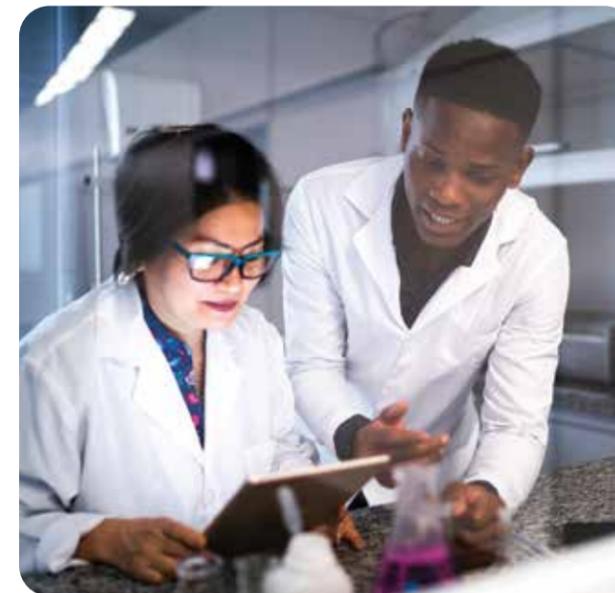
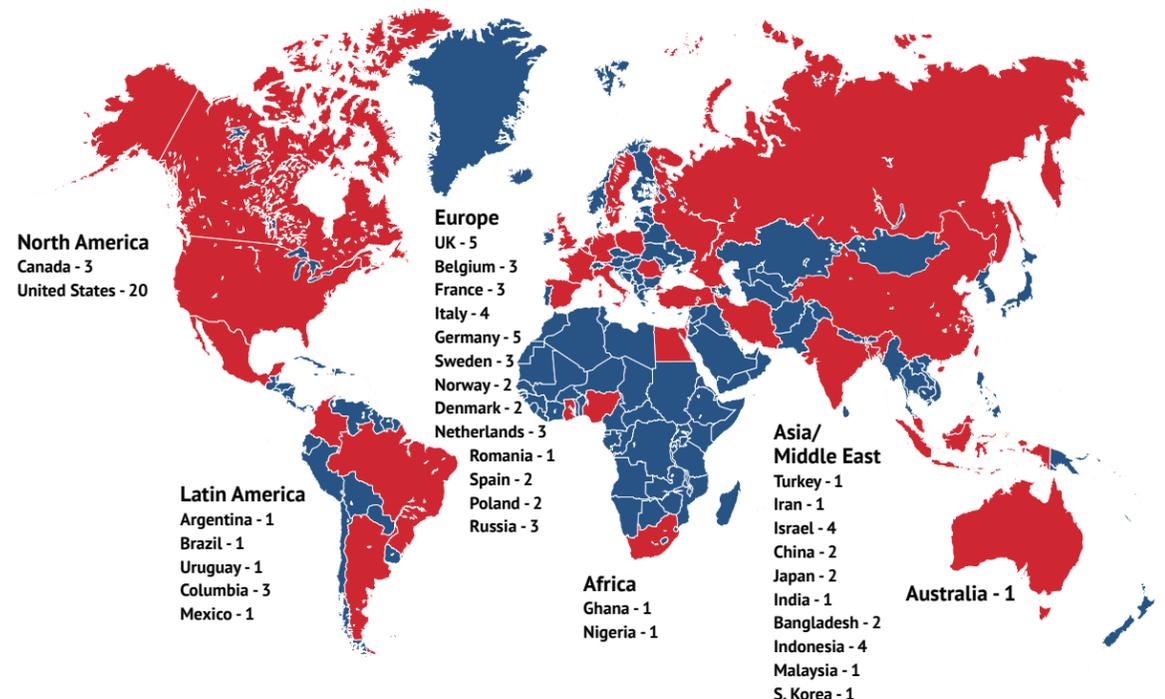
worldwide scale. The repository of translated versions of the Rome IV adult diagnostic questionnaire in the multiple languages used for the global study, including their linguistic validation (cognitive debriefing) and cultural adaptation, is an essential asset for future research efforts involving international participation.

**Domino Trial**

The DOMINO trial (Diet Or Medication in Irritable bowel syndrome) is a randomized study designed to evaluate the short-term efficacy and long-term health economic impact of a dietary intervention compared to pharmacotherapy with a musculotropic spasmolytic agent for newly diagnosed or newly treated irritable bowel syndrome in primary care. This trial is funded by the Belgian Government, is pragmatic, and aims at optimizing primary care. It uses questionnaires that were developed for the Rome IV Global Epidemiology study in Belgium and also serves as an opportunity to collect biobank material from primary care IBS patients. Patients are

randomized to treatment with OB 60 mg t.i.d., the traditional first-line medical therapy for IBS in Belgium, or by a FODMAP lowering diet, provided via a new smartphone application. Before and after 8 weeks of treatment, patients completed questionnaires evaluating demographics, stool types, Rome IV criteria, IBS-Symptom Severity (IBS-SSS), anxiety (GAD), depression (PHQ9) and somatization (PHQ15). By the end of 2019, the targeted 470 patients were enrolled, and 95% of the subjects provided biobanking samples for genetics, serum, and stool analysis. Patients with an improvement of at least 50 points on IBS-SSS are considered a responder. At baseline, 71% of these primary care-diagnosed IBS patients fulfill the Rome 4 criteria. (74% female, mean age 42±0.9 years, and mean BMI of 24±0.3). The following IBS-SSS distribution was found: 4, 16, 41, 39 % for normal, mild, moderate, and severe IBS-SSS, respectively. Patients were characterized according to the stool pattern: diarrhea (27%), constipation (23%), mixed stool type (38%) and normal (12%). The initial results of the study will be submitted for presentation at UEGW 2020.

**World Distribution of RFRI Investigators**  
91 investigators in 33 countries



**ROBOT Project**

The RFRI is initiating the ROME foundation BiOmarker and phenotyping project (ROBOT) in the first half of 2020. Initially, the study will start in a limited number of sites, to expand to more sites over the coming years. The ROBOT aims to develop a state-of-the-art biobank and database of patients with all types of DGBI, recruited from an international network of top international research sites. Patients in the database are thoroughly characterized in terms of clinical phenotype and associated demographic, medical history, psychosocial and lifestyle factors. Also, fecal, blood, and urine samples are collected and stored in a standardized fashion using common standard operational procedures. From a subset of patients, also biopsies from the upper and/or lower GI tract are collected depending on the predominant symptom profile. This growing collection of bio-samples and clinical/demographic data will enable evaluation of different biomarkers in large groups of very well-characterized individuals from different parts of the world and assessment of their validity for use as diagnostic and /or predictive tools. A centralized electronic database will enable easy study of profiles of available clinical phenotypes and identification of available bio-samples to assess the feasibility of new research or analyses.

**RFRI - Bloating Survey**

This study focuses on symptoms of bloating and distention in the general population, acquiring data via a nationwide population-based Internet survey of adults in three countries: United States, Mexico and United Kingdom (2000 survey completers in each country). Quota-based sampling will be applied to obtain survey samples with the same age and sex groups composition in each country: 50% females and 50% males; 40% individuals of ages 18-39 years, 40% of ages 40-64 years, and 20% ages 65 and older. The subject sample in each country will also have nationwide geographic distribution.

The project research protocol is designed collaboratively by the RFRI and Danone, is subsidized by Danone, and is scheduled to be initiated in the second half of 2020. The a priori hypotheses to be evaluated are: (a) different personal factors and symptoms characterize the subset of individuals who report bloating or distention compared to those without these symptoms; (b) certain personal factors and symptoms distinguish bloating from distension that may reflect different pathophysiologic mechanisms; and (c) subgroups of individuals meeting Rome IV diagnostic criteria for Functional Abdominal Bloating/Distention will report only bloating or only distention and have different associated characteristics. Evaluation of data pertinent to the last hypothesis may yield identification of characteristic clinical features warranting subtyping of patients that may be amenable to different, more specific forms of treatment. Additionally, a sub-study in 1500 subjects (500 from each country) will address the relationship of bloating and/or distention symptoms with dietary factors in detail. The findings are also likely to help guide future refinement of the Rome diagnostic criteria for functional bloating and distention.



## COPYRIGHT AND LICENSING COMMITTEE



**Olafur Palsson PsyD**  
Copyright and Licensing  
Data Manager



**Iram Haq, MPH**  
Rome Research Institute,  
Research Assistant

The Rome Foundation has long offered research questionnaires for licensing, which are increasingly in demand internationally by a large number of pharmaceutical companies, clinical research organizations and medical education providers, including universities and colleges among others, as well as by individual researchers. Recently the list of instruments the Rome Foundation has available has expanded significantly because we are acquiring an increasing number of copyrights, translations and localizations of the various questionnaires for international research use. Because of this, our licensing program has grown exponentially in the last few years, to a point where it is now helping to sustain the Foundation and support its mission in addition to meeting the needs of the international research communities.

Among the most commonly requested questionnaires for licensing over the past couple of years have been the Bristol Stool Form Scale (BSFS), the IBS Severity Scale Score (IBS-SSS), and the IBS Quality of Life instrument (QOL), and of course the adult and pediatric Rome IV diagnostic questionnaires. We have recently added the Global Improvement Scale (GIS), Patient Education Needs Questionnaire (PEQ), Bristol Stool Form Scale-Pediatric (BSFS-PED), and the IBS Patient-Physician Relationship Survey (PPRS). Many of these instruments are already in stock in a wide variety of language and country adaptations. For example, the Bristol Stool Form Scale can now be obtained from the Rome Foundation in 107 different translations and country adaptations. Further, when a questionnaire in the

foundation's portfolio is needed in a language or country localization that is not already available, the Copyright and Licensing Committee can offer step-by-step guidance for getting such translations or adaptations done responsibly and professionally.

If you are a researcher, academician, clinician or student looking for validated research questionnaires in the functional GI area, your first stop should be the Rome copyright and licensing page, where you will see on our newly revised web form a list of the questionnaires you can obtain, and where you can directly request exactly what you need: <https://theromefoundation.org/products/copyright-and-licensing/>

Licensing questionnaires from the Rome Foundation will require a licensing fee if you have funding for your project in the way of internal, grant or sponsorship (for example, if you need the instruments for a grant-funded research study or for commercial purposes). If you have no such funding, there is no fee for use of the questionnaires except a standard processing fee. Note, however, that you must have a license in order to use any and all of the questionnaires that the Rome Foundation offers, even if you are only going to use them in an unfunded project. We have a modest fee for Rome Foundation's review of the screen shots if administered digitally to assure their accuracy.

We hope that you will take advantage of our ever-expanding resource of the Rome Foundation's questionnaire collection, and we strive to make the process of obtaining these instruments as efficient and helpful as possible. We look forward to hearing from you and helping you with your questionnaire needs!

Mark Schmitter, Marketing/Copyrights and Licensing Director oversees and administers all licensing requests for the Foundation. Copyright and Licensing committee members are Ami Sperber, Director of Translations and Douglas Drossman as Co-Chairs, Olafur Palsson as Chief of Operations and Iram Haq serves as the Copyright and Licensing Coordinator.

## ROME CRITERIA: SETTING THE STAGE FOR RESEARCH IN THE 21ST CENTURY

The Rome Foundation has carried many roles since its inception but perhaps most important is its influence on the field relating to the genesis and maturation of disorders of gut-brain interaction (DGBI). Since Rome IV was published in 2016, we have been systematically replacing "functional GI disorders – FGID" with DGBI because it is a more scientifically based description of these disorder and is less stigmatizing.

	"Organic" GI disorder	Motility disorder	Disorders of Gut-Brain Interaction
Primary domain	Organ morphology	Organ function	Illness experience
Criterion	Pathology (disease)	Altered motility	Symptoms
Measurement	Histology Pathology Endoscopy Radiology	Motility Visceral sensitivity	Motility Visceral sensitivity Symptom criteria (Rome) Psychometric
Treatment options	Medications Surgery Ther. endoscopy	Pro / anti-kinetics Surgery Pacing / Stimulator	Pro / anti-kinetics Neuromodulators Behavioral
Examples	Esophagitis Peptic ulcer IBD Colon cancer	Diffuse esoph. spasm Gastroparesis Pseudo-obstruction Colonic inertia	Esophageal chest pain Functional dyspepsia IBS Centrally mediated abdominal pain

Figure 11

To understand this, we must be clear on the distinction regarding classification of the various gastrointestinal disorders. As shown in Figure 11, we have traditionally defined disorders based on evident pathology (organic GI disorder), altered motility (motility disorder) or symptoms (functional GI disorder, using the original term). The Rome Foundation in developing and promoting the use of symptom-based criteria have in effect created the concept of functional GI disorders, now called more appropriately disorders of gut-brain interaction<sup>1</sup>. Historically the functional GI disorders had their genesis almost 30 years ago (Figure 12) when a symptom-based classification system developed. While gastrointestinal symptoms have been reported by individuals for millennia, the classification into syndromes

first began with research on GI motility in the 1940's and 1950's. At this time notable GI physiologists like Stuart Wolf and Tom Almy<sup>2,3</sup> attempted to correlate gut motility changes with symptoms. Motility research was dominant in the latter half of the 20th century. However, by the late 1980's it was becoming evident that motility alone was not sufficient to explain GI symptoms or symptom-based disorders. A breakthrough occurred around 1990 with two new entries into the field. First was the research by William Whitehead<sup>4,5</sup>, Emeran Mayer<sup>6</sup>, and others who began to report the concept of visceral hypersensitivity, i.e., characterizing pain reports by what later was recognized as augmented afferent signaling rather than motility. The second was the classification system for functional GI disorders published in 1990 which evolved into the Rome Criteria. This symptom-based classification categorized patients with various symptom patterns into diagnoses that were amenable to many research models as shown in Figure 12. This has had a major impact on our scientific understanding of these disorders. Currently the Rome criteria are used by regulatory agencies, investigators and clinicians around the world.

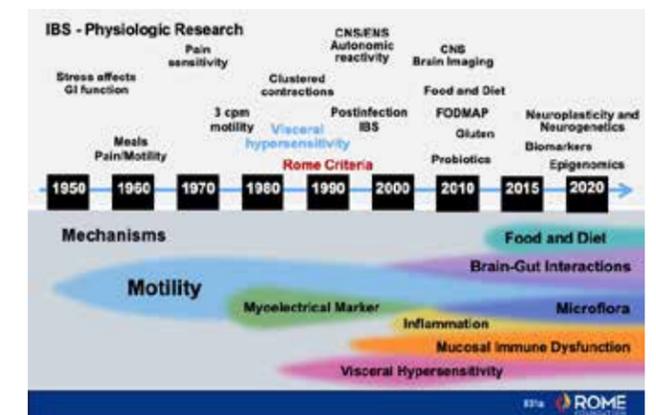


Figure 12

**Reference List**

1. Drossman DA, Functional Gastrointestinal Disorders: History, Pathophysiology, Clinical Features and Rome IV, *Gastroenterol* 2016;126:2-1279.
2. Almy T P. Experimental studies on the irritable colon. *Am J Med* 1951;10:60.
3. Wolf S, Almy T P. Experimental observations on cardiospasm in man. *Gastroenterol* 1949;13:401-421.
4. Whitehead W E, Holtkotter B, Enck P, Hoelzl R, Holmes K D, Anthony J, Shabsin H S, Schuster M M. Tolerance for rectosigmoid distention in irritable bowel syndrome. *Gastroenterol* 1990;98:1187-1192.
5. Mayer E A, Raybould HE. Role of visceral afferent mechanisms in functional bowel disorders. *Gastroenterol* 1990;99:1688-1704.
6. Drossman D A, Thompson W G, Talley N J, Funch-Jensen P, Janssens J, Whitehead W E. Identification of subgroups of functional bowel disorders. *Gastroenterology International* 1990;3:159-172.

## RESEARCH PROGRAMS AWARDS

The Rome Foundation has sponsored research by young investigators since 2007. The goals of the research program, chaired by Magnus Simren, MD, PhD, are two: (1) to increase knowledge of the epidemiology and pathophysiology of the Disorders of Gut-Brain Interaction (DGBI); and (2) to interest young investigators in research and clinical practice in the area of Disorders of Gut-Brain Interaction (DGBI) and motility disorders.

### Rome—AGA Research Award

The Research Committee is charged with developing guidelines for an annual research award program, overseeing the process of soliciting applications and reviewing them, and monitoring the progress of grants awarded through semiannual reports from awardees. Through a partnership with the American Gastroenterological Association, we awarded two grants of up to \$50,000 annually to postdoctoral research fellows, junior faculty, or established investigators seeking to develop new areas of research. 2020 was the last year for this joint grant collaboration.

#### 2020 – TWO AWARDS

**Principal Investigator: Nitin K. Ahuja, MD, MS**

Title: Shifts in the Gut Microbiome Following Dietary Modification in Irritable Bowel Syndrome

**Principal Investigator: Bindu Chandrasekharan, PhD**

Title: Investigating the efficacy of probiotics to address opioid-induced constipation

#### 2019 – TWO AWARDS

**Principal Investigator: Joan W. Chen, MD**

Title: Single-Arm Pilot Trial of Digital Cognitive Behavioral Therapy in Gastroesophageal Reflux Disease Patients with Insomnia

**Principal Investigator: Arpana Gupta, PhD**

Title: Cognitive Behavioral Therapy Leads to Bidirectional Changes in Brain-Gut Axis for Obesity

#### 2018 – TWO AWARDS

**Principal Investigator: Faranak Fattahi, PhD**

Title: Modeling diabetic gastroparesis using human pluripotent stem cells.

**Principal Investigator: Shaoyong Yu, MD**

Title: Expression and function of an “Itch” receptor MrgprC11 in sensory afferent neurons in the GI tract.

#### 2017 – TWO AWARDS

**Principal Investigator: Giuseppe Cipriani, PhD (USA)**

The contribution of circulating monocytes on gastric muscularis propria in the development of diabetic gastroparesis.

**Principal Investigator: Geoffrey Preidis, MD, PhD (USA)**

Title: Bile Acid Receptor Mediated Dysmotility in Protein-Energy Undernutrition.

#### 2016 – TWO AWARDS

**Principal Investigator: Izumi Kaji, PhD (USA)**

Title: Enteric neural FFA3 activation regulates colonic motility.

**Principal Investigator: Ans Pauwels, MPharmSc, PhD (Belgium)**

Title: Is refractory gastro-esophageal reflux disease a disease spanning the organic-functional spectrum? Role of visceral hypersensitivity.

#### 2015 – TWO AWARDS

**Principal Investigator: Miranda van Tilburg, PhD (USA)**

Title: Validation of the pediatric Rome IV criteria.

**Principal Investigator: Madhusudan Grover MBBS (USA)**

Title: Barrier function alterations in post-infectious irritable bowel syndrome.

#### 2014 – TWO AWARDS

**Principal Investigator: Stacy Menees, MD, MS (USA)**

Title: A randomized controlled trial to assess the efficacy of the low FODMAP diet in patients with fecal incontinence and loose stools.

**Principal Investigator: Kok Ann Gwee, FAMS, FRCP, PhD (Singapore)**

Title: The Chinese and Caucasian Brain Study: A neuroanthropological evaluation of the ROME III criteria.

#### 2013

**Principal Investigator: Maria Vicario, PhD (Spain)**

Title: Identification of signaling pathways and active biological networks associated with the role of eosinophils in stress-induced exacerbations of IBS.

#### 2012

**Principal Investigator: Nicholas J. Talley, MD, PhD (Australia)**

Title: Usefulness of Rome III symptoms, psychological characteristics and cytokines in accurately diagnosing FGIDs.

#### 2011

**Principal Investigator: Lars Agreus, MD, PhD (Sweden)**

Title: Functional dyspepsia and functional heartburn: Natural history of symptoms in the general population and validity of Rome III upper gastrointestinal diagnostic criteria.

#### 2010

**Principal Investigator: Javier Santos Vicente, MD (Spain)**

Title: Role of mucosal eosinophils in the physiopathology of intestinal inflammation in irritable bowel syndrome.

#### 2009

**Principal Investigator: Miranda van Tilburg, PhD (USA)**

Title: Validation of the Child/Adolescent Rome III Criteria.

#### 2008

**Principal Investigator: Madhulika Varma, MD (USA)**

Title: Comprehensive validation of the Rome III constipation module.

### Ray Clouse Award for the Best Paper

The Rome Foundation established an award in memory of Ray E. Clouse, MD, a gastroenterologist and scholar at Washington University School of Medicine and a devoted member of the Rome Foundation. Ray's academic career spanned 27 years of research, teachings and writings that has left an indelible mark in the field of functional gastrointestinal and motility disorders and of gastroenterology in general.

The Rome Foundation will present a \$1000 prize to the first author of the best research article published in the field of Functional Gastrointestinal or Motility Disorders for the preceding calendar year. This prize will be presented at the current year's Rome Foundation Reception at DDW. The following individuals have been winners of the Ray Clouse Prize:

#### 2021

**Magdy El-Salhy, MD, PhD, et al.**

Title: Efficacy of fecal microbiota transplantation for patients with irritable bowel syndrome in a randomized, double-blind, placebo-controlled study. Gut. 2020 May;69(5):859-867

**Chamara Basnayake, MD, et al.**

Title: Standard gastroenterologist versus multidisciplinary treatment for functional gastrointestinal disorders (MANTRA): an open-label, single-center, randomized controlled trial. Lancet Gastroenterol Hepatol. 2020 Oct;5(10):890-899.

#### 2020

**Dr. Annette Fritscher-Ravens**

Title: Many Patients with Irritable Bowel Syndrome Have Atypical Food Allergies Not Associated with Immunoglobulin E. Gastroenterology. Fritscher-Ravens A, Pflaum T, Mösinger M, Ruchay Z, Röcken C, Milla PJ, Das M, Böttner M, Wedel T, Schuppan D. 2019 Jul;157(1):109-118.e5.

#### 2019

**Gry Irene Skodje, MD, (Norway)**

Title: Fructan, Rather Than Gluten, Induces Symptoms in Patients With Self-Reported Non-Celiac Gluten Sensitivity. Gastroenterology. 2018 Feb;154(3):529-539.e2

#### 2018

**Sara Botschuijver, MSc, (The Netherlands)**

Title: Intestinal Fungal Dysbiosis Is Associated With Visceral Hypersensitivity in Patients With Irritable Bowel Syndrome and Rats. Gastroenterology 2017;153:1026–1039.

## RESEARCH PROGRAMS AWARDS CONTINUED...

### 2017

#### Mira M. Wouters, PhD (Belgium)

Title: Histamine Receptor H1-Mediated Sensitization of TRPV1 Mediates Visceral Hypersensitivity and Symptoms in Patients With Irritable Bowel Syndrome. *Gastroenterology* 2016;150:875-887. PMID: 26752109.

### 2016

#### NJ Talley, MD, PhD (Australia)

Title: Effect of Amitriptyline and escitalopram on functional dyspepsia: a multicenter, randomized controlled study. *Gastroenterology* 2015;149:340-9. PMID: 25921377.

### 2015

#### Annette Fritscher-Ravens, MD, PhD (Germany)

Title: Confocal endomicroscopy shows food-associated changes in the intestinal mucosa of patients with irritable bowel syndrome. *Gastroenterology* 2014; 147:1012-20. PMID: 25083606.

### 2014 - TWO AWARDS

#### Kirsten Tillisch, MD (USA)

Title: Consumption of fermented milk product with probiotic modulates brain activity. *Gastroenterology* 2013;144:1394-401. PMID 23474283.

#### Maria Vazquez-Roque, MD (USA)

Title: A controlled trial of gluten-free diet in patients with irritable bowel syndrome-diarrhea: effects on bowel frequency and intestinal function. *Gastroenterology* 2013;144:903-11. PMID: 23357715.

### 2013

#### Mats B.O. Lowen (formerly Larsson), MD, PhD (Sweden)

Title: Brain responses to visceral stimuli reflect visceral sensitivity thresholds in patients with irritable bowel syndrome. *Gastroenterology* 2012;142:463-72. PMID: 22108191.

### 2012

#### Nathalie Bertiaux-Vandaele, (France)

Title: The expression and the cellular distribution of the tight junction proteins are altered in irritable bowel syndrome patients with differences according to the disease subtype. *Am J Gastroenterol* 2011;106:2165-73. PMID: 22008894.

### 2011 - TWO AWARDS

#### QiQi Zhou, MD, PhD (USA)

Title: MicroRNA-29a regulates intestinal membrane permeability in patients with irritable bowel syndrome. *Gut* 2010;59:775-84. PMID: 2891786.

#### Tamira K Klooker, MD (Netherlands)

Title: The mast cell stabilizer ketotifen decreases visceral hypersensitivity and improves intestinal symptoms in patients with irritable bowel syndrome. *Gut* 2010;59:1213-21. PMID: 20650926.

### 2010

#### Hanneke Beaumont, MD, PhD (Netherlands)

Title: The position of the acid pocket as a major risk factor for acidic reflux in healthy subjects and patients with GORD. *Gut* 2010;59:441-51. PMID: 19651625.

### 2009 - TWO AWARDS

#### Anurag Agrawal, PhD, MRCP (UK)

Title: Bloating and distention in irritable bowel syndrome: The role of visceral sensation. *Gastroenterology* 2008;134:1882-9. PMID: 18455167.

#### John E. Pandolfino, MD (USA)

Title: Achalasia: A new clinically relevant classification by high-resolution manometry. *Gastroenterology* 2008;135:1526-33. PMID: 18722376.

### 2008

#### Krisztina Gecse, MD (Hungary)

Title: Increased faecal serine protease activity in diarrhoeic IBS patients: a colonic luminal factor impairing colonic permeability and sensitivity. *Gut* 2008;57:591-9. PMID 18194983.

## Ken Heaton Award for Most Cited Paper

The Rome Foundation also offers a \$1000 prize for the most frequently cited research paper on functional gastrointestinal and motility disorders. This award is named in honor of the late Kenneth Heaton for his ground-breaking contributions to the development of positive diagnostic criteria for irritable bowel syndrome (the Manning Criteria) and the pathophysiology of constipation (the Bristol Stool Scale). Dr. Heaton (1936-2013) was a Consultant Physician at the Bristol Royal Infirmary, and Reader in Medicine at the University of Bristol. The Rome Foundation Board of Directors selects this paper based on the Science Citation Index, and the winner is announced at Digestive Disease Week.

Articles on functional gastrointestinal and motility disorders published from January to December in the penultimate year before DDW and indexed in PubMed will be evaluated. Note that there is a one-year lag between the publication of the paper and its consideration for the prize; this is to allow enough time for the paper to be recognized and cited. This \$1000 prize will be presented at the Rome Foundation Reception at DDW. Previous winners of this award are listed below:

### 2021 - TWO WINNERS:

#### Rapat Pittayanon, MD

Title: Gut Microbiota in Patients With Irritable Bowel Syndrome-A Systematic Review. Pittayanon R, Lau JT, Yuan Y, Leontiadis GI, Tse F, Surette M, Moayyedi P. *Gastroenterology*. 2019 Jul;157(1):97-108.

#### Stuart Spechler, MD

Title: Randomized Trial of Medical versus Surgical Treatment for Refractory Heartburn. Spechler SJ, Hunter JG, Jones KM, Lee R, Smith BR, Mashimo H, Sanchez VM, Dunbar KB, Pham TH, Murthy UK, Kim T, Jackson CS, Wallen JM, von Rosenvinge EC, Pearl JP, Laine L, Kim AW, Kaz AM, Tatum RP, Gellad ZF, Lagoo-Deenadayalan S, Rubenstein JH, Ghaferi AA, Lo WK, Fernando RS, Chan BS, Paski SC, Provenzale D, Castell DO, Lieberman D, Souza RF, Chey WD, Warren SR, Davis-Karim A, Melton SD, Genta RM, Serpi T, Biswas K, Huang GD. *N Engl J Med*. 2019 Oct 17;381(16):1513-1523.

### 2020

#### Peter Holger-Johnsen

Title: Fecal microbiota transplantation versus placebo for moderate-to-severe irritable bowel syndrome: a double-blind, randomized, placebo-controlled, parallel-group, single-center trial. Johnsen PH, Hilpüsch F, Cavanagh JP, Leikanger IS, Kolstad C, Valle PC, Goll R. *Lancet Gastroenterol Hepatol*. 2018 Jan;3(1):17-24.

### 2019

#### Keith McIntosh, MD (Canada)

Title: FODMAPs alter symptoms and the metabolome of patients with IBS: a randomized controlled trial. *Gut*. 2017 Jul;66(7):1241-1251.

### 2018

#### Doris Vandeputte, PhD (Belgium)

Title: Stool consistency is strongly associated with gut microbiota richness and composition, enterotypes and bacterial growth rates. *Gut*. 2016 Jan;65(1):57-62. doi: 10.1136/gutjnl-2015-309618. Epub 2015 Jun 11.

### 2017

#### G De Palma, (Canada)

Title: Microbiota and host determinants of behavioural phenotype in maternally separated mice. *Nature Communications* 2015;6; 7735. doi: 10.1038/ncomms8735. PMID: 26218677.

### 2016

#### Emma P. Halmos, PhD (Australia)

Title: A diet low in FODMAPs reduces symptoms of irritable bowel syndrome. *Gastroenterology* 2014;146:67-75. PMID:24076059.

### 2015

#### Jessica Biesiekierski, PhD (Australia)

Title: No Effects of Gluten in Patients with Self-Reported Non-Celiac Gluten Sensitivity after Dietary Reduction of Fermentable, Poorly-Absorbed, Short-Chain Carbohydrates. *Gastroenterology* 2013;145:320-8. PMID: 23648697.

## RESEARCH PROGRAMS AWARDS CONTINUED...

### 2014 – TWO WINNERS:

#### Madhusudan Grover, MBBS (USA)

Title: Clinical-histological associations in gastroparesis: results from the gastroparesis clinical Research Consortium. Neurogastroenterol Motil 2012;24:531-9. PMID: 22339929.

#### Natasha Koloski, PhD (Australia)

Title: The brain-gut pathway in functional gastrointestinal disorders is bidirectional: a 12-year prospective population based study. Gut 2012;61:1284-90. PMID: 22234979.

### Rome Foundation – Aldo Torsoli Foundation Research Award

The Rome Foundation also hands out a joint award with the Aldo Torsoli Foundation in the area of Functional GI Disorders.

This award is given to a mid-level or senior level clinician researcher with an academic record of research, education, and patient care in the area of gut brain interactions (DGBIs). Candidates must have completed an MD or PhD and be currently active in DGBI research. The recipient of the award is selected by a joint Scientific Selection Committee composed of six members, three from each Foundation. The award of \$10,000 will be presented during the Rome Foundation Annual Reception at DDW. Following DDW, the recipient will also give a lecture about their work, which will eventually be available for online streaming.

### 2021:

#### Carlo DiLorenzo, MD- (USA)

### 2020:

#### Alexander Ford, M.D. - (UK)

### 2019:

#### Roberto De Giorgio, MD (Italy)

### Rome Foundation International Research Awards in DGBI

The objective of this RF Research award is to provide investigators funds to help establish their research careers or support projects that represent new research directions. The intent of the award is to stimulate research in DGBI by providing new or preliminary data that can lead to larger grant applications. We encourage applications for DGBI research globally, and in geographical areas where DGBI research is not widely present.

### 2021 WINNERS

**Camden Matherne- University of North Carolina at Chapel Hill, USA:** Estimating the prevalence of FEDs and associated psychiatric comorbidities and health-related symptoms in a clinically severe sample of youth with DGBI.

**Daniel Keszthelyi- Maastricht University Medical Center, the Netherlands:** Understanding the role of the 'wandering' nerve in abdominal pain using functional brain imaging

**Shaman Rajindrajith- University of Colombo, Sri Lanka:** A Randomized Control Trial on the Effectiveness of Mindfulness-Based Stress Reduction on Functional Abdominal Pain/Irritable Bowel Syndrome in Children

**Idowu Senbanjo- University College of Medicine, Ikeja, Lagos, Nigeria:** Improving the awareness and management of Disorders of Gut-Brain Interaction among health care practitioners in Lagos State, Nigeria.

## ROME FOUNDATION FELLOWSHIP PROGRAM

The Rome Foundation Fellowship Program is our way of acknowledging Scientists and clinicians who have contributed their services to the Rome Foundation and have achieved international recognition for their work. Rome Foundation Fellows (RFF) are selected by a credentials committee, based on the following criteria:

### Rome Foundation Clinical Fellow:

- Completion of clinical training in a well-established program
- At least 10 years of practice
- At least 3 first authored publications in peer reviewed journals
- Has worked with the Rome Foundation as a chapter, working team or committee member, and/or is well-recognized as a clinical leader in DGBI

Rome Foundation Fellows are permitted and encouraged to add the RFF designation on their signature line.

### Rome Foundation Academic Fellow:

- Completion of a well-established research training program
- At least 10 years of research
- At least 10 first authored publications in peer reviewed journals
- Has been a primary recipient of 3 federal, or industry grants
- Has worked with the Rome Foundation as a chapter, working team or committee member, and/or is well-recognized as a clinical leader in DGBI

### WE ARE PLEASED TO ANNOUNCE THE FOLLOWING AWARDEES FOR 2021:



**Sarah Kinsinger, PhD**  
2021 Clinical Rome Fellowship  
Awardee



**Darren Brenner, MD**  
2021 Clinical Rome Fellowship  
Awardee



**Madhusudan (Madhu) Grover, M.B.B.S.**  
2021 Academic Rome Fellowship  
Awardee

### CONGRATULATIONS TO ALL OUR IMPRESSIVE ROME FELLOWS!

Albena Halpert, MD • USA • Brooks Cash, MD • USA • Shin Fukudo, MD • Japan • Fernando Azpiroz MD, PhD • Spain • Mary Joan Gerson PhD • USA • John Pandolfino MD • USA • Shirikant Bangdiwala PhD • Canada • Uday Ghoshal MD • India • Henry Parkman MD • USA • Giovanni Barbara MD • Italy • Peter Gibson MD • Australia • Jay Pasricha MBBS, MD • USA • Marc Benninga MD • Netherlands • David Grundy MD • UK • Eamonn Quigley MD, FRCP • USA • Adil Bharucha MBBS, MD • India • C. Prakash Gyawali MD • India • Satish Rao MD, PhD • USA • Guy Boeckxstaens MD, PhD • Belgium • William Hasler MD • USA • Javier Santos MD • Spain • Lionel Bueno MD • France • Margaret Heitkemper RN • USA • Max Schmulson MD • Mexico • Michael Camilleri MD • USA • Lesley Houghton PhD • UK • Robert Shulman MD • USA • C. Ross Carter MD • Scotland • Jeffrey Hyams MD • USA • Magnus Simren MD • Sweden • Francis Chan MD, FRCP • China • Jan Irvine MD, FRCP • Canada • Ami Sperber MD • Israel • Lin Chang MD • USA • Laurie Keefer PhD • USA • Brennan Spiegel MD • USA • William Chey MD, AGAF, FACP • USA • John Kellow MD • Australia • Robin Spiller MD, MSC • UK • Giuseppe Chiarioni MD • Italy • Charles Knowles PsyD • UK • Vincenzo Stanghellini MD • Italy • Enrico Corazzari MD, PhD • Italy • Jeffrey Lackner PsyD • USA • Hidekazu Suzuki MD, PhD • Japan • Peter Cotton MD, FRCP • USA • Brian Lacy PhD, MD • USA • Jan Tack MD, PhD • Belgium • Michel Delvaux MD • France • Anthony Lembo MD • USA • Nicholas Talley MD, PhD • Australia • Carlo DiLorenzo PhD • USA • Rona Levy MSW, PhD • USA • Grant Thompson MD, FRCPC • Canada • Douglas Drossman MD • USA • Allison Malcolm MD, MBBS, FRACP • Australia • Kirsten Tillisch MD • USA • Grace Elta MD • USA • Fermin Mearin MD • Spain • Miranda van Tilburg PhD • USA • Xiucui Fang MD • China • Hiroto Miwa MD, PhD • Japan • Stephen Vanner MD • Canada • Ronnie Fass MD • USA • Samuel Nurko MD • USA • Nathalie Vergnolle PhD • France • Christine Feintle PhD • Australia • Edith Okeke BMBCh, FWACP, FRCP • Nigeria • William Whitehead PhD • USA • Richelle Felt-Bersma MD, PhD • Netherlands • Lukas Oudenhove MD, PhD • Belgium • Peter Whorwell MD, PhD • UK • Alex Ford MBChB, MD, FRCP • UK • Olafur Palsson PsyD • USA • Frank Zerbib MD, PhD • France • Carlos Francisconi MD, PhD • Brazil

# CURRICULUM TO TEACH COMMUNICATION SKILLS TO OPTIMIZE THE PATIENT-PROVIDER RELATIONSHIP



## A Rome Foundation – DrossmanCare Collaboration

Douglas A. Drossman

Patient and clinician satisfaction is being compromised in our health care system due to an ineffective patient-provider relationship<sup>1-3</sup>. Patients have become dissatisfied with the care they receive, and physicians feel burdened and distressed. Ultimately, this unfulfilled need reduces care quality and leads to mutual dissatisfaction between patient and provider. This issue is particularly relevant for patients with Disorders of Gut-Brain Interaction (DGBI), formerly called functional GI disorders<sup>4</sup>. Medical evaluations for structural diagnoses are negative and psychological stigma may be imposed<sup>5</sup>. In current times and with this group of patients, clinicians often feel pressured to focus their time on “sicker” patients or prioritize RVUs toward procedures rather than provide face-to-face care<sup>6</sup>.

The Rome Foundation's global network of research and educational scientists and providers and its resources have established a partnership with the Center for Education and Practice of Biopsychosocial Care (DrossmanCare [www.drossmancenter.com](http://www.drossmancenter.com)), who have for years created educational programs in communication skills training. Together we established a curriculum to facilitate the learning of communication skills<sup>1</sup> to optimize patient-centered care<sup>7</sup>. Since its inception in late 2018, we have developed various highly successful programs, as discussed below.

This collaboration benefits health care providers treating patients with DGBI's and ultimately benefits our patients. This curriculum uses written, visual and interactive methods to teach patient-centered care and practical communication skills even in the most challenging clinical interactions. These educational materials have already been used at national and international fora over several years, and new and more innovative learning tools recently produced offer more extensive techniques for learning. This program has become quite successful and is a significant feature of

the Rome Foundations educational portfolio. Many of our programs are supported by industry sponsorship. We would like to thank Salix, Ironwood, Abbvie and Commonwealth pharmaceuticals for their support of this program.

### OUR AIM AND OBJECTIVES ARE:

**Aim.** To create a collaborative, multimodal educational program to teach communication skills, patient-centered care, psychosocial assessment, and shared decision making to optimize the patient-provider relationship among patients with disorders of gut-brain interaction.

**Objectives.** 1) To develop and implement a curriculum to teach several health care sectors: gastroenterologists in academic practice and community care, fellows in training, clinicians in primary care, medical students and advanced practice provider. 2) To publish peer-reviewed consensus and evidence-based research studies to provide recommendations and clinical practice guidelines.

Implementation of Educational Curriculum: The curriculum provides multimodal learning to various healthcare providers in person and online formats.

### 1. Educational videos as downloads or DVDs for teaching and self-learning. These include:

a. Self-learning educational videos and print materials. These materials provide basic and intermediate level learning.

i. A TED-like lecture explains why patients with DGBIs may be stigmatized and ways to prevent this through effective communication: <http://bit.ly/2HbpVDy>.

ii. A teaching video demonstrates key principles of a nonfacilitative and facilitative interview: <http://bit.ly/2H7MHb3>.

iii. There is a written guide to teach providers how to implement patient-centered care in the clinical setting: <https://romedross.video/2YphMDd>

iv. The Rome Foundation and DrossmanCare have created a series of over 60 brief educational videos (Patient Educational Q&A) covering a broad range of topics on DGBI and communication skills on our website <https://theromefoundation.org/patient-educational-q-a/>

b. Training videos. These video programs are designed as “trigger tapes” to facilitate learning in group settings or for self-learning. In some cases, we have found that patients also benefit from viewing them. This series is available as downloads and on flash drives. The programs cover a variety of challenging issues occurring in the clinical setting.

**i. Communication 101:** A video approach to help clinicians rapidly convey key clinical messages to patients with DGBI. This basic-level series offers thirty-two brief (5 minute) videos where 15 thought leaders in Neurogastroenterology educate patients on common clinical issues. We cover all major topics relevant to patients with DGBI: how to prescribe medications for constipation, how to refer to a psychologist, what is the brain-gut axis, how to you discuss early trauma, how do you explain IBS, and many more. This program can be used to educate clinicians to effectively communicate the key messages, to be a resource to show patients, or to serve as a learning tool for patients. <https://romedross.video/2WBhSpi>

**ii. Communication 101.5:** Tips and Techniques to Address Challenging Interactions in Clinical Practice. Just released is an intermediate-level training program that explains how to address challenging situations that arise when seeing patients with Disorders of Gut-Brain Interaction (DGBI). The program provides eight 5-7 minute clinical scenarios where providers may be confronted with issues that may be difficult to manage, confusing, or even lead to confrontation with the patient. With this learning series, providers can watch as an expert offers methods to address these interaction difficulties in a fashion that leads to consensus and resolution. Viewers will learn to understand the patient's perspective and underlying interpersonal dynamics. They can learn to avoid negative interactions, learn how to offer empathy, negotiate and set boundaries, and ultimately help the patient leave the office trusting and satisfied with the care plan. The clinical scenarios include how to interact with the patient: requesting unneeded opioids, asking for treatment of SIBO that is not indicated, asking for unnecessary tests or claiming multiple diagnoses not established, being overinvolved during a visit with her teenage daughter, refusing to take a neuromodulator for pain, and reluctant to discuss a relevant history of early trauma.

**iii. Communication 202:** A deeper understanding of GI illness through a patient-centered approach. This advanced-level innovative video learning tool teaches the sophistication and complexity of the medical interview. Within the context of a clinical visit, the program demonstrates educational techniques to improve communication skills, patient-centered care, psychosocial assessment, shared decision making, and methods to optimize the patient-provider relationship. The 6 cases relate to patients with DGBI who also have underlying co-morbidities and psychosocial issues (e.g., trauma, loss, sexual issues, aging) that affect the patients' illness experience and behaviors. Thus, the medical symptoms serve only as a template to explore the patient's understanding, associated psychological features, patient concerns, and behaviors, and at a deeper level the psychosocial derivatives of the illness that drives the clinical presentation. Thus, the clinician can utilize more advanced methods to optimize patient care. Each clinical vignette has four learning components: a) an interview using an ineffective interview style, b) an interview using an effective facilitative style, c) commentary from the patient as to his or her perception of the interview: what worked and didn't work, and d) a step-by-step analysis of the interview including the key verbal and non-verbal messages. <https://romedross.video/2zebE5L>

**2. Symposia, webinars and podcasts.** Our program provides current and upcoming programs symposia and webinars for gastroenterologists, trainees, mid-level and allied health care practitioners in communication skills. Examples include:

a. Multimodal educational webinars. These are usually done with key opinion leaders and a patient where key elements of IBS are discussed, followed by case histories (MDCP) and diagnostic algorithms followed by the presentation of effective communication techniques and then video and discussion of a patient/patient advocate. There are four segments: <http://bit.ly/2qfcd08>.

b. Workshop presentations using video to facilitate group learning. These highly successful programs start with a lecture on tips and techniques to optimize the patient-provider relationship, and videos discussed above are used to provide case examples. This model of presentation has been used at several national and international for a <https://romedross.video/ACGWorkshop>

**Introduction to Clinical Skills Development:  
Key Elements of Good Patient-Doctor Communication  
Douglas Drossman M.D.**

% of attendees who rated each presentations aspect as Excellent\*

	Santa Fe Oct. 2018 N=17	New York Jan. 2019 N=15	San Antonio Feb. 2019 N=16	Myrtle Beach June 2019 N=11	Chicago Oct. 2019 N=24
Knowledge gained	88.8%	100%	100%	88.9%	73.3%
Presentation effectiveness	88.8%	100%	100%	100%	82.4%
The material presented was clear and understandable	100%	100%	100%	90.9%	91.7%
The information will be useful to me in my line of work	100%	100%	100%	90.0%	79.2%
The presenter seemed knowledgeable	100%	100%	100%	90.0%	91.7%
The handouts provided (when available) were useful.	100%	90.9%	90.9%	90.0%	94.1%
The speaker met the objectives as stated	100%	100%	100%	90.0%	91.7%

\*Ratings based on: Excellent, Very good, Good, Fair, Poor

c. Podcasts about the patient-provider relationship. Particularly during the COVID-19 period of time we have produced several podcasts on communication skills and the patient provider relationship. Some teach methods <https://romedross.video/ANMSStigma> <http://romedross.video/reachMDkeystrategies> and others involve the provider and patient presenting their perspectives on optimal care <https://romedross.video/ReachMDPPR>, <https://romedross.video/ChefAllive>

**3. Educational workshops for faculty and trainees at medical centers.** We have conducted workshops on-site at medical centers to teach effective communication methods. However, this has temporarily been halted due to COVID-19 and have led us to produce more webinars and online symposia (see above). One was conducted in collaboration with the AGA, and a summary of the program is seen here: <http://bit.ly/2s4U6Td>. We conducted a series of workshops at Johns Hopkins Medical Center based on the faculty's request to increase faculty skills in this area. The program was highly successful based on the participants' ratings and positive feedback from patients being cared for by these faculty. We have also conducted workshops for psychiatry faculty at Columbia University Medical Center and at GI programs at other medical centers, including Mt. Sinai in NYC, the University of Virginia in Charlottesville, Atrium Health in Charlotte, NC and several others. See feedback from two of the programs.

**4. Publications on Communication and guidelines.** We have published articles relating to communication skills and the patient-provider relationship in a highly rated peer-reviewed journal.

- a. A primer on the basics of communication skills for all clinicians<sup>1</sup>
- b. A review of the challenges with our current health care system that impedes the ability to practice patient-centered care. Guidelines to improve patient-centered skills and recommendations to address these challenges are also included<sup>5</sup>

- c. A set of guidelines to optimize that patient-provider relationship through effective communication skills<sup>8</sup>
- d. Addressing the concept of stigma in the patient-provider relationship<sup>9</sup>
- e. The use of paired clinical narratives by a patient and her doctor to show the mutual perspectives on complex cases of DGBI<sup>10-13</sup>
- f. A Rome Foundation Working Team Report on Communication Skills and the Patient-provider relationship (to be submitted). This working team is completing its work and will be submitting to a major journal. It contains an evidence-based

**Workshop on Communication Skills to Enhance  
the Provider-Patient Relationship  
Douglas Drossman M.D. & Johannah Ruddy, M.Ed.**

% of attendees who rated each presentations aspect as Excellent\*

	Santa Fe Oct. 2018 N=17	New York Jan. 2019 N=15	San Antonio Feb. 2019 N=16	Myrtle Beach June 2019 N=11	Chicago Oct. 2019 N=17
Knowledge gained	88.8%	100%	100%	87.5%	91.7%
Presentation effectiveness	88.8%	100%	100%	100%	100%
The material presented was clear and understandable	100%	100%	100%	100%	100%
The information will be useful to me in my line of work	100%	92.9%	100%	80.0%	88.2%
The presenter seemed knowledgeable	100%	100%	100%	90.0%	100%
The handouts provided (when available) were useful.	92.3%	100%	100%	90.0%	100%
The speaker met the objectives as stated	100%	100%	100%	90.0%	100%

\*Ratings based on: Excellent, Very good, Good, Fair, Poor

review of the literature showing impact of communication skills and training on various outcomes. There is also attention to cross-cultural issues and cultural competence, factors that affect good patient-doctor communication like reduced time, EMR, dualism, stigma etc. There is also a section for pediatrics and the patient's perspective. Finally, there are consensus and evidence-based recommendations for technique and committee recommendations for research, training and system change.

g. A book on DGBI and the Patient-Doctor Relationship. "Gut Feelings: Disorders of gut-Brain Interaction and the Patient-Doctor Relationship"<sup>2</sup> was released in December 2020 and over 500 books were sold in two months. Written by Doug Drossman and Johannah Ruddy, it provides the conceptual aspects of brain-gut interactions and the biopsychosocial model, cataloging all the DGBIs with information on pathophysiology, diagnosis, and treatment, and offer methods to optimize the patient-doctor relationship, which includes the patient's perspective.

<https://romedross.video/GutFeelingsWebsite>

**5. "Train the Trainers" Intensive Education to Teach Facilitation Skills.** The Train the Trainer brings in thought leaders in DGBI to become facilitators at our future communication skills programs. These individuals were selected based on the recognition that they are key opinion leaders, have the expertise as educators, and practice patient-centered care. We have conducted three 6-hour sessions that involved teaching how to conduct small group learning, using trigger videos, role play, and facilitating Balint-type learning. These are certification programs, and the attendees are now qualified to co-facilitate future programs based on available funding. These and future programs will allow for continuation of our educational efforts nationally and regionally. These programs' success is seen in the figure below listing participants' level of learning to be a facilitator.

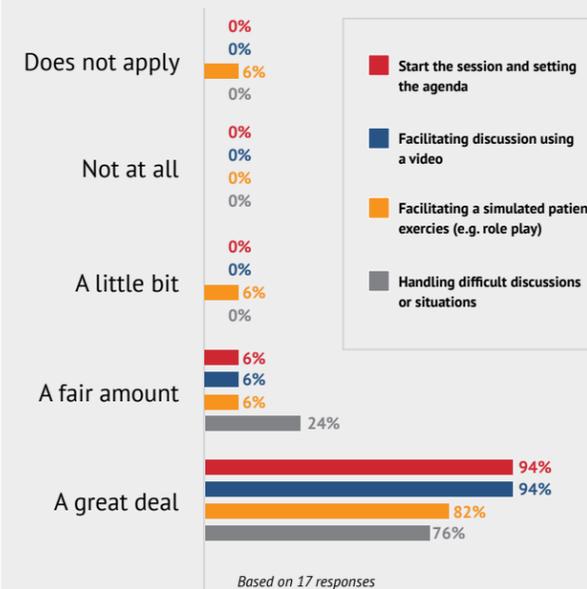
**6. Visiting scholar preceptorship programs.** The Rome Foundation and DrossmanCare instituted a visiting scholar program where faculty, practitioners and trainees can visit key programs to learn about DGBI. To date over 20 have attended this program. We plan to resume the Visiting Scholar Program after COVID-19 ends.

**7. Communication Skills Research Program.**

a. Evaluation of Communication Skill Training Programs. We believe it essential to understand the effect of attendee satisfaction and its impact on practice. Thus, we created a research component to our educational curriculum. We embedded online questionnaires in all programs to obtain feedback and created research instruments to help facilitate this research<sup>14-16</sup>.

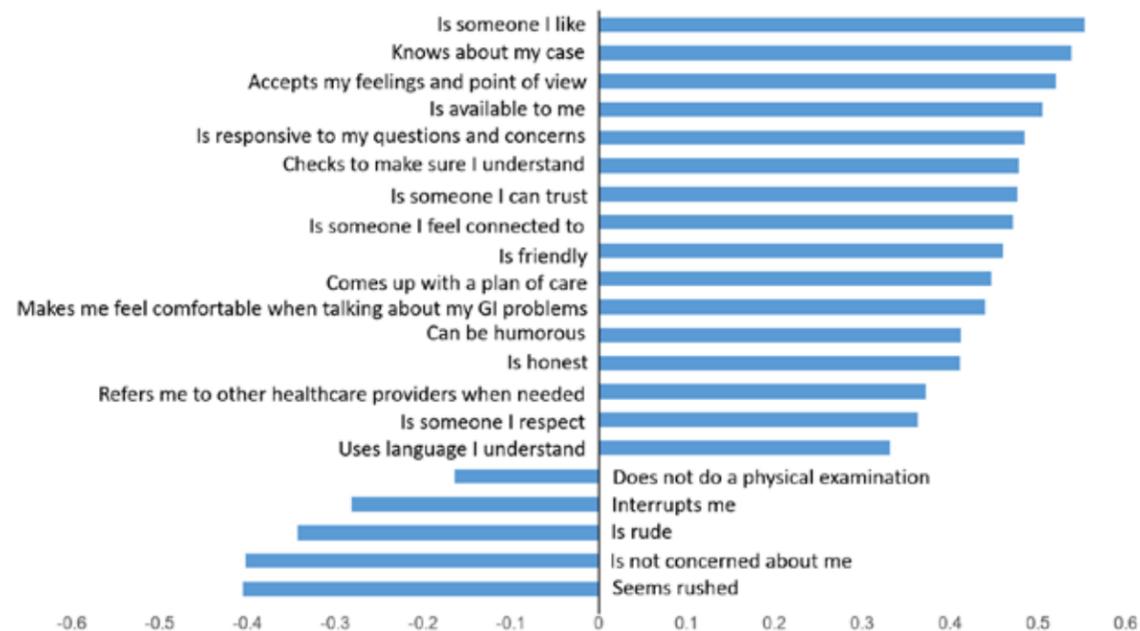
b. Survey to Identify Key elements in the Physician-Patient Relationship that Contribute to Patient Satisfaction. We surveyed 173 patients seeking health care from GI faculty members who underwent a communication workshop at Johns Hopkins medical center. This was done to determine the value of the clinician training concerning patient satisfaction. The key questionnaires included two validated questionnaires developed by Dr. Drossman: The Satisfaction with Care Scale (SAT-37), and the Patient-Provider Relationship scale – Patient Version (PPRS-Patient). These questionnaires, in addition to demographic factors, patient symptoms, and psychological scores, were administered to

**How much participants learned in following areas:**



## CURRICULUM TO TEACH COMMUNICATION SKILLS TO OPTIMIZE THE PATIENT-PROVIDER RELATIONSHIP CONTINUED...

### Correlations of patient PPRS items with Overall Satisfaction (SAT-37)



the patients to accomplish four objectives: 1) identify the critical factors in the patient-provider relationship that predict overall satisfaction with care, 2) perform exploratory factor analysis to identify specific clinical aspects in the patient-provider relationship, 3) perform multivariate analyses to determine the robustness of these factors in predicting overall satisfaction, and 4) develop a short version of the physician-patient relationship scale that predicts satisfaction with the care to be used as a clinical and research tool to assess physician performance in the clinical setting (PPRS Patient Version Short Form). Figure 4 shows the correlations of the Physician-Patient Relationship Scale items with overall clinical satisfaction (SAT-37). The figure below shows the correlations of the patient PPRS items with overall patient satisfaction. (In press *Neurogastroenterology and Motility* 2021)

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## ROME LIBRARY

All of our educational programs and tools have been updated based on the Rome IV recommendations.

### Primary Care Book

For many years, the Rome Foundation has heard from primary care physicians that our educational materials are “too complex, cumbersome, and not efficient” for practical day-to-day use. Taking this as a challenge, in 2010 the Board of Directors prioritized the effort to find ways to learn more about how primary care physicians understand and approach diagnosis and treatment of DGBIs. We approached Pali Hungin, MD, a leading expert in the primary care of Disorders of Gut Brain Interactions (DGBIs), and he formed an international committee of primary care clinicians working in DGBI, and this group has led our educational materials for primary care. The Rome Foundation Primary Care Committee also published two articles on how non-gastroenterologists see DGBIs and the Rome IV primary care book. This then led to the primary care book as a distillation of Rome IV knowledge targeted to the needs of primary care providers. This efficiently organized book is designed to help the busy primary care physicians and other non-gastroenterological providers who see patients with these disorders.

### Multi-Dimensional Clinical Profile (MDCP)

The Rome Multi-Dimensional Clinical Profile (MDCP) 3rd edition is now available and is continuing to redefine the ways in which clinicians can care for patients having even the most complex DGBI. This 3rd edition offers 89 cases, more than double that in the first edition and all cases have been updated to reflect the latest up-to-date science and treatments. The MDCP, just released in its third edition, redefines the ways in which clinicians can care for patients having even the most complex functional GI disorders. The 3rd edition is a case-based learning module that updates the content of the first MDCP book published in 2021. There are over 89 new cases, more than double that in the first edition, and all cases are revised to with the latest up-to date science and treatments.

Through case-based learning, discerning clinicians can understand the complexities and dimensionality that exist with these disorders. For example, a patient with IBS-D having

mild and occasional symptoms of abdominal discomfort and loose stools and functioning without impairment would be treated quite differently than a patient with the same diagnosis having continuous severe and disabling pain and comorbid anxiety disorder with fears of incontinence when leaving the house.

Through the expertise of the Rome Board Members, the previous cases were revised and newer diagnostic entities were added, including post COVID-19 infection and ARFID. This 3rd edition truly addresses the full depth and breadth of clinical decision-making for DGBI. Furthermore, we also updated all 18 pediatric cases (neonate-toddler and child-adolescent) and the multi-cultural cases where sociocultural influences affect symptom presentation, and where treatment must be geared to the patient's cultural perspective.

### Rome Foundation Visiting Scholar Program

The Rome Foundation Visiting Scholar Program is another way for researchers and clinicals to visit with key leaders in DGBI and learn not just about advanced research techniques and patient focused care but also advanced communication skills to assist them in better managing their patients and get one on one advice on more advanced patient scenarios that they might be encountering in their own patient populations.. These programs allow for fellows and junior faculty to spend two to three days on site with our board members and shadow them in clinic. They observe the clinical interaction and then debrief at the end of the clinic day on what they experienced. They also meet with departmental heads and investigators as available depending on their research interest. This program is critical in developing the next generation of providers in becoming skilled communicators and exceptional physicians managing and treating patients with DGBI.

### GI Genius

The Rome Foundation in partnership with LogicNets®, the developer of an intelligent decision-support automation platform produced the GI Genius, formerly known as the Rome IV Interactive Clinical Decision Toolkit. This new intelligent software system addresses the sophistication and

## ROME CAMPUS - CME LIBRARY CONTINUED...

complexity of DGBI diagnosis and treatment by providing an online resource to assist practitioners in achieving optimal clinical outcomes. It offers a powerful online and interactive approach for accessing the combination of the Rome IV Diagnostic Algorithms and the MDCP treatment guidelines on-demand and at the point of care. In 2019 we added more information on the psychosocial aspects of patient care and the use of neuromodulators and behavioral interventions to help clinicians know when they should consider centrally targeted treatments. We also included all of the Rome IV diagnostic and treatment recommendations for the pediatric populations, making this software incredibly valuable to pediatricians and pediatric gastroenterologists.

### Rome IV Slide Sets

The Rome Foundation has developed over 700 images and slides for Rome IV and additionally two other slide sets for presentation: the Rome IV Multi-Dimensional Clinical Profile (MDCP) slide set and the Rome IV Diagnostic Algorithms set. The slides include notes and references covering the

information provided in the Rome IV book. Designed by the world's leading experts in functional GI disorders, the program allows for self-learning and presentations using the most up-to-date information. Purchase the entire slide set collection, specific modules by topic, or individual slides. They are available exclusively from the Rome Foundation website.

### Website

Our updated and redesigned website provides educational information to the public and to health care professionals. Visitors can view our news and updates, order our educational products, download the Rome IV criteria, learn about our research grant programs and educational programs, view videos of the communication skills workshop, and learn about meetings and events. In addition, visitors can request licensing to use the Rome IV questionnaires and all of the other research instruments, including the BSFS. Visitors may also join our mailing list or become an Associate to receive periodic updates on Rome Foundation activities and our quarterly e-newsletters.

## GI Genius, formerly known as the Rome IV Interactive Clinical Decision Toolkit

The GI Genius has continued to be updated. In addition to updates to the scientific content for the treatment of Functional Gastrointestinal Disorders, we have made updates to the clinical information, and treatment recommendations for adults. To support these changes, additional references have been included throughout the program to help improve the user experience of our program. Additionally, we have updated the psychosocial treatment and evaluation portion of the program, to help our users best serve the needs of their patients in a comprehensive way.

Furthermore, the Rome Foundation is excited to announce the Pediatric Diagnostic and Treatment algorithms in our interactive toolkit. Working with Dr. Samuel Nurko, the Rome Foundation has released new diagnostic algorithms for recurrent nausea and vomiting, early satiety and epigastric pain, and abdominal pain, along with the corresponding treatment algorithms. Each are complete with up-to-date scientific information supporting each clinical decision, with supporting references. With these new updates, the Rome Foundation hopes to continue to serve as the gold standard for the diagnosis and treatment for all patients with FGIDs.



Use this QR Code to watch the GI Genius marketing video



## ROME FOUNDATION/AGA INSTITUTE LECTURESHIPS AT DDW

In 2008, the Rome Foundation and the American Gastroenterological Association (AGA) launched a "prime time" lectureship at DDW with the goal to have outstanding speakers present on the broader areas of health care as related to the functional GI and motility disorders. At DDW in May 2021, we are pleased to have three speakers discuss "Cannabinoids In GI Disorders: A New Understanding, Use and Abuse".

### The talks will be:

- **Endocannabinoid System and Its Mechanistic Role In Nausea and Vomiting and Chronic Abdominal Pain** (35 minutes)  
Keith A. Sharkey
- **Thangam Venkatesan Beneficial and Adverse Effects of Cannabinoids on Functional GI Disorders and Symptoms** (35 minutes)  
Thangam Venkatesan



Keith A. Sharkey



Thangam Venkatesan

### Previous Lectures from this series are listed below:

- **2019** - Making Treatment Choices for Functional GI Disorders (Disorders of Gut-Brain Interaction) with Lin Chang, MD, Medical and Psychological Co-morbidities Influencing Therapeutic Choices; Magnus Simren, MD, PhD, The Role of Biomarkers in Patient Management; Jan Tack, MD, PhD Clinical and Patient Factors that Affect Treatment Outcomes
- **2018** - "Post-infection Functional GI Disorders (FGIDS)" with Giovanni Barbara, University of Bologna, Italy; "Gut Microbiome-Brain Interactions: Relevance for FGIDs" with Premysl Bercik, McMaster University, Canada; "Microbiota Modulation in FGIDS: Probiotics, Antibiotics and FMT" with Eamonn M. Quigley, Houston Methodist, USA
- **2017** - "EndoFLIP for Functional Esophageal Disorders" with John Pandolfino, Northwestern University, USA; "Magnetic Resonance Imaging of the Intestine in IBS and Chronic Constipation" with Robin Spiller, University of Newcastle, Australia; and "Novel Brain Imaging Techniques in IBS" with Emeran Mayer, David Geffen School of Medicine at UCLA
- **2016** - "Overview of Rome IV: Changes in Criteria and New Educational Concepts" with Douglas A. Drossman, Drossman Center; "Functional Gastrointestinal Disorders" with Nicholas J. Talley, University of Newcastle, Australia; "Lower Gastrointestinal Functional Bowel Disorders" with Fermin Mearin, Hospital Quirón Teknon, Spain
- **2015** - "Clinical Practice and Research for FGIDs in the Technology Era". "Clinical practice in a social media environment" with Ryan Madnick MD; University of North Carolina; "Use of health information technology in clinical practice" with William D. Chey MD; University of Michigan; "How health information technology on the internet can be used in clinical research" with Patrick Furey; ConsumerSphere
- **2014** - "Understanding and Treating the Brain's Contribution to Pain": "Central mechanisms of pain" with Irene Tracey, PhD; Oxford Centre for Neuroethics; "Behavioral interventions for pain management" with Laurie Keefer, PhD; Northwestern University; "Centrally targeted pharmacotherapy for chronic abdominal pain" with Douglas A. Drossman, MD; Center for Biopsychosocial Patient Care and UNC
- **2013** - "The Role of Food Sensitivities and Microbiota in Functional GI Disorders" with Sheila Crowe, MD from the University of California in San Diego, CA; "Food sensitivities and food allergies: The clinical perspective" and Kevin Whelan, PhD from King's College, London; "Understanding the mechanisms underlying the interaction of food and gut microbiota in FGIDs"
- **2012** - "Intestinal Permeability: Does it Explain the Symptoms of Functional GI Disorders?" with Giovanni Barbara, MD from the University of Bologna; "Regulation of Intestinal Permeability in Health and Disease" with Alessio Fassano, MD from the University of Maryland and "Esophageal Permeability: Does it Explain the Symptoms of NERD?" with Roy Orlando, MD from the University of North Carolina at Chapel Hill
- **2011** - "The Role of Neurogenesis in the Brain" with Tarique Perera MD from Columbia University in NYC and "The Role of Neurogenesis in the Enteric Nervous System and its Implications for Functional GI Disorders" with Michael D. Gershon MD from Columbia University in NYC
- **2010** - "Understanding Gut Microbiota: A New Era in Gastroenterology" with Dr. Erwin G. Zoetendal from Wageningen, Netherlands
- **2009** - "Motility Assessments for Functional GI Disorders: How far does it get us?" with Dr. Juan-R. Malagelada, Professor of Gastroenterology at Hospital Universitari Vall d'Hebron in Barcelona
- **2008** - "Lessons from our Patients" with Ms. Gina Kolata, Science Writer for the New York Times

## ROME FOUNDATION WORKING TEAMS

### Active Rome Working Teams – 2019-2024

#### PLAUSIBILITY OF PATHOPHYSIOLOGICAL MECHANISMS FOR DGBI

**Jan Tack, MD, PhD, chair**

**Nicholas J. Talley, MD, PhD, co-chair**

Giovanni Barbara • ESNM

Michael Camilleri • ANMS

Florenca Carbone • Coordinating team

Lin Chang • ANMS

Ram Dickman • ESNM

Shin Fukudo • ANMA

Uday Goshal • ANMA

Ignacio Hannah • SLNG

Laurie Keefer • ANMS

Oh Young Lee • ANMA

Ana Maria Madrid • SLNG

Daniel Pohl • ESNM

Edoardo Savarino • ESNM

Max Schmulson • SLNG

Jordi Serra • ESNM

Magnus Simren • ESNM

Karen Van den Houte • Coordinating team

#### COMMUNICATION SKILLS TO IMPROVE THE PPR

**Douglas Drossman, MD, chair**

Lin Chang, MD

Jill Deutsch, MD

Alex Ford, MD

Albena Halpert, MD

Kurt Kroenke, MD

Johannah Ruddy, MD

Julie Snyder, PsyD

Ami Sperber, MD

Samuel Nurko, MD

#### OVERLAP WORKING TEAM

**Magnus Simrén, Sweden, chair**

Giovanni Barbara, Italy, co-chair

Imran Aziz, UK

Sarah Ballou, USA

Lin Chang, USA

Alexander Ford, UK

Shin Fukudo, Japan

Samuel Nurko, USA

Carolina Olano, Uruguay

Miguel Saps, USA

Gregory Sayuk, USA

Kewin TH Siah, Singapore

Lukas Van Oudenhove, Belgium

#### BRAIN-GUT PSYCHOTHERAPIES

**Laurie Keefer, PhD, chair**

Sarah Ballou, PhD

Douglas Drossman, MD

Sigrid Elsenbruch, PhD

Brjann Ljotsson, PhD

Gisela Ringstrom, PhD

### Completed Rome Working Teams – 2018-2020

#### NEUROMODULATORS FOR FGIDS

(Gastroenterology 2018;154:1140-1171)

**Douglas A. Drossman, Chair**

**Jan Tack, Co-chair**

Hans Tornblom

Lukas Van Oudenhove

Alex Ford

Eva Szigethy

#### POST-INFECTION IBS

(Gastroenterology 2019;158:46-58)

**Giovanni Barbara, Chair**

**Madhu Grover, Co-Chair**

Maura Corsetti

Premysl Bercik

Lena Ohman

Mirjana Rajilic

Uday Ghoshal

#### PHARMACOLOGICAL TRIALS

##### IN CHILDREN WITH CONSTIPATION

(Neurogastroenterol Motil 2018;30:e13294)

**Miguel Saps, Chair**

Ilan Koppen

Marc Benninga

Sam Nurko

John Lavigne

Carlo Di Lorenzo

#### BRAIN IMAGING IN DGBI

(Gut, 2019;68:1701-1715)

**Emeran Mayer, Chair**

Jennifer Labus

Qasim Aziz

Irene Tracey

Lukas Van Oudenhove

David Borsook

Petra Schweinhardt

Sigrid Eisenbruch

David Borsook

### Completed Working Teams 2009-2016

#### GUIDELINES FOR BRAIN IMAGING IN THE FGIDS

**Emeran Mayer Chair, Qasim Aziz Co-Chair**

Neurogastroenterol Motil 2009;21:579-596

#### OUTCOMES/ENDPOINTS IN PHARMACEUTICAL CLINICAL TRIALS

**Michael Camilleri Chair**

Gastroenterology 2009;137:1944-1953

#### GUIDELINES FOR SEVERITY IN IBS

**Douglas A. Drossman Chair, Lin Chang Co-Chair**

Am J Gastro 2011;106:1749-1759

#### ROLE OF INTESTINAL FLORA IN FGIDS

**Magnus Simren Chair, Giovanni Barbara Co-Chair**

Gut 2012;62:159-176

#### ASIAN WORKING TEAM FOR FGIDS

**Kok Ann Gwee Chair, William Whitehead Co-Chair**

Neurogastroenterol Motil. 2015; 21:83-92

Neurogastroenterol Motil 2016;22:240-70.

#### MULTINATIONAL, CROSS-CULTURAL RESEARCH

**Ami D. Sperber Chair**

Alim Pharmacol Ther 2014;40:1094-1102

Neurogastroenterol Motil 2014;26:1368-1385

#### FOOD AND DIET

**William Chey Co-Chair, Jan Tack Co-Chair**

Am J Gastroenterol. 2013; 108:694-697

Am J Gastroenterol 2013; 108:698-706

Am J Gastroenterol 2013; 108: 707-717

Am J Gastroenterol 2013; 108: 718-727

Am J Gastroenterol 2013 108: 728-736

Am J Gastroenterol 2013 108: 737-747

Am J Gastroenterol 2013; 108: 748-758

#### PRIMARY CARE IN FGIDS

**Hungin A.P. Co-Chair, Heidelbaugh J Co-Chair**

Neurogastroenterol Motil 2015;27:750-763

Alim Pharm & Ther. 2014;40:1133-1145

#### PHARMACOLOGICAL TRIALS FOR CHILDREN - IBS

**Saps, M. Chair**

Neurogastroenterol Motil 2016;11:1619-1631

## BRAIN-GUT PSYCHOTHERAPIES WORKING TEAM

There is now adequate evidence to support the integration of brain-gut psychotherapies [BGPs] into gastroenterology care. BGPs are believed to directly influence gastrointestinal (GI) symptoms, particularly pain and discomfort, as well as improve coping and quality of life. As GI Psychologists and other mental health providers become more available with the growth of training opportunities through the Rome Foundation and its members, there is an urgent need to inform GI practitioners about the structure, modes of delivery and evidence-base for existing. This Working Team will provide an authoritative document on BGPs from internationally recognized experts, including recommendations for what works for whom and will also highlight some of the promising areas for future research.

## COMMUNICATION SKILLS WORKING TEAM

**The Influence of Communication Skills on the Patient-Provider Relationship: A review of the Evidence and Recommendations for Implementation.** This working team is chaired by Dr. Doug Drossman and involves an international multi-disciplinary panel of experts. The aim is to review the evidence for the influence of communication skills (verbal and nonverbal) on patient and provider satisfaction, adherence to treatment and clinical outcomes, and to provide guidelines for their implementation in clinical practice.

We believe that the application of practical communication skills and patient-centered care may reverse this downward trend in the PPR. However, while this has heuristic value for some educators and clinicians, the scientific basis for benefit has not been established. Therefore, a multidisciplinary Rome Foundation Working Team was created with the following objectives:

- To review the scientific evidence in medicine, behavioral science, and gastroenterology on the effect of enhanced communication skills and patient-centered care on a) patient-provider satisfaction, b) adherence to treatment, c) clinical outcomes.
- To review specific factors that influence the patient-provider relationship: a) sociocultural aspects, b) health care system constraints, and c) the patient perspective
- To review the outcome of communication skills training on learner satisfaction and clinical behaviors; to provide guidelines to providers to help them improve their communication skills in a time-efficient manner.
- To make recommendations to improve the PPR with consideration to providing: a) guidelines to learn and teach communication skills, b) educational programs for curricula, recertification, and CME, c) Incentivization for providers and educators who utilize or teach communication skills, d) further recommendations for research

### Committee Composition

**Laurie Keefer, PhD-Chair**

Mount Sinai (New York City, USA)

**Douglas Drossman, MD**

UNC/DrossmanCare (Chapel Hill, USA)

**Sigrid Elsenbruch, PhD**

University of Essen (Germany)

**Brjánn Ljótsson, PhD**

Karolinska Institute (Sweden)

**Sarah Ballou, PhD**

Harvard (Boston, USA)

**Gisela Ringstrom, PhD**

University of Gothenburg (Sweden)

### Committee Composition

**Douglas Drossman, MD, chair**

**Lin Chang, MD**

**Jill Deutsch, MD**

**Alex Ford, MD**

**Albena Halpert, MD**

**Kurt Kroenke, MD**

**Johannah Ruddy, MEd**

**Julie Snyder, PsyD**

**Ami Sperber, MD**

**Samuel Nurko, MD**

## OVERLAP AND CO-MORBIDITY WORKING TEAM

For many patients with DGBI, overlapping non-GI conditions such as fibromyalgia, headaches, gynecological and urologic conditions, sleep disturbances and fatigue are common, as well as overlap among DGBI in different regions of the GI tract. These overlaps strongly influence patient management and outcome. Shared pathophysiology may explain this, but details are not fully understood. This overlap has been shown to be of great relevance for DGBI:

- Presence of overlapping DGBI from different GI regions is strongly associated with e.g. increasing health care consumption, presence of non-GI symptoms, reduced quality of life, reduced work productivity and overall more severe GI symptoms.
- Co-existing non-GI symptoms/syndromes such as fibromyalgia, migraine, dyspareunia, chronic fatigue syndrome, interstitial cystitis in patients with DGBI are associated with e.g. worse outcome in general, and reduced psychological general well-being.

Furthermore, symptoms considered to be caused by a DGBI may in fact have a detectable organic cause, and in patients with a diagnosed organic GI disease, symptoms not clearly explained by the pathology defining this disease are common. A diagnosis of organic disease, excludes by virtue a diagnosis of DGBI. The Rome Criteria are instrumental to set the boundaries between these two extremes of the spectrum creating a dichotomy between functional and organic gastrointestinal disorders. Nonetheless, there are scenarios in which these boundaries became blurred, including the following:

- The existence of an organic, potentially recognizable cause of DGBI symptoms, which emerge in subgroups of patients upon in depth investigation (e.g., bile acid malabsorption, microscopic colitis, intestinal parasitosis, non-celiac sprue). These investigations are not required in most patients with DGBI and should be confined to selected cases.
- The development of symptoms fulfilling criteria for DGBI (e.g., so called functional dyspepsia-like, irritable bowel syndrome-like symptoms) in patients in remission from an organic disease (e.g., quiescent IBD, celiac disease on a gluten free diet, diverticular disease in the absence of evidence of overt inflammation)

This working team will review the literature regarding underlying mechanisms / pathophysiology, including CNS filtering that can explain different types of overlap among different DGBI, with non-GI symptoms/syndromes and with organic GI disease. Particular focus will be on identifying overarching or shared concepts to explain these associations, e.g. central hypersensitivity.

1. Describe the prevalence, symptoms patterns and clinical impact of co-existing non-GI symptoms / syndromes, assess potential geographic and demographic differences, and address how the presence of these symptoms relates to GI symptom patterns in specific DGBI. The focus will be on fibromyalgia, chronic fatigue syndrome and interstitial cystitis, but other overlapping non-GI symptoms/syndromes will also be reviewed.
2. Provide guidance on how the presence of co-existing non-GI symptoms/syndromes influences burden of the disease, outcome and patient management, including how to prioritize different treatment strategies. Discuss how centrally vs. peripherally acting treatments should be used, including the use of behavioral treatments.
3. Describe the prevalence, symptoms and overlap patterns and clinical impact of overlapping DGBI, assess potential geographic and demographic differences, and address how the presence of this overlap relates to other characteristics of patients with DGBI.
4. Provide guidance on how overlapping DGBI influences burden of the disease, outcome and patient management. Discuss how centrally vs. peripherally acting treatments should be used, including the use of behavioral treatments.

### Committee Composition

**Magnus Simrén, chair**, Sweden

**Giovanni Barbara, co-chair**, Italy

**Imran Aziz**, UK

**Sarah Ballou**, USA

**Lin Chang**, USA

**Alexander Ford**, UK

**Shin Fukudo**, Japan

**Samuel Nurko**, USA

**Carolina Olano**, Uruguay

**Miguel Saps**, USA

**Gregory Sayuk**, USA

**Kewin TH Siah**, Singapore

**Lukas Van Oudenhove**, Belgium

## OVERLAP AND CO-MORBIDITY WORKING TEAM CONTINUED...

5. Describe the prevalence, symptom patterns and clinical impact (contribution to symptoms implications for therapy) of organic recognizable causes in DGBI, e.g. bile acid malabsorption, microscopic colitis, small intestinal bacterial overgrowth
6. Provide guidance on further testing to identify organic causes of symptom development (phenotype, severity, geographic region etc.)
7. Describe the prevalence and characteristics of DGBI symptoms in patients with chronic organic disease in remission or overlapping with organic disease (e.g. IBD, celiac disease, diverticular disease)
8. Provide guidance on further testing and management of DGBI symptoms in patients with organic disease in remission, including how to prioritize different treatment strategies. Discuss how centrally vs. peripherally acting treatments should be used, including the use of behavioral treatments.
9. Provide guidance on how overlapping conditions (overlap among DGBIs, overlap between DGBI and non-GI somatic symptoms/syndromes, DGBI symptoms in patients with organic GI diseases) should be addressed and managed in the context of clinical trials.
10. Provide recommendations for future research on these topics.

## PLAUSIBILITY WORKING TEAM

DGBI are characterized by the presence of a variety of chronic, typically episodic symptoms attributed to the gastrointestinal tract in the absence of an underlying histological, biochemical, or physiological mechanism that consistently explains the symptoms. Several putative pathophysiological mechanisms have been proposed, including disordered motility, visceral hypersensitivity, low-grade inflammation, altered microbiota, immune activation, adverse reactions to foods and central nervous system dysfunction (which may or may not be related to psychological dysfunction), etc. Despite the fact that these disturbances have been reported in patients with DGBI, their relevance to symptom generation remains the subject of debate, in part because of the absence of a clearly established causal or even temporal relationship between symptoms and observed abnormal function, as well as the lack of treatments to specifically target the putative underlying mechanisms. Several cross-sectional studies attempting to correlate symptoms with pathophysiological mechanisms in DGBIs have been criticized because they failed to explain a given symptom in all patients, or because of an inability to rule out other contributing mechanisms. The assessment of the nature and the severity of symptoms in DGBI depends on patient self-reports, which often lacks specificity and sensitivity. In addition, it is often assumed that DGBIs consist of subgroups with heterogeneous symptoms and different underlying pathophysiology. The Rome criteria have made this explicit for some (e.g. stool pattern-based IBS subtypes; EPS and PDS for functional dyspepsia) but not all DGBIs.

Researchers involved in pathophysiological studies have proposed many mechanisms underlying DGBI and used variable arguments and observations to support the relevance of these individual candidate mechanisms. To advance the field there is

### Committee Composition

**Jan Tack, MD, PhD, chair**

**Nicholas J. Talley, MD, PhD, co-chair**

**Giovanni Barbara** • ESNM

**Michael Camilleri** • ANMS

**Florencia Carbone** • Coordinating team

**Lin Chang** • ANMS

**Ram Dickman** • ESNM

**Shin Fukudo** • ANMA

**Uday Goshal** • ANMA

**Ignacio Hannah** • SLNG

**Laurie Keefer** • ANMS

**Oh Young Lee** • ANMA

## PLAUSIBILITY WORKING TEAM CONTINUED...

a need to identify the level of relevance of such putative pathophysiological processes, as this would enhance the knowledge and may prioritize target for therapeutic innovation or optimization.

In 2017, a group of international experts including some Rome Board members developed plausibility criteria for mechanisms in functional gastrointestinal disorders and published these as a paper in *Gut*. The plausibility criteria are based on aspects such as presence, temporal association, correlation between level of impairment and symptom severity, induction in healthy subjects and treatment response or congruent natural history. In addition, a plausibility numerical score was proposed, based on the strength of evidence. In the paper, the plausibility criteria were applied to 4 specific mechanisms in 3 different functional disorders.

There is a clear opportunity to approach the various DGBIs and the proposed underlying mechanisms in a systematic fashion. In case of IBS, for instance, the plausibility of altered fecal microbiota composition, or increased mucosal permeability, or anxious co-morbidity as mechanism underlying symptom generation could be assessed. There are similar examples for each putative pathophysiological mechanism in each DGBI. This approach will provide a novel and critical review of our current DGBI disease concepts and establish the areas of knowledge and uncertainty.

## WORKING TEAM COMMITTEES - COMPLETED

## POST-INFECTION IBS

*Gastroenterology* 2019;156:46-58.

### Rationale and Objectives

There is consistent evidence indicating that functional dyspepsia (FD) and irritable bowel syndrome (IBS) can develop following an episode of acute infectious gastroenteritis, with an overall OR of 2.5 for the presence of a FGID at six months postinfection compared to controls. Several new data have been published in the last 10 years on post-infectious functional GI disorders, particularly detailing the epidemiology, risk factors, pathophysiology and the involvement of the microbiota. For these reasons, our Working Team took on the task to comprehensively review the literature in this area and make consensus-based recommendations.

#### The objectives of this working team were to:

- Critically review the existing literature on the role of infections in functional GI disorders, with focus on clinical and translational aspects. This will include epidemiological issues, risk factors, the role of microbiota and the immune system, the relevance of animal models, diagnosis, prognosis, and management.
- Based on the literature search, provide recommendations how to implement the current knowledge into clinical practice, in order to improve the health of our patients.
- Give recommendations for future work to improve the current knowledge on postinfectious functional GI disorders.
- Summarize the results in an extensive, and clinically useful, review.

**Manuscript published in *Gastroenterology* 2019;156:46-58.**

### Committee Composition

**Giovanni Barbara, Chair** (Italy)

**Madhusudan Grover, Co-Chair** (USA)

**Premysl Bercik** (Canada)

**Maura Corsetti** (UK)

**Uday Ghoshal** (India)

**Lena Ohman** (Sweden)

**Mirjana Rajilić-Stojanović** (Serbia)

## GUIDELINES FOR BRAIN IMAGING IN THE DGBIS

*Neurogastroenterology & Motility*; 21(6), 579 - 596, May 2009

A working team on brain imaging in the functional GI disorders was organized after the completion of the Rome III. This committee, led by Emeran Mayer (Chair) and Qasim Aziz (Co-Chair), began their work in July 2005 developing documents on brain imaging in the functional GI disorders. Additional committee members selected for the project were Doug Bremner (Emory University), Mark Kern (Medical College of Wisconsin), Braden Kuo (Harvard), Richard Lane (University of Arizona), Bruce Naliboff (UCLA), and Irene Tracey (University of Oxford).

The charge to this committee was to review available literature on standards for brain imaging assessment in medicine and establish recommendations for the conduct of brain imaging studies in the functional GI disorders.

The committee developed an outline, assigned topics to committee members, and worked through email to develop drafts of the brain imaging document. The members then convened a meeting just before attending the 12th Annual Meeting of the Organization for Human Brain Mapping in Florence, Italy and again in Cambridge in September 2006, to review and revise the documents to resolve any gaps or conflicts.

Since that time the committee has worked diligently to ensure that this keystone document for brain imaging in FGIDs was further updated by new research in the literature. In addition, members of the UCLA Center for Neurobiology & Stress assisted in further updating the report with new literature and responded to peer reviews for publication.

**The journal article was published in *Neurogastroenterology & Motility*, May 2009. Mayer EA, Aziz Q, Coen S, Kern M, Labus JS, Lane R, Kuo B, Naliboff B, Tracey; Brain imaging approaches to the study of functional GI disorders: A Rome Working Team Report; *Neurogastroenterology & Motility*; 21(6), Pages 579 - 596, May 2009**



### Committee Composition

#### **Emeran A. Mayer, MD, Chair**

David Geffen School of Medicine at UCLA,  
Center for Neurovisceral  
Sciences & Women's Health UCLA  
Los Angeles, CA, USA

#### **Qasim Aziz, PhD, FRCP (London), Co-Chair**

The Wingate Institute  
London, UK

#### **J. Douglas Bremner, MD**

Atlanta VA Medical Center  
Decatur, GA, USA  
Emory University School of Medicine  
Atlanta, GA, USA

#### **Mark Kern, PhD**

Medical College of Wisconsin  
Dysphagia Institute  
Milwaukee, WI, USA

#### **Braden Kuo, MD**

Harvard Medical School  
Massachusetts General Hospital  
Boston, MA, USA

#### **Richard D. Lane, MD, PhD**

University Of Arizona  
Tucson, AZ, USA

#### **Bruce D. Naliboff, PhD**

David Geffen School of Medicine at UCLA  
Center for Neurovisceral  
Sciences & Women's Health UCLA  
Los Angeles, CA, USA

#### **Irene Tracey, PhD**

University of Oxford  
Oxford, UK

## WORKING TEAM ON GUT-BRAIN NEUROMODULATORS FOR DGBIS (DISORDERS OF GUT-BRAIN INTERACTION)

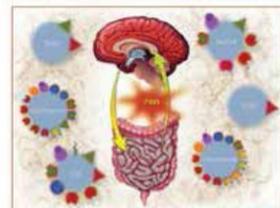
Gastroenterology 2018;154:1140-1171

We are pleased to announce that this working team has been successful in its efforts this year to bring to attention new ways to treat gastrointestinal pain. The use of centrally targeted medications (gutbrain neuromodulators) including various classes of antidepressants, anxiolytics, the newer atypical antipsychotics, and alpha 2 ligand agents have shown benefit in somatic pain syndromes, yet their investigation in disorders of gut brain interaction has been very limited and the clinical application of these agents within clinical practice lacks sophistication, precision and specificity. Furthermore, there are very little data available on the differential effects of central treatments on specific types of GI symptom (i.e. epigastric pain, pain in IBS, abdominal bloating, early satiation, belching, nausea, and non-cardiac chest pain) and no centrally targeted agent has been approved by a regulatory agency for these disorders.

This working team successfully published their article in the March issue of Gastroenterology and was featured on the cover (see Figure 13). The article, “**Neuromodulators for Functional Gastrointestinal Disorders (Disorders of Gut-Brain Interaction): A Rome Foundation Working Team Report**” (Gastroenterology 2018;154:1140-1171), discusses central neuromodulators as follows:

- Reviews psychiatry, medicine and gastroenterology on their physiological effects on the brain and gut
- Reviews available studies on the treatment of GI pain, as to their overall efficacy and selective value over other treatments
- Discusses differential actions of these medications (e.g., SSRI, SNRI, TCA, atypicals, etc.) on GI pain
- Identifies GI and other adverse events and side effects of the various agents.
- Recommends the selection of agents for various clinical profiles (e.g. IBS-D, C, functional dyspepsia, CVS, chest pain, nausea/vomiting/weight loss, etc.)
- Provides recommendations as to how treatment should be introduced to the patient through the use of effective communication
- Clarifies how opioid agents relative to non-opioid agents are used to manage pain in FGIDs.

### Neuromodulators for Functional GI Disorders (Disorders of Gut-Brain Interaction): A Rome Foundation Working Team Report



Drossman DA (chair), Tack J (co-chair), Ford AC, Szigethy E, Tornblom H, Van Oudenhove L. Gastroenterology 2018;154:1140-1171

### Committee Composition

**Douglas A. Drossman, MD, Chair**  
(Gastroenterology, Psychiatry/  
Psychosomatic Medicine)  
US

**Jan Tack, MD, PhD, Co-Chair**  
(Gastroenterology, GI physiology)  
Belgium

**Alex Ford**  
(Gastroenterology, Meta-analysis)  
UK

**Eva Szigethy**  
(Psychiatry)  
US

**Hans Ford Tornblom**  
(Gastroenterology)  
Sweden

**Lukas Van Oudenhove, MD, PhD**  
(Psychiatry)  
Belgium

## ROME FOUNDATION RESEARCH INSTITUTE ANNUAL REPORT



Douglas A. Drossman, MD  
(Executive Committee)



Magnus Simren MD, PhD  
(Research Director)



Jan Tack MD, PhD  
(Executive Committee)

### Background and Organization of RFRI

The Rome Foundation Research Institute (RFRI) is a subsidiary organization of the Rome Foundation, an international non-profit academic organization dedicated to improving the lives of patients with Disorders of Gut-Brain Interaction (DGBI) formerly called Functional GI Disorders. The RFRI was created in 2018 to advance the scientific understanding of DGBI through development of a semi-autonomous entity that will promote and support research in the field of DGBI. <https://theromefoundation.org/research-institute-rome-foundation/>

**Vision.** To be the global leader in DGBI research

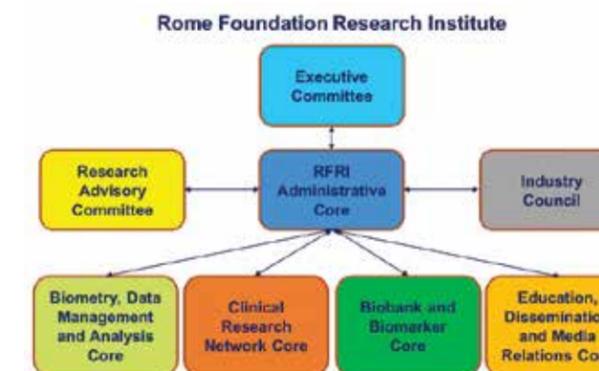
**Mission.** To improve the lives of patients with DGBI through ground-breaking research

**Aim.** To increase the knowledge of the causes, identification, treatment and care of patients with DGBI.

**Implementation.** To establish an international academic research initiative with leading experts, in order to facilitate global DGBI research through collaboration with industry and academic partners, and with the following objectives:

- Develop a centralized data acquisition and research coordinating center.
- Serve as an international clearinghouse for investigators and industry in the development, administration and analysis of clinical research in DGBIs.
- Develop a portfolio of current and future study protocols and an accessible database of knowledge which can be adapted to address specific questions regarding DGBIs pathophysiology, impact, diagnosis and treatment.

**Legal Structure and Governance.** The RFRI is governed by the Executive Committee consisting of: Magnus Simren MD, PhD (Director and Chair of Executive Committee of RFRI and Board Member of RF), Douglas Drossman MD (RF President Emeritus and COO) and Jan Tack MD, PhD (RF President). It is a Type I supporting organization of the Rome Foundation (RF) under Section 509(a)(3) of the US Internal Revenue Code. The corporate office is located in North Carolina, USA, therefore for legal and tax purposes the RFRI is represented by Douglas Drossman MD (President) and Johannah Ruddy (Secretary/Treasurer).



Organizational Structure Figure 1 demonstrates the organizational structure.

**Executive Committee (EC).** The EC (Drossman, Simren - chair, Tack) supports and directs all activities of the RFRI and is ultimately responsible for assuring that the aims and objectives of the program are achieved. The terms for the members are for five years and are renewable with the replacement process staggered to allow for gradual change of leadership.

**Administrative Core (AC).** The AC is responsible for the oversight of the day to day activities of the RFRI relating to research administration and program implementation, training, education and dissemination of information, collaboration with sponsors and outside agencies, and quality control of all core programs. The AC consists of the three members of the EC, an administrator (Johannah Ruddy M.Ed., Executive Director of the RF) the research manager of the RFRI (Olafur Palsson Psy.D.), and an external industry consultant who advises the Executive Committee on prospective and ongoing collaborations with commercial organizations within the Life Sciences sector (biopharmaceutical, device, and diagnostics companies) (Doug Levine, MD). The AC is advised by the RAC and the Industry Council (see below)

**Research Advisory Committee (RAC).** The RAC functions as advisory to the AC as a contributor of ideas, and as a repository to review and revise research proposals. Currently, it is composed of RF Board members who have been selected based on their academic record of scientific achievement, their ability to evaluate, conduct and analyze scientific data related to DGBI, and as well as demographic and geographic diversity issues. RAC members are responsible to participate in the various Cores discussed below. Current RAC members include: Giovanni Barbara MD, William Chey MD, Lin Chang MD, Laurie Keefer PhD, John Kellow MD, Samuel Nurko MD, MPH, Max Schmulson MD, and Ami Sperber MD, MSPH. In the future, the RAC may include members external to the RF board providing they meet the described guidelines, and their participation will help to serve future needs of RFRI.

**Industry Council (IC).** The IC is advisory to the AC and is comprised of representatives from pharmaceutical and device companies who share the mission of and sponsor the RFRI. Members of the IC interact with the AC in an advisory capacity and review the activities of the RFRI which may include: discussion of ongoing research studies, exchange of ideas for planned initiatives, review of operations of all cores, evaluation of research data, and participation in bilateral or collaborative research studies with privileged status. The current IC member is Machel Manuel, Vice President and Head of Global Medical Scientific Affairs at Ironwood Pharmaceuticals. Additional industry members to the IC will be included as additional sponsors come aboard.

**Biometry, Data Management and Analysis Core (Biometry Core).** The Biometry Core is responsible for providing and/or ensuring the standards for high quality data management systems, quality assurance processes, and statistical analytic aspects for the RFRI. Core members include Olafur Palsson Psy.D. who is the research manager and director of the Core, Shrikant Bangdiwala Ph.D., the statistician (co-director), William Whitehead PhD a former RF Board member, Ami Sperber MD MSPH, and Iram Haq, research coordinator. We would like to welcome Carolyn Morris Ph.D. who has joined us as an additional statistical analyst. She worked for over 10 years at the UNC Center for Functional GI and Motility Disorders with Dr. Drossman and will be available for upcoming research projects on a part time basis. This core is actively involved with ongoing research proposals currently in effect as discussed below.

**Clinical Research Network Core (Research Core).** The Research Core is responsible for providing the infrastructure and maintaining the standards for clinical investigative studies involving epidemiological, clinical, outcomes, and treatment studies. It is co-directed by Lin Chang MD and William Chey MD and members include: Laurie Keefer PhD, Samuel Nurko MD, Ami Sperber MD, MSPH and Jan Tack MD, PhD. This Core serves as a clearinghouse for research and is responsible for identification and selection of study centers. This includes: a) responsibility for large scale multicenter studies, b) clinical trials of new and existing treatment interventions, c) organizing and conducting clinical trials of non-pharmacological interventions, d) developing and validating patient reported outcomes (PROs) for DGBI, e) coordinating with the biometry core the development of operations of deep clinical phenotyping including demographic, Rome criteria, psychometric and clinical questionnaires, f) reviewing seed grant and large scale research proposals, and g) maintaining and coordinating, under the direction of the Biometry Core a pool of leading investigators and special population resources.

**Biobank and Biomarker Core (Biobank Core).** This core is responsible for the coordination of acquisition, storage and processing of biological samples including: blood, stool, urine, biopsy, luminal fluids and breath samples. It also is responsible for data acquisition relating to measurement of

motility or sensitivity physiological testing, peptide hormone assays, assessment of structural and functional alterations in the CNS, pharmacogenomics and other biological data. Finally, in collaboration with the biometry core, the biobank core identifies centers and experts to obtain for analysis biological samples and assist in their processing. The members are Giovanni Barbara MD (Director), Max Schmulson MD (co-director) and Magnus Simren MD, PhD, and additional members will be appointed based on expertise needed.

**Education, Dissemination and Media Relations Core (Education Core).** The Education Core serves primarily to assure quality control in the dissemination of research knowledge that is accumulated from the RFRI and support its translation into clinical practice. The Core members are Douglas Drossman MD (director), Johannah Ruddy (administrator and Executive Director of the RF), and Mark Schmitter (marketing director of the RF). This core assures that the information provided by the RFRI to external organizations, media and journals and other publications printed and digital, will be scientifically based, unbiased and non-commercial. The core also serves to monitor media, publications and other communications from external sources (e.g., news bureaus, scientific organizations, industry) to be sure the information provided is accurate, scientifically based and unbiased.

### Activities of the RFRI for 2020

Introduction. Over the past year the RFRI developed and consolidated the infrastructure as follows: further refinement of the biometry and biobank cores, the creation of a database of investigators and the development of the RFRI Investigator Platform (RFRI-IP) to obtain clinical phenotyping data from our research sites. We also engaged in several existing and planned research studies. These include: the development of data analysis of the Rome Foundation Global Epidemiology Study, implementation of two clinical trials: the Domino and ROBOT studies, the development of a research contract with Danone Pharmaceuticals to begin in January 2020, and consultations concerning prospective projects with two pharmaceutical companies. Finally, we are most pleased to have Ironwood Pharmaceuticals under the directorship of Mike Shetzline MD as a full diamond sponsor for 3 years.

We are also pleased to welcome Takeda Pharmaceuticals directed by Karen Lasch MD as a gold sponsor for 3 years. What follows is a detailed description of these activities.

### Infrastructure Development

#### Development of the Biobank and Biomarker Core

In order to be able to perform multinational, multicenter studies with the goal to identify diagnostic and predictive biomarkers of relevance for patients with DGBI, the RFRI spent a considerable amount of time creating this core and determining optimal sampling and storing procedures for biosamples in multicenter settings. This work led by the chair and the co-chair of this committee, in close collaboration with the members of the Executive Committee and the Research Manager. We decided not to create a central biobank for logistical and regulatory reasons. Instead participating research centers in the multicenter studies will each store their own samples locally according to predefined specifications, and upon request and after agreement ship their samples for analyses. We created detailed Standard Operating Procedures (SOPs) for collection and storage of fecal, urine, blood, and saliva samples, as well as biopsies, where details regarding sampling, equipment needed, storage, and transportation are provided. Regarding biopsies, separate SOPs for esophageal, gastroduodenal and colonic biopsies have been developed. Information about available samples and storage conditions for each subject will be entered into a database and linked with clinical phenotyping data available for that subject in the RFRI Investigator Platform (see below). Hence, the planning in the biobanking and biomarker core done in close collaboration with the biometry core.

Currently the biobank and biomarker core consist of a small group of RFRI members (see above), but additional members based on expertise needed will be appointed during the coming year.

#### Creation and Application of the RFRI Investigator Platform for Clinical phenotyping

The RFRI is currently developing a secure Internet-based data collection system, the RFRI Investigator Platform (RFRI-

IP), that will be used across all the research sites in the Global Research Network (see below) to collect detailed and uniform clinical phenotyping data on large panels of patients with DGBI. At many of the research sites, the patients in the phenotyping database will also have associated biosamples (these will be our ROBOT project sites), and the availability of those samples. This will quickly create an unprecedented large central clinical research database that can be used to (a) rapidly invite large sets of patients with well-known characteristics to participate in specific research studies; (b) conduct analyses for papers by site investigators, individually or in collaboration, and by the RFRI or commissioned by sponsors; and (c) assess feasibility and provide pilot information for grant applications and sponsored projects. Additionally, questionnaire data collected in the unified phenotyping will be instantly scored and will be available in the clinical encounters, and thus clinically useful.

All patient data collection using the RFRI-IP will be strictly de-identified and HIPAA and GDPR compliant. To minimize costs and demands on staff at clinical research sites, data collection will be predominantly self-administered by patients, using easy-to-use web-based assessment that works on any computer device and any web browser. The primary patient evaluation method will be via computer tablets used in the waiting rooms, but the assessment will be fully mobile-device compatible so patients can use their own mobile phones if preferred. Staff-assisted entry and paper questionnaires will only be used in exceptional circumstances if needed.

The patient phenotyping assessment will consist of an initial 20-25 min. patient-completed questionnaire, and a shorter assessment (5-10 min.) in return clinic visits, primarily designed to update information on clinical status in the database. These patient-completed assessments will be supplemented with a limited set of information from the medical record, added by the research site staff.

The phenotyping dataset collected on each participating patient, stored and available for queries and research use in the RFRI central database, will include the following: Demographic questions; clinical diagnoses; responses to

the Rome IV Diagnostic Questionnaire with scoring for 22 different DGBI diagnoses; characteristics and history of current GI symptoms; co-morbid GI and non-GI medical conditions; history of GI-relevant medical tests, medical procedures and surgeries; psychological symptom scores; quality of life scores; prescription and non-prescription medications used; and self-management methods used by the patient for GI symptoms. The availability and nature of biosamples from each patient (with summary of findings if the samples have been analyzed) will be recorded in the same central RFRI database along with the phenotyping data.

**Creation of the Global Research Network.** An essential part of carrying out the mission of the RFRI is the establishment of an active Global Research Network of leading and highly productive investigators in the DGBI domain, who will coordinate their research efforts to produce compatible clinical datasets and biosamples on large numbers of DGBI patients, and who operate with sufficiently uniform research methodology to make large multi-center and multi-national research studies quicker and more efficient to implement than previously possible. The first sites in the network will include some of the world's top DGBI centers, and the plan was to start systematically collecting data with the RFRI Investigator Platform in 2020, but due to the Pandemic, this has been postponed to 2021. These will be the following centers:

- KU Leuven, Belgium (PI: Jan Tack, MD, PhD)
- University of California Los Angeles, USA (PI: Lin Chang, MD);
- University of Michigan, USA (PI: Bill Chey, MD);
- Queen's University School of Medicine, Canada (PI: Steve Vanner, MD, MSc)
- Harvard Medical School, USA (PI: Anthony Lembo, MD)
- University of Gothenburg, Sweden (PI: Magnus Simren, MD, PhD)
- Universidad Nacional Autónoma de México (UNAM), Mexico (PI: Max Schmulson, MD)
- University of Bologna, Italy (PI: Giovanni Barbara, MD, PhD)

These first sites will help to refine and test the unified data collection system and operating procedures of the network. Additional sites will then be invited to join the research network in phases, starting in the second half of 2020, and

the number of sites in the network is expected to grow rapidly after that. That expectation is supported by the great interest that DGBI investigators world-wide have shown in joining the RFRI Global Research Network. A preliminary survey among Rome-affiliated researchers in 2018 resulted in 91 investigators in 33 countries expressing strong interest in joining the network (see figure).



**Engagement with Industry Consultant.** We are pleased to have Doug Levine MD as our external industry consultant. Assistance to the Executive Committee has been provided by advising on pharmaceutical industry perspectives and practices on engagement of external investigators to inform RFRI strategic approaches for establishing research collaborations:

- Supported start-up of Danone project: review of research proposal drafts, budgets, contract, and teleconference minutes
- Supported engagement with prospective research collaborator (Alnylam): reviews of research proposal drafts, company communications, and meeting minutes; provision of rare disease resources for patient-finding for project; participation in teleconferences and on-site protocol planning meeting; review of research protocol and budget drafts
- General activities with Executive Committee: participation in regular meetings; reviews of meeting minutes, reports, and internal planning documents (RFRI infrastructure, sponsorship agreements, ROBOT study proposal)

## Research Activities

**Rome Foundation Global Epidemiology Study Data Analysis and Publication Status.** The global study was initiated in 2013 with the establishment of its Executive Committee, a group of 13 leaders in the field who developed the study design and methodology. The primary aims of the global study are to conduct an extensive multinational epidemiological study of all the DGBIs, to obtain reliable regional and local estimates of DGBI prevalence, to evaluate the reasons for differences among regions by collecting data on multiple potentially associated factors, and to generate hypotheses to further advance our understanding of the pathophysiology of IBS and the other DGBIs. Secondary aims are to generate a database that can serve as a source of data mining and be integrated with other similar databases in the future, and to establish a network of FGID experts with a track record of research collaboration on a global scale. A tertiary aim is to establish a repository of translated versions of the Rome IV adult diagnostic questionnaire in multiple languages including linguistic validation (cognitive debriefing) and cultural adaptation.

The planning stage concluded at the beginning of 2016 in advance of the publication of the Rome IV questionnaire. At that time the translation process was begun through a professional translation company (Transperfect Inc.). The questionnaires were translated into 21 languages and localized into an additional 18 versions.

In all, 33 countries participated in the study. Data were collected by Internet survey (Qualtrics, Ltd.) in 26 countries where this was feasible. In 7 countries in which this was not the case we conducted house-to-house personal interviews. In two countries, China and Turkey we conducted both types of survey. The pre-defined demographic parameters were 50% females and 50% males, and an age distribution of 40% for 18-39 years, 40% for 40-64 years, and 20% for 65+ years. The data collection phase was completed in 2018 with a final database of 73,076 respondents: 36,148 women (49-47%) and 36,928 men (50-53%). Equal sex distribution and the pre-planned age ranges were successfully achieved with both surveying methods. The participating countries and the data collection method in each country are depicted in this map.

## ROME FOUNDATION RESEARCH INSTITUTE ANNUAL REPORT CONTINUED...



In the 26 Internet countries we achieved excellent national geographic representation with close approximation to official census figures in these countries. The household studies were not designed to be nationally representative, but rather to be representative samples of the general population in the communities in which they were conducted. This was accomplished.

We formulated a protocol for Policy and Procedures for Access to the Database, Conduct of Data Analyses, and Publications; in parallel we established a Database Committee, a Statistical Analysis Committee, and a Publications Committee. Initial statistical analyses were conducted by the Central statistical analysis core headed by Dr. Shrikant Bangdiwala at McMasters, Canada. We also vetted candidates for global study statisticians and established regional and local statistical analysis cores. A one and one-half day Global Study Statistical Workshop was held in Barcelona Spain in October 2019 for individuals who will serve as analysts of data for regional and local manuscripts and investigators who intend to be lead authors of manuscripts from the study. The workshop was led by Drs. Sperber, Palsson, and Bangdiwala and was attended by close to 40 participants from around the world.

We completed data analysis for the first global paper and the first manuscript, summarizing the major findings, was published in the January 2021 issue of Gastroenterology (Sperber AD, Bangdiwala SI, Drossman DA, Ghoshal UC, Simren M, Tack J, et al. Worldwide Prevalence and Burden of Functional Gastrointestinal Disorders, Results of Rome Foundation Global Study. *Gastroenterology*. 2021;160:99-114).

We also presented two abstracts at DDW 2020 and two more at UEGW 202 based on the initial study results. A paper on Overlapping DGBI has been submitted for publication and 10-15 more papers are in various stages of preparation for publication.

We have a submission website to submit proposal for abstracts or papers based on the study databases. These are submitted on official online submission forms and all proposals undergo a review process (including the statistical analysis plan) similar to editorial reviews in medical journals, but with the aim of improving and approving the proposals, not rejecting them.

We are also in the process of establishing a closed online forum for study investigators and statisticians (consistent with a "chat room") where free interchange of ideas, questions, and information related to the study will be shared.

In March-May 2021 we will be conducting an 8-session CME course on the Global Study with presentation of study results expanded to a general course on DGBI with multiple case presentations and discussion based on the Multidisciplinary Clinical Profile (MDCP) approach. The sessions will be present live and will remain available online for a year to all paying participants.

### Domino Trial

The DOMINO trial (Diet Or Medication in Irritable bowel syndrome) is a randomized trial to evaluate the short-term efficacy and long-term health economic impact of a dietary intervention compared to pharmacotherapy with a muscolotropic spasmolytic agent for newly diagnosed or newly treated irritable bowel syndrome in primary care. This trial is funded by Belgian Government Money, is pragmatic and aims at optimizing primary care. It uses questionnaires that were developed for the Rome IV Global Epidemiology study in Belgium and also serves as an opportunity to collect biobank material from primary care IBS patients. Patients are randomized to treatment with OB 60 mg t.i.d., the traditional first-line medical therapy, or by a FODMAP lowering diet, provided via a smartphone application. Before and after 8 weeks of treatment, patients completed questionnaires

evaluating demographics, stool types, Rome IV criteria, IBS-Symptom Severity (IBS-SSS), anxiety (GAD), depression (PHQ9) and somatization (PHQ15).

As of December 4th, 2019 a total of 466 of the targeted 470 patients were enrolled and 95% of the subjects provided biobanking samples for genetics, serum and stool analysis. Patients with an improvement of at least 50 points on IBS-SSS were considered as a responder. The following paragraphs summarize abstracts regarding this study, which were submitted to FNM 2020 and to DDW 2020.

At baseline, 70 % of these primary care-diagnosed IBS patients fulfill the Rome 4 criteria. (74% female, mean age 42±0.9 years, and mean BMI of 24±0.3). The following IBS-SSS distribution was found: 4, 16, 41, 39 % for normal, mild, moderate, and severe IBS-SSS respectively. Patients were characterized according to the stool pattern: diarrhea (27%), constipation (23%), mixed stool type (38%) and normal (12%). Respectively 59% and 70% of patients treated with OB and diet were IBS-SSS responders. In the OB group, responders had significantly higher somatization scores compared to non-responders (10.5±0.5 vs 9.0±0.4, p=0.01), but both groups had comparable demographic and other clinical characteristics. Responders to the diet were significantly younger than non-responders (mean age 39±1 vs 44.6±2 (p=0.03). Diet response was not determined by the stool pattern subtype, but Rome+ patients were significantly more likely to respond to the diet compared to Rome- (p=0.002).

Last patient enrollment is expected around December 10th, 2019. The primary endpoint analysis is anticipated in early February 2020.

### ROBOT Project

During this year, the RFRI has finalized the detailed planning of the Rome foundation BiOmarker and phenotyping project (ROBOT), to support the launch of this multinational project. The plan was to launch this project during 2020 at a small number of sites, but due to the Pandemic the strat of the study has been postponed to 2021. After this initial launch in a few highly specialized clinical research units, we aim to expand this project to more sites in the coming year/years. The aim of

ROBOT is to develop a state-of-the-art biobank and database of patients with DGBI, supported by an international network of top international research sites. Patients in the database will be thoroughly characterized as follows: clinical phenotype and associated demographic, medical history, psychosocial and lifestyle factors will be established, fecal, blood and urine samples will be collected and stored in a standardized fashion, and in select sites biopsies from the upper and/or lower GI tract will be collected depending on the predominant symptom profile. The collection of biosamples and data will enable evaluation of different biomarkers in large groups of very well-characterized individuals in different parts of the world and assessment of their validity for use as diagnostic and /or predictive tools. A centralized electronic database will enable development of profiles of available clinical phenotypes and biosamples at any time to assess the feasibility of new studies.

ROBOT will involve leading DGBI research sites that recruit patients in different parts of the world. In the first phase of ROBOT each center will recruit ≥100 patients who fulfill diagnostic criteria (Rome IV) for at least one DGBI, with the aim of having a 50:50 split between predominantly upper, i.e. esophageal and gastroduodenal, and lower, i.e. bowel and anorectal DGBI (to be separately negotiated with each site, depending on their expertise and research focus, with the aim to have an overall 50:50 split across sites). Each site will ideally also include 20-50 healthy controls without current GI symptoms. All patients will complete questionnaires and provide information for the RFRI clinical phenotyping tool (see below). In most patients, blood, fecal and urine samples will also be collected, as well as GI biopsies in some of the sites where this is possible, and the samples will be stored at the individual sites in a local biobank. In select centers, a small number of patients will also undergo physiologic testing. Thus, based on site capabilities, patient characterization / data collection in ROBOT will vary and yield different levels of integrated information from individual sites:

1. RFRI clinical phenotyping tool alone
2. RFRI clinical phenotyping tool and collection of biosamples.
3. RFRI clinical phenotyping tool, collection of biosamples, and performance of physiologic testing.

Each investigator will “own” the samples from his/her patients, and will be included as an author in publications / projects in which his/her samples are used. After discussions with participating investigators, a study management committee will make decisions about prioritization of proposals for sample analyses from individual investigators and/or external collaborators, e.g. RFRI sponsors / academic collaborators. Specifically, if approved, samples will be shipped to analytical centers from the local biobanks; after the analyses are completed, the remainder of the samples will be shipped back to the local biobanks at the sites for continued storage.

The current goal is to start this ambitious project in a small number of centers during 2021, and expand to more sites in the coming year/years.

### RFRI-Danone Survey

This study focuses on symptoms of bloating and distention in the general population and is currently in final stages of preparation. Data will be acquired via a nationwide population-based Internet survey of adults in three countries: United States, Mexico and United Kingdom. The project research protocol is designed collaboratively by the RFRI and Danone, is subsidized by Danone, and is scheduled to be initiated in 2020.

The study is designed to serve a number of different descriptive and hypothesis-driven aims. The a priori hypotheses to be evaluated are: (a) different personal factors and symptoms characterize the subset of individuals who report bloating or distention compared to those without these symptoms; (b) certain personal factors and symptoms distinguish bloating from distention that may reflect different pathophysiologic mechanisms; and (c) subgroups of individuals meeting Rome IV diagnostic criteria for Functional Abdominal Bloating/Distention will report only bloating or only distention and have different associated characteristics. Evaluation of data pertinent to the last hypothesis may yield identification of characteristic clinical features warranting subtyping of patients that may be amenable to different, more specific forms of treatment. Descriptive aims include: (a) characterizing prevalence, frequency and severity of current (last 24 hours) and chronic

bloating and/or distention in the adult population; (b) overlap of these symptoms with other related GI symptoms and Rome IV diagnoses (IBS, functional dyspepsia, functional constipation and functional diarrhea); and (c) quantification of the quality of life impairment and health care utilization effects of having these symptoms. Additionally, a sub-study will address the relationship of bloating and/or distention symptoms with dietary factors in detail.

A total of 6000 adults will be surveyed in the U.S., U.K., and Mexico (2000 survey completers in each country) via a secure Internet survey, using Qualtrics Research Suite survey software. Quota-based sampling will be applied to obtain survey samples with the same age and sex groups composition in each country: 50% females and 50% males; 40% individuals of ages 18-39 years, 40% of ages 40-64 years, and 20% ages 65 and older. The subject sample in each country will also have nationwide geographic distribution.

The contents of the survey include demographic variables, Rome IV diagnostic questionnaire modules for gastroduodenal disorders and functional bowel disorders, questions about bloating and distention rated separately for the previous 3 months (as opposed to the question on a combination asked in Rome IV), the Intestinal Gas Questionnaire, questions about association of bloating/distention to meals, the PHQ-12 non-GI physical symptom questionnaire, selected medical and health history, questions about medications used regularly (at least once a week), and questions about anxiety and depression symptoms, stress, sleep, exercise, diet, quality of life, height and weight, and healthcare utilization.

A subset of 1500 subjects (500 from each country) of the 6000 who complete the main survey in each of the three countries will be selectively invited to also complete a follow-up sub-study survey two weeks later to retrospectively assess their total diet over the past 3 months. This will be done via the validated 25-minute online VioScreen food frequency questionnaire assessment provided by Viocare Technologies. This will be the first study to examine both current and chronic presence of bloating/distention and numerous potential associated factors in the same population-based sample. The large and demographically balanced multi-

national sample will allow presentation of a comprehensive picture of the scope of these symptoms and their impact in the population, as well as the relative prevalence and overlap of bloating vs. distention. It is anticipated that this project will result in multiple influential scientific publications that will significantly advance the state of knowledge about the nature of these symptoms in the general population. The findings are also likely to help guide future refinement of the Rome diagnostic criteria for functional bloating and distention.

### RFRI-Danone Study on Persons with GI Disturbance not Meeting Rome Criteria

#### Education Core: Rome-DrossmanCare Communications Program Analyses.

Over the last year the Rome Foundation in collaboration with the Center for Education and Practice of Biopsychosocial Care (DrossmanCare) conducted several workshops, symposia and train the trainer sessions to help clinicians improve their communication skills. The RFRI took on the responsibility to study the value of these programs. Thus, we embedded online questionnaires in all programs to obtain feedback. We also undertook a survey of over 300 patients seeking health care from GI faculty members who underwent a communication workshop at Johns Hopkins medical center. This was done in part to determine the value of the clinician training with regard to patient satisfaction. This involves two validated questionnaires developed by Dr. Drossman: the satisfaction with care scale, and the patient provider relationship (PPR) scale. These questionnaires, in addition to patient general symptoms and anxiety scores will be used to evaluate patient perceptions both before and after their faculty providers attend the communication workshop. We are currently looking at predictors of patient satisfaction and perception of the PPR through multivariate analysis and will include in these models based on the contribution of the faculty that attended the workshop along with other predictor variables. We will then revise our program based on some of these responses and continue to evaluate all communication programs in future activities.

### Consultations with Industry.

Over the past year the RFRI consulted with two companies.

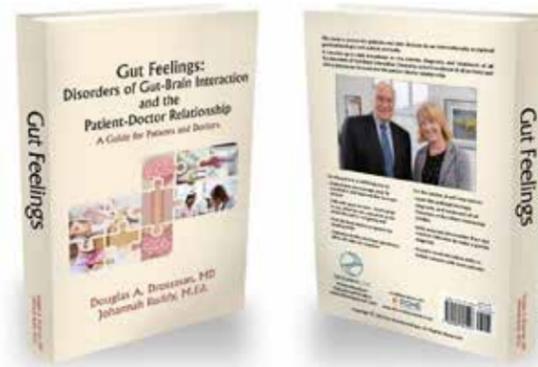
- **Transparency and Rose Pharmaceuticals.** Drs. Drossman, Chang and Chey consulted on the protocol of a Phase IIb study evaluating the efficacy and safety of the GLP-1 analogue ROSE-010 in reducing moderate to severe acute abdominal pain in IBS. The RFRI received \$20,000 for this effort.
- **Alnylam Pharmaceuticals.** Upon the request of the company, Dr. Drossman initiated a study proposal that was further modified by Drs. Tack, Simren, Palsson and Bangdiwala to identify hepatic type porphyria (primarily AIP) at multiple sites globally. Dr. Doug Levine served as external industry consultant to the Executive Committee. The initial proposal was approved by the company. Subsequently a full day meeting with the above consultants was held in June of 2019 to finalize the proposal which was submitted to the company. Unfortunately, several months ago a change of senior leadership and a shift in research priorities led the company to inform us that this study was dropped.

### Conclusion

For 2020, the RFRI advanced in its position to become a global leader in DGBI research. With the support of Ironwood Pharmaceuticals, we established an efficient infrastructure consisting of an Executive Committee, academic and industry advisory boards and five cores. To date, we consulted with two pharmaceutical companies on their programs, designed and implemented our own epidemiological studies and clinical trials, initiated the ROBOT and Domino programs, established the ability to collect biosamples, and are beginning to analyze and publish the results. The RFRI continues several international studies and is building a global research network to expand our research capability. We believe that these activities will continue to grow over the next year and fulfill our mission: To improve the lives of patients with DGBI through ground-breaking research.

## GUT FEELINGS BOOK

**Gut Feelings: Disorders of Gut-Brain Interaction and the Patient-Doctor Relationship, was written as a collaboration by Douglas Drossman, MD and Johannah Ruddy M.Ed with one main goal: to improve the care of patients with DGBI.**



**Gut Feelings is broken down into four easy-to-read sections**

**PART 1:** A Conceptual Understanding of the History, Philosophy, and Scientific Basis for the Disorders of Gut-Brain Interaction (DGBI)

**PART 2:** The Disorders of Gut-Brain Interaction (DGBI)

**PART 3:** Maximizing the Patient-Doctor Relationship. This section includes key elements to optimize the patient-doctor relationship with a guide for patients about self-management, and what they should do to maximize the care they are to receive, including problem-solving techniques.

**PART 4:** Information for the Doctor. This section is designed for the doctor and discusses aspects of shared responsibility and ways to use the book as a guide in working with patients.

The scientific explanations are presented in simple-to-understand terms, and many of the vital educational elements include the patient's perspective. There are also case histories and videos to bring to life the learning experience. Special features include a glossary to aid patients in understanding technical terms, beautiful illustrations, cartoons, and a resource page to find top-tier clinical programs that see patients with DGBIs. Check out the book here: <https://drossmancare.com/gut-feelings-book>



Douglas Drossman, MD



Johannah Ruddy M.Ed

## PATIENT Q&A VIDEO LIBRARY

The Rome Foundation is proud to now offer a library of videos for patient and providers designed to offer easy to understand explanations of all DGBI diagnosis and treatments along with other topics such as communication, the role of stigma, shame, trauma and stress and more. See our listing now: <https://theromefoundation.org/patient-educational-q-a/>



One of the Rome Foundation's objectives is to "develop and provide educational resources to optimize clinical management." The new Rome Campus is designed to provide easy access to resources in our ever-growing library of on-demand educational programs. <https://theromefoundation.org/welcome-to-the-rome-campus/>

Here, you will find all of the lectures, videos and training tools of Rome. You can access full CME symposia at anytime or you can even claim single CME credits for free through our accredited CME educational activities listed below. We will be adding more as they become available.

### On Demand CME Programs Available Now

- The Rome Foundation Global Epi Study & Clinical Applications Symposium
- The Rome Foundation Educational Program- Diagnosing and Treating DGBI in the Primary Care Setting

- The Rome Foundation Basic Skills Training in GastroPsych
- The Rome Foundation GastroPsych Hypnosis Training

### Earn Free CME credits

#### Free Understanding and Management of Patients with Chronic Abdominal Pain and Narcotic Bowel Syndrome

This CME activity features a patient with a history of chronic abdominal pain to illustrate the clinician and pathophysiological features, the psychosocial aspects, and how to devise a management strategy. *1 CME credit*

#### Esophageal and Gastroduodenal Disorders

This CME activity covers the basics for diagnosing and treating disorders of the upper and lower GI. *1 CME credit*

#### Key Elements of Good Patient/Provider Communication

This CME activity covers the key elements of good provider/patient communication to optimize patient care, decrease burnout, and increase provider and patient satisfaction. *1 CME credit*

Learn from the World's Leading Experts to Understand and Explain to Patients Complex Issues in Disorders of Gut-Brain Interaction (DGBI)



EARN 3.0 CME CREDITS

## COMMUNICATION 101 Basic

- Thirty-two brief (5 minute) videos demonstrate how 15 thought leaders in Neurogastroenterology educate patients on common clinical issues
- The videos cover all major topics relevant to patients with DGBI
- This program can be used to educate clinicians to effectively communicate key messages, as a resource to show patients, or as a learning tool for patients

A Joint Initiative from



"The experts in these videos clearly and concisely teach clinicians and patients about the complexities of these disorders. The feedback has been overwhelmingly positive."  
Douglas A. Drossman, MD

This educational video series was developed by Douglas A. Drossman, MD, world-renowned expert in Gut-Brain Disorders and patient communication skills, in partnership with leading experts across the globe. The cutting-edge information offered in these videos is now available for provider and patient learning.

A Deeper Understanding of GI Illness Through a Patient-Centered Approach



EARN 3.25 CME CREDITS

## COMMUNICATION 202 Advanced

- Learn to navigate your most challenging clinical cases and improve patient-provider satisfaction
- Optimize the patient-provider relationship and save time by learning effective communication skills
- Use our tips and techniques to successfully identify underlying fears and concerns, address treatment non-adherence, reduce conflict and increase patient engagement

A Joint Initiative from

2019 Rome Foundation Survey of GI Faculty and Fellows  
How positively do you believe this program will affect your practice?



Program developed by Douglas A. Drossman, MD, world-renowned expert in Gut-Brain Disorders and communication skills. The methods have been taught at training programs internationally and are now available for self-learning.

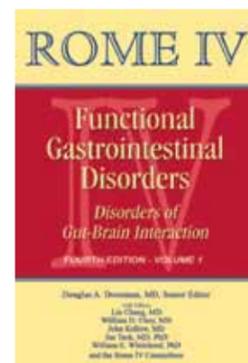


"It's not what you do but how you do it that makes the difference."  
Douglas A. Drossman, MD

# EDUCATIONAL PRODUCTS

## Rome IV Educational Books

The Rome IV educational materials include several books, each serving different purposes. They are available as hard copy books and as part of the Rome Online online subscription.



### Rome IV Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction (Fourth Edition)

As with earlier book editions beginning in 1994, the Rome IV textbook is a comprehensive update of knowledge in DGBIs and in the Rome IV diagnostic criteria. It is a 1,500-page, two-volume book created by 117 internationally recognized clinicians and investigators in the field.

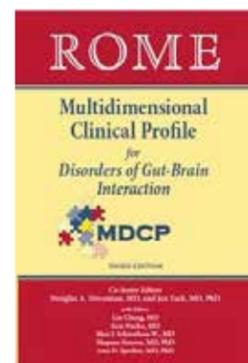
As with earlier book editions beginning in 1994, the Rome IV textbook is a comprehensive update of knowledge in DGBIs and in the Rome IV diagnostic criteria. It is a 1,500-page, two-volume book created by 117 internationally recognized clinicians and investigators in the field.

**Volume I** contains a comprehensive set of background chapters on neurogastroenterology (basic science and physiology); pharmacology, pharmacokinetics and pharmacogenomics; age, gender, women's health and the patient's perspective; cross-cultural aspects of DGBIs; the role of the microenvironment (food and microbiota); and biopsychosocial aspects of assessment and management.

**Volume II** provides the key clinical information on 33 adult and 17 pediatric DGBIs from esophagus to anorectum, as well as a newly developed chapter on centrally mediated disorders of gastrointestinal pain. For each DGBI we provide recent information on the epidemiology, pathophysiology, and psychosocial aspects along with evidence- and consensus-based recommendations on diagnosis and treatment. Volume II also contains new information and the

revised Rome IV diagnostic criteria for adult and pediatric DGBIs. Also there are appendices that contain key reference information including the Rome IV diagnostic criteria tables, a comparison of the Rome III and Rome IV criteria, a flowchart to assist in the biopsychosocial assessment of patients with DGBIs and how to treat or when to seek a mental health consultant. There are also the validated Rome IV pediatric and adult questionnaires criteria for epidemiological and clinical research.

**Volume 1 \$99.95 50% off**  
**Volume 2 \$99.95 50% off**  
**Two-volume package as hard copy or e-book \$149.95 50% off**



### New and now available! Rome Multidimensional Clinical Profile for Disorders of Gut-Brain Interaction: MDCP (Third Edition)

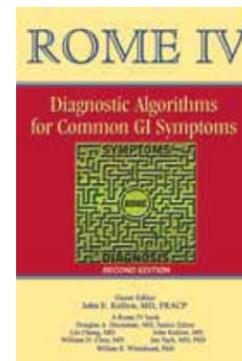
The MDCP redefines the ways in which clinicians can care for patients having even the most complex functional GI disorders. The 3rd edition is a case-based learning module that updates the content of the first MDCP book published in 2021. There are over 89 new cases, more than double that in the first edition, and all cases are revised to with the latest up-to date science and treatments.

The book helps the clinician understand the complexity and dimensionality of these disorders. Discerning clinicians recognize that just making a diagnosis is not sufficient to determine treatment. For example, a patient with IBS-D having mild and occasional symptoms of abdominal discomfort and loose stools and functioning without impairment would be treated quite differently than a patient with the same diagnosis having continuous severe and disabling pain and comorbid anxiety disorder with fears of incontinence when leaving the house.

We accomplished this task in a short time by acquiring the expertise of our Rome Board Members, who revised the previous cases and added newer diagnostic entities (such as OIC—opioid-induced constipation, narcotic bowel syndrome, cannabinoid hyperemesis syndrome, and esophageal reflux hypersensitivity) and who also provided

additional cases to increase the variety of clinical presentations that occur in real-life practice, often with dual or multiple diagnoses including post-COVID-19 infection and ARFID. Thus, this 3rd edition truly addresses the full depth and breadth of clinical decision-making for DGBIs. Furthermore, we have updated all 18 pediatric cases (neonate-toddler and child-adolescent) and the multi-cultural cases where sociocultural influences affect symptom presentation, and where treatment must be geared to the patient's cultural perspective. In this way, any diagnosis, for example, IBS or dyspepsia, has multiple clinical cases ranging from mild to severe, with or without associated comorbidities or sociocultural influences or with psychological comorbidities. As before, the MDCP identifies and classifies five components of every case scenario that include the categorical Rome diagnosis (Category A), additional subclassifications leading to more specific treatments (Category B, e.g., IBS-D or IBS-C, EPS or PDS), the personal impact of the disorder on the patient (Category C), psychosocial influences (Category D), and physiological abnormalities or biomarkers (Category E). This framework is intuitively clear and the organizational approach is both pragmatic and useful.

**Soft cover or e-book \$49.95**



### Rome IV Diagnostic Algorithms for Common GI Symptoms (Second Edition)

The diagnostic criteria, designed primarily for research, has a limited role in clinical practice. Patients don't go to doctors complaining of IBS, or sphincter of Oddi dysfunction; they present with symptoms of abdominal pain, nausea, vomiting and constipation, among others. Accordingly, the Foundation initiated a multiyear committee process to address this concern by incorporating diagnostic decision making, information about testing and the use of the symptom-based criteria into a series of clinical algorithms.

For the 1st edition published in 2010 as a special issue of the American Journal of Gastroenterology, 15 common gastrointestinal symptom presentations were created, and from that entry point, the committees developed evidence-based and cost-effective diagnostic pathways that followed each of these clinical presentations.

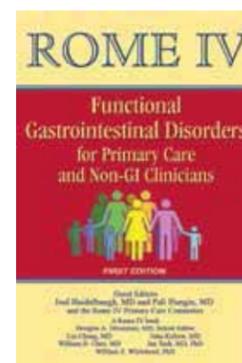
This 2nd edition, with guest editor John Kellow, MD, was developed concurrent with that of the Rome IV book. Thus we called upon the Rome IV chapter committee members to accomplish this update and revision with the creation of new algorithms, all consistent with Rome IV diagnostic guidelines and criteria. Now there are 19 algorithms for adults,

**Soft Cover or e-book \$39.95**

and 10 for neonates, toddlers, children and adolescents. The book is organized into 8 separate chapters that cover the symptom presentations of the primary GI regions in adults (esophagus, gastroduodenal, biliary, bowel, anorectal and centrally mediated abdominal pain) as well as the symptom presentations in neonate/toddlers and children-adolescents.

Each chapter has an introductory discussion section to help the reader understand the nature and underlying pathophysiology of the symptoms relative to that region or age group and then move on to discuss for each chapter anywhere from two to fourteen algorithms. Then for each algorithm we include features that bring the information to clinical reality: a) a case report linked to the algorithm in order to demonstrate real-life application, b) a color-coded algorithm graphic using standard "yes-no" decision tree methodology for branched decision making, c) links for each box to information that explains in detail the reasons for the clinical decision or the diagnostic assessment method and d) up-to-date references to support the clinical information. Thus, each common GI symptom yields a clinically meaningful diagnostic algorithm image and incorporates diagnostic testing recommendations, ending with specific diagnoses. When other structural disorders are excluded, the path leads to the Rome diagnostic criteria and ultimately the diagnosis of the DGBI.

Finally, there is an appendix that includes the Rome IV Diagnostic Criteria for reference and also the Rome IV Psychosocial Alarm Questionnaire to help providers decide when in the evaluation is referral to a mental health consultant recommended.



### Rome IV Functional Gastrointestinal Disorders for Primary Care and Non-GI Clinicians (First Edition)

As noted, one of the Rome IV initiatives was that of reaching a larger audience of non-gastroenterologists. We have partnered with leaders in the primary care field to create a primary care book, co-edited by Joel Heidelbaugh, MD, and Pali Hungin, MD.

For many years, the Rome Foundation has heard from primary care physicians that our educational materials are "too complex, cumbersome, and not efficient" for practical day-to-day use. Taking this as a challenge, in 2010 the Board of Directors prioritized the effort to find ways to learn more about how primary care physicians understand and approach diagnosis and treatment of DGBIs. We approached Pali Hungin, MD, a leading expert in the primary care of DGBIs, to help us develop a mechanism for the Foundation to offer relevant educational materials for primary care. This led to formation of the Rome Foundation Primary Care Committee, which published two articles on how non-gastroenterologists see DGBIs, and this eventually culminated in the Rome IV primary care book. This efficiently organized book is designed to help the busy primary care physicians and other nongastroenterological providers who see patients with these disorders.

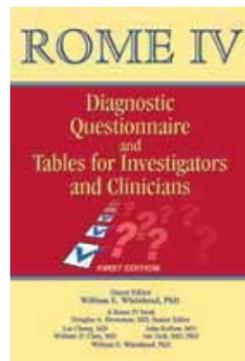
**Soft Cover or e-book \$24.95**

The book is organized into 12 chapters that cover the spectrum of DGBIs, but in a fashion that is specifically designed to address the diagnoses most commonly seen, with emphasis on "how to" diagnosis and treatment information. Chapters first address the burden of DGBIs on the patient and their relation to other functional somatic syndromes. Following this is general information relating to diagnostic and management strategies for primary care, patient-centered approaches to care, and then an understanding of these disorders from a biopsychosocial perspective.

The second part addresses the most important DGBIs: esophageal, gastroduodenal (functional dyspepsia), bowel (e.g., IBS and constipation), anorectal (e.g., dyssynergic defecation and incontinence), childhood disorders for neonates-toddlers and children/adolescents, centrally mediated disorders of GI pain (e.g., chronic pain and narcotic bowel syndrome) and finally multicultural aspects of DGBIs. The book concludes with the comprehensive list of the Rome IV DGBIs and their diagnostic criteria.



# EDUCATIONAL PRODUCTS



## Rome IV Diagnostic Questionnaires and Tables for Investigators and Clinicians (First Edition)

The Rome Foundation maintains a major commitment to the creation and dissemination of good research in the field of DGBIs. To properly study patients having these disorders we need to identify them in as precise a way as possible. Hence, we have proposed, created and disseminated the use of diagnostic criteria and questionnaires for epidemiological and clinical research. As such the Rome criteria have been recommended by the U.S. FDA, the EMA and other regulatory agencies for clinical trials, and they remain the only method used to diagnose patients by epidemiological surveys.

To maintain this initiative for Rome IV, we developed an extensive multinational program to first create the Rome criteria through our Rome IV chapter committees, and, in addition, validate and also translate the questionnaires containing these criteria research. We have done this not only for adults but also adolescents and young children.

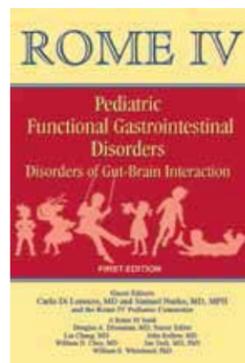
Soft Cover or e-book \$34.95

This book, guest edited by William Whitehead, PhD, provides, in one compact volume, all that is needed for researchers and clinicians to perform studies in English-speaking countries. The book begins with an introduction by Dr.

Whitehead, follows with chapters about DGBIs and the Rome IV process, and then contains a chapter on the development and validation of the Rome IV questionnaires.

The second section is the heart of the book: 1) the diagnostic questionnaires for adult functional GI disorders, 2) the psychosocial alarm questions for DGBIs to help clinicians decide when to refer patients for mental health treatment, and 3) the diagnostic questionnaires for pediatric DGBIs with questionnaire sets for children and adolescents as well as neonates and toddlers.

Finally the appendices provide supplemental information including a reference table of all the Rome IV diagnostic criteria, a comparison table between Rome III and Rome IV criteria for investigators who may have used Rome III in previous studies, and finally a psychosocial assessment flowchart created by the Biopsychosocial committee to guide clinicians in the biopsychosocial care of their patients.

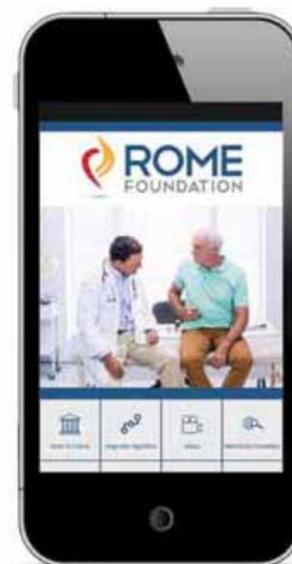


## Rome IV Pediatric Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction (First Edition)

The field of pediatric DGBIs has grown over the last two decades, and for this reason we have decided to publish a separate book on pediatric DGBIs, which is extracted from the main Rome IV chapter material. This book has an introduction by co-guest editors Samuel Nurko, MD (chair of the Neonate-Toddler Committee) and Carlo Di Lorenzo, MD (chair of the Child-Adolescent Committee).

Following this are the two updated and expanded pediatric chapters of Rome IV and also newly validated sets of the pediatric diagnostic questionnaires and criteria, a series of pediatric Multidimensional Clinical Profile (MDCP) cases for the Rome IV book, and a set of diagnostic algorithms for both neonate-toddler and child-adolescent. Thus, the pediatric gastroenterologist can possess a complete but compact book on DGBIs relative to his or her specialty.

Soft Cover or e-book \$59.95



## Rome App

The Rome Foundation App for iOS and Android is a brand new tool that gives quick access on your mobile device to: The Rome Criteria, Diagnostic Algorithms, a large video library as well as easy links to all of the educational resource products available

This mobile application allows users to interact with the Rome Foundation's educational resources in a new and convenient way. The application allows for direct availability of the adult and pediatric Rome IV criteria and is available for co-purchase along with access to the Rome IV Clinical Decision Toolkit. Users will also have access to several features including:

- the Rome IV criteria for diagnosing DGBI,
- the Rome IV diagnostic algorithms (for a small user fee)
- educational videos demonstrating effective communication techniques, lectures, how to use the MDCP, algorithms and GI Genius, webinars and satellite symposia
- Access to our social media (Twitter, Instagram and Facebook)
- Information about all Board members
- Meet the Rome Foundation, a comprehensive view of all Rome programs and activities
- a product information page to order educational materials
- a quick link to the Rome Foundation website to search for more information

This App was developed in conjunction with our collaborators at Precisions Marketing Partners and is another step taken by the Rome Foundation to remain at the forefront of medical education for all clinicians treating FGIDs.

## Rome IV Online Subscriptions

A **major** enhancement to our educational program will be to provide all books online on a subscription basis, allowing the individual to do free-text searching across all book platforms. For example, searching “functional dyspepsia” will lead to links in the Rome IV books, algorithms, MDCP, pediatrics and primary care. We believe that this will be a very popular option for clinicians and investigators as it will always be accessible through a password and can be purchased with several options.

**SUBSCRIPTION PRICES:**  
**One month: \$29.95**  
**Six months: \$159.95**  
**One year: \$250**  
**Lifetime: \$350**  
**(life of book ~ 10 years)**

### Rome IV Online Subscription Bulk Order Pricing

BULK ORDERS	1-9	10-24	25-49	50-99	100-249	250-499	500-999	1000+
1 month Subscription	\$29.95	\$26.95	\$25.50	\$23.95	\$22.50	\$20.95	\$17.95	\$14.95
6 months Subscription	\$159.95	\$143.95	\$135.95	\$127.95	\$119.95	\$111.95	\$95.95	\$79.95
1 Year Subscription	\$297.95	\$267.95	\$252.95	\$237.95	\$223.50	\$208.50	\$178.95	\$148.95
Lifetime (about 10 years)	\$497.95	\$448.00	\$423.25	\$398.50	\$373.50	\$348.50	\$298.75	\$248.95

# EDUCATIONAL PRODUCTS

## Rome IV Slide Sets

### Rome IV MDCP Slide Set

3 month trial subscription - \$29.95 | Renew annually for \$89.95

The MDCP is an effective educational tool not only for case-based self-learning but also for presentation at conferences. This slide set contains 72 cases (2-3 slides each case containing the history, the MDCP categories and the recommended treatments).

### Rome IV Slide Set

Total slide set of almost 700 PowerPoint images \$595.95 or \$5/image

The online version of the Rome IV book contains over 650 images and videos from the print and online Rome IV chapters, and 58 slides of the Rome IV diagnostic criteria. Each image has a legend and reference for self-learning or for the PowerPoint presentation at meetings.

### Rome IV Diagnostic Algorithm Slide Set

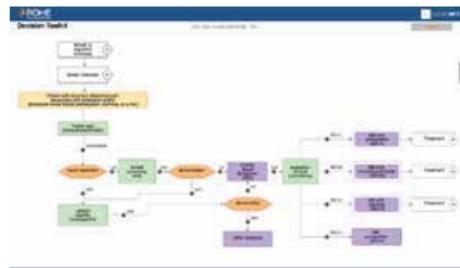
Slide set of 35 images \$29.95/set

This set of 35 slides includes all the clinical presentations in the Rome IV Diagnostic Algorithm book. Each slide shows the recommended algorithm for each diagnostic workup and also included is the text information explaining the decision pathways



## GI Genius Interactive Clinical Decision Toolkit

This new intelligent software program created by the Rome Foundation and LogicNets addresses the sophistication and complexity of diagnosis and treatment through an intelligent platform that interactively helps practitioners achieve the most optimal clinical outcomes. Using the database of knowledge through combining the diagnostic algorithm and MDCP books the program takes the clinician from assessment to treatment using decision pathways created by the Rome Foundation Board of Directors and the Rome IV chapter committee members.



3 month trial subscription - \$29.95 | Renew annually for \$89.95

Participants learn interactively. The program responds to input by the clinician and then interactively guides practitioners through optimal diagnostic and treatment pathways. The intelligent software also continues to learn. User input is retained and catalogued. When decision branches occur that contain uncertainties, the information is presented to the board of experts who help modify the algorithm in order to improve its performance. This program will aid practitioners around the world to successfully access Rome expertise, diagnose and treat patients, increase their own knowledge and credentials, and contribute to outcomes-based learning facilitated by this constantly learning system.

## Rome Foundation's Brain-Gut Axis Card

Do you need to explain the Brain-Gut Axis to your patients?



Download this free card <https://theromefoundation.org/resources/rome-foundations-brain-gut-axis-card/>.

## COMMUNICATION 101 Basic

### A Video Approach to Help Clinicians Rapidly Convey Key Clinical Messages to Patients with Disorders of Gut-Brain Interaction.

This newly released video learning tool is available for any clinician that treats patients with DGBI. Using the expertise of 15 key opinion leaders in the field, we have them demonstrate in 5 minutes how they educate patients on 32 topics covering 11 content areas. Included are some of the most common clinical issues that arise in the course of a clinical visit. These include: "What is the Brain-Gut Axis," "How do You Use a Secretagogue," "How Do you Recommend a Patient to Go to a Mental Health Provider," "What is a Neuromodulator," "How to Explain Constipation and Dyssynergic Defecation" and many more.

See more from the website: <https://www.communication101.org/vsl1586551670692>

## COMMUNICATION 101.5 Intermediate

### Tips and Techniques to Address Challenging Interactions in Clinical Practice

Communication 101.5 is a unique video learning tool for clinicians that explains how to address challenging situations when seeing patients with Disorders of Gut-Brain Interaction (DGBI). During a clinic visit, clinicians may be faced with difficult issues to address or may even lead to confrontation. The clinician must navigate the interview in a fashion that leads to resolving the underlying problems, improving patient and doctor satisfaction, and arriving at a mutually agreed-upon plan of care. Through this video learning series, Communication 101.5, clinicians can watch as a leading expert in the field offers methods to address these interaction difficulties in a fashion that leads to consensus and resolution.

This video program provides 4-8 minute videos that encapsulate the clinical challenges and their resolution. Included are eight seemingly complex interviews occurring during a clinic visit. The doctor uses specific methods and techniques to resolve the obstacles, improve the patient-doctor interaction and result in a mutually agreed-upon care plan. Each video demonstration also provides a time-coded point-by-point description of the dialogue, giving the interpretation of the underlying issues and interview techniques that allow the doctor to negotiate through the sequence of events.

See more from the website: <https://www.communication1015.org/vsl1618934633547>

## COMMUNICATION 202 Advanced

### New Innovative Video Learning Tool

This innovative video learning tool teaches the sophistication and complexity of the medical interview as a means to optimize the patient provider relationship. Within the context of a clinical visit, the program demonstrates educational techniques to improve communication skills, by employing simulations of ineffective and effective interview technique as well as detailed critique of the interview methods. This knowledge leads to patient centered care, effective psychosocial assessment, and shared decision making. The information provided within the interview applies to patients with most any medical diagnosis.

Visit [www.communication202.org](http://www.communication202.org) for more information.



Created by Douglas A. Drossman, MD in collaboration with Rome Foundation and DrossmanCare.



# ROME IV COMMITTEES

Rome IV Chapter Committees			
<b>Fundamentals of Neurogastroenterology: Basic Science (Kellow)*</b>	<b>Fundamentals of Neurogastroenterology: Physiology/Motility-Sensation (Whitehead)*</b>	<b>Intestinal Microenvironment and FGIDs (Chey)*</b>	<b>pharmacological pharmacokinetic and pharmacogenomic aspects of fgids (Tack)*</b>
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<b>Age, Gender and Women's Health and the Patient (Chang)*</b>	<b>Multicultural Aspects of FGIDs (Chang)*</b>	<b>Biopsychosocial Aspects of Functional Gastrointestinal Disorders (Drossman)*</b>	<b>Esophageal Disorders (Tack)*</b>
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<b>Anorectal Disorders (Whitehead)*</b>	<b>Childhood FGIDs: Neonate/Toddler (Chang)*</b>	<b>Childhood FGIDs: Child/Adolescent (Chey)*</b>	<b>Design of Treatment Trials for FGIDs (Whitehead)*</b>
<b>Adil E. Bharucha, MD, Chair (US)</b> <b>Satish S. C. Rao, MD, PhD, Co-Chair (US)</b> Giuseppe Chiarioni, MD (Italy) Richelle Felt-Bersma, MD, PhD (Netherlands) Charles H. Knowles, PhD (UK) Allison Malcolm, MD (Australia) Arnold Wald, MD (US)	<b>Samuel Nurko, MD, Chair (US)</b> <b>Marc A. Benninga, MD, Co-Chair (Netherlands)</b> Christophe Faure, MD (Canada) Paul E. Hyman, MD (US) Ian St James-Roberts, PhD (UK) Neil L. Schechter, MD (US)	<b>Carlo Di Lorenzo, MD, Chair (US)</b> <b>Jeffrey S. Hyams, MD, Co-Chair (US)</b> Miguel Saps, MD (US) Robert J. Shulman, MD (US) Annamaria Staiano, MD (Italy) Miranda A.L. van Tilburg, PhD (US)	<b>Brennan Spiegel, MD, Chair (US)</b> <b>Jan E. Irvine, MD, Co-Chair (Canada)</b> Jan Tack, MD, PhD, Co-Chair (Belgium) Michael Crowell, PhD (US) Kok-Ann Gwee, MD, PhD (Singapore) Meiyun Ke, MD (China) Max Schmulson, MD (Mexico) William W. Whitehead, MD (US)

\*Chapter Associate Editor

Rome IV Working Team Committees					
<b>Microbiota</b>	<b>Cross-Cultural</b>	<b>Food &amp; FGIDs</b>	<b>Severity</b>	<b>Asian-Rome</b>	<b>Brain Imaging</b>
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Overview of IBS/functional disorders and evolution of Microbiome role.	Develop plans to facilitate multinational research in the FGIDs, and formulate recommendations and guidelines for FGID research from a cross-cultural perspective.	Systematic assessment of the interaction between food/nutrients and FGID symptom pathogenesis and treatment.	Summarize current research and to make recommendations as to how the concept of severity should be integrated in investigative studies as well as applied in clinical practice.	Conduct a multinational survey using standardized methodology to confirm these observations and make recommendations for the development of Rome IV criteria that are more inclusive for Asian patients.	Developed a consensus understanding of various brain imaging modalities as related to FGIDs. Presented an update of lit. in this area, made recs. for future standardization in their use for patients.

Rome IV Support Committees			
<b>Questionnaire</b>	<b>Systematic Review</b>	<b>Multi-Dimensional Clinical Profile</b>	<b>Primary Care</b>
William E. Whitehead, PhD (US)	Paul Moayeddi, MD (Canada)	Douglas Drossman, MD (US)	Pali Hungin, MD (UK)
Olafur Palsson, PsyD (US) Ami Sperber MD (Israel) Brennan Spiegel, MD (US) Robin Spiller, MD (UK) Jan Tack, MD, PhD (Belgium) Miranda van Tilburg, PhD (US) Lynn Walker, PhD (US) Yunsheng Yang, MD (China)	William D. Chey, MD (US) Hashem El-Serag, MD (US) Alexander Ford, MD (UK) Grigoris Leontiadis, MD, PhD (Canada)	Fernando Azpiroz, MD, PhD (Spain) Lin Chang, MD (US) William D. Chey, MD (US) John Kellow, MD (Australia) Magnus Simrén, MD, PhD (Sweden) Robin Spiller, MD (UK) Jan Tack, MD, PhD (Belgium) William E. Whitehead, PhD (US)	Bill Cayley, MD (US) Lin Chang, MD (US) Niek DeWit, MD, PhD (Netherlands) Joel Heidelbaugh, MD (US) Jean Muris, PhD (Netherlands) Ceciel Rooker (US) Greg Rubin, MD (UK) Bohumil Seifert, PhD (Czech Republic) W. Grant Thompson, MD (Canada)
Ensured that the questionnaire accurately reflected the criteria, was translatable into key languages and was validated through cooperation with. Reviewed the existing body of literature relevant to the chapter committee topics, and provided 500-2000 articles reviewed by the relevant chapter committee.	Reviewed the existing body of literature relevant to the chapter committee topics, and provided 500-2000 articles reviewed by the relevant chapter committee.	Provided subcategorization of FGIDs beyond the diagnostic criteria that is helpful in treatment. The profiles will vary among individuals with the same diagnosis. This related (for example) to subsetting IBS into IBS-C, D or M, addressing the type/degree of physiological dysfunction (e.g. with fecal incontinence) or biomarkers, the presence of psychosocial comorbidities, and overall severity/ disability.	Applied the Rome IV criteria in a fashion that is beneficial to primary care physicians and health care extenders.

# COLLABORATION

The Rome Foundation seeks to collaborate with and support membership organizations that share similar goals:

- Promote global recognition and legitimization of DGBIs
- Advance the scientific understanding of their pathophysiology
- Optimize clinical management for these patients
- Develop and provide educational resources to accomplish these goals

The Rome Foundation continues to establish collaborative efforts with academic and public organizations as well as regulatory agencies that share similar goals to advance the field of functional GI and motility disorders and to help those patients so afflicted. Our previous and current associations are with the IFFGD, AGA Institute, ANMS, FDA, EMA, ACG, GI Health Foundation, Medscape. and MyGIHealth, GastroGirl/ GIONDemand

## Rome Foundation Sponsors

The Rome Foundation is grateful to our industry sponsors who continue to financially support our mission to advance and promote the field of functional gastrointestinal disorders through research and educational initiatives.



### Benefits of Rome Foundation Sponsorship include the following:

- Pre-release access and opportunity to review Rome committee recommendations on Rome criteria revisions
- Pre-release access to all academic documents
- Acknowledgment in all marketing publications and projects
- Collaboration on educational activities of interest
- Ability to become a Rome Foundation Research Institute Sponsor
- Waiver of licensing fees on use of Rome Foundation research instruments and intellectual property for use in clinical trials. (e.g. Bristol Stool Scale, IBS-SSS, Rome Diagnostic Criteria, etc.)
- Participation in annual advisory meetings of the Rome Foundation Advisory Council at DDW
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- Discount on bulk orders of Rome products
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Improving the Lives of People with Disorders of Gut Brain Interaction

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