



# MEET THE ROME FOUNDATION

2022-2023

**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 2022 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
- Growth in our 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. To date, we have seen five published articles highlighting regional and country specific data from the Global Study. We anticipate another 13 to be published in the coming year.

**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 4th year and have several exciting projects underway, including two sponsored studies with Danone Nutricia and the kickoff of the ROBOT and data results from the DOMINIO study. 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 Rome Foundation Working Team on Communication was published in Gastroenterology in 2021 and has been very well received. 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 Communication 101.5; each has its role in teaching methods and techniques to improve the patient-provider relationship. In addition, in 2021 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>. Now in 2022, we have published a second book, Gut Feelings: The Patient's Story, highlighting the illness journey of eight patients who share their experiences with chronic illness and with the health care system. This book will resonate with patients and providers illustrate the value of the patient provider relationship to improve clinical outcomes. 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 continues to be improved upon 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 112 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 over 800 facebook and 3000 twitter followers. We have also added a new series “Rome Foundation Grand Rounds” which are posted monthly with top leaders in the field discussing important topics in DGBI.

**Research and Rome Fellowship awardees.** We are pleased to announce that awardees for 2022 Rome Awards include:

- Heidi Staudacher, PhD- Deakin University, Melbourne Australia
- Bonney Reed, PhD- Emory University, USA

- Andy Dharma, MD, Universitas Airlangga, Indonesia
- Kumolu-Johnson Tolulope- University College of Medicine, Lagos, Nigeria

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 2022 the clinical fellow awardees are: Sarah Ballou, PhD, Pali Hungin, MD, Baha Moshiree, MD, Carolina Olano, MD, Dan Dumitrascu, 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 CEO  
Rome Foundation



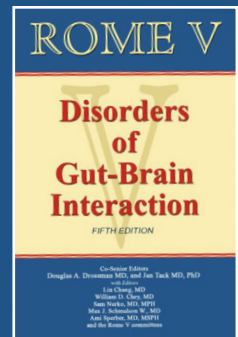
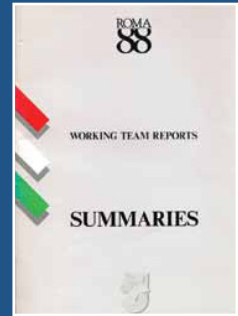
**Jan Tack MD, PhD**  
President and Chairman  
of the Board  
Rome Foundation

# 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.



## Our Mission

To improve the lives of people with Disorders of Gut Brain Interactions

## Our 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

## 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)
- Gastro Psych Section (2017)
- "What Do you Hear - Communication Curriculum" 2019
- Global Epidemiology Study 2021
- Start of work for Rome V 2022



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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
- Rome IV and Rome V
- Sponsors - Information/Opportunities
- Sponsorship of Rome Activities
- Upcoming Events/Symposia
- Website
- Financials

**Contact:** Johannah Ruddy  
[jruddy@theromefoundation.org](mailto:jruddy@theromefoundation.org)

### *For Information on:*

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

**Contact:** Michelle Berry  
[mberry@theromefoundation.org](mailto:mberry@theromefoundation.org)

### *For Information on:*

- Rome Visiting Scholar
- Rome Partners Program
- Rome Communication Program

**Contact:** Mauricio Rojas  
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### *For Information on:*

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

**Contact:** Mark Schmitter  
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### *For Information on:*

- Financials and Sponsors- Contract/Billing:

**Contact:** Debra Wideman  
[Dwideman@theromefoundation.org](mailto:Dwideman@theromefoundation.org)

### *For Information on:*

- GastroPsych Education or Credits
- Rome Pediatric Education or Credits
- Contact a Board Member

**Contact:** Tamioka Blair  
[TBlair@theromefoundation.org](mailto:TBlair@theromefoundation.org)

**All other general inquiries:**  
[admin@theromefoundation.org](mailto: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 and Chairman of the Board, 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

Ardelyx

Biomerica

Nestle Health Science

Takeda Pharmaceuticals

Abbvie

Danone Nutricia Research

Salix Pharmaceuticals

Yangtze River

Alfa Sigma

Ironwood Pharmaceuticals

Sanofi

### ACADEMIC ADVISORY COUNCIL

American Gastroenterological Association

International Foundation for Gastrointestinal Disorders

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



### **Douglas A. Drossman, MD, RFF** **Chief Executive Officer & President Emeritus, 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



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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...

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### **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**

**Chief, 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



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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...

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### **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, FACP, RFF**

**Senior Associate Consultant at Mayo Clinic  
Jacksonville, FL, USA**

Brian E. Lacy, Ph.D., M.D., FACP 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



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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...

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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 Bogota, 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 Gonzáles"

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 has 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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Chief Operating Officer &  
Executive Director



**Mauricio Rojas, MD MPH,**  
Senior Medical Program Administrator



**Michelle Berry**  
Director, Sales, Exhibits and Events



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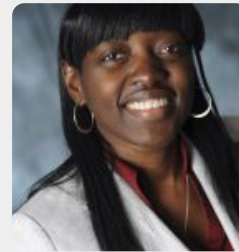
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Director of Marketing, Licensing  
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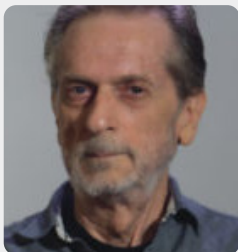
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Medical Illustrator



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Education and Exhibit Coordinator, GastoPsych  
Program Admin and EA to the CEO



**Davis Stillson**  
Videographer



**Eric Chapman**  
Information Technology Director



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



# GLOBAL EPIDEMIOLOGY STUDY INITIATIVE

by Ami Sperber, MD



The global study was initiated in 2013 with 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: a) conduct an extensive multinational epidemiological study of all the DGBIs, b) 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 c) to generate hypotheses to advance further our understanding of the pathophysiology of IBS and the other DGBI. Secondary aims are to: a) generate a database that can serve as a source of data mining and be integrated with other similar databases in the future, and b) to establish a network of FGID experts with a track record of research collaboration on a global

scale. A tertiary aim is to develop a repository of translated versions of the Rome IV adult diagnostic questionnaire in multiple languages, including linguistic validation (cognitive debriefing) and cultural adaptation.

In all, 33 countries participated in the study. The participating countries and the data collection method in each country are depicted in this map – See Figure 2

Data were collected by Internet survey (Qualtrics, Ltd.) in 26 countries where this was feasible. We conducted house-to-house personal interviews in 7 countries where this was not the case. In two countries, China and Turkey, we conducted both types of surveys. The pre-defined demographic parameters were 50% females and 50% males, and age distribution of 40% for 18-39 years, 40% for 40-64 years, and 20% for 65+ years.

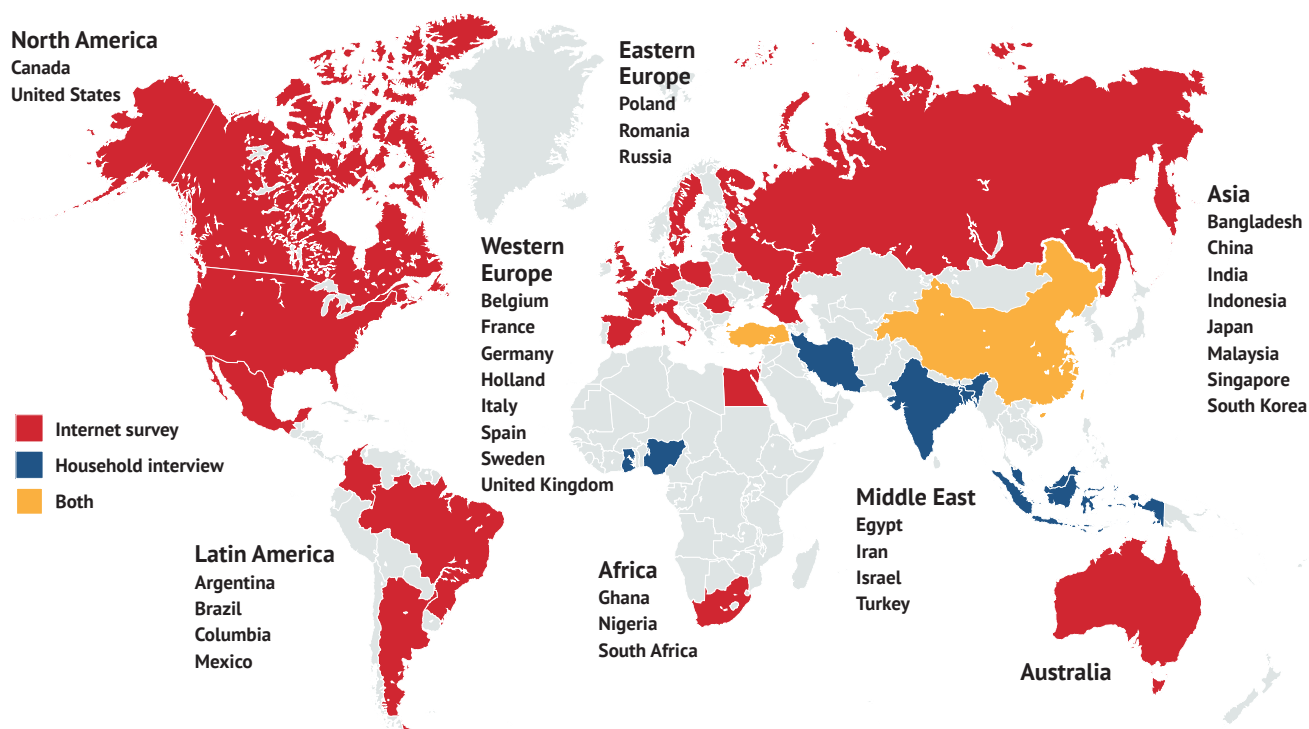


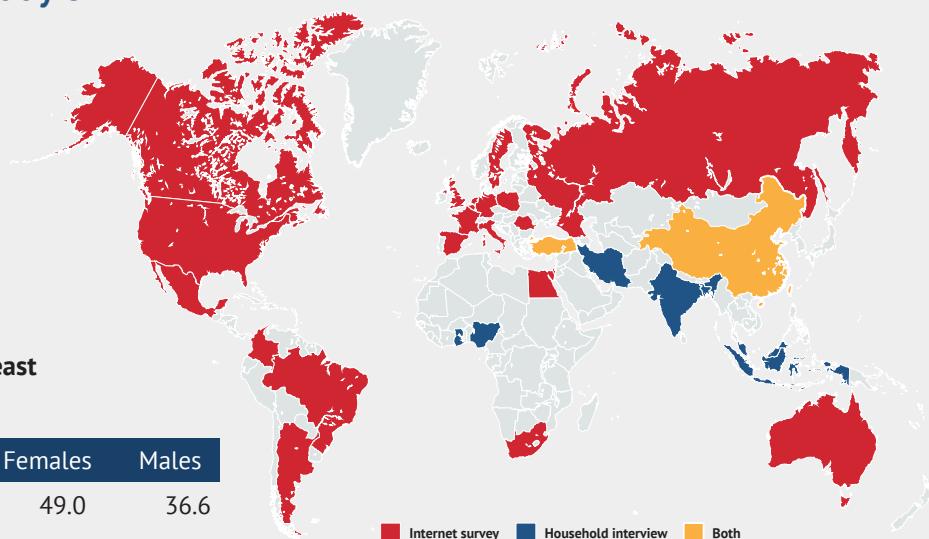
Figure 2 – Countries participating in Global Epidemiology Study

## 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



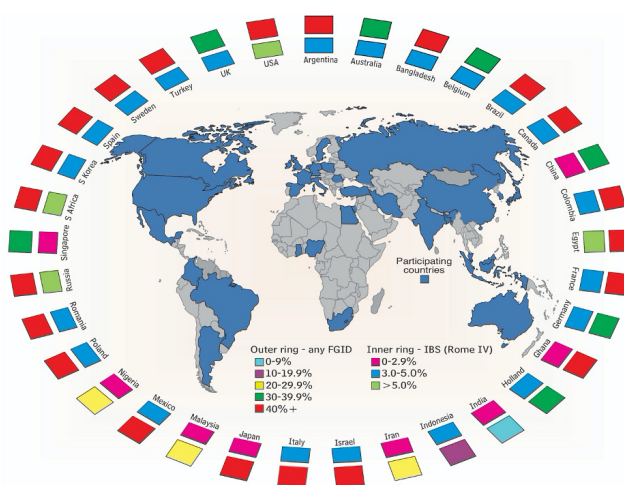
The data collection phase was completed in 2018 with a final database of 73,076 respondents: 36,148 women (49-47%) and 36,928 men (50-53%). We successfully achieved equal sex distribution and pre-planned age ranges with both surveying methods.

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 McMaster, Canada. We 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, attended by about 40 participants from around the world, 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.

We have a website to submit proposals for abstracts or papers based on the study database. All proposals undergo a review process (including the statistical analysis plan) like editorial reviews in medical journals, but to improve and approve the proposals, not reject them.

The first paper, summarizing the major findings, was published in 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). The following is the graphical abstract from that paper:

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



### Worldwide Prevalence of Functional GI Disorders

## GLOBAL EPIDEMIOLOGY STUDY INITIATIVE CONTINUED...

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

Since the initial paper, we have published four other articles, and another one is under review in a top-tier journal. The 4 published papers are:

1) Sperber AD, Freud T, Aziz, I. et al. (2021). Greater overlap of Rome IV disorders of gut-brain interactions leads to increased disease severity and poorer quality of life. *Clin Gastroenterol Hepatol* <https://doi.org/10.1016/j.cgh.2021.05.042>.

2) Josefsson A, Hreinsson JP, Simrén M, Tack J, Bangdiwala SI, Sperber AD, Palsson OS, Törnblom H. (2022) Global prevalence and impact of Rumination syndrome. *Gastroenterol* 2021 162: 731-742. doi: 10.1053/j.gastro.11.008

3) Sperber AD, Freud T, Abu-Freha N, Shibli F, Brun R, Bangdiwala, SI, Palsson OS, Dickman R. (2022) The Epidemiology of Disorders of Gut-Brain Interaction in Israel: Results from the Rome Foundation Global Epidemiology Study. *Neurogastroenterol Motil*. doi: 10.1111/nmo.14323.

4) Colomier E, Melchior C, Algera, JP, Hreinsson JP, Störsrud S, Törnblom H, Van Oudenhove L, Palsson OS, Bangdiwala SI, Sperber AD, Tack J, Simrén S. (2022) Global prevalence and burden of meal-related abdominal pain. *BMC-Medicine* 20:71. doi.org/10.1186/s12916-022-02259-7.

Twenty other studies have been approved and are in varying stages of data analysis and manuscript preparation.

We are receiving more proposals for study on a regular basis and the global study database will also be used for studies under the auspices of the Rome Foundation Research Institute (RFRI) and by a major global study data mining project to provide background data for the Rome V committees, led by Drs. Sperber, Palsson, and Bangdiwala.

We have presented abstracts at multiple scientific meetings including DDW and UEGW, starting in 2020 and will be presenting 6 posters at DDW 2022:

- 1) Gastroparesis-like symptoms - Abstract # 3695758 on May 21
- 2) Diet and DGBI - Abstract # 3693820 (e-poster)
- 3) Burden of Pain in DGBI - Abstract # 3691932 on May 23
- 4) Psychological factors in DGBI - Abstract 3696085 on May 23
- 5) Factor analysis - Abstract # 3698357 on May 23
- 6) DGBI Romania - Abstract # 3692626 on May 24

The Rome Foundation Global Epidemiology Study is an ongoing process that should continue to provide important findings for papers and to support other research in the future. It already serves as a major reference in the field of Gastroenterology in general, and Neuro-Gastroenterology in particular.



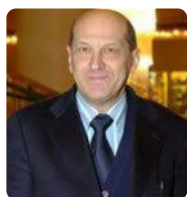
# ACTIVE COMMITTEES

## 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. An important 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



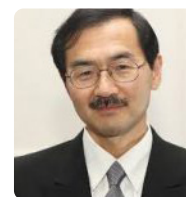
**Dan Dumitrascu, MD, PhD**  
2nd Medical Department  
of Internal Medicine  
University of Medicine  
and Pharmacy  
Cluj-Napoca, Romania



**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



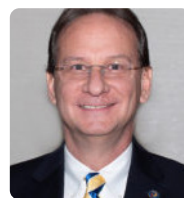
**Shin Fukudo, MD, PhD**  
Department of  
Behavioral Medicine  
Tohoku University Graduate  
School of Medicine  
Seiryō Aoba, Japan



**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**  
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



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

## ACTIVE COMMITTEES CONTINUED...

### 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 four years, our group has expanded to over 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 2022. 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



**Committee Chair:**  
Sarah Kinsinger, PhD



**Committee Chair:**  
Laurie Keefer, PhD

- 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

#### **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**  
**@RomeGastroPsych!!!**



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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:**  
Samual Nurko, MD, MPH, RFF



**Committee Chair:**  
Miguel Saps, MD

In early 2022, the Rome Pediatric Education Committee launched its first annual Pediatric Virtual Symposium. This two-day event featured six of the top pediatric GI experts in the world and garnered a large live audience. This program is now available with CME accreditation on-demand, for access to the full programming on your own schedule! Register Now at <https://romedross.video/PediatricSymposium2022>



EARN UP TO 10 CME CREDITS\*

# PEDIATRIC

## VIRTUAL SYMPOSIUM

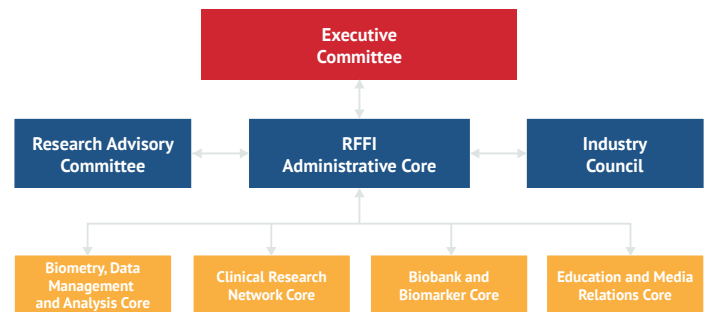
FOR DISORDERS OF GUT BRAIN INTERACTION

# ON DEMAND





**Magnus Simrén,  
MD, PhD**  
Rome Foundation Research  
Institute Director



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.

Over the past two years 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 data analysis of the Rome Foundation Global Epidemiology Study, completion of the Domino clinical trial and implementation of the ROBOT studies, a contract with Danone Pharmaceuticals to study abdominal bloating, 2021-2022, and consultations concerning prospective projects with two pharmaceutical companies.

Development and launch of the RFRI Investigator Platform (RFRI-IP) for clinical phenotyping

The RFRI-IP is a secure Internet-based data collection system has just been completed. The RFRI Investigator Platform (RFRI-IP) 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 this phenotyping database will also have associated bio-samples (these will be our ROBOT project sites), and it will be possible to link findings from those bio-samples to their phenotyping data. The RFRI-IP will begin recruiting patients from the ROBOT project at the Gothenborg and Leuven sites in Summer 2022.

The use of the RFRI-IP online data collection system will quickly create an unprecedented large central clinical research database that can be used to (a) rapidly invite sets of patients with well-known characteristics to participate



in specific research studies; (b) conduct analyses for research 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 to doctors and patients at each participating site as well.

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 the clinical research sites, data collection will be predominantly self-administered by patients, utilizing easy-to-use web-based assessment that works on any computer device and in any web browser. The primary patient evaluation method will be by patients at home prior to clinic visits or via computer tablets in the waiting rooms. The assessment will be fully mobile-device compatible so patients can use their mobile phones to complete the assessments 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 25-30 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;
- Frequency and severity of current GI symptoms;
- Co-morbid GI and non-GI medical conditions;
- History of GI-relevant medical tests, medical procedures and surgeries;
- Psychological symptom and 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 bio-samples from each patient (with summary of findings if the samples have been analyzed) will be recorded in the 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. The network will coordinate its research efforts to produce compatible clinical datasets and bio-samples on large numbers of DGBI patients. It will operate with sufficiently uniform research methodology to make large multicenter and multinational 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.

The first two sites in the Global Research Network will systematically collect data with the RFRI Investigator Platform in the first half of 2022 and will pilot test the platform. These sites are:

- University of Gothenburg, Sweden (PI: Magnus Simren, MD, PhD)
- KU Leuven, Belgium (PI: Jan Tack, MD, PhD)

Several other sites will join the Global Research Network within the next year and start collecting data via the RFRI-IP into the uniform central database. Early additional sites in the network are likely to include the following:

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

## World Distribution of RFRI Investigators

81 investigators in 33 countries

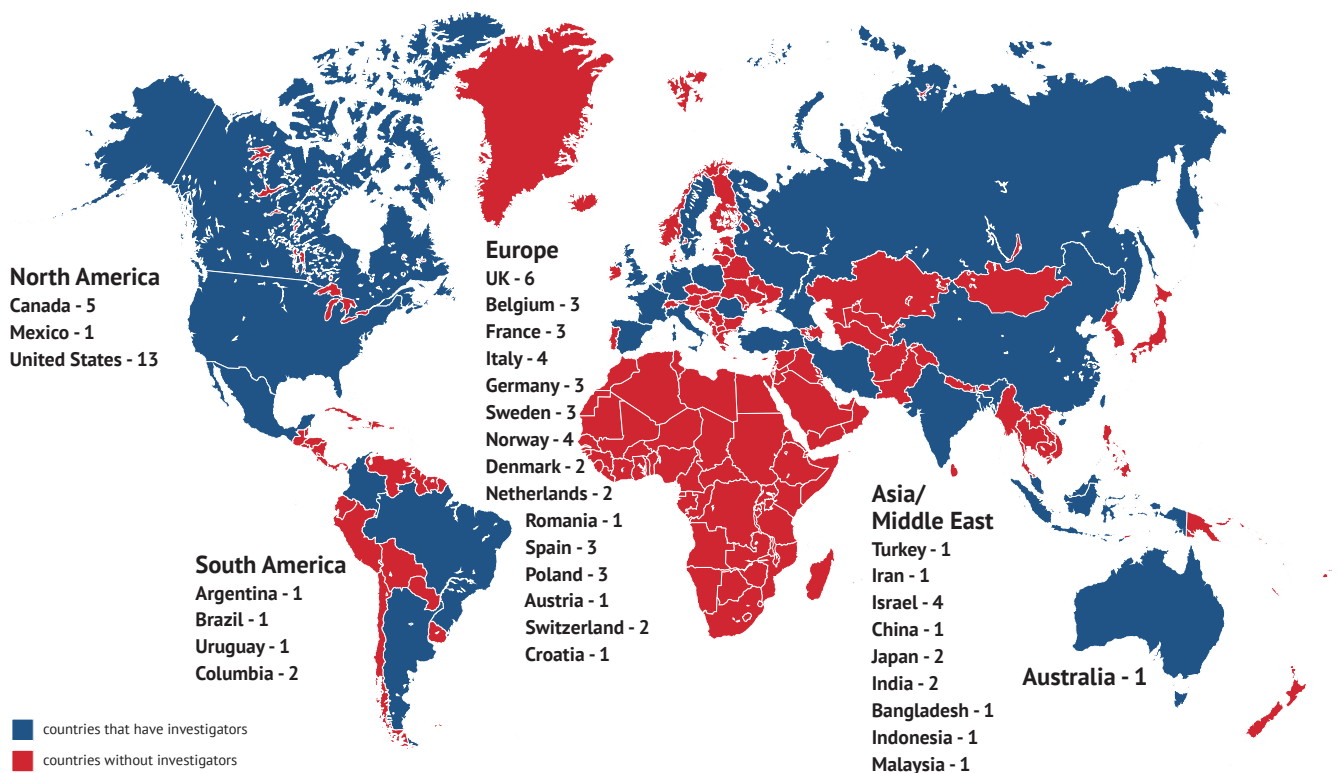


Figure 1 – RFRI investigators by country location

The number of sites in the RFRI Global Research Network is expected to grow rapidly beyond the ones listed above. The great interest supports that expectation that DGBI investigators world-wide have shown in joining the RFRI Global Research Network. A survey among Rome-affiliated DGBI researchers in late 2020 resulted in 81 investigators in 33 countries who have either confirmed participation in the network or expressed strong interest in joining it (see figure 1).

### **Domino Trial**

The DOMINO trial (Diet Or Medication in Irritable bowel syNdrOme) was a randomized trial 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 was funded by Belgian Government Money, was pragmatic and aimed at optimizing primary care. It used questionnaires that were developed for the Rome IV Global Epidemiology study in Belgium and also served as an opportunity to collect biobank material from primary care IBS patients. Patients were 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). The study ended in the Summer of 2020, with a total of 470 patients enrolled and 95% of the subjects providing biobanking samples for genetics, serum and stool analysis for microbiota and biochemical parameters. Patients were randomized to medication or the diet app, and those 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 and 2021. The primary outcome data were a plenary presentation at the 2021 DDW.

At baseline, 71% of these primary care-diagnosed IBS patients fulfilled the Rome 4 criteria (Rome+). 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%).

453 primary care IBS patients (41±15 years, 76% female, 71% Rome+) were randomized to either OB (n=231) or diet app (n=227). The responder rate in the diet group (71%) was significantly higher compared to OB (61%) after 8 weeks of treatment ( $p=.03$ ) and this was more pronounced in Rome+ (77% vs. 62%,  $p=.005$ ). During the follow-up period, the diet group maintained a significantly higher responder rate (6 months: diet: 74%; OB: 58%,  $p<.001$ ). Mean IBS-SSS improved significantly over time in both groups (OB: 267±100 vs 170±109 ( $p<.001$ ); diet: 267±96 vs 188±109 ( $p<.001$ )), but with significantly larger improvement in the diet arm compared to OB ( $p=.02$ ). Both with OB and diet, significant improvement was observed for IBS-QoL (OB=-7.34 ( $p<.001$ ) vs diet=-8.07 ( $p<.001$ )) and levels of anxiety (OB=-0.99 ( $p<.001$ ) vs diet=-1.19 ( $p<.001$ )), depression (OB=-1.09 ( $p<.001$ ) vs diet=-1.36 ( $p<.001$ )) and somatization (OB=-1.31 ( $p<.001$ ) vs diet=-1.80 ( $p<.001$ )), but without significant difference between treatment groups ( $p>.05$ ). Female gender (OR=,  $p=.04$ ) was a response predictor for diet-treated patients whereas higher somatization (OR=,  $p=.002$ ) was a predictor of OB treatment response.

The revised version of the primary outcome manuscript is currently under review in Gut, and a decision is likely to be made over the next weeks.

In addition, the genetic samples were analyzed for predictors of response to either treatment. Below is a summary of the abstract which will be presented as oral presentation at the DDW 2022.

459 patients with physician-diagnosed IBS were randomized to receive a FODMAP lowering diet through a smartphone app (n=227) or a treatment with the antispasmodic agent otilonium bromide (n= 232). Improvement of 50 points in the IBS Symptom Severity Score (IBS-SSS) after 8 weeks of treatment was considered a responder. Whole genome



single nucleotide polymorphism (SNP) Global Screening Arrays from Illumina were used to obtain genotype data from every patient. A selection of 6 and 7 candidate genes respectively for the diet and medication arms was tested for association with treatment response in a logistic regression model using plink2. IBS-SSS was significantly improved for both groups after 8 weeks of treatment ( $p < 0.001$ ). In the diet group 71% (95% CI: 65-77) of patients were responders, which was significantly higher than the 61% (95% CI: 54-68) responder rate in the medication arm ( $p = 0.03$ ).

SNPs from three genes (SLC6A4, TRPA1, CACNA1C) were associated with a response to medication and from two genes (IL5RA and CCR3) with response to dietary intervention respectively. Two of these SNPs are linked to expression quantitative loci (eQTL): Allele rs2020934G in the serotonin reuptake transporter gene SLC6A4 was associated with higher OB response rate ( $p = 9.05 \times 10^{-5}$ ) and increased mRNA expression in aorta, breast, esophagus and adipose tissues. Allele rs7617872A from the C-C Motif Chemokine Receptor 3 gene CCR3 was associated with increased response to dietary intervention ( $p = 2.17 \times 10^{-6}$ ) and increased expression of CCR3 in whole blood.

This allows us to conclude that, in a group of primary care IBS patients, symptomatic response to a pharmacological or dietary intervention was associated with SNPs inviting further genetic studies in this direction. The SNP associated with medication response is linked to peripheral expression of a serotonin reuptake transporter- the mechanistic link to treatment with otilonium bromide remains elusive. The SNP associated with response to diet maps to a gene coding for a chemotactic receptor mainly expressed on eosinophils, suggesting a possible role for eosinophil chemotaxis in the symptomatic response to reduced FODMAP intake.

Future publications will include the role of gut microbiota composition in the response to either treatment arm, the baseline characteristics of primary care IBS patients, a health economic impact analysis of the study, analysis of the link between symptoms and treatment response on one hand and stool or blood markers (calprotectin, elastase, secretory immunoglobulin A, beta defensin, C-reactive protein) on the other hand.

### **ROBOT Project**

RFRI finalized the 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 in 2021 at a small number of sites, but due to the Pandemic and conflicting projects, the start of the study has been postponed to 2022. The project is now approved by the Ethical review board in Gothenburg, Sweden and recruitment of subjects will start in the spring of 2022, followed by launch in Leuven, Belgium during 2022 as well. After this initial launch in a few highly specialized clinical research units, we plan to expand this project to more sites. 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 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 the evaluation of different biomarkers in large groups of well-characterized individuals in different parts of the world. We will then assess 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 global DGBI research sites. In the first phase of ROBOT each center will recruit  $\geq 100$  patients who fulfill Rome IV diagnostic criteria for at least one DGBI. This will begin in May, 2022. We aim to have a 50:50 split between predominantly upper, i.e. esophageal and gastroduodenal, and lower, i.e. bowel and anorectal DGBI. This will be to be separately negotiated with each site, depending on their expertise and research focus. 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 sites where this is possible. 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 their patients and will be listed as an author in publications / projects where their 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 program in Gothenborg will begin in May and the one in Leuven in June, 2022. There will be a few more centers beginning in the fall 2022..

#### **RFRI-Danone Bloating Survey**

This study was a secure multi-national Internet population survey of 5978 adults in the United States, Mexico and United Kingdom, conducted to evaluate bloating, distention and other gas-related symptoms along with a wide range of potentially related factors. The study was designed collaboratively by the RFRI and Danone and sponsored by Danone.



The study aimed to assess population prevalence of bloating, distention and other gas-related symptoms and their associations with demographics, other symptom characteristics, diet, DGBI, quality of life impairment and healthcare utilization; assess population prevalence of Rome IV Functional Abdominal Bloating/Distention and to what extent bloating-only, distention-only and mixed subgroups exist within that diagnosis; and assess the impact of bloating, distention and combination of both on QoL and healthcare utilization. The survey contents included demographics, Rome IV diagnostic questionnaire modules

for gastroduodenal disorders and functional bowel disorders, questions about bloating and distention rated separately for the previous 3 months, 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, and questions about anxiety and depression symptoms, stress, sleep, exercise, diet, quality of life, height and weight, and healthcare utilization. A subset of 1437 participants also completed a 25-minute online VioScreen follow-up survey about their total diet over the past 3 months.

This is the first study to examine both current and chronic presence of bloating/distention and numerous potential associated factors in the same population-based sample. It is yielding a comprehensive picture of the scope of these symptoms and their impact in the population, as well as revealing the relative prevalence and overlap of bloating vs. distention. The study has resulted in three scientific abstracts presented at UEG Week and DDW, with more to follow, and the first paper on the findings is currently in preparation. In addition, we are working with Danone to examine the Global Study patient data to characterize the worldwide prevalence of people in 26 countries who are classified as having sub-clinical GI symptoms (bothersome but not meeting Rome IV Criteria) and will assess the associated impact on quality of life (QoL), healthcare utilization, and psychological wellbeing. We will also compare these individuals to people with DGBI and non-GI individuals in terms of sociodemographic, dietary, lifestyle, medication use, psychosocial & clinical variables.

# COPYRIGHT AND LICENSING COMMITTEE



**Mark Schmitter**  
Director of Licensing and  
Copyrights



**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.

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

2834 ROME FOUNDATION

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 gutbrain 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.

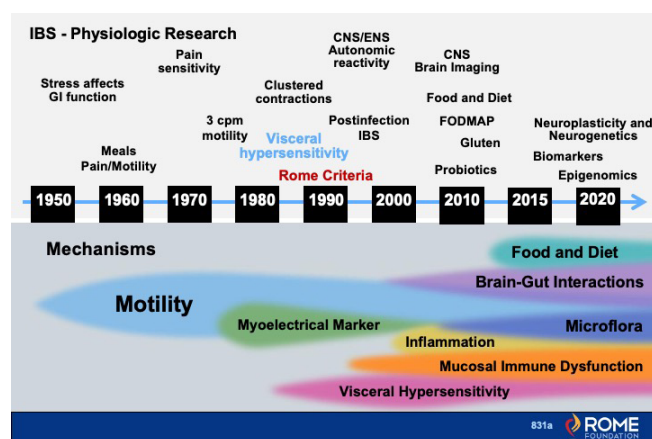


Figure 12

## Reference List

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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.

## RESEARCH PROGRAMS AWARDS CONTINUED...

### 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:

### 2022

**Javier Aguilera-Lizarraga, PhD, Leuven, Belgium**

Title: Local immune response to food antigens drives meal-induced abdominal pain. Aguilera-Lizarraga J, Florens MV, Viola MF, Jain P, Decraecker L, Appeltans I, Cuende-Estevez M, Fabre N, Van Beek K, Perna E, Balemans D, Stakenborg N, Theofanous S, Bosmans G, Mondelaers SU, Matteoli G, Ibiza Martínez S, Lopez-Lopez C, Jaramillo-Polanco J, Talavera K, Alpizar YA, Feyerabend TB, Rodewald HR, Farre R, Redegeld FA, Si J, Raes J, Breynaert C, Schrijvers R, Bosteels C, Lambrecht BN, Boyd SD, Hoh RA, Cabooter D, Nelis M, Augustijns P, Hendrix S, Strid J, Bisschops R, Reed DE, Vanner SJ, Denadai-Souza A, Wouters MM, Boeckxstaens GE. *Nature*. 2021 Feb;590(7844):151-156

### 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, Mössinger 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.

**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.



## RESEARCH PROGRAMS AWARDS CONTINUED...

### 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:

### 2022

#### Magdy El-Salhy, MD, Norway

Title: Efficacy of faecal microbiota transplantation for patients with irritable bowel syndrome in a randomised, double-blind, placebo-controlled study. *El-Salhy M, Hatlebakk JG, Gilja OH, Bråthen Kristoffersen A, Hausken T. Gut*. 2020 May;69(5):859-867.

### 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.

**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.

**2022:****Hans Tornblom MD- (Sweden)****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.

**2022 WINNERS****Heidi Staudacher, PhD- Deakin University, Melbourne**

**Australia:** Nocebo response to fermentable carbohydrate dietary challenge: A randomized double blind placebo-controlled crossover challenge trial

**Bonney Reed, PhD- Emory University, USA:** HRV biofeedback augmentation in pediatric patients with IBS

**Andy Darma, MD, Universitas Airlangga, Indonesia:**

Prevalence and risk factors of DGBI among adolescents during COVID-19 Pandemic: A multicenter study in Indonesia

**Kumolu-Johnson Tolulope- University College of Medicine,**

**Lagos, Nigeria:** Functional Gastrointestinal Disorders in Infants and Toddlers in Lagos, Nigeria

**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 2022:



**Baha Moshiree, MD**  
2022 Clinical Rome  
Fellowship Awardee



**Carolina Olano, MD**  
2022 Clinical Rome  
Fellowship Awardee



**Sarah Ballou, PhD**  
2022 Clinical Rome  
Fellowship Awardee



**Pali Hungin, MD**  
2022 Clinical Rome  
Fellowship Awardee



**Dan Dumitrascu, MD**  
2022 Clinical Rome  
Fellowship Awardee

### CONGRATULATIONS TO ALL OUR IMPRESSIVE ROME FELLOWS!

Sarah Kinsinger, PhD • Darren Brenner, MD • Madhusudan (Madhu) Grover, M.B.B.S. • Alben 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 Di Lorenzo PhD • USA • Rona Levy MSW, PhD • USA • Grant Thompson MD, FRCP • 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 • Xiucai 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 Feinle 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 Francisoni 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 100 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/>



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

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/ChefAJLive>

**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>3</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 was published in the November issue of Gastroenterology. It provides an evidence-based review of the literature showing impact

#### 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

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

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.

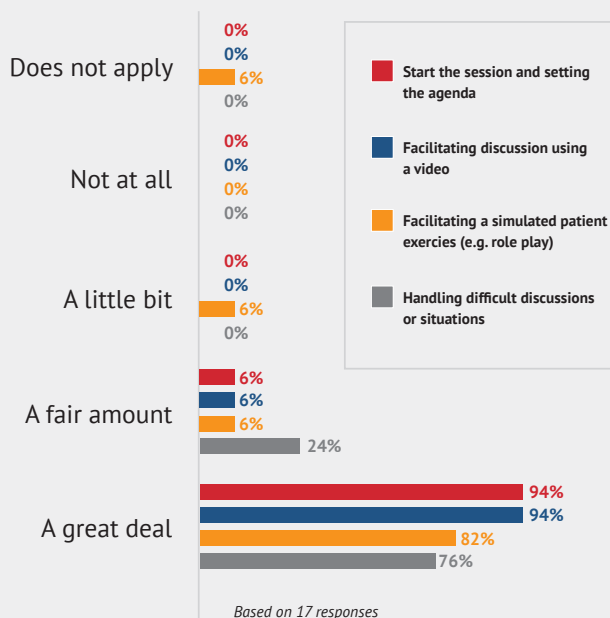
g. A book on DGBI and the Patient-Doctor Relationship. "Gut Feelings: Disorders of gut-Brain Interaction and the Patient-Doctor Relationship"<sup>2</sup> was released in December 2020 and over 500 books were sold in two months. Written by Doug Drossman and Johannah Ruddy, it provides the conceptual aspects 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>

Now just released is a second book "Gut Feelings: The patient's story" which provides patient narratives to help patients and providers understand the nature of collaborative patient-centered care.

**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.

### How much participants learned in following areas:



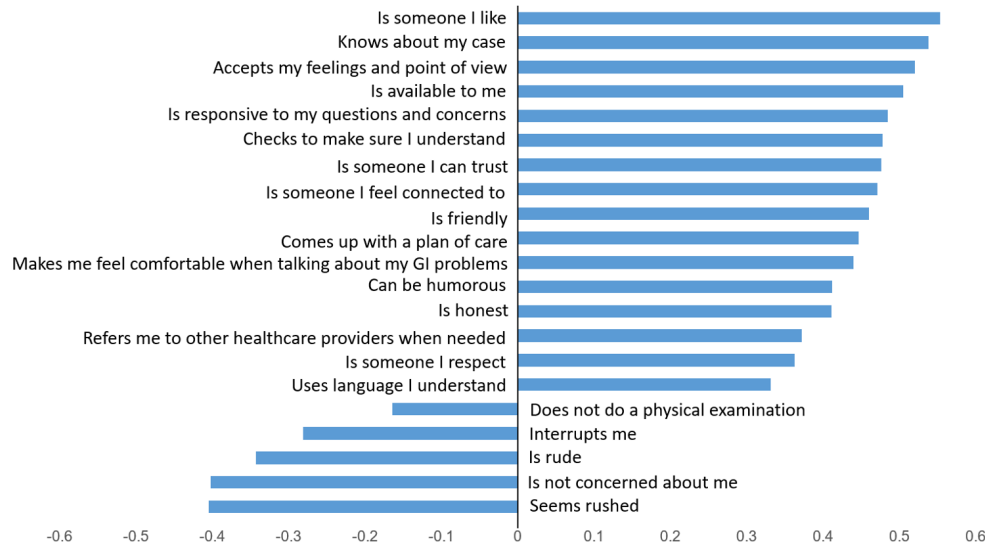
**6. Visiting scholar preceptorship programs.** The Rome Foundation and DrossmanCare instituted a visiting scholar program where faculty, practitioners and trainees can visit key programs to learn about DGBI. To date over 20 have attended this program. We plan to resume the Visiting Scholar Program after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

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



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 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.

### References

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# ROME FOUNDATION EDUCATIONAL RESOURCES

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 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.



**ROME FOUNDATION**  
**GRAND ROUNDS**  
FOR DISORDERS OF GUT BRAIN INTERACTION

A virtual, interactive and intensive educational opportunity on topics related to Disorders of Gut-Brain Interaction (DGBI).

**LIVE & ON-DEMAND CME LEARNING OPPORTUNITY**

Register now for on demand access: <https://romedross.video/grand-rounds>

# ROME FOUNDATION - AGA INSTITUTE LECTURE

The Rome-AGA lectureship in 2022 will focus on the Coronavirus disease 2019 (COVID-19) infection and its presentation of respiratory symptoms as well as gastrointestinal (GI) symptoms. A review of data of 2023 patients found a GI-symptom incidence ranging from 3.0% to 79%. GI symptoms associated with COVID-19 infection include diarrhea, nausea and vomiting, abdominal pain and anorexia. In addition, SARS-CoV-2 can be detected in the stool of infected patients, implicating the possibility of fecal-oral transmission. Disorders of gut-brain interaction (formerly known as functional GI disorders) can develop after an infectious gastroenteritis, e.g. post-infection IBS. There are reports that DGBI can also occur after COVID-19 infection. In addition, patients with pre-existing DGBI may experience sustained flares of their symptoms after being infected with COVID-19.

Lastly, the psychological impact of the COVID-19 pandemic and a SARS-CoV-2 infection in patients with DGBI, which are stress-sensitive conditions and can coexist with psychological disorders, can be substantial.

Rome Foundation and the American Gastroenterology Association (AGA) 14th Annual Rome Foundation – AGA Institute Lecture at Digestive Diseases Week in San Diego, CA on Sunday, May 22, 2022 from 8-9:30am.

## The talks will be:

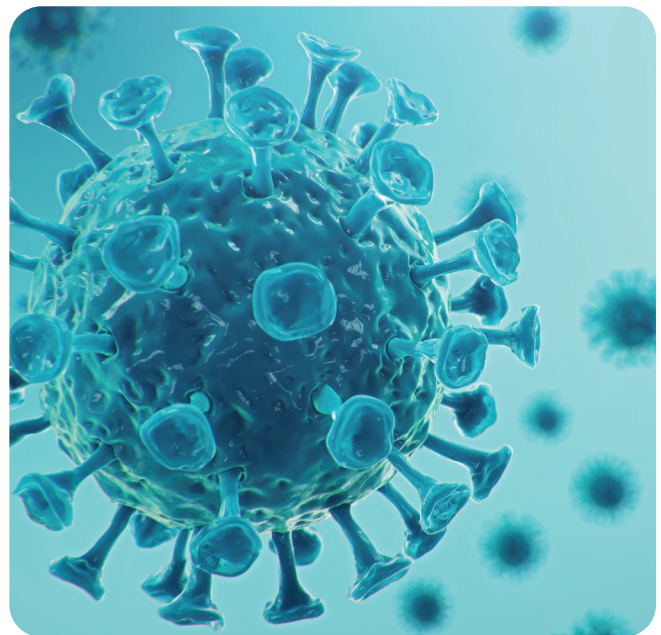
- **Post-COVID IBS and other DGBI: Prevalence, Incidence and Symptom Impact** (40-minute lecture, 10-minute Q&A) - Giovanni Barbara, MD
- **Psychosocial impact of COVID in Patients with DGBI** (30-minute lecture, 10-minute Q&A) - Sarah Ballou, PhD



*Giovanni Barbara, MD*



*Sarah Ballou, PhD*



## Rome Foundation/AGA Institute Lectureships at DDW

- **2022** - Post-Covid IBS and other DGBI: Prevalence, Incidence and Symptom Impact- Giovanni Barbara, MD Psychosocial Impact of COVID in patients with DGBI- Sarah Ballou, PhD
- **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 Gastroduodenal 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 – 2020-2023

### PLAUSIBILITY OF PATHOPHYSIOLOGICAL MECHANISMS FOR DGBI

**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

Ana Maria Madrid • SLNG

Daniel Pohl • ESNM

Edoardo Savarino • ESNM

Max Schmulson • SLNG

Jordi Serra • ESNM

Magnus Simren • ESNM

Karen Van den Houde • Coordinating team

### 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

## Completed Rome Working Teams – 2018-2022

### 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

### BRAIN-GUT PSYCHOTHERAPIES

**Laurie Keefer, PhD, chair**

Sarah Ballou, PhD

Douglas Drossman, MD

Sigrid Elsenbruch, PhD

Brjann Ljotsson, PhD

Gisela Ringstrom, PhD

### 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

### 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, Med

Julie Snyder, PsyD

Ami Sperber, MD

Samuel Nurko, MD

## 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

## 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.

### 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...

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.
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.

## 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



## 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 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.

### 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**



## ROME WORKING TEAM REPORT ON BRAIN-GUT BEHAVIOR THERAPIES FOR DISORDERS OF GUT-BRAIN INTERACTION

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.

Keefer, L., Ballou, S.K., Drossman, D.A., Ringstrom, G., Elsenbruch, S., Ljótsson, B., 2022. A Rome Working Team Report on Brain-Gut Behavior Therapies for Disorders of Gut-Brain Interaction. *Gastroenterology* 162, 300–315

### 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)

## A REVIEW OF THE EVIDENCE AND RECOMMENDATIONS ON COMMUNICATION SKILLS AND THE PATIENT-PROVIDER RELATIONSHIP: A ROME FOUNDATION WORKING TEAM REPORT

**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 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

Drossman, D.A., Chang, L., Deutsch, J.K., Ford, A.C., Halpert, A., Kroenke, K., Nurko, S., Ruddy, J., Snyder, J., Sperber, A., 2021. A Review of the Evidence and Recommendations on Communication Skills and the Patient-Provider Relationship: A Rome Foundation Working Team Report. *Gastroenterology* 161, 1670–1688

### Committee Composition

**Douglas Drossman, MD, chair**

**Lin Chang, MD**

**Jill Deutsch, MD**

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# ROME FOUNDATION RESEARCH INSTITUTE ANNUAL REPORT



Douglas A. Drossman, MD  
(Executive Committee)



Magnus Simren MD, PhD  
(Research Director)



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(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 the 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

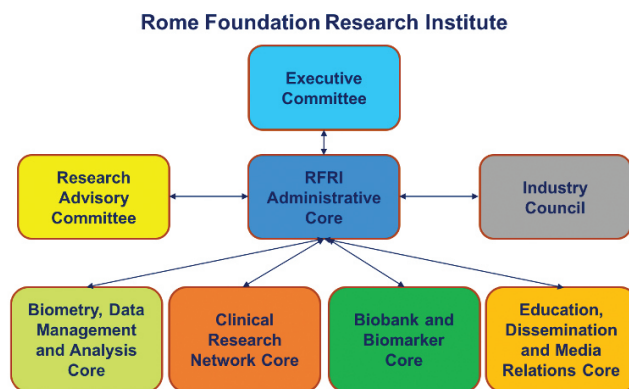
**Mission.** To improve the lives of patients with DGBI through ground-breaking research

**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, the RFRI is represented by Douglas Drossman MD (President) and Johannah Ruddy (Secretary/Treasurer) for legal and tax purposes.



**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.

# ROME FOUNDATION RESEARCH INSTITUTE ANNUAL REPORT CONTINUED...

**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 executive committee members, the Biometry Director (Shrikant Bangdiwala PhD), the Senior Study Coordinator (Ami Sperber MD, MSPH), the data manager of the RFRI (Olafur Palsson Psy.D.), an external industry consultant who advises on collaborations with commercial organizations in the Life Sciences (biopharmaceutical, device, and diagnostics companies) (Doug Levine, MD) and an RFRI administrator (Johannah Ruddy M.Ed., Executive Director of the RF). The AC is also advised by the RAC and the Industry Council (see below)

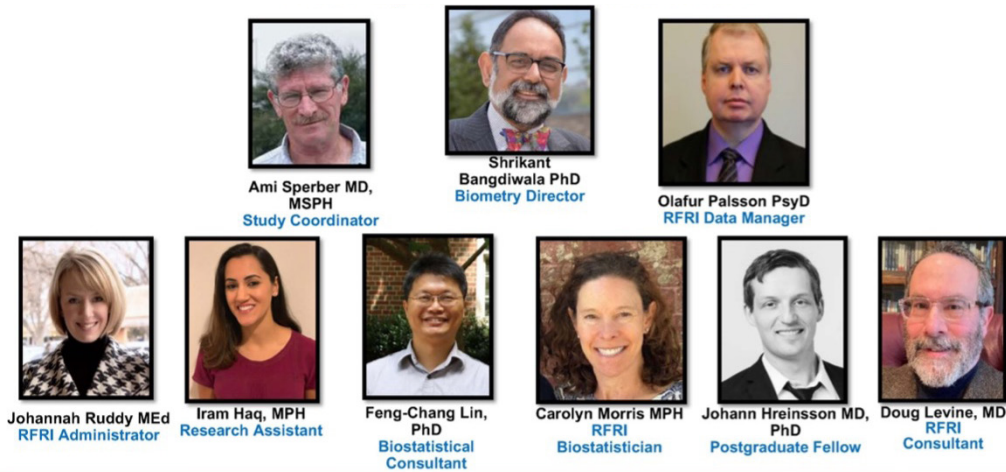
**Research Advisory Committee (RAC).** The RAC serves as an advisory to the AC as a repository to review and revise research proposals. Currently, the TAD is composed of RF Board members who have been selected based on their academic record of scientific achievement, their ability to evaluate, conduct, and analyze scientific data related to DGBI, in consideration of demographic and geographic diversity issues. RAC members are responsible for participating in the various Cores discussed below. Current RAC members include: Giovanni Barbara MD, William Chey MD, Lin Chang MD, Laurie Keefer PhD, Brian Lacy, MD, Samuel Nurko MD, MPH, Max

Schmulson MD, and Ami Sperber MD, MSPH. The RAC may include members external to the RF board, providing they meet the described guidelines, and their participation will help serve the 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 members are Michael Shetzline, MD PhD, Christina Almansa MD, for Ironwood Pharmaceuticals, and Vijay Yajnik MD, and Mena Boules MD for Takeda Pharmaceuticals. Additional industry members will be added as new sponsors come on board.

**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. It works under the direction of the Executive Committee. Core members include Shrikant Bangdiwala Ph.D., the biometry director Olafur Palsson Psy.D. who is the data manager and coordinator of

## Rome Foundation Research Institute Biometry Core and Administration



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activities, Carolyn Morris PhD, biostatistician, Feng-Cheng Lin, biostatistical consultant, Ami Sperber MD MSPH, senior study coordinator, Johann Hreinsson MD, study administration, and Iram Haq, research coordinator. This Core is actively involved with ongoing research proposals, 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 identifying and selecting 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.

**Development of the Biobank and Biomarker Core.** To perform multinational, multicenter studies that will identify diagnostic and predictive biomarkers of relevance for patients with DGBI, the RFRI created this Core to determine optimal sampling and storing procedures for bio-samples in multicenter settings. The chair and the co-chair lead this committee, in close collaboration with the members of the Executive Committee and the Research Manager. Logistical and regulatory issues prevented us from creating a central biobank. Therefore, participating research centers in the multicenter studies will store their samples locally according to predefined specifications. When agreed upon, the centers will ship their samples for analysis. Detailed Standard Operating Procedures (SOPs) guide the collection and storage of fecal, urine, blood, saliva samples, and tissue biopsies. This

includes details regarding sampling, equipment needed, storage, and transportation. In addition, 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 biobanking and biomarker core planning is done in close collaboration with the biometry core.

The biobank and biomarker core will appoint additional members based on their expertise during the coming years. Education, Dissemination and Media Relations Core (Education Core). The Education Core serves primarily to assure quality control in disseminating research knowledge 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, journals, and other publications printed and digital, will be scientifically based, unbiased, and non-commercial. The Core also monitors media, publications, and other communications from external sources (e.g., news bureaus, scientific organizations, industry) to ensure the information provided is accurate, scientifically based, and unbiased.

## Activities of the RFRI for 2022

Introduction. Over the past two years, the RFRI developed and consolidated the infrastructure with further refinement of the biometry and biobank cores, creating a database of investigators, and developing 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 Rome Foundation Global Epidemiology Study data analysis, completion of the Domino clinical trial and implementation of the ROBOT studies, a contract with Danone Pharmaceuticals to study gals and abdominal bloating, 2021-2022, 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 and Cristina Almansa, MD as a full diamond sponsor and Vijay Yajnik MD and Mena Boules MD of Takeda Pharmaceuticals as a gold sponsor. What follows is a detailed description of these activities.

## Infrastructure Development

### Development and launch of the RFRI Investigator Platform (RFRI-IP) for clinical phenotyping

The RFRI-IP is a secure Internet-based data collection system has just been completed. The RFRI Investigator Platform (RFRI-IP) 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 research sites, the patients in this phenotyping database will also have associated bio-samples (these will be our ROBOT project sites), and it will be possible to link findings from those bio-samples to their phenotyping data. The RFRI-IP will begin recruiting patients from the ROBOT project at the Gothenburg and Leuven sites in Summer 2022.

The use of the RFRI-IP online data collection system will quickly create an unprecedented large central clinical research database that can be used to (a) rapidly invite sets of patients with well-known characteristics to participate in specific research studies; (b) conduct analyses for research 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 available in the clinical encounters, and thus clinically useful to doctors and patients at each participating site.

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 the clinical research sites, data collection will be predominantly self-administered by patients, utilizing easy-to-use web-based assessment that works on any computer device and in any web browser.

The primary patient evaluation method will be by patients at home prior to clinic visits or via computer tablets in the waiting rooms. The assessment will be fully mobile-device compatible so patients can use their mobile phones to complete the assessments 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 25-30 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;
- Frequency and severity of current GI symptoms;
- Co-morbid GI and non-GI medical conditions;
- History of GI-relevant medical tests, medical procedures and surgeries;
- Psychological symptom and 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 bio-samples from each patient (with summary of findings if the samples have been analyzed) will be recorded in the 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. The network will coordinate its research efforts to produce compatible clinical datasets and bio-samples on large numbers of DGBI patients. It will operate with a sufficiently uniform research methodology to make large multicenter and multinational 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.

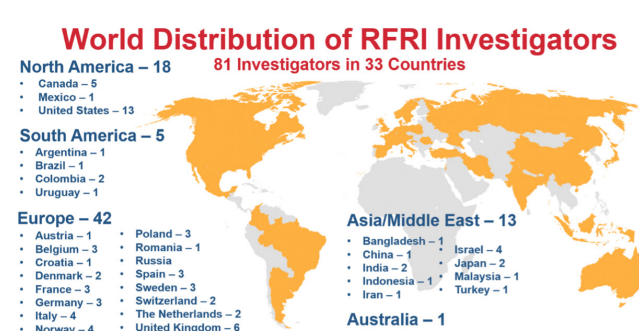
The first two sites in the Global Research Network will systematically collect data with the RFRI Investigator Platform in the first half of 2022 and will pilot test the platform. These sites are:

- University of Gothenburg, Sweden (PI: Magnus Simren, MD, PhD)
- KU Leuven, Belgium (PI: Jan Tack, MD, PhD)

Several other sites will join the Global Research Network within the next year and start collecting data via the RFRI-IP into the uniform central database. Early additional sites in the network are likely to include the following:

- University of California Los Angeles, USA (PI: Lin Chang, MD);
- University of Michigan, USA (PI: William Chey, MD);
- Queen's University School of Medicine, Canada (PI: Steve Vanner, MD, MSc)
- Harvard Medical School, USA (PI: Anthony Lembo, MD)
- Universidad Nacional Autónoma de México (UNAM), Mexico (PI: Max Schmulson, MD)
- University of Bologna, Italy (PI: Giovanni Barbara, MD)

We expect that the number of sites in the RFRI Global Research Network will grow over the next few years. DGBI investigators world-wide have shown in joining the RFRI Global Research Network. A survey among Rome-affiliated DGBI researchers in late 2020 resulted in 81 investigators in 33 countries who have either confirmed participation in the network or expressed strong interest in joining it (see figure 1).

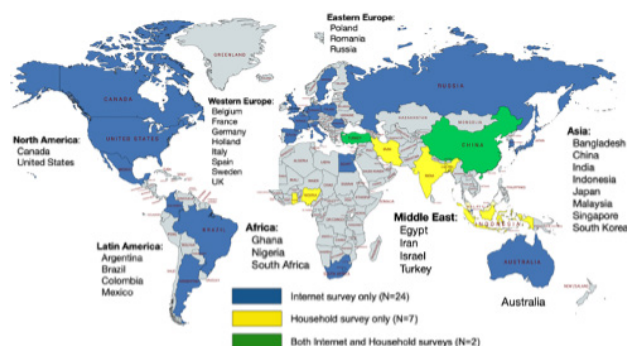


**Figure 1 – RFRI investigators by country location**

Engagement with Industry Consultant. We are pleased to have Doug Levine MD continue as our external industry consultant. His assistance to the Executive Committee through advisement on pharmaceutical industry perspectives, practices, and engagement of external investigators to inform RFRI approaches for establishing research collaborations and sponsorships is invaluable. Through his support of the collaborative projects, review of research proposal drafts, budgets and contracts, internal planning documents related to RFRI infrastructure, and funding support strategies, we are well-positioned for the coming years.

Rome Foundation Global Epidemiology Study Data Analysis and Publication Status. The global study was initiated in 2013 with 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: a) conduct an extensive multinational epidemiological study of all the DGBIs, b) 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 c) to generate hypotheses to advance further our understanding of the pathophysiology of IBS and the other DGBI. Secondary aims are to: a) generate a database that can serve as a source of data mining and be integrated with other similar databases in the future, and b) to establish a network of FGID experts with a track record of research collaboration on a global scale. A tertiary aim is to develop a repository of translated versions of the Rome IV adult diagnostic questionnaire in multiple languages, including linguistic validation (cognitive debriefing) and cultural adaptation.

In all, 33 countries participated in the study. The participating countries and the data collection method in each country are depicted in this map – See Figure 2



**Figure 2 – Countries participating in Global Epidemiology Study**

Data were collected by Internet survey (Qualtrics, Ltd.) in 26 countries where this was feasible. We conducted house-to-house personal interviews in 7 countries where this was not the case. In two countries, China and Turkey, we conducted both surveys. The predefined demographic parameters were 50% females and 50% males, and 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%). We successfully achieved equal sex distribution and pre-planned age ranges with both surveying methods.

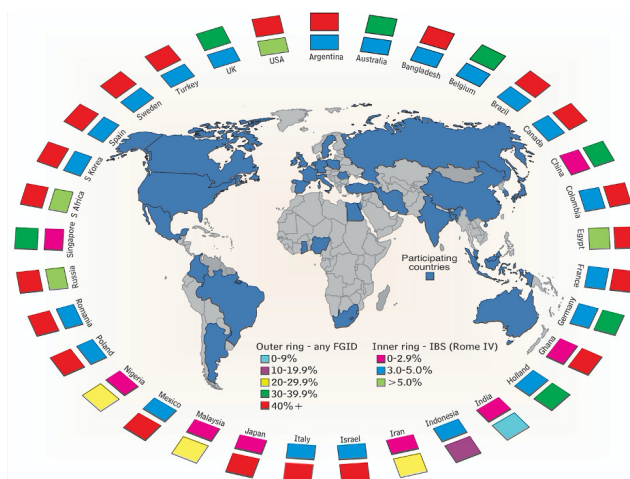
We established a Database Committee, a Statistical Analysis Committee headed by Dr. Shrikant Bangdiwala at McMaster, Canada, to do the initial analyses, and a Publications Committee. We vetted candidates for global study statisticians and established regional and local statistical analysis cores. We held a one and one-half day Global Study Statistical Workshop in Barcelona, Spain in October 2019. About 40 participants attended who would serve as data analysts for regional and local manuscripts and investigators who intend to be lead authors of manuscripts from the study.

We have a website to submit proposals for abstracts or papers for studies related to the database. All submissions undergo a review process (including the statistical analysis plan) like

editorial reviews in medical journals, but to improve and approve the proposals, not reject them.

The first paper, summarizing the major findings, was published in *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). The following is the graphical abstract from that paper:

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



**Worldwide Prevalence of Functional GI Disorders**

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

Since the initial paper, we have published four other articles, and another one is under review in a top-tier journal. The four published papers are:

- 1) Sperber AD, Freud T, Aziz, I. et al. (2021). Greater overlap of Rome IV disorders of gut-brain interactions leads to increased disease severity and poorer quality of life. *Clin Gastroenterol Hepatol* <https://doi.org/10.1016/j.cgh.2021.05.042>.

2) Josefsson A, Hreinsson JP, Simrén M, Tack J, Bangdiwala SI, Sperber AD, Palsson OS, Törnblom H. (2022) Global prevalence and impact of Rumination syndrome. *Gastroenterol* 2021 162: 731-742. doi: 10.1053/j.gastro11.008

3) Sperber AD, Freud T, Abu-Freha N, Shibli F, Brun R, Bangdiwala, SI, Palsson OS, Dickman R. (2022) The Epidemiology of Disorders of Gut-Brain Interaction in Israel: Results from the Rome Foundation Global Epidemiology Study. *Neurogastroenterol Motil*. doi: 10.1111/nmo.14323.

4) Colomier E, Melchior C, Algera, JP, Hreinsson JP, Störsrud S, Törnblom H, Van Oudenhove L, Palsson OS, Bangdiwala SI, Sperber AD, Tack J, Simrén S. (2022) Global prevalence and burden of meal-related abdominal pain. *BMC-Medicine* 20:71. doi.org/10.1186/s12916-022-02259-7.

Twenty other studies have been approved and are in varying data analysis and manuscript preparation stages.

We are receiving more proposals for study regularly. The Rome Foundation Research Institute (RFRI) will now coordinate studies related to the global study database, including global study data mining, to provide background data for the Rome V committees. Drs. Sperber, Palsson, and Bangdiwala will lead this work.

We have presented abstracts at multiple scientific meetings including DDW and UEGW, starting in 2020 and will be presenting 6 posters at DDW 2022:

- 1) Gastroparesis-like symptoms - Abstract # 3695758 on May 21
- 2) Diet and DGBI - Abstract # 3693820 (e-poster)
- 3) Burden of Pain in DGBI - Abstract # 3691932 on May 23
- 4) Psychological factors in DGBI - Abstract 3696085 on May 23
- 5) Factor analysis - Abstract # 3698357 on May 23
- 6) DGBI Romania - Abstract # 3692626 on May 24

The Rome Foundation Global Epidemiology Study is an ongoing process that should continue to provide essential findings for papers and support other future research. It already serves as a significant reference in Gastroenterology in general and Neuro-Gastroenterology in particular.

### **Domino Trial**

The DOMINO trial (Diet Or Medication in Irritable bowel syNdrOme) was a randomized trial for newly diagnosed or treated patients with IBS in primary care to evaluate a dietary intervention's short-term efficacy and long-term health economic impact compared to pharmacotherapy with a muscolotropic spasmolytic agent. The Belgian Government funded this trial, which was pragmatic and aimed at optimizing primary care. It used questionnaires developed for the Rome IV Global Epidemiology study in Belgium and served as an opportunity to collect biobank material from primary care IBS patients. Patients were 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).

The study ended in the Summer of 2020, with 470 patients enrolled and 95% of the subjects providing biobanking samples for genetics, serum, and stool analysis for microbiota and biochemical parameters. Patients were randomized to medication or the diet app, and those 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 and 2021. The primary outcome data were a plenary presentation at the 2021 DDW.

*At baseline, 71% of these primary care-diagnosed IBS patients fulfilled the Rome IV criteria (Rome+). 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%).*

*453 primary care IBS patients (41±15 years, 76% female, 71% Rome+) were randomized to either OB (n=231) or diet app (n=227). The responder rate in the diet group (71%) was significantly higher compared to OB (61%) after 8 weeks of treatment (p=.03) and this was more pronounced in Rome+*



(77% vs. 62%,  $p=.005$ ). The diet group maintained a significantly higher responder rate during follow-up (6 months: diet: 74%; OB: 58%,  $p<.001$ ). Mean IBS-SSS improved significantly over time in both groups (OB:  $267\pm100$  vs  $170\pm109$  ( $p<.001$ ); diet:  $267\pm96$  vs  $188\pm109$  ( $p<.001$ )), but with significantly larger improvement in the diet arm compared to OB ( $p=.02$ ). Both with OB and diet, significant improvement was observed for IBS-QoL (OB= $-7.34$  ( $p<.001$ ) vs diet= $-8.07$  ( $p<.001$ )) and levels of anxiety (OB= $-0.99$  ( $p<.001$ ) vs diet= $-1.19$  ( $p<.001$ )), depression (OB= $-1.09$  ( $p<.001$ ) vs diet= $-1.36$  ( $p<.001$ )) and somatization (OB= $-1.31$  ( $p<.001$ ) vs diet= $-1.80$  ( $p<.001$ )), but without significant difference between treatment groups ( $p>.05$ ). Female gender (OR=,  $p=.04$ ) was a response predictor for diet-treated patients whereas higher somatization (OR=,  $p=.002$ ) was a predictor of OB treatment response.

The revised version of the primary outcome manuscript is currently under review in Gut, and a decision is likely to be made over the next weeks.

In addition, we analyzed the genetic samples for predictors of response to either treatment. Below is a summary of the abstract, which will be an oral presentation at DDW 2022.

*459 patients with physician-diagnosed IBS were randomized to receive a FODMAP lowering diet through a smartphone app ( $n=227$ ) or a treatment with the antispasmodic agent otilonium bromide ( $n=232$ ). Improvement of 50 points in the IBS Symptom Severity Score (IBS-SSS) after 8 weeks of treatment was considered a responder. Whole genome single nucleotide polymorphism (SNP) Global Screening Arrays from Illumina were used to obtain genotype data from every patient. A selection of 6 and 7 candidate genes respectively for the diet and medication arms was tested for association with treatment response in a logistic regression model using plink2. IBS-SSS was significantly improved for both groups after 8 weeks of treatment ( $p<.001$ ). In the diet group 71% (95% CI: 65-77) of patients were responders, which was significantly higher than the 61% (95% CI: 54-68) responder rate in the medication arm ( $p=0.03$ ).*

SNPs from three genes (SLC6A4, TRPA1, CACNA1C) were associated with a response to medication and from two genes (IL5RA and CCR3) with response to dietary intervention

respectively. Two of these SNPs are linked to expression quantitative loci (eQTL): Allele rs2020934G in the serotonin reuptake transporter gene SLC6A4 was associated with higher OB response rate ( $p=9.05\times10^{-5}$ ) and increased mRNA expression in aorta, breast, esophagus and adipose tissues. Allele rs7617872A from the C-C Motif Chemokine Receptor 3 gene CCR3 was associated with increased response to dietary intervention ( $p=2.17\times10^{-6}$ ) and increased expression of CCR3 in whole blood.

This allows us to conclude that, in a group of primary care IBS patients, symptomatic response to a pharmacological or dietary intervention was associated with SNPs inviting further genetic studies in this direction. The SNP associated with medication response is linked to peripheral expression of a serotonin reuptake transporter- the mechanistic link to treatment with otilonium bromide remains elusive. The SNP associated with response to diet maps to a gene coding for a chemotactic receptor mainly expressed on eosinophils, suggesting a possible role for eosinophil chemotaxis in the symptomatic response to reduced FODMAP intake.

Future publications will include: a) the role of gut microbiota composition in response to either treatment arm, b) the baseline characteristics of primary care IBS patients, c) a health economic impact analysis of the study, and d) an analysis of the link between symptoms and treatment response on one hand and stool or blood markers (calprotectin, elastase, secretory immunoglobulin A, beta-defensin, C-reactive protein) on the other hand.

### **ROBOT Project**

RFRI finalized the planning of the **RO**me foundation **BiO**marker and phenotyping project (ROBOT), to support the launch of this multinational project. The plan was to launch this project in 2021 at a small number of sites. However, due to the Pandemic and conflicting projects, the start of the study has been postponed to 2022. The Ethical review board now approves the project in Gothenburg, Sweden. The recruitment of subjects will start in the spring of 2022, followed by launch in Leuven, Belgium during the summer of 2022. After this initial launch in a few highly specialized clinical research units, we plan to expand this project to more sites.

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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 characterized to include: 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 bio-samples and data will enable the evaluation of different biomarkers in large groups of well-characterized individuals in different parts of the world. We will then assess 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 global DGBI research sites. In the first phase of ROBOT each center will recruit  $\geq 100$  patients who fulfill Rome IV diagnostic criteria for at least one DGBI. This will begin in May, 2022. We aim to have a 50:50 split between predominantly upper, i.e. esophageal and gastroduodenal, and lower, i.e. bowel and anorectal DGBI. This will be to be separately negotiated with each site, depending on their expertise and research focus. 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 and GI biopsies in sites where this is possible. 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 bio-samples.
3. RFRI clinical phenotyping tool, collection of bio-samples, and performance of physiologic testing.

Each investigator will “own” the samples from their patients and be listed as an author in publications/projects where their 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 program in Gothenburg will begin in May and the one in Leuven in June, 2022. There will be a few more centers beginning in the fall 2022..

#### **RFRI- Bloating Survey, sponsored by Danone Nutricia Research**

This study was a secure multinational Internet population survey of 5,978 adults in the United States, Mexico and the United Kingdom, conducted to evaluate bloating, distention and other gas-related symptoms and a wide range of potentially related factors. The study was designed collaboratively by the RFRI and Danone and sponsored by Danone.

The study aimed to a) assess the population prevalence of bloating, distention and other gas-related symptoms and their associations with demographics, other symptom characteristics, diet, DGBI, quality of life impairment, and healthcare utilization; b) assess the population prevalence of Rome IV Functional Abdominal Bloating/Distention and to what extent bloating-only, distention-only and mixed subgroups exist within that diagnosis; and c) assess the impact of bloating, distention and combination of both on QoL and healthcare utilization.

The survey contents included demographics, Rome IV diagnostic questionnaire modules for gastroduodenal disorders and functional bowel disorders, questions about bloating and distention rated separately for the previous 3 months, 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,

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

and questions about anxiety and depression symptoms, stress, sleep, exercise, diet, quality of life, height and weight, and healthcare utilization. A subset of 1437 participants also completed a 25-minute online VioScreen follow-up survey about their total diet over the past 3 months.

This is the first study to examine both the current and chronic presence of bloating/distention and numerous potential associated factors in the same population-based sample. It is yielding a comprehensive picture of the scope of these symptoms and their impact in the population and reveals the relative prevalence and overlap of bloating vs. distention. The study has resulted in three scientific abstracts presented at UEG Week and DDW, with more to follow, and the first paper on the findings is currently in preparation.

### **Study of Sub-Threshold Patients-Sponsored by Danone Nutricia Research**

In addition, we are finalizing the Global Study data to characterize the global prevalence of people in 26 countries who are classified as having sub-threshold GI symptoms (bothersome but not meeting Rome IV Criteria for diagnosis). We plan to evaluate the associated impact on quality of life (QoL), healthcare utilization, and psychological wellbeing. We will also compare these individuals to people with DGBI and non-GI individuals in terms of sociodemographic, dietary, lifestyle, medication use, psychosocial & clinical variables. The results should prove to be quite interesting to see the burden of symptoms in people with GI distress who have yet to receive a diagnosis.

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

**Evaluation of Communication Skill Training Programs.** Over the last several years, the Rome Foundation, in collaboration with the Center for Education and Practice of Biopsychosocial Care (DrossmanCare) conducted several workshops, and symposia and train the trainer sessions PRE-COVID 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. These data are available to Rome Foundation and RFRI sponsors on request.

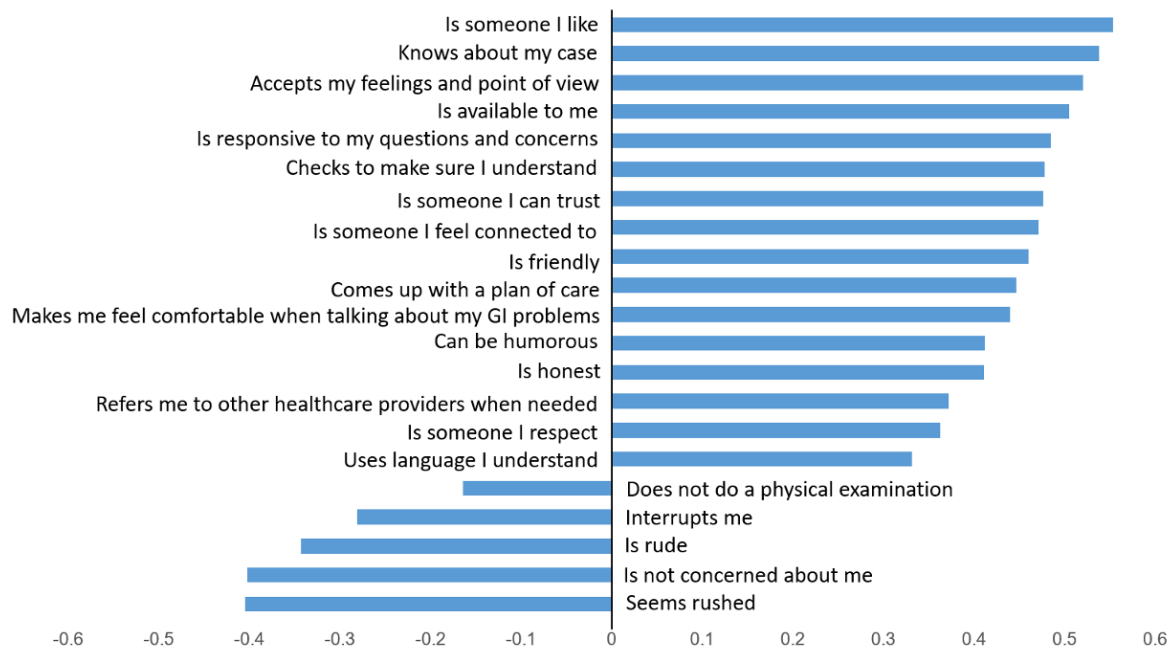
### **Survey to Identify Key elements in the Physician-Patient Relationship that Contribute to Patient Satisfaction and Development of a Short Form PPR Scale for Research and Clinical Care.**

We surveyed 173 patients seeking health care from GI faculty members who underwent a communication workshop at Johns Hopkins medical center. We sought to determine the value of 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 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 factors 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 items in the Physician-Patient Relationship Scale with overall clinical satisfaction (SAT-37). See figure 4.

This study is published: Drossman DA, Palsson O, Stein E, Ruddy J, O'Brien Lennon AM. What elements in the physician-patient relationship (PPR) contribute to patient satisfaction: Development of a short form PPRS-Patient Version (PPRS-Patient SF) Questionnaire. *Neurogastroenterol Motil* 2022;34:e14191. <https://doi.org/10.1111/nmo.14191>

**Consultations with Industry.** Over the past several years, the RFRI consulted with industry relating to surveys and related studies in the area of DGBI.

- **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



**Figure 4. Correlations of patient PPRS items with Overall Satisfaction (SAT-37)**

analogue ROSE-010 in reducing moderate to severe acute abdominal pain in IBS.

- **Alnylam Pharmaceuticals.** Upon the company's request, Dr. Drossman initiated a study proposal 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 an external industry consultant to the Executive Committee. The company approved the initial proposal. 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, a change of senior leadership and a shift in research priorities led the company to withdraw the study application
- **Arena Pharmaceuticals.** RFRI consulted to develop a detailed proposal for Arena to access the Rome Foundation's Global Epidemiology Study of Functional Gastrointestinal Disorders database. The goal was to evaluate the phenotypic features of patients with chronic abdominal pain

- **Sanofi Pharmaceutical.** We are presently consulting with Sanofi to evaluate the characteristics of individuals having abdominal pain in the Global Epidemiology Database

### **Conclusion**

For 2021, the RFRI advanced to become a global leader in DGBI research. With the support of Ironwood Pharmaceuticals and Takeda Pharmaceuticals, we established an efficient infrastructure consisting of an Executive Committee, academic and industry advisory boards, and five cores. We consulted with four pharmaceutical companies on their programs, designed and implemented our epidemiological studies and clinical trials, completed the Domino study and initiated the ROBOT program, established the ability to collect bio-samples, and are beginning to analyze and publish the results. The RFRI continues several international studies and builds 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.



# ROME FOUNDATION CLINICAL DIAGNOSTIC CRITERIA FOR DISORDERS OF GUT- BRAIN INTERACTION

The Rome criteria, which define disorders of gut-brain interaction (DGBIs), are extensively applied in epidemiologic research, pathophysiologic studies, treatment trials, and clinical practice. The requirement for long periods of symptom presence and high symptom frequencies facilitated the use of the Rome criteria in epidemiology studies and treatment trials but has hampered clinical application when these requirements were not fulfilled. The Rome Foundation proposes a modification of the diagnostic criteria for clinical practice, where a DGBI diagnosis can still be made if (1) the nature of the symptoms corresponds to those in the DGBI Rome IV diagnostic criteria and (2) the symptoms are bothersome (interfering with daily activities or requiring attention, causing worry or interference with quality of life). If this is the case, a lower frequency and a shorter duration (8 weeks or more) than those required for the Rome DGBI diagnostic threshold are allowed, provided that there is clinical confidence that other diagnoses have been sufficiently ruled out based on presentation and additional investigations as needed. Applying these criteria for clinical practice will allow the clinician to make a diagnosis, reduce unnecessary diagnostic studies, and enhance the patient-provider relationship. Further research is needed to validate these recommendations.

## Challenges Relating to the Rome Symptom-Based Criteria for Clinical Use

As the Rome criteria became more established over time for research, clinicians began to debate their use for clinical practice.<sup>19–23</sup> One example is related to the change in criteria for IBS from Rome III to Rome IV. The new criteria increased the specificity of the diagnosis at the expense of its sensitivity and identified a patient group with more severe disease, and the prevalence of IBS in the global study dropped by 50%.<sup>24</sup> Thus, patients with milder IBS symptoms would not meet the criteria for Rome IV as they did for Rome III. Another major concern was the need for clinicians to make a subthreshold diagnosis for DGBI diagnoses in general when a patient does not meet the full Rome criteria used in research but other clinical evidence supports the diagnosis.

An example is if the patient meets the qualitative symptom criteria, but the symptoms have existed for less time than the Rome criteria require. For research purposes, the Rome IV criteria require symptom onset 6 months before the diagnosis and symptoms meeting the Rome IV criteria to have been present during the previous 3 months to exclude the possibility of other diagnoses. This approach increases the reliability of patient selection for epidemiologic studies. It also ensures adequate time to exclude other diagnoses and provide sufficient symptom duration for treatment trials that require symptoms to be present for several months. However, in the clinical setting, patients may be adequately evaluated within a shorter time. This would occur with a patient presenting with chest pain repeatedly over several weeks when the cardiologic and gastroenterological investigations have determined a likely esophageal cause. However, a strict application of the Rome IV diagnostic criteria for functional chest pain requires a symptom history of 6 months.<sup>25</sup>

Furthermore, in Asia, prompt endoscopy is a rule for individuals with dyspeptic symptoms. The majority of patients may consult a physician as early as 1 month after the appearance of dyspeptic symptoms. This highlights the need to diagnose at the time of a negative endoscopy result, as demonstrated in Asian publications. However, the more extended time requirement of the Rome criteria has been implicated in the observation that most patients with epigastric symptoms and negative endoscopy results are diagnosed with chronic gastritis.<sup>26,27</sup>

*continued on next page...*

# Rome Foundation Clinical Diagnostic Criteria for Disorders of Gut-Brain Interaction (DGBI)

The Rome IV criteria are extensively used to diagnose DGBI in epidemiological and pathophysiological research, and treatment trials. The criteria require six months of symptoms and high symptom frequencies to exclude other disease. This limits its diagnostic value in clinical practice when the provider can use judgment to diagnose based on the clinical evaluation.

The Rome Foundation now provides modified diagnostic criteria<sup>1</sup> for clinical practice, where a DGBI diagnosis can be made based on clinical confidence and investigations that exclude other diagnoses without time and frequency restrictions.



## Modification of Rome criteria for clinical practice diagnosis:

1

Clinical criteria should be based on previously validated Rome IV symptom descriptors.

2

Bothersomeness must be considered when symptoms interfere with daily life.

3

Frequency of symptoms is an important factor to consider but should not be an obligatory criteria for all cases

4

Physicians can shorten the duration criteria when all other diagnoses can confidently be excluded.

<sup>1</sup>Drossman DA, Tack J. Rome Foundation Clinical Diagnostic Criteria for Disorders of Gut-Brain Interaction. *Gastroenterology* 2022;162:675-679. 34808139 DOI: 10.1053/j.gastro.2021.11.019



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## The following are needed to meet the Clinical Criteria:

### Qualitative Symptom Criteria

- The qualitative features of the Rome IV Diagnostic Criteria must be met

### Bothersomeness

- Sufficiently bothersome symptoms to seek medical care or daily activity and quality of life

### Frequency criteria

- A frequency lower than traditional criteria threshold is permitted provided that the symptoms are bothersome enough to affect daily activity or require treatment

### Duration criteria

- The Rome IV six-month duration is not required. We suggest an 8-week duration to exclude other diagnoses.

### Exceptions are:

- when the clinician is satisfied that medical evaluation excludes other disorders or
- infrequent symptom episode disorders (e.g., CVS, proctalgia fugax)

## Rome IV Clinical Criteria\*

### Irritable Bowel Syndrome

Recurrent abdominal pain associated with 2 or more:

Related to defecation

and

Onset associated with a change in frequency of stool

and

Onset associated with a change in form (appearance) of stool

\*Criteria fulfilled for eight weeks

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## ROME FOUNDATION CLINICAL DIAGNOSTIC CRITERIA FOR DISORDERS OF GUT- BRAIN INTERACTION CONTINUED...

Also, the frequency of the symptoms occurring in clinical settings may be less than the stated criteria. For example, with Rome IV, the frequency thresholds were based on a strict application of epidemiologic data (90th percentile).<sup>16</sup> However, frequencies out of this threshold may still affect the patient's quality of life or functioning, making it highly desirable for a diagnosis and targeted treatment to be made. Examples include cyclic vomiting syndrome, biliary pain, or abdominal migraine (in children). As the Rome criteria's impact grew with time, they were also applied in some settings for billing purposes, which restricted reimbursement for services if patients had symptoms not (yet) meeting the duration requirements.<sup>28</sup>

The discrepancy between the Rome research criteria and clinical diagnoses became even more prominent with the publication of the Rome IV criteria, where changes in specific parameters compared to Rome III made the diagnosis less prevalent and defined a population with more severe disease.<sup>20–24,29</sup> In addition, the extent to which doctors are familiar with and apply the Rome diagnostic criteria is not clear. This is particularly important because patients with DGBI are treated at multiple levels of care, including gastroenterologists, family physicians, internists, surgeons, and others. A study conducted by the Rome Foundation Working Team on Multinational, Cross-Cultural Research showed very different degrees of familiarity with and application of the Rome III diagnostic criteria in India, Mexico, Italy, and South Korea.<sup>30</sup> It is reasonable to assume that with the development of clinical criteria, their relevance to clinicians will increase, as will the degree of their application in clinical practice.

### Rationale and Recommendations for Rome Foundation Clinical Criteria

Based on the emerging discrepancy between the Rome criteria and their clinical application, by consensus of the Rome Foundation Board of Directors, we developed a modification for the Rome IV diagnostic criteria in clinical practice. We propose 4 factors to consider when offering recommendations for clinical criteria.

- **Nature of symptoms.** The qualitative clusters of symptoms used in the Rome criteria represent the DGBI diagnostic syndromes. In effect, these symptom clusters are consistent across populations and have been supported and validated by epidemiologic, factor analytic, and clinical cohort studies in many cases.<sup>31</sup> We recommend that the clinical criteria be based on the Rome IV symptom descriptors and clusters.
- **Bothersomeness.** Symptoms are bothersome when they interfere with daily activities, require attention or worry, and are perceived to cause impairment in quality of life. It is the bothersomeness of symptoms that leads patients to seek health care and for doctors to treat. Also, bothersomeness is a concurrent validation measure in health-related quality of life research, such as the Irritable Bowel Syndrome-Quality of Life Questionnaire (IBS-QOL).<sup>32</sup> Furthermore, the Rome IV criteria use bothersomeness for some diagnoses like functional dyspepsia.<sup>33</sup> We believe that the degree of bothersomeness patients report influences clinical judgments to identify and treat the DGBIs. Therefore, we recommend the addition of bothersomeness as a clinical criterion for diagnosis.
- **Frequency of symptoms.** In epidemiologic studies, symptom abnormality is based on frequencies outside 90% confidence limits or outside of 2 standard deviations from the mean.<sup>16</sup> A statistical symptom frequency abnormality may be considered a clinical relevance criterion. However, some symptoms in clinical practice may be within normal epidemiologic ranges and still be clinically relevant based on bothersomeness or impairment of daily function or quality of life. This occurs when clinicians make judgments to diagnose and treat not by frequency but by an immediacy that patients bring to the clinic visit: if the symptoms are bothersome enough to seek medical care, require treatment, or are sufficient to justify a diagnosis. When this happens, we recommend that the frequency of symptoms not be an obligatory criterion for diagnosis.

- **Duration.** The Rome IV criteria require at least 6 months since symptom onset and 3 months meeting the diagnostic criteria.<sup>1,16,24,31</sup> The timeframe primarily excludes short-lived conditions such as an acute infection or minor events, where the symptoms are likely to disappear or be evaluated sufficiently to exclude other diagnoses. This long timeframe allows their application in epidemiologic studies. However, the duration criteria can be shortened, mainly when a clinician has evaluated the symptoms sufficiently and is satisfied that other diagnoses are confidently excluded.

Using these guidelines provides the opportunity for clinicians to rule out other diagnoses sufficiently. Clinicians will evaluate symptom patterns, risk factors, and other patient characteristics to select additional investigations if needed. If all elements are in keeping with a DGBI diagnosis, the diagnosis can be made with confidence despite a lower frequency and duration.

## Proposal for Clinical Criteria

We recommend that the following be fulfilled to meet the Rome Foundation clinical criteria:

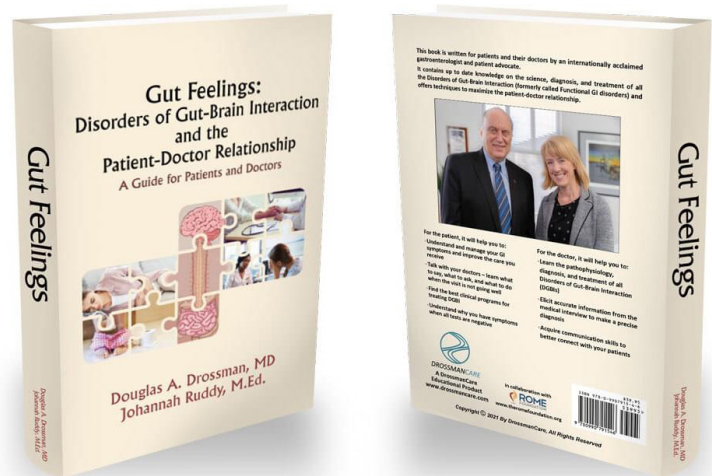
- **Qualitative symptom criteria.** The qualitative features of the Rome IV criteria must be met. See the Supplementary Materials for a listing of the modified Rome IV clinical criteria.
- **Bothersomeness.** Patients should have sufficiently bothersome symptoms to seek care or affect daily activity (personal and professional). Within this context, the symptoms are severe enough to affect their quality of life. For this criterion, the clinician would endorse “Patient reports the symptoms as bothersome.”
- **Frequency criteria.** A frequency lower than the Rome IV threshold is permitted, provided that the symptoms are bothersome enough to interfere with daily activity or require treatment.
- **Duration criteria.** The Rome IV requirement of a 6-month duration of symptoms is not required. To provide some assurance that other diagnoses have been excluded, we suggest that symptoms be present for the previous 8 weeks. Exceptions to the duration requirement are (1) when the clinician needs to make an earlier diagnosis and is satisfied that the medical evaluation excludes other disease or (2) for diagnoses where the symptoms occur infrequently and intermittently (eg, cyclic vomiting syndrome, abdominal migraine, biliary pain, and proctalgia fugax).

The use of these criteria assumes that other diagnoses have been sufficiently ruled out based on the clinical presentation and additional investigations when needed. These criteria do not replace the standard Rome IV criteria for clinical trials or epidemiologic or pathophysiologic studies.



# 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



Jannah Ruddy, M.Ed

## GUT FEELINGS: THE PATIENT'S STORY

### Personal Accounts of the Illness Journey by Douglas A. Drossman MD and Johannah Ruddy M.Ed.

Learning from patient narratives to better manage Disorders of Gut-Brain Interaction (DGBI) and improve the Patient-Provider Relationship (PPR)



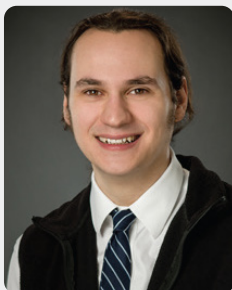
With every passing day, I learn how to make the most of my time and to direct my energy on things that I have the power to control while letting go of things I cannot. Throughout this experience, I have gained a tremendous amount of insight into my life and what is important."

*Katherine*



In the most difficult time of your illness, the illness might seem like a curse, but as you heal, you can use it to help you connect with others and learn to truly advocate for yourself."

*Lesley*



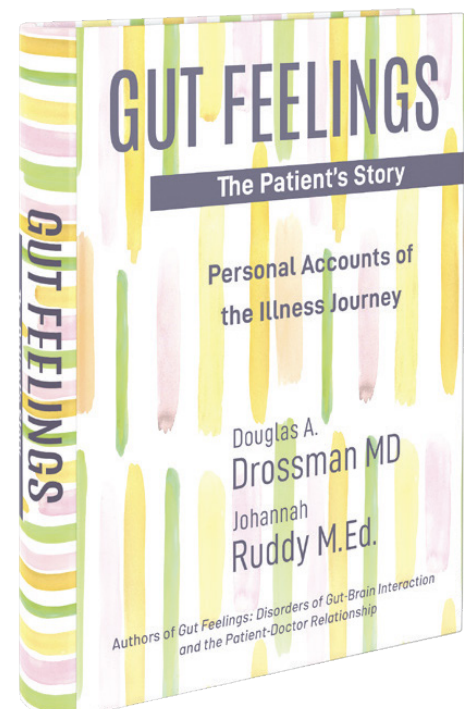
I am inspired and determined to use my experiences in a constructive way to help patients like myself who encounter misunderstanding, neglect, or abuse in our medical system. I want to be an advocate."

*Stephen*



**Optimal care of DGBI is a collaboration where patient and provider achieve mutual goals:**

The provider elicits the patient's illness experience and applies that knowledge along with the science of neurogastroenterology to select diagnostic strategies and optimize treatment. The patient communicates to the provider the illness experience in a meaningful manner and then participates in diagnostic and patient decision making. This is patient-centered care.



# PROGRESSIVE VIDEO TRAINING TO OPTIMIZE THE PATIENT-PROVIDER RELATIONSHIP

COMMUNICATION **101**  
Basic

COMMUNICATION **101.5**  
Intermediate

COMMUNICATION **202**  
Advanced



## The Communication Bundle is a Must Have For Clinicians!

This video education series offer a progressive learning approach to developing communication skills to improve patient and provider care satisfaction. Starting with the basic information to discuss with patients (101), the learner moves on to handle the most common challenging situations that come up in DGBI care (101.5). Once these skills are acquired, the provider can learn more sophisticated methods to elicit underlying issues that generate the symptoms and the ways to remedy them (202). The three videos are bundled and available at a discount.

- Graded educational program from basic to advanced
- Build your communication skills as you move from one module to another
- Learn at your own pace while you gain more and more advanced skills
- Earn 9 CME credits for completing all the programs
- 101 tells you what you need to say to patients about their diagnoses and treatments – plain and simple
- 101.5 helps you get through those challenging interactions when you only have a few minutes
- 202 is a deeper dive into understanding the bases for the symptoms and the best ways to manage them

**Rome Foundation/DrossmanCare Video Education Series**

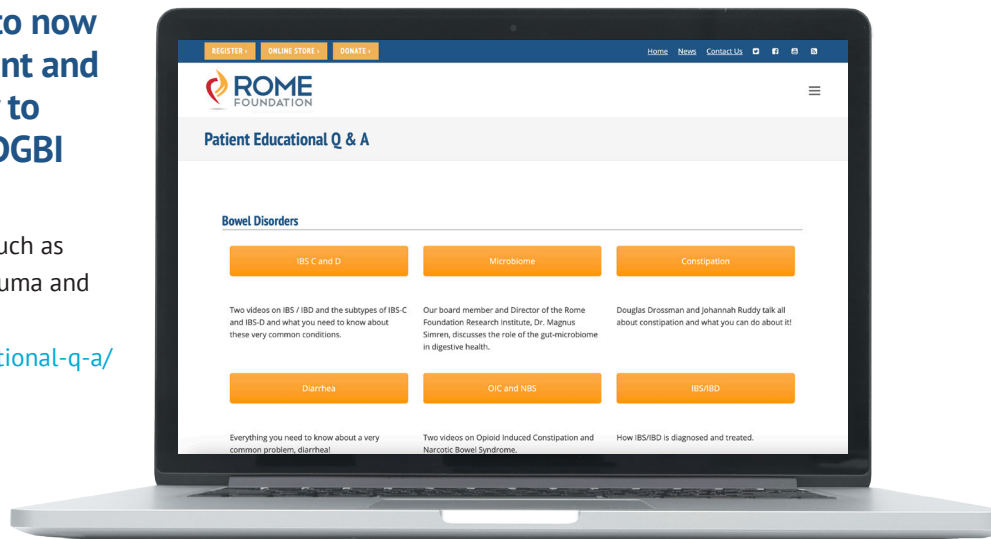
**Order Today: <https://romedross.video/Commprogram>**

## 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.

Get these resources 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

- 2022 Rome Grand Rounds sessions
- 2022 Rome Pediatric DGBI Symposium
- 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

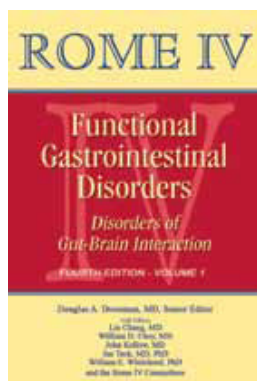
This CME activity covers the key elements of good provider/patient communication to optimize patient care, decrease burnout, and increase provider and patient satisfaction. *1 CME credit*



# 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.

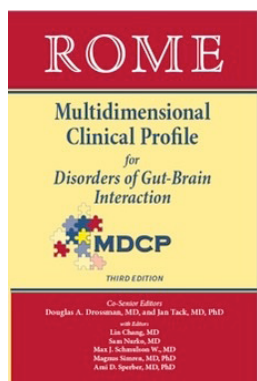
As with earlier book editions beginning in 1994, the Rome IV textbook is a comprehensive update of knowledge in DGBIs and in the Rome IV diagnostic criteria. It is a 1,500-page, two-volume book created by 117 internationally recognized clinicians and investigators in the field.

**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

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

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.



### 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.

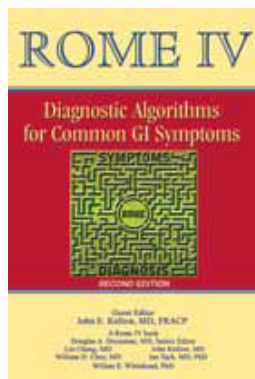
The book helps the clinician understand the complexity and dimensionality of these disorders. Discerning clinicians recognize that just making a diagnosis is not sufficient to determine treatment. For example, a patient with IBS-D having mild and occasional symptoms of abdominal discomfort and loose 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

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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.





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## 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.

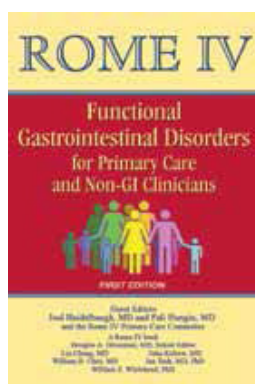
For the 1st edition published in 2010 as a special issue of the American Journal of Gastroenterology, 15 common gastrointestinal symptom presentations were created, and from that entry point, the committees developed evidence-based and cost-effective diagnostic pathways that followed each of these clinical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

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.



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

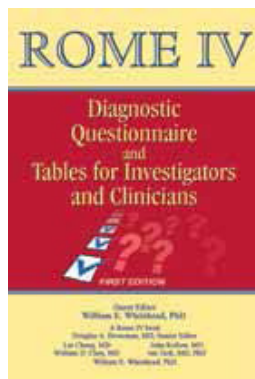
As noted, one of the Rome IV initiatives was that of reaching a larger audience of non-gastroenterologists. We have partnered with leaders in the primary care field to create a primary care book, co-edited by Joel Heidelbaugh, MD, and Pali Hungin, MD.

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.

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.

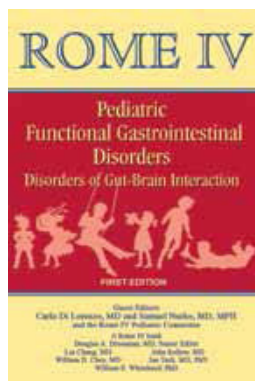
Soft Cover or e-book \$34.95

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.

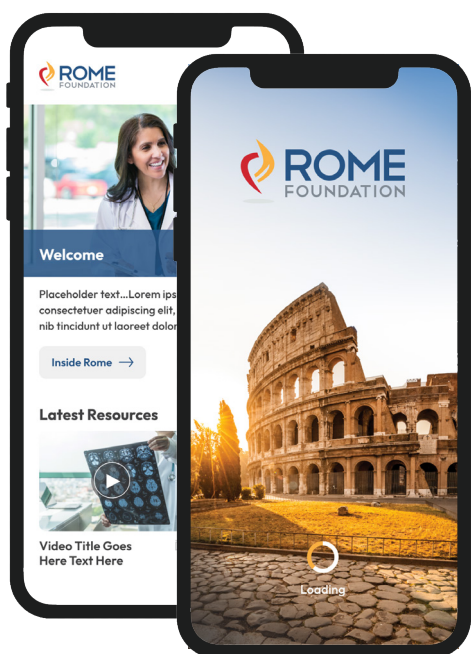
Soft Cover or e-book \$59.95

## Rome 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/>.



## Rome App - New and Updated!

The Rome Foundation App for iOS and Android has been completed revamped and design to use as a reference for clinical use as well as your one-stop for the best in Rome education and resources. Find the Rome Criteria, the Rome diagnostic algorithms, patient education resources, key videos, pocket cards, the Bristol Stool Form Scale and more!

This app, developed with our partners at Vienna Creative, will offer a new user experience with the ability to save your favorite resources in the app to your own “My Rome” section for quick and easy access on the go.

Launching in summer, 2022, this app will be your favorite clinical resource, right in the palm of your hand!

## 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
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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

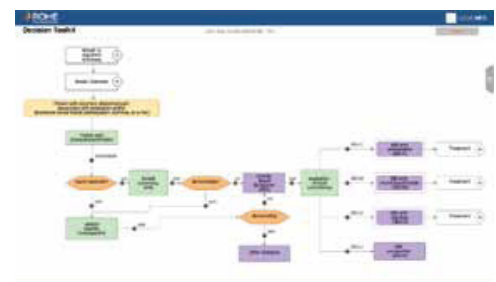


3 month trial subscription - \$29.95 | Renew annually for \$89.95

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.

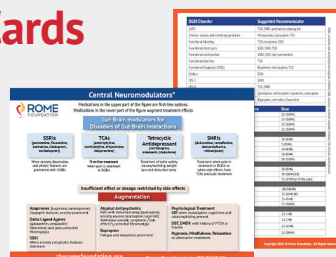
## GI Genius Interactive Clinical Decision Toolkit

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.

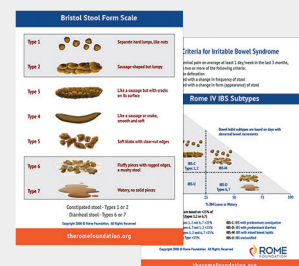


## Other Pocket Cards

### Central Neuromodulators



### Bristol Stool Form Scale



Download this free cards at <https://theromefoundation.org/resources/pocket-cards/>

## COMMUNICATION 101

### 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

### 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

### 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 V

One of the major functions of the Rome Foundation is to update and revise medical information on the DGBI and the Rome Criteria. This has been accomplished beginning with Rome I (1994), Rome II (2000), Rome III (2006) and Rome IV (2016). We are now beginning Rome V, which will be completed in 2026. The process relies on obtaining recent scientific evidence and using consensus (Dephi approach) to create a variety of educational documents. These documents evolve over a five-year period and are peer reviewed. The Rome V textbooks will be published in reduced form in *Gastroenterology* as a 13th edition.

The Rome V products will include: Rome V textbook (Vol I & II), a pediatric version, a primary care version and questionnaires and tables book. This information is extracted to create the diagnostic (Rome V Algorithms) and treatment (Rome V MDCP) books. In addition, all of these products are available in digital formats (E-books and Rome V online- containing all books). The Rome Foundation GI Genius Interactive Software program will also be updated to accommodate changes from Rome V.

Rome V Chapter Committees					
Fundamentals of Neurogastroenterology- Basic Science	Fundamentals of Neurogastroenterology: Physiological Aspects and Clinical Implications	Intestinal Microenvironment and DGBI	Pharmacokinetic and Pharmacogenomic Aspects of DGBI	Age, Race, Gender, Women's Health, and the Patient Experience	
<b>Gary M. Mawe, PhD</b> Co-chair <b>Beverley Greenwood, PhD</b> Co-chair Stuart Brierley Brian Gulbrandsen Gerard Clark Kara Margolis Art Beyder	<b>Lesley Anne Houghton, PhD, FRSB, RFF, AGAF, FACG- Co-Chair</b> <b>Roberto DeGiorgio- Co-Chair</b> Guy Boeckstaens John F Cryan Tim Vanuytsel Phil Dinning Mauro D'Amato Bill Hasler	<b>Eamonn M Quigley, MD</b> <b>Madhusudan Grover, MBBS</b> Giovanni Barbara Bruno Chumpitazi William D. Chey Christine Feinle-Bisset Harriett Schellekens	<b>Michael Camilleri, MD</b> <b>Giovanni Sarnelli, MD, PhD</b> Colin Howden Beverley Greenwood van Meerveld Angelo Izzo Viola Andresen Karen Jones	<b>Albena Halpert, MD co-chair</b> <b>Margaret Heitkemper, PhD, RN co-chair</b> Susanna Walter, MD Yuri Saito, MD Lucinda Harris, MD Muriel Larauche, PhD Kyle Staller, MD Johannah Ruddy M.Ed	
Social and Cultural Factors of DGBI	Psychosocial Aspects of DGBI	Functional Esophageal Disorders	Functional Gastroduodenal Disorders	Functional Bowel Disorders	
<b>Gerald J Holtmann, MD, PhD, MBA</b> <b>Reuben K. Wong, MD</b> Xiucui Fang Uday Ghoshal Justin Lee Agata Mulak Purna Kayshap	<b>Rona L. Levy, MSW, PhD, MPH</b> <b>Sigrid Elsenbruch, PhD</b> Sarah Ballou Laurie Keefer Lukas Van Oudenhove Miranda VanTilburg Dipesh Vasant	<b>John E. Pandolfino, MD</b> <b>Sabine Roman, MD PhD</b> Ronnie Fass Shobna Bhatia Edoardo Savarino Frank Zerbib Prakash Gyawali	<b>Vincenzo Stanghellini, MD</b> <b>Hans Tornblom, MD, PhD</b> Nick Talley Hidekazu Suzuki Florencia Carbone Jan Tack André Smout Bill Hasler	<b>Anthony Lembo, MD</b> <b>Maura Corsetti, MD, PhD</b> Andrea Shin Magnus Simren Brian Lacy Xiaohua Hou Max Schmulson Brooks Cash	
Centrally Mediated Disorders of Gastrointestinal Pain	Functional Gallbladder and Sphincter of Oddi Disorders	Functional Anorectal Disorders	Pediatric Upper Disorders of Gut-Brain Interaction	Pediatric Lower Disorders of Gut-Brain Interaction	Design of Treatment Trials for Functional Gastrointestinal Disorders
<b>Qasim Aziz, PhD</b> <b>Shin Fukudo, MD, PhD</b> Douglas A. Drossman, MD Eva Szigethy Lukas Van Oudenhove Adam Farmer Asbjorn Drewes	<b>B. Joseph Elmunzer, MD, MSc</b> <b>Enrico Stefano Corazzari, MD</b> Grace Elta Marianna Arvanitakis Emily Winslow Roberto De Giorgio Andrea Laghi	<b>Satish S. C. Rao, MD, PhD, FRCP</b> <b>Emma V. Carrington</b> Adil Bharucha Allison Malcolm Jose Remes-Troche Ugo Grossi Leila Neshatian	<b>Marc A. Benninga, MD</b> <b>Rachel Rosen, MD, MPH</b> Usha Krishnan Christophe Faure Nathalie Rommel Osvaldo Borelli Alan Silverman Michiel van Wijk Carlos Velasco	<b>Carlo Di Lorenzo, MD</b> <b>Miguel Saps, MD</b> Annamaria Staiano Nikhil Thapar Miranda Van Tilburg Shaman Rajindrath Katja Kovacic Arine Vlieger Bruno Chumpitazi	<b>Greg Sayuk, MD, MPH</b> <b>Alex Ford, MD</b> Brian Lacy Florencia Carbone Darren Brenner Simon Knowles Heidi Staudacher

## Working Team Committees

These are content oriented and provide a database of information that can be used by the Rome Chapter Committees. These committees are currently underway. The information that develops from these committees will be published as free-standing reviews of the field and may include recommendations or guidelines. The Rome V Chapter Committees will use this information in their work.

Rome V Working Team Committees				
Brain-Gut Psychotherapies	Communication	Food and Diet*	Plausibility	Overlap in DGBI*
<b>Laurie Keefer, PhD</b> Brjánn Ljótsson, PhD Douglas A. Drossman, MD Sarah Ballou, PhD Sigrid Elsenbruch, PhD Gisela Ringstrom, PhD	<b>Douglas A. Drossman, MD</b> Lin Chang, MD Johannah Ruddy, MEd Alben Halpert, MD Alex Charles Ford, MD Kurt Kroenke, MD, MACP Samuel Nurko, MD, MPH Jill Deutsch, MD Julie Snyder, PsyD Ami Sperber, MD, MSPH	<b>William D. Chey, MD, AGAF, FACP, FACP</b> <b>Jan Tack, MD, PhD</b> Steve Vanner Bill Chey David Sanders Jan Tack Heidi Staudacher	<b>Jan Tack, MD, PhD</b> <b>Nicholas Talley, MD</b> Ana Maria Madrid Daniel Pohl Edoardo Savarino Florencia Carbone Giovanni Barbara Ignacio Hanna Jan Tack Jordi Serra Laurie Keefer Lin Chang Magnus Simren Max Schmulson Michael Camilleri Oh Young Lee Ram Dickman Shin Fukudo Uday Goshal	<b>Magnus Simren, MD, PhD</b> <b>Giovanni Barbara, MD</b> Gregory Sayuk Lin Chang Sarah Ballou Carolina Olano Shin Fukudo Lukas Van Oudenhove Imran Aziz Alexander Ford Kewin TH Siah Miguel Saps Samuel Nurko

## Support Committees

These committees are designed to assist the chapter committees in their work. An example would be the systematic review committee which will provide relevant articles for the Rome V committee work. Support committees may also use the information from the chapter committees for related purposes. Examples would be the Questionnaire Committee or the Primary Care Committee. These committees have begun their work and they will continue through the Rome V chapter committee activities.

Rome V Support Committees				
Assessment and Outcomes	Global Epidemiology	Non Pharmacological Care	Primary Care	Questionnaire
<b>Anthony Lembo, MD</b> Vipul Jairath, MD Eric Shah, MD Prashant Singh, MD Jan Tack, MD, PhD Daphne Ang, MD Oliver Chassany, MD, PhD Miguel Saps MD	<b>Ami Sperber, MD, MPH</b> Kant Bangdiwala PhD Oli Palsson PsyD Xiucui Fang, MD	<b>Laurie Keefer, PhD</b> <b>Sarah Kinsinger, PhD</b> Giuseppe Chiarioni Bonney Reed Sarah Ballou Livia Guadagnoli Liesbeth Ten Cate	<b>Joel J. Heidelbaugh, M.D., FAAP, FACP</b> Bold Pali Hungin, MD Pali Hungin, MD Niek J. de Wit MD, PhD Bohumil Seifert MD, PhD Jean W. M. Muris, MD Parvathi Perumareddi, DO	<b>Brian E. Lacy, MD, PhD</b> <b>Olafur Palsson, PsyD</b> Ami Sperber MD MPH Magnus Simren, MD, PhD Tiffany H. Taft, PsyD Marc Beninga, MD



# 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 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
- Opportunity to make presentations at Rome Foundation Advisory Council meetings
- Participation in Rome Foundation sponsored conferences
- Opportunity to sponsor research grants through the Rome Foundation Research Institute
- Opportunity to sponsor and participate in symposia and meetings
- Discount on bulk orders of Rome products
  - Rome IV books
  - Computer-Based Learning Program
  - Working team report



Improving the Lives of People with Disorders of Gut Brain Interaction

Rome Foundation, Inc. | 14460 Falls of Neuse Rd | Suite 149-116 | Raleigh, NC 27614

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