ROME FOUNDATION

MEET THE ROME FOUNDATION

2023-2024

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

THEROMEFOUNDATION.ORG

WELCOME FROM OUR PRESIDENT AND OUR CEO

We are pleased to present this update on the Rome Foundation over the past year and discuss our current and future initiatives. We continue to grow in the number of activities and their scope. In this 2023 report, we take the opportunity to summarize our key current and future programs. These include:

- Global Epidemiology Study publication, ongoing analysis and publications
- Rome Foundation Research Initiative (RFRI) activities
- Innovative educational programs for Gastroenterologists, primary care APPs and other Allied health providers
- Growth in our Communication Program and new award
- Upgraded website and social media activities
- Research and Clinical Awards and Rome Fellowships
- Rome V

Global Epidemiology Study publication, ongoing analysis and publications Thanks to Ami Sperber, MD MSPH director of the Global Epidemiology Study, we are in the last phase of this remarkable project. Since the first publication in January 20211 , we have published 15 studies containing global and country-specific data on the prevalence, sociodemographic, methodological, and psychosocial features of DGBI, We are also pleased to announce that the journal Neurogastroenterology and Motility will be publishing a special edition of 13 additional studies. This Issue was edited by Drs Ami Sperber, Xiucai Fang, Dan Dumitrascu and Max Schmulson.

Rome Foundation Research Institute (RFRI) The RFRI, coordinated by Magnus Simren (director), Jan Tack, and Doug Drossman, is a subsidiary organization of the Rome Foundation that promotes and supports research in DGBI. In only 5 years, we have developed a centralized international clearinghouse for data acquisition and research, a global network of Investigators, an RFRI Investigator platform (RFRI-IP) to allow deep phenotyping of patients and a biobank initiative under the direction of Madhu Grover for collection of study samples. Our biometry core, headed by Olafur Palsson and Kant Bangdiwala, has led to collaborative studies with Danone Pharmaceuticals evaluating Individuals with sub-diagnostic DGBI, bloating, and distension. We published the completed Domino study, a trial of medication vs. dietary treatment of primary care IBS (https://pubmed.ncbi.nlm.nih.gov/35483886/) and our Robot Biomarker and Phenotyping project is well underway. Upcoming projects include epidemiological and clinical analyses of cyclic vomiting syndrome, gastroparesis, and abdominal pain. We want to thank Ironwood and Takeda Pharmaceuticals for their support. 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 APPs and Allied health providers The COVID-19 experience facilitated our development of more online programs. We have undertaken a major upgrade of our website to accommodate more online CME programs, and we converted our regional on-site CME programs to be entirely online. Some of our most successful programs include our Rome Foundation Grand Rounds, our GastroPsych Online Learning Programs, and our new Pediatric Educational Activities. While we plan to return to on-site educational programs, our online activities will continue and will provide enduring content for self-learning and CME to maximize the learning experience. See more about the Rome Campus here https://theromefoundation.org/welcome-to-the-rome-campus/.

Communication Program Thanks to the support of our industry sponsors, Abbvie, Ironwood, Salix and Ardelyx our Rome Foundation - DrossmanCare Communication program continues to grow https://romedross.video/Collaboration, and has expanded to reach larger audiences. Through a series of recent publications, 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. We have also begun reaching patients and

providers in our two books written by Drs. Drossman and Ms Ruddy: "Gut Feelings: Disorders of Gut-Brain Interaction and the Patient-Doctor Relationship" https://romedross.video/GutFeelingsWebsite, and 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. Stay tuned for our third book, "Gut Feelings: Providers Achieving Patient-Centered Care" where we will present the narratives of several international key opinion leaders in DGBI who are committed to providing the best patient-centered care. To move this effort forward, we are continuing more Intensive programs for academicians and clinicians with full-day workshops and day-and-a-half Train the Trainers programs.

Upgraded website and social media activities We have upgraded our website ffor easier navigation https://theromefoundation.org/ and offer more online education programs on our "Rome Campus," which includes CME programs and other educational programs in a consolidated web page. https://theromefoundation.org/welcome-to-the-rome-campus/. We are also providing more DGBI content, which has increased the number of readers attracted to our website (30% increase over the last year). Included with this content upgrade is our post: "What is a DGBI" as well as more updates with new scientific publications. Our patient Q&A has become our most popular website, with over 125 videos packed with information. 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 Clinical Awards and Rome Fellowships
We are excited to announce a new award, The Rome Foundation Douglas Drossman Award for Communication and Patient-Centered Care in DGBI. The Board of Directors created this to honor Dr. Drossman's lifetime commitment to teaching communication skills to optimize the patient-provider relationship. The annual award will be given to a provider in the field of DGBI who has achieved excellence in communication skills and patient-centered care through clinical practice, teaching and mentoring. Applicants can be nominated or self-nominated. Learn more about this award here: https://loom.ly/kFot8HI

- **Rome/Drossman Awardee:** Lin Chang, MD

Our other awards Include:

- **2022 Ken Heaton Awardee:** Ami Sperber, MD, MPH
- **2022 Ray Clouse Awardee:** Zlatan Mujagic, MD PhD
- **Rome Research Awards:**
  - Yasmin Nasser, MD, PhD, FRCPC
    Calgary Division of Gastroenterology & Hepatology
  - Imran Aziz, MD, MBChB, MRCP
    University of Sheffield, UK
  - Manik Gemilyan MD, PhD, MPH
    Yerevan State Medical University after Mkhitar Heratsi, Armenia

Rome V We are now entering the 3rd year of the Rome V process to be completed In 2026 with the Rome V publications and the special issue of Gastroenterology which will publish the Rome V committee reports. Drs. Drossman and Tack are co-senior editors and the editors Include Lin Chang, Bill Chey, Sam Nurko, Max Schmulson and Ami Sperber. There are 18 chapter committees and working team and support committees comprising 144 authors in 27 countries. At DDW this year, we will hold a Rome V symposium for committee members and our industry sponsors to offer updates on our activities. We would like to thank our industry sponsors: Abbvie, Alfa Sigma, Ardelyx, Bayer, Biomerica, Danone Health Science, Ironwood, Nestle, Salix, Sanofi, Takeda, and Yangtze River for their support

We are so grateful to all of you for your support of the Rome Foundation and look forward to future collaborations.

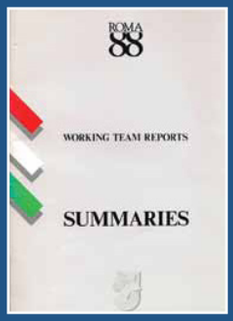
Douglas A. Drossman MD
CEO and President Emeritus

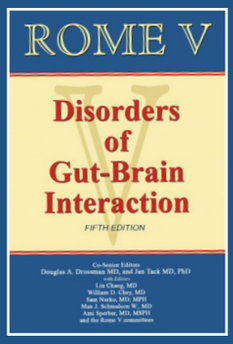
Jan Tack MD, PhD
President of the Board

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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CONTACT INFORMATION

For Information on:
- Research Institute (RFRI)
- Global Study
- Public Relations
- Rome IV and Rome V
- Sponsors - Information/Opportunities
- Sponsorship of Rome Activities
- Website
- Rome Pediatrics
- Rome Food and Diet
- Rome Communication

Contact: Johannah Ruddy
jruddy@theromefoundation.org

For Information on:
- Rome Visiting Scholar
- Tradeshow/Exhibits
- Online order support

Contact: Michelle Berry
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For Information on:
- Rome V Committee Support
- Rome Partners Program
- International Sponsorship and Education

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
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For Information on:
- GastroPsych Education or Credits
- Contact a Board Member
- Education Credits on Rome Campus

Contact: Tamieka Blair
TBlair@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), American College of Gastroenterology (ACG), 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
Bayer
Ironwood Pharmaceuticals
Sanofi
Abbvie
Biomerica
Nestle Health Science
Takeda Pharmaceuticals
Alfa Sigma
Danone Nutricia Research
Salix Pharmaceuticals
Yangtze River

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 Biopsychosocial, 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 NIHNCCAM 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" and a second book "Gut Feelings: The Patient's Story".

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

Janssen Award for Clinical Research (1999), the American Psychosomatic Society President's Award (2003), the AGA Joseph B. Kirsner – Fiterman Award in Clinical Research (2005) the AGA Mentors Research Scholar Award (2007), and the American Journal of Gastroenterology Lectureship (2011). He has also received several "Who's Who", "Patient Choice" and "Best Doctors" citations over the past 20 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 Chief Executive Officer and President Emeritus. He has been editor in chief of Rome I, II and III books and currently of Rome IV published in 2016, and is co-senior editor of Rome V to be published in 2026. 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 Executive Officer 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 Pharmachological Science. He is, or has been, a member of the Editorial Board of Gut, American Journal of Gastroenterology, Neurogastroenterology and Motility, the American Journal of Physiology and other international scientific Journals.

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

ROME FOUNDATION - PRESIDENT AND BOARD CONTINUED...

Lin Chang, MD, RFF

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

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

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

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

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

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.

Xiucai 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. Xiucai 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 (from1995), 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. Xiucai Fang, together with Dr. Meiyun Ke, translated Rome III textbook into Chinese, making Rome III the first foreign language version of Rome textbook. She then introduced the Rome criteria in the Chinese Medical Tribune with the special column, whose activities spread the Rome criteria and related knowledge of FGIDs in China. Dr. Fang joined to the Rome IV team as a member of Multi-cultural Aspects of FGIDs Committee. In 2016, she organized Chinese colleagues to translate Rome IV textbook into Chinese, she is also a coeditor-in-chief of Chinese version of MDCP (second edition), and the principal reviewer of Chinese version DGBIs for Primary Care and Non-GI Clinicians. Dr. Fang is the fellow of Rome Foundation; she also served as the member of international liaison committee.

ROME FOUNDATION - PRESIDENT AND BOARD CONTINUED...

Laurie Keefer, PhD, RFF

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

Laurie Keefer, PhD, is a clinical health psychologist specializing in gastroenterology. She received her PhD from SUNY Albany in 2003 where she studied group-based cognitive therapy for IBS, and then continued her training as a resident and fellow in health psychology at Rush University in Chicago IL. In 2006, she set up one of the first fully integrated GI Psychology programs in the country at Northwestern University, where she was on the faculty for 10 years. During this time she built an NIH funded research program focused on the development and implementation of brain-gut psychotherapies for IBS, GERD and IBD and received the first NIH funded Training Grant (T32) for GI Physiology and Psychology, focused on preparing young professionals for careers in psychogastroenterology. She has held elected leadership positions in the field, including as a member of Council for the American Neurogastroenterology and Motility Society and as a Commissioner for the American Psychological Association's Commission for the Recognition of Specialties and Proficiencies in Professional Psychology.
Dr Keefer is Director of the Gaining Resilience through Transitions [GRITTTM]-IBD Program at the Icahn School of Medicine at Mount Sinai in NYC, overseeing a multidisciplinary team of clinicians and scientists to provide early, effective psychosocial care for high risk pediatric and adult patients with Inflammatory Bowel Diseases. Her current research program focuses on resilience and the application of positive psychology interventions in this population.

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

Brian E. Lacy, MD, PhD, FACG, RFF

Senior Associate Consultant at Mayo Clinic
Jacksonville, FL, USA

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

Dr. Lacy's clinical and basic science research interests focus on disorders of gastrointestinal motility, with an emphasis on irritable bowel syndrome, achalasia, dyspepsia, gastroparesis, acid reflux disease, constipation, intestinal pseudo-obstruction and visceral pain. He is the author of 195 peer-reviewed articles on gastrointestinal motility disorders and functional bowel disorders, in addition to multiple text book chapters. Dr. Lacy is a reviewer for a number of scientific journals, and is a member of a number of different scientific organizations, including the American College of Gastroenterology, the American Gastroenterology Association, and the American Neurogastroenterology & Motility Society. Dr. Lacy is the co-author of a book for the

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

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

Samuel Nurko, MD, MPH, RFF

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

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

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

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

ROME FOUNDATION - PRESIDENT AND BOARD CONTINUED...

Ami Sperber, MD, MSPH, RFF

Emeritus Professor of Medicine
Faculty of Health Sciences
Ben-Gurion University of the Negev
Beer-Sheva, Israel

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

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

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

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

Rome Foundation Administration

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Chief Operating Officer &
Executive Director

Mauricio Rojas, MD MPH,
Senior Medical Program Administrator

Michelle Berry
Director, Sales, Exhibits and Events

Debra Wideman
Finance Director

Mark Schmitter
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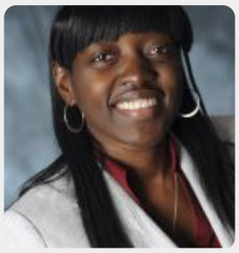
and Copyrights



Tamieka Blair
Director of Educational Initiatives, GastroPsych &
Social Media Coordinator, EA to CEO

Claudia Rojas
Latin America Coordinator

Davis Stillson
Videographer

Eric Chapman
Information Technology Director

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 RFGES 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 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.

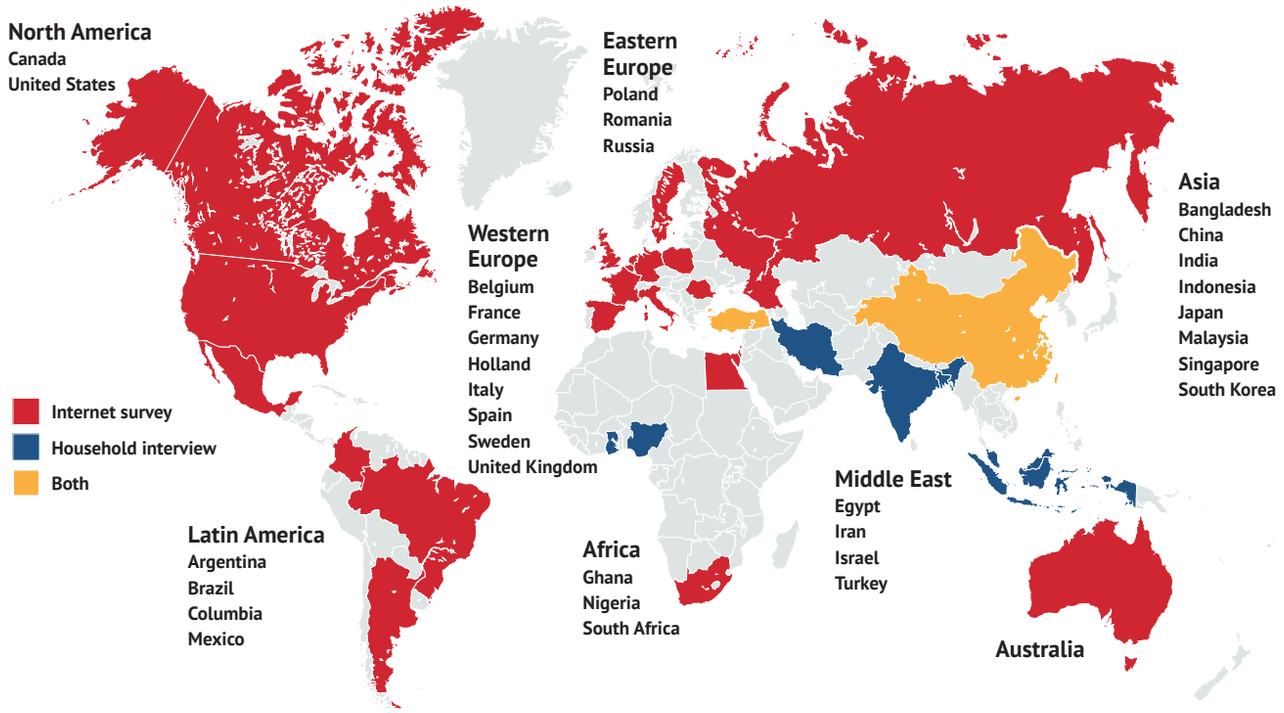
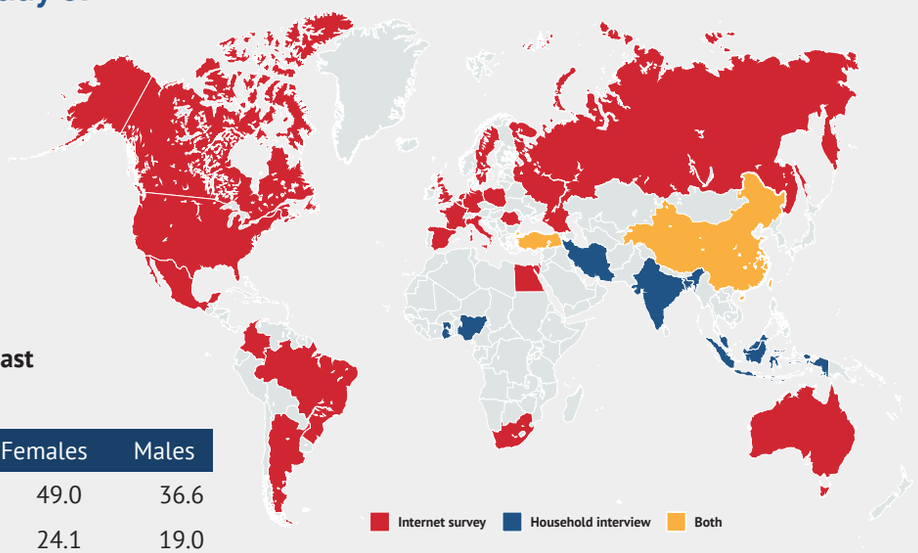


Figure 2 – Countries participating in Global Epidemiology Study

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

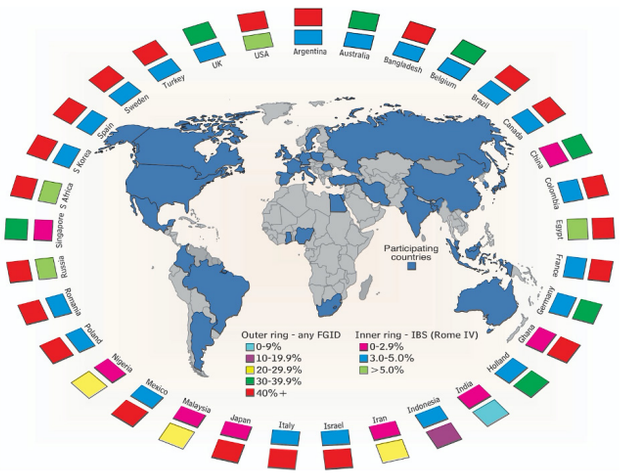
We established a Database Committee headed by Dr. Olafur Palsson, a Statistical Analysis Committee headed by Dr. Shrikant Bangdiwala at McMaster University, Canada, to do the initial analyses, and a Publications Committee headed by Dr. Ami Sperber. We vetted candidates for global study statisticians 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. We now have over 20 statisticians working with us on various paper in progress.

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.

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.

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...

This paper was rated as one of the most impactful papers of the year by AGA and as a "hot paper" by Web of Science.

To the date of this report, we have published 9 RFGES papers and 3 others are under review in leading journals:

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.

3) Josefsson A, Hreinsson JP, Simrén M, Tack J, Bangdiwala SI, Sperber AD, Palsson OS, Törnblom H. (2022) Global prevalence and impact of Rumination syndrome. Gastroenterology 2021 162: 731-742.

4) 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. Neurogastroenterology Motility.

5) 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.

6) Dumitrascu DL, Freud T, Ismaiel A, Bangdiwala SI, Palsson OS, Sperber AD. Epidemiology and Burden of Disorders of Gut-Brain Interaction in Romania: A Subgroup Analysis of the Rome Foundation Global Epidemiology Study. J Gastrointestinal Liver Dis. 2022.

7) Huang IH, Schol J, Khatun R, Carbone F, Van den Houte K, Colomier E, et al. Worldwide prevalence and burden of gastroparesis-like symptoms as defined by the United European Gastroenterology (UEG) and European Society for Neurogastroenterology and Motility (ESNM) consensus on gastroparesis. United European Gastroenterology J. 2022.

8) Luo Y, Camey SA, Bangdiwala SI, Palsson OS, Sperber AD, Keefer LA. Global patterns of prescription pain medication usage in disorders of gut-brain interactions. Neurogastroenterol and Motility. 2022:e14457

9) Knowles S, Skvarc D, Ford AC, Palsson O, Bangdiwala S, Sperber A, et al. Negative impact of disorders of gut-brain interactions on health-related quality of life: results from the Rome Foundation Global Epidemiology Study. Gastroenterology. 2023; In Press

An editorial paper has been published on the RFGES: Tack J, Drossman DA. The Rome Foundation Global Epidemiology study: Research opportunities national and worldwide. Neurogastroenterol Motility. 2022;34:e14431

To date, thirty-seven other studies have been approved and are in varying data analysis and manuscript preparation stages. This includes 15 papers to be published in a special issue of Neurogastroenterology and Motility scheduled to appear around DDW 2023. We continue to receive proposals for studies based on the RFGES database.

We have presented abstracts at multiple scientific meetings including DDW and UEGW, starting in 2020. We recently presented 6 abstracts at UEGW 2022, 4 oral presentations and 2 modified poster presentations:

1) Palsson et al. Causes of lower Rome IV vs. Rome III irritable bowel syndrome (IBS) prevalence: analysis of data from the Rome foundation global epidemiology study (RFGES) (oral presentation).

2) Palsson, et al. Sub-diagnostic gastrointestinal symptoms are common in the global adult population: assessment of prevalence and impact (moderated poster presentation)

3) Burton-Murray et al. Dynamic symptom networks in disorders of gut-brain interaction: a network-based approach with the Rome Foundation global epidemiology study database (oral presentation)

4) Hreinsson et al. Factor analysis confirms validity of Rome IV criteria for major disorders of gut-brain interaction (DGBI) globally across geographical regions, and by sex and age groups (oral presentation)

5) Tornkvist et al. Specifying the unspecified. A global study of unspecified functional bowel disorder (moderated poster presentation)

6) Frandemark et al. Work productivity and activity impairment in subject with disorders of gut-brain interaction: data from the Rome Foundation Global Epidemiology Study (oral presentation)

10 abstracts were submitted to DDW 2023 and 9 of the 10 have been accepted as poster presentations:

1. Vasant et al. Epidemiology of DGBI in UK
2. Mulak et al. Sex differences in DGBI in Poland
3. Fukudo et al. Comparison of Rme III vs. Rome IV IBS in Japan country
4. Broeders, Devolder et al. Prevalence of DGBI in French- and Dutch-speaking populations in Belgium
5. Schmulson et al. 4-country Latin America study – Argentina, Brazil, Colombia, Mexico
6. Simren et al. Effect of different IBS definitions
7. Ballou, Lembo, et al. Prevalence and impact of bloating
8. Hreinsson, Simren et al. Prevalence and burden of DGBI: comparison between W. Europe and Asia
9. Yuying et al. Anorectal pain syndromes
10. Josefsson, Tornkvist, et al. DGBI in Sweden

Rome V Epidemiology Support Committee

This committee is the liaison between the RFGES and the Rome V project. The committee is coordinating studies involving RFGES data mining, to provide background data for the Rome V committees, in particular analyses related to clinical criteria for DGBI. The committee is comprised of Drs. Sperber, Palsson, and Bangdiwala.

The two main current projects are:

1) A global assessment and comparison of frequency thresholds for DGBI-related symptoms and diagnoses by country and geographic region through mining of the RFGES database. The analyses have been completed and the results will be circulated among and explained to all relevant Rome V chapter committees. This process will be completed in advance of the chapter committee meetings at DDW 2023.

2) A new 10-country study on factors associated with the bothersomeness of symptoms, their impact on quality of life, and the decision to consult with a doctor about the symptoms. The questionnaire for this study is close to finalization after we complete focus groups in Australia and the US to assess the proposed questions, following which the English questionnaire will be translated into the languages of the participating countries and the survey of 2,000 in each of 10 countries will be conducted by Internet. We expect to complete data collection by the end of Summer 2023.

A second study will survey 5 doctors in each of the participating countries to gain an understanding of doctors' perspectives on how symptoms of IBS, FD, and IBS+FD affect their patients and which factors are the most central to the clinical effect of symptoms. We hope to complete this study by the end of 2023.

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.

ACTIVE COMMITTEES

ROME FOUNDATION GastroPsych

Psychogastroenterology is the application of psychological science and practice to gastrointestinal (Gi) health and illness.

Rome Psychogastroenterology Group

The field is multidisciplinary and has scientific underpinnings in experimental psychology, behavioral intervention science and cognitive neuroscience, among other disciplines. The field is comprised of a range of professionals, including health psychologists, psychiatrists, social workers, gastroenterologists, advanced practice providers, physical therapists, speech-language pathologists, dietitians and nurses who are committed to a whole-person philosophy of digestive health care, embodied by the biopsychosocial model. The Rome GastroPsych group is a subsection of the larger Rome Foundation and creates an opportunity for connection and collaboration between scientists, academics, clinicians and trainees worldwide.

Our Mission, Vision and Membership

Our long-term vision is for psychogastroenterology principles and practices to be incorporated into all aspects of digestive health care and research. We believe that the mind and body should always be considered in the context of each other, and that mental and physical health is of equal importance with respect to digestive wellness. We are incrementally building a community of professionals dedicated to this approach who can share their best practices, identify and fill gaps in our knowledge, establish strong, multidisciplinary research collaborations and train the next generation of scientists and clinicians.

Founded in 2017 by GI health psychologists Laurie Keefer, PhD and Sarah Kinsinger, PhD, ABPP, our organization has grown to 433 members from around the world.

Our organization has grown to

433 members

from around the world.

Met 2021 goal to increase membership >25%

Members ranged between 0 and 45 years in practice (Mean 5.7y, SD = 9.3)

95% of members already completed a professional degree

59% accept clinical referrals

There is also an active Early Career Committee, with 47 members from 8 countries.

Continuing Education Programming and Other Training Opportunities in 2022

Training and Education is currently our most active group and key source of revenue. We added two co-chairs this year- Kate Tomasino (Northwestern) and Kari Baber (UPenn, pediatric) to help Sarah with programming initiatives.

We currently offer over 30 hours of CE/CME on-demand and regular live programming. We recently received 5-year approval to maintain our status as a CE Sponsor through APA. We also created a pathway for Group Practices (Psychology or Medicine) interested in GastroPsych staff training to buy a CE "Bundle" for $2000 for a practice to train up to 5 clinicians annually.

We initiated (and seek to continue) the following in 2023:

GASTROPSYCH PEDIATRIC CASE CONFERENCE SERIES

This clinical case series will highlight pediatric gastrointestinal (GI) conditions and associated challenges that are commonly encountered by mental health providers in clinical practice. Each seminar will be one hour in length and feature a psychogastroenterology provider presenting on his/her area of expertise. The seminar will include a didactic presentation, including an overview of the medical condition, the rationale for psychological treatment, and the scientific basis for the approach. This will be followed by a case example to illustrate the condition and approach being presented. The program will draw upon current research findings related to the content as well as the clinical practice knowledge of the presenter. The program will conclude with a moderated question and answer session. These are also available on demand.

CASE CONSULTATION GROUPS

GI psychologists are often asked to create and/or modify entire programs involving a variety of components, including clinical, administrative, and academic (research and/or teaching). Often operating as part of a multidisciplinary team in which they are the only, or one of few, behavioral health providers(s) can make this uniquely both exciting and challenging. These 4 groups provide a safe, confidential space in which members ask questions, discuss challenges, report successes, share information and brainstorm together. Group members are at different stages of both professional and program development, and work in a variety of diverse settings and geographical locations, which makes for interesting and rich discussions. Group members often share helpful content with one another, for example a program brochure, an intake form, etc.

- **Complex Adult Cases**
- **Pediatric and Young Adult Consultation Group**
- **Trainee Consult Group**
- **GastroPsych in Academic Settings**

GASTROINTESTINAL PHYSIOLOGY FOR THE PSYCHOLOGIST

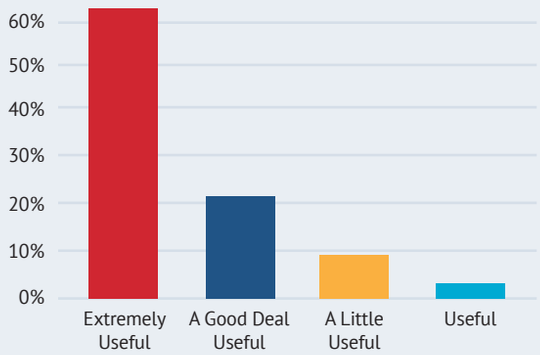
Level: Beginner

Date: Fall 2022

Description: This course provided an overview of normal gastrointestinal motility including normal functions of transportation secretion and absorption.

Presenter: Dr. Jean Fox, MD is a consultant in Gastroenterology and an assistant professor of Medicine at the Mayo Clinic in Rochester Minnesota. Dr. Fox is a clinical gastroenterologist who cares for patients with complex motility disorders and disorders of gut-brain interaction.

How useful was the content of this CE program for your practice or other professional development?



Did this program enhance your professional expertise?

100% answered Yes.

Would you recommend this program to others?

97% answered Yes.

Opportunities for Rome GastroPsych Support and Partnership: Our Future is Bright

The future of our gastropsych community is dependent on our ability to grow, engage and train our membership. Our accomplishments over the past four years speaks to the need and interest among healthcare providers for programming that will enhance access to the field of psychogsatroenterlogy. We are eager to build upon this success and are seeking financial support to sustain and expand our activities in 2023.

GOALS

Continue providing high quality CE programs for GastroPsych providers with an emphasis on content that will appeal to providers from a wider range of disciplines.

Proposed program topics for 2023 (seeking industry sponsorship/disease state education support):

GI Physiology for the Psychologist (basic and advanced).

This programming would offer disease state education not only to mental health professionals, but also the multidisciplinary team of professionals involved in the care of patients with chronic digestive diseases (primary care physicians, advanced practice providers, dietitians, physical therapists). Potential topics for the series could include:

- Pathophysiology of Functional Bowel Disorders and evidence-based treatments for IBS, including neuromodulators.
- Medical evaluation and management for common esophageal conditions, including GERD, EoE, and achalasia.
- Inflammatory Bowel Disease diagnosis and management.

Models of Integrated Care: What to do with what you have!

This programming is designed to educate non mental health providers on how to create a practice model for integrated care in a variety of settings (private practice, academic practice, hospital based, community, etc.). Potential topics for the series could include

- Seeking buy-in for integrated care in your practice setting: How to be a physician and administrative champion
- Considerations in choosing your integrated team: Understanding the roles, competencies and training of your mental health professionals
- How to leverage your integrated care team more efficiently: Case conceptualization and shared methodology
- The role of technology in integrated care: Best practices

Psychosocial Impact of Perianal Crohn's Disease

There are currently no training opportunities for multidisciplinary GI providers on how to address the unique psychosocial needs of patients with perianal Crohn's disease. Rome GastroPsych would like to fill this gap by offering the following lecture series on this important topic:

- The Psychosocial Needs of Patients with Perianal Crohn's Disease
- Impact of perianal Crohn's disease on Sexual Functioning
- Gynecological Aspects of Perianal Crohn's Disease

We have already scheduled the following for 2023 and are open to sponsorship/ support to offset member registration costs:

BASIC SKILLS TRAINING IN PSYCHOGASTROENTEROLOGY

Level: Introductory

Date: Fall 2023

Description: We are excited to announce that we will be offering an updated version of our Basic Skills Course in Psychogastroenterology to incorporate recent advances in the field. This full day introductory workshop will provide mental health practitioners with foundational skills to work successfully with patients with Disorders of Gut-Brain Interaction. International experts in psychogastroenterology will cover the scientific rationale for utilizing psychological techniques with DGBI patients, discuss assessment and treatment planning, and explain the basic structure and efficacy behind BGBTs for adult patients. The training will also provide guidance on working with a multidisciplinary team of GI providers and tips for developing an integrated GI psychology practice.

(CBT-AR)

Level: Intermediate

Date: June 7th, 2023

Description: This 2 hr workshop will provide guidance on how to implement CBT-AR when working with patients with chronic digestive disorders.

Presenter: Kamryn Eddy, Phd is Co-Director of the Eating Disorders Clinical and Research Program at Massachusetts General Hospital and an Associate Professor of Psychology in the Department of Psychiatry at Harvard Medical School.

INTEGRATING GROUP THERAPY INTO GI BEHAVIORAL HEALTH PRACTICE

Level: Beginner

Date: April 4, 2023

Description: This 1 hr training will provide psychologists with a foundation of knowledge of how to integrate group therapy into their practice and then successfully maintain it over time. The course will cover the benefits of group treatment for IBS and IBD, drawing on both empirical data and our own experience (e.g., clinical efficacy and utility, productivity, time management, etc.) as well as address logistical issues (e.g., recruitment, scheduling, documentation, confidentiality, the utilization of remote technology, billing, etc.), different types of groups to consider (e.g., CBT, gt-directed hypnotherapy, support groups) and particular issues which might arise with regard to each.

Presenters: Jessica Gerson, Ph.D. is senior psychologist in the Department of Gastroenterology at NYU Langone and is a clinical psychologist with a specialization in GI Behavioral Health.

Jessica Salwen-Deremer, PhD, DBSM, is a licensed clinical psychologist and Diplomate in Behavioral Sleep Medicine. She is an Assistant Professor of Psychiatry & Medicine at the Geisel School of Medicine at Dartmouth and sees patients with a variety of digestive disorders in the section of Gastroenterology at Dartmouth-Hitchcock.

CONTINUATION OF: PEDIATRIC DGBI CASE CONFERENCE SERIES

CONTINUATION OF: ADULT CLINICAL CASE CONFERENCE SERIES

Other initiatives we are working towards in 2023:

- Create an Early Career Research Award that support innovation in the field of psychogastroenterology
- Maintain and update our website, including the development of new content to attract and engage members as well as creating Rome GastroPsych branded handouts and treatment materials available through our online resource library

COSTS

Opportunities to Support us with a 40K+ contribution:

- Sponsor 1-2 basic or advanced CME/CE professional training events [range from 4-8 hours]
- Sponsor 1-2 early career research award (20K @) for investigators with focus in psychogastroenterology
- Sponsor our Virtual Grand Rounds programming

Sponsors of the Rome GastroPsych Education Programs receive:

1. Acknowledgement in all programming materials, on website and on program slides at beginning of each program
2. Acknowledgement in the annual report and the Meet the Rome Foundation annual booklet to members, sponsors and KOLs globally
3. Invitation to attend annual GastroPsych section meeting at DDW as a guest
4. Invitation to host a booth at GastroPsych symposium or workshop
5. Opportunity to train your company's sales and/or clinical team on the role of gastropsychology in the management of chronic digestive disorders (IBS, FD, Gastroparesis, Crohn's disease, ulcerative colitis, Celiac disease, etc).
6. Opportunity for consultation on patient education materials related to brain gut behavior therapies and provider education materials on appropriate referrals and indications for gastropsychology

ACTIVE COMMITTEES CONTINUED...

Rome Foundation Pediatric Committee

Committee Chair:
Samual Nurko, MD, MPH, RFF

Committee Chair:
Miguel Saps, MD

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.

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

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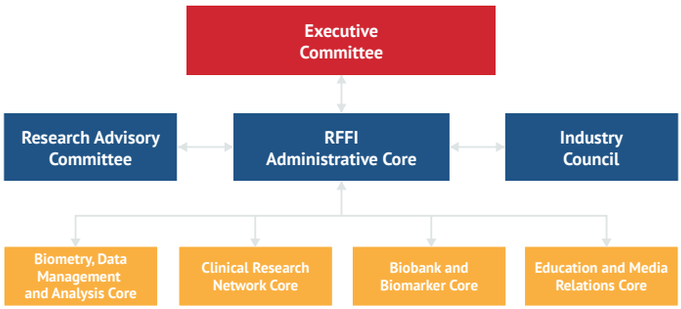
Magnus Simrén, MD, PhD
Rome Foundation Research Institute Director



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 by developing 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, 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 developing, administering, and analyzing 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 CEO) 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.

Douglas Drossman MD
Executive Committee

Magnus Simren MD, PhD
RFRI Director
Executive Committee

Jan Tack MD, PhD
Executive Committee

ROME FOUNDATION RESEARCH INSTITUTE

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 Co-Director (Shrikant Bangdiwala PhD), the data manager of the RFRI and Biometry Co-Director (Olafur Palsson Psy.D.), the Senior Study Coordinator (Ami Sperber MD, MSPH), 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., COO & 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 RAC is composed of RF Board members who have been selected based on their academic record of scientific achievement, and 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 comprises 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, for Ironwood Pharmaceuticals, and Ioannis Petrakis 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 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 the core's co-directors Shrikant Bangdiwala Ph.D. and Olafur Palsson Psy.D., who is also the data manager and coordinator of activities; Carolyn Morris MPH, biostatistician, Ami Sperber MD MSPH, senior study coordinator, and Johann Hreinsson MD, PhD, statistician, and study administration. This Core is actively involved with ongoing research proposals, as discussed below.

Ami Sperber MD, MSPH
Senior Study Coordinator

Madhu Grover MBBS
Biobank Director

Shrikant Bangdiwala PhD
Biometry Co-Director
Chief Biostatistician

Carloyn Morris MPH
RFRI Biostatistician

Olafur Palsson PsyD
Biometry Co-Director
RFRI Data Manager

Johann Hreinsson MD
RFRI Biostatistician

Johannah Ruddy Med
RFRI Administrator

Goud Levine, MD
RFRI Consultant

Clinical Research Network Core (Research Core). The Research Core is responsiblef or providing the infrastructure and maintaining the standards for clinical investigative studies involving epidemiological, clinical outcomes, and treatment studies. It is codirected 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 patientreported 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. Madhu Grover MBBS, and Magnus Simren MD co-chair this core 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, COO 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.

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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 and launching 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 collaborative study with Danone Nutricia Research to study gas-related symptoms in the general population, and consultations concerning prospective projects with two pharmaceutical companies.

Finally, we are most pleased to have Ironwood Pharmaceuticals under the directorship of Mike Shetzline MD as a diamond sponsor and Ioannis Petrakis 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 that is custom-designed. 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 biosamples to their phenotyping data. The RFRI-IP was launched in April of 2022 at the Gothenburg, Sweden site, where it has been successfully piloted, and several additional clinical sites in Europe and the U.S. are currently preparing to start data collection with this system, including in Leuven in Belgium and the Mayo Clinic in Rochester in the U.S.

The use of the RFRI-IP online data collection system is expected to 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 are automatically scored by the computer system and instantly available for use in the clinical encounters, and thus clinically useful to doctors and patients at each participating site.

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

The patient phenotyping assessment consists 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 patientcompleted assessments are 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, includes 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) is 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 with detailed patient phenotyping, and many of the sites will also collect associated bio-samples on their DGBI patients. The network 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 early sites in the network will include some of the world's top DGBI centers.

The first two sites in the Global Research Network 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:

- The Mayo Clinic, Rochester, Minnesota, USA
- 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)
- Universidad Nacional Autónoma de México (UNAM), Mexico (PI: Max
- Schmulson, MD)
- University of Bologna, Italy (PI: Giovanni Barbara, MD)
- Rouen Normandy University, France (PI: Chloé Melchior, MD)
- University of Sheffield, UK (PI: Imran Aziz, MD)
- Tel Aviv University, Israel (PI: Ram Dickman, MD)
- Washington University, St Louis, USA (PI: Gregory Sayuk, MD)

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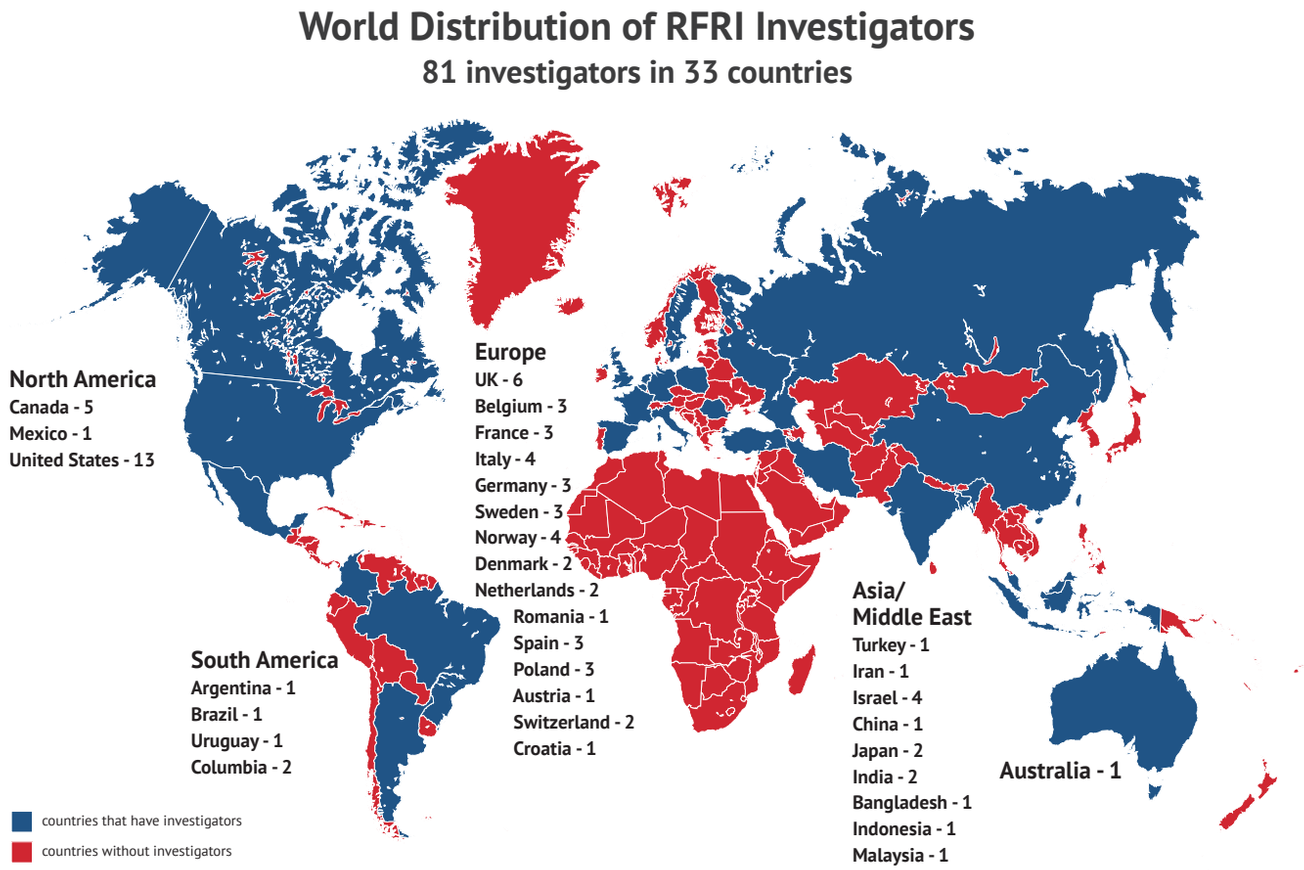

Figure 1 – RFRI investigators by country location

With several sites anticipated to be fully operational in the research network by the end of 2023, the network will be able to start offering unique research opportunities of interest to sponsors and industry based on the coordinated data collection. 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).

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.

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 musculotropic spasmolytic agent (otilonium bromide, OB). 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. Patients were randomized to medication or the diet app, and those with an improvement of at least 50 points on IBS-Symptom Severity Scale (IBSSSS) were considered responders. Before and after 8 weeks of treatment, patients completed questionnaires evaluating demographics, stool types, Rome IV criteria, IBSSSS, anxiety (GAD), depression (PHQ9) and somatization (PHQ15).

The study randomized 459 patients (41±15 years, 76% female), recruited by 61 primary care practitioners. At baseline, 70% of these primary care-diagnosed IBS patients fulfilled the Rome IV criteria (Rome+). Although this was optional, 95% of the subjects provided biobanking samples for genetics, serum, and stool analysis for microbiota and biochemical parameters. Based on the IBS-SSS, 41 and 39% of patients had moderate or severe IBS, respectively. Stool pattern subtype distribution was IBS-D 27%, IBS-C 23%, IBS-M 38% and IBS-U 12%.

The responder rate after 8 weeks, defined as an improvement of at least 50 points on the IBS-SSS, was significantly higher with diet compared with otilonium bromide (71% versus 61%), p=0.03) and the difference was more pronounced in the Rome+ subgroup (77% versus 62%, p=0.004). Patients allocated to the diet app were 94% treatment adherent compared with 73% in the medication arm (p<0.001). The significantly higher response rate with diet was already observed after 4 weeks (62% versus 51%), p=0.02) and a high symptom response persisted during follow-up. Predictors of response were female gender (OR=2.08, p=0.04) for the diet and a higher somatization score (PHQ15; OR=1.10, p=0.02) for otilonium bromide. It was concluded that a FODMAP-lowering diet application was superior to a spasmolytic agent in improving IBS symptoms. A FODMAPlowering diet should be considered the first-line treatment for IBS in primary care.

The primary outcome manuscript was published in Gut. (Diet or medication in primary care patients with IBS: the DOMINO study - a randomized trial supported by the Belgian

Health Care Knowledge Centre and the Rome Foundation Research Institute. Carbone F, Van den Houte K, Besard L, Tack C, Arts J, Caenepeel P, Piessevaux H, Vandenberghe A, Matthys C, Biesiekierski J, Capiau L, Ceulemans S, Gernay O, Jones L, Maes S, Peetermans C, Raat W, Stubbe J, Van Boxstael R, Vandeput O, Van Steenbergen S, Van Oudenhove L, Vanuytsel T, Jones M, Tack J; DOMINO Study Collaborators; Domino Study Collaborators. Gut. 2022 Nov;71(11):2226-2232.)

In addition, we analyzed the genetic samples for predictors of response to either treatment. Significant association with a response to OB was detected for polymorphisms in 3 genes: SLC6A4, TRPA1 and CACNA1C. Polymorphisms from two genes were associated with a response to dietary intervention: IL5RA and CCR3. Expression data from publicly available databases support an impact of the polymorphisms in SLC6A4 and in CCR3 on protein expression in the gastrointestinal tract. The predictive role of the polymorphism in the serotonin transporter gene SLC6A4 is in line with the antispasmodic properties of otilonium bromide. The association of a genetic polymorphism in CCR3 with response to dietary treatment suggests that (altered) eosinophil function plays a role in diet-related symptom generation in IBS. These genetic associations need to be studied in future larger cohorts.

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The genetic analysis from the DOMINO study was also published in Gut. (Genetic analyses of treatment response in primary care IBS, a pilot study. Balsiger LM, Van den Houte K, Zheng T, Toth J, Besard L, Franke A, D'Amato M, Tack J, Carbone F. Gut. 2022 Sep 23:gutjnl-2022-328430.)

Several upcoming publications from the DOMINO trial are being finalized:

a) Analysis of the role of gut microbiota composition: Gut microbiota composition in newly diagnosed primary care irritable bowel syndrome: a sub-analysis of the DOMINO trial.

b) Details on the baseline characteristics of primary care IBS patients: Characteristics and impact of IBS in newly diagnosed patients from primary care.

c) Health economic impact analysis: A Cost-Consequence Analysis based on the randomized controlled DOMINO trial: dietary intervention dominant over pharmacotherapy for newly diagnosed or newly treated irritable bowel syndrome in primary care.
d) An analysis of the relevance of stool or blood biomarkers: Inflammatory biomarkers in newly diagnosed primary care irritable bowel syndrome: a sub-analysis of the DOMINO trial.

e) A separate paper on the diet arm: DOMINO trial post-hoc analysis: evaluation of the diet effects on symptoms in IBS subtypes.

f) A separate paper on the otilonium bromide arm: Symptom response and determinants of outcome in a large cohort of primary care IBS patients treated with otilonium bromide.

ROBOT Project

RFRI finalized the planning of the ROme foundation BiOmarker and phenotyping projecT (ROBOT), to support the launch of this multinational project in 2021. The launch of this project was delayed due to the Pandemic and focus on other projects, but in 2022 the project was approved by the ethical review board in Gothenburg, Sweden and recruitment of subjects was started in the fall of 2022. In 2023 the project will be launched in Leuven, Belgium, followed by launch in several sites in the US, potentially after a central IRB application procedure, as well as in France, UK, Mexico, and Israel. In addition, expansion to other sites around the globe is now planned and active discussion with other sites about their participation are currently ongoing. With the finalization of the RFRI-IP, and SOPs for data collection and storage, the expansion of this project globally can now proceed rapidly as the interest in participation is high.

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 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 bio samples at any time to assess the feasibility of new studies. Hence, the ROBOT includes data from the RFRI-IP with detailed patient phenotypic characterization, as well as bio samples and physiological data.

ROBOT will involve leading global DGBI research sites. In the first phase of ROBOT each center will recruit ⩾100 patients who fulfill Rome IV diagnostic criteria for at least one DGBI. The project has started in 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. Eligible sites will ideally also include 20-30 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 has begun in 2022 and will commence in Leuven early 2023, and other sites in the US and Europe will follow under 2023. There is an ongoing attempt to establish a single IRB that will oversee the project at various U.S. sites. This will enable standardization of the protocol across sites, reduce IRB associated workload for study teams at each site, facilitate faster implementation of the changes to the protocol and procurement of future funding from the federal agencies and industry partners.

RFRI- survey of bloating and other gas-related symptoms, sponsored by Danone Nutricia Research

This study was a secure 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. 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 populationbased sample. It is yielding a comprehensive picture of the scope of these symptoms. The findings show that in a 24-hour period, almost all people in the three-nation survey sample experienced some gas-related symptoms, with the prevalence ranging from 39% for bloating to 81% for flatulence. Greater number of gas-related symptoms was associated with poorer physical and mental QoL, higher scores on life stress, anxiety, depression and non-GI body symptom scores, and increased healthcare utilization. The average amount of gas-related symptoms was markedly higher in people in Mexico compared to the U.S. and U.K. The study also revealed great excess of gas-related symptoms in individuals with gastroduodenal and bowel DGBI. The study has resulted in three scientific abstracts presented at UEG Week and DDW, and the first paper is being submitted for publication.

Study of sub-diagnostic GI symptoms in the general population, sponsored by Danone Nutricia Research

We completed analysis of the 26-country Global Epi Study Internet survey dataset to assess the global prevalence and associated characteristics of people who have frequent GI symptoms but do not meet Rome IV criteria for any DGBI diagnosis. The findings revealed that one in four adults have such sub-diagnostic symptoms, and that they are associated with substantial adverse impact on quality of life

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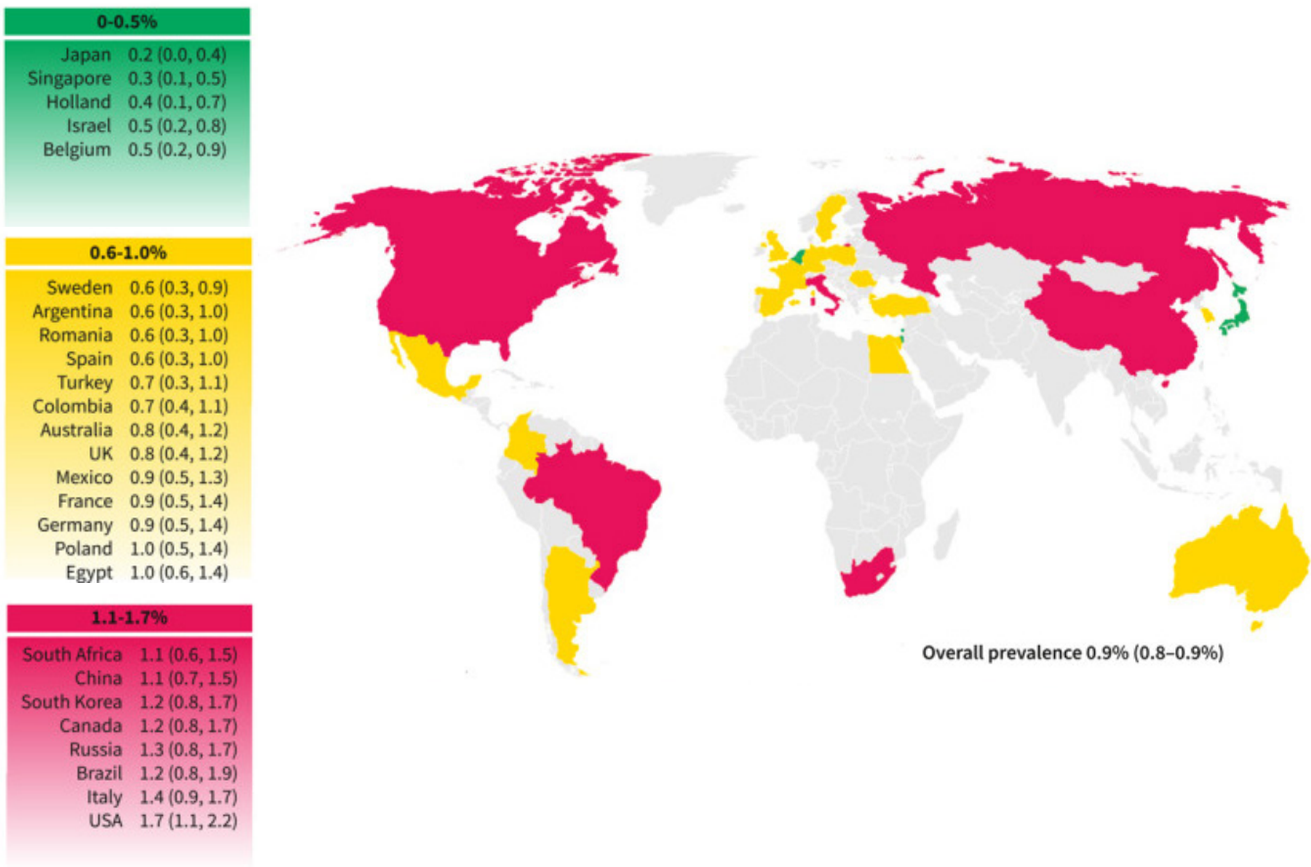


and psychological wellbeing as well as increase in needs for healthcare. An abstract from the study was presented at UEG Week 2022, and a paper describing the main findings has been completed and is being submitted for publication.

Gastroparesis, Functional Dyspepsia and Cyclic Nausea Vomiting Syndrome.

Gastroparesis is a condition characterized by epigastric symptoms and significantly delayed gastric emptying rate in absence of any mechanical obstruction. Gastroparesis is a well-known complication of diabetes, especially type 1 diabetes, and may also occur following upper gastrointestinal tract surgery, but in the largest subgroup no underlying cause is identified and these patients are referred to as having idiopathic gastroparesis. The epidemiology of gastroparesis in primary care is not fully elucidated, as this would require procedures such as gastric emptying tests to make a firm diagnosis. Moreover, clinical or hospital records do not seem to provide accurate information as gastric emptying test usage varies widely across countries and, moreover, poorly validated and poor-quality testing is not infrequently used in less specialized clinical practice.

Analysis of the prevalence of gastroparesis-like symptoms in the Rome Foundation Global epidemiology study

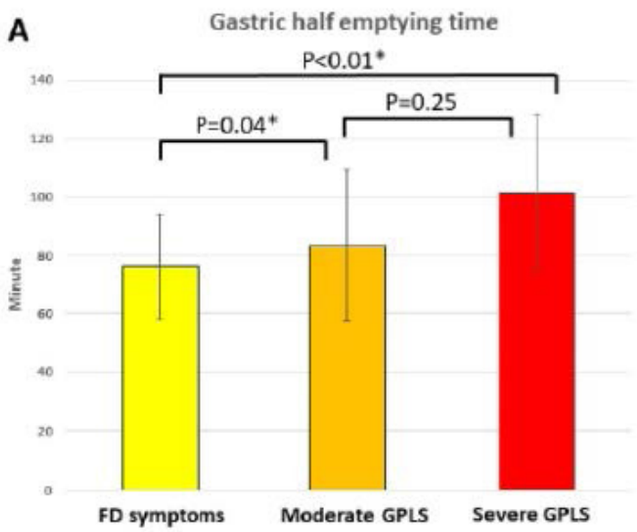
The results of the Rome Foundation Global Epidemiology Study will provide the opportunity to compare our results by identifying a suggestive symptom-pattern and subsequently to determine the prevalence of gastroparesis. Recently, the UEG and European Society for Neurogastroenterology and motility consensus defined Gastroparesis as a condition characterized by delayed gastric emptying in the absence of mechanical obstruction, with a symptom pattern of nausea

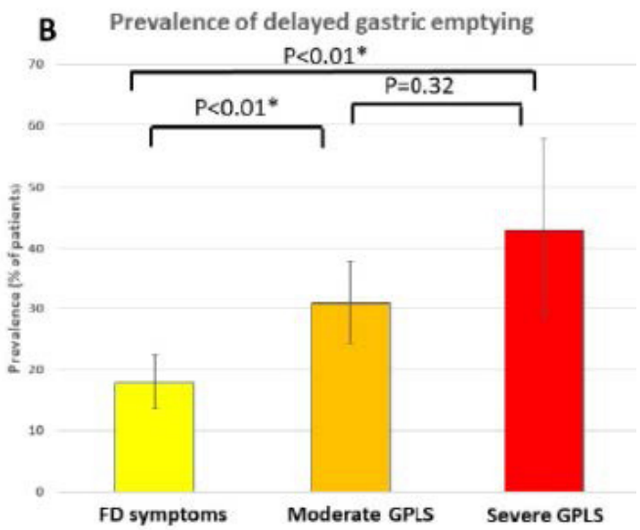
and/or vomiting and overlapping postprandial distress syndrome. In the online survey part of the Rome Foundation Global Epidemiology Study, 54,127 respondents from 26 countries completed the questionnaires. We selected subjects with gastroparesis-like symptoms (nausea and/or vomiting ⩾1 day/week and simultaneous postprandial distress syndrome symptoms). Patients reporting organic gastrointestinal disease, or fulfilling criteria for selfinduced vomiting, cyclic vomiting or cannabinoid hyperemesis syndrome were excluded. We found that the global prevalence of gastroparesis-like symptoms was 0.9% overall and 1.3% among diabetic individuals. Subjects with gastroparesis-like symptoms had significantly lower body mass index, QoL, more non-gastrointestinal somatic complaints, symptoms of anxiety and depression, higher medication usage and doctor visits in the overall and diabetic population, compared to subjects without these symptoms. The data show that gastroparesis-like symptoms are common worldwide and more common in diabetic patients. The symptom complex is associated with multiple aspects of illness and an increased healthcare consumption.

The epidemiological analysis has been published in UEG Journal: Worldwide prevalence and burden of gastroparesis-like symptoms as defined by the United European Gastroenterology (UEG) and European Society for Neurogastroenterology and Motilit (ESNM) consensus on gastroparesis. Huang IH, Schol J, Khatun R, Carbone F, Van den Houte K, Colomier E, Balsiger LM, Törnblom H, Vanuytsel T, Sundelin E, Simrén M, Palsson OS, Bangdiwala SI, Sperber AD, Tack J. United European Gastroenterol J. 2022 Oct;10(8):888-897.

Analysis of the association of gastroparesis-like symptoms and delayed gastric emptying at different levels of care

In a next phase, the link between gastroparesis-like symptoms and delayed gastric emptying will be studied in two cohorts: a group of subjects with upper gastrointestinal symptoms recruited from primary care and a group of subjects with upper gastrointestinal symptoms and negative endoscopy recruited from specialist care, to undergo gastric emptying testing and symptom assessment. For the former group, recruitment is still ongoing. In specialist care, in 637 patients from Leuven University Hospital, gastroparesis-like symptoms were associated with a significantly higher likelihood of having delayed emptying compared to patients with only dyspeptic symptoms: 33.2% versus 17.6%, p<0.01. Patients with gastroparesis-like symptoms had a significantly lower body mass index (19.9 (15.7-23.1) vs 21.2 (18.2-24.8), p<0.01). The rate of delayed emptying was higher in those





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with severe gastroparesis-like symptoms compared to those with moderate symptoms (42.9 vs. 30.7%). In addition, a cohort of patients in the Belgian diabetic association is invited to undergo gastric emptying testing and symptom assessment. This will generate data on association between gastroparesis-like symptoms and delayed gastric emptying in this specific disease cohort.

The association of the gastroparesis-like symptom pattern with gastric emptying rate was published in Alimentary Pharmacology and Therapeutics: Prevalence of delayed gastric emptying in patients with gastroparesis-like symptoms. Huang I, Schol J, Carbone F, Chen YJ, Van den Houte K, Balsiger LM, Broeders BB, Vanuytsel T and Tack J. Aliment Pharmacol Ther 2023 in press.

International consensus on gastroparesis definition

The definition, clinical characteristics, and existence as a clinical entity of gastroparesis is currently facing many challenges and controversies. Despite considerable industry efforts, there is a lack of approved therapy for gastroparesis. A recent paper from the NIH/NIDDK gastroparesis clinical research consortium suggests that functional dyspepsia and idiopathic gastroparesis are indistinguishable entities which are on the same spectrum. There is a clear need to identify the level of consensus on gastroparesis and its different aspects, at an international level. Moreover, functional dyspepsia is relevant to the Rome Foundation as it is one of the most prevalent disorders of gut-brain interaction.

To initiate this process, the Rome Foundation has contacted all international motility societies, asking their interest in such a consensus, and asking them to identify 2 participants. A favorable response was obtained from all societies. A first meeting with the participants was held at Digestive Disease Week 2022, with a number of attendees in person and a number of them dialing into a video link connection. The participants discussed the scope and content of the consensus project, its timelines, and practicalities. The panel decided to focus on idiopathic gastroparesis only. A large set of voting statements was generated over the coming months. A literature survey supporting each of the statements is being finalized in January 2023. The first voting round will take place in February 2023. The second voting round will happen end of March 2023. A face-toface meeting will be held in April 2023 and, if necessary, at DDW 2023. Manuscript drafting is planned for the second half of 2023.

Analysis of the epidemiology of cyclic nausea vomiting syndrome and other vomiting disorders Cyclic vomiting syndrome (CVS) is a disorder of gut–brain interaction characterized by severe episodic emesis, separated by periods of relative wellness. Many associated symptoms, such as gastrointestinal, autonomic, and behavioral symptoms, are observed in patients with CVS. Prior to the Rome Foundation Global Epidemiology Study, epidemiologic studies on CVS have been limited and the syndrome is thought to be uncommon. There is increasing interest in the condition from academics and industry. Moreover, the role of cannabinoid use and the overlap with/ differentiation of CVS from other nausea and vomiting disorders are a hot topic.

The Rome Foundation Global Epidemiology Study provides a unique opportunity to analyze these factors. A diagnosis of CVS can be conclusively made based on the ROME IV criteria and does not require any additional tests if the criteria are fulfilled (even though this is frequently carried out in everyday clinical practice and can provide support for the diagnosis and exclude other differential diagnoses). This makes CVS an excellent diagnosis to study using the global epidemiology study database.

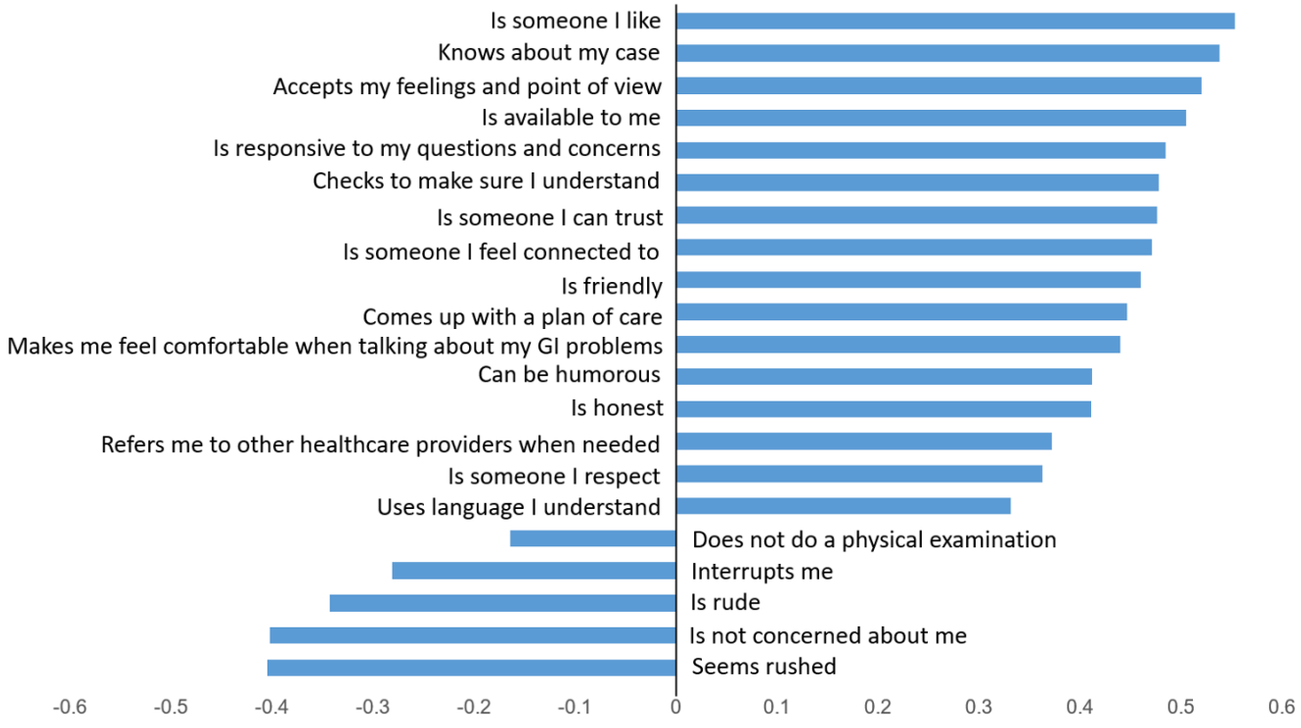
An analysis is being started to describe the prevalence of CVS throughout the world, define the association between CVS and other nausea and vomiting disorders, as well as with other medical conditions, and to test the association between CVS and prescription pain medicine or cannabinoid intake. In addition, we will assess the impact of CVS on quality of life, explore the association between CVS and demography, somatization, and psychological distress (somatization, anxiety, and depression) and explore the effects of CVS on health care consumption.

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

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



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in the patientprovider 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).

This study is published: Drossman DA, Palsson O, Stein E, Ruddy J, O'Broin 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. This study evaluated the efficacy and safety of the GLP-1 analogue ROSE- 010 in reducing moderate to severe acute abdominal pain in IBS.
- Alnylam Pharmaceuticals. The RFRI consuled with Alnylam on the development of a proposal to evaluate the prevalence of porphyria. We developed a proposal that was used in their studies.
- Arena Pharmaceuticals. RFRI consulted to develop a detailed proposal for Arena to access the database of the Rome Foundation's Global Epidemiology Study of Functional Gastrointestinal Disorders. 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 2022, 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 expect that these activities will continue to grow over the next year and fulfill our mission: To improve patients' lives with DGBI through ground-breaking research.

COPYRIGHT AND LICENSING COMMITTEE

Mark Schmitter
Director of Licensing and Copyrights

Mauricio Rojas, MD MPH,
Senior Medical Program Administrator

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 it mission in addition to meeting the needs of the internatonal 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!

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.

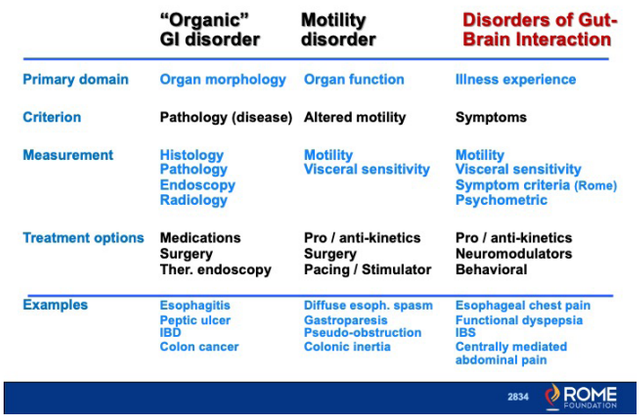


Figure 11

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 interaction1. 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[2,3] 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[4,5], Emeran Mayer[6], and others who began to report the concept of visceral hypersensitivity, i.e., characterizing pain reports by what later was recognized as augmented afferent signaling rather than motility. The second was the classification system for functional GI disorders published in 1990 which evolved into the Rome Criteria. This symptom-based classification categorized patients with various symptom patterns into diagnoses that were amenable to many research models as shown in Figure 12. This has had a major impact on our scientific understanding of these disorders. Currently the Rome criteria are used by regulatory agencies, investigators and clinicians around the world.

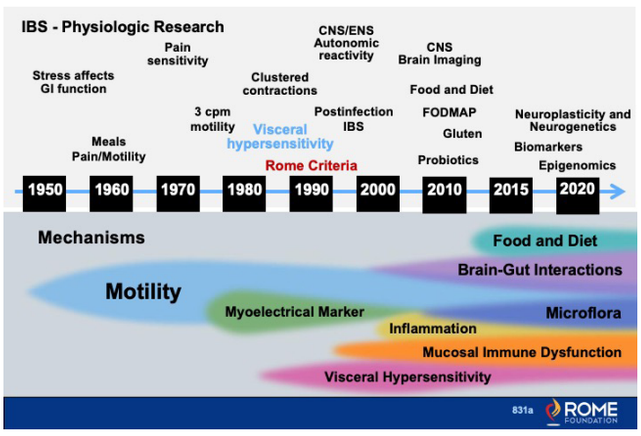


Figure 12

Reference List

1. Drossman DA, Functional Gastrointestinal Disorders: History, Pathophysiology, Clinical Features and Rome IV, Gastroenterol 2016;1262-1279.
2. Almy T P. Experimental studies on the irritable colon. Am J Med 1951;10:60.
3. Wolf S, Almy T P. Experimental observations on cardiospasm in man. Gastroenterol 1949;13:401-421.
4. Whitehead W E, Holtkotter B, Enck P, Hoelzl R, Holmes K D, Anthony J, Shabsin H S, Schuster M M. Tolerance for rectosigmoid distention in irritable bowel syndrome. Gastroenterol 1990;98:1187-1192.
5. Mayer E A, Raybould HE. Role of visceral afferent mechanisms in functional bowel disorders. Gastroenterol 1990;99:1688-1704.
6. Drossman D A, Thompson W G, Talley N J, Funch-Jensen P, Janssens J, Whitehead W E. Identification of subgroups of functional bowel disorders. Gastroenterology International 1990;3:159-172.

RESEARCH PROGRAMS AWARDS

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

Rome—AGA Research Award

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

2020 – TWO AWARDS

Principal Investigator: Nitin K. Ahuja, MD, MS
Title: Shifts in the Gut Microbiome Following Dietary Modification in Irritable Bowel Syndrome

Principal Investigator: Bindu Chandrasekharan, PhD
Title: Investigating the efficacy of probiotics to address opioid-induced constipation

2019 – TWO AWARDS

Principal Investigator: Joan W. Chen, MD
Title: Single-Arm Pilot Trial of Digital Cognitive Behavioral Therapy in Gastroesophageal Reflux Disease Patients with Insomnia

Principal Investigator: Arpana Gupta, PhD
Title: Cognitive Behavioral Therapy Leads to Bidirectional Changes in Brain-Gut Axis for Obesity

2018 – TWO AWARDS

Principal Investigator: Faranak Fattahi, PhD
Title: Modeling diabetic gastroparesis using human pluripotent stem cells.

Principal Investigator: Shaoyong Yu, MD
Title: Expression and function of an "Itch" receptor MrgprC11 in sensory afferent neurons in the GI tract.

2017 – TWO AWARDS

Principal Investigator: Giuseppe Cipriani, PhD (USA)
The contribution of circulating monomcytes on gastric muscularis propria in the development of diabetic gatroparesis.

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.

RESEARCH PROGRAMS AWARDS CONTINUED...

Principal Investigator: Kok Ann Gwee, FAMS, FRCP, PhD (Singapore)
Title: The Chinese and Caucasian Brain Study: A neuroanthropological evaluation of the ROME III criteria.

2013

Principal Investigator: Maria Vicario, PhD (Spain)
Title: Identification of signaling pathways and active biological networks associated with the role of eosinophils in stress-induced exacerbations of IBS.

2012

Principal Investigator: Nicholas J. Talley, MD, PhD (Australia)
Title: Usefulness of Rome III symptoms, psychological characteristics and cytokines in accurately diagnosing FGIDs.

2011

Principal Investigator: Lars Agreus, MD, PhD (Sweden)
Title: Functional dyspepsia and functional heartburn: Natural history of symptoms in the general population and validity of Rome III upper gastrointestinal diagnostic criteria.

2010

Principal Investigator: Javier Santos Vicente, MD (Spain)
Title: Role of mucosal eosinophils in the physiopathology of intestinal inflammation in irritable bowel syndrome.

2009

Principal Investigator: Miranda van Tilburg, PhD (USA)
Title: Validation of the Child/Adolescent Rome III Criteria.

2008

Principal Investigator: Madhulika Varma, MD (USA)
Title: Comprehensive validation of the Rome III constipation module.

Ray Clouse Award for the Best Paper

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

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

2023

Zlatan Mujagic, MD, PhD,
Integrated fecal microbiome metabolome signatures reflect stress and serotonin metabolism in irritable bowel syndrome Mujagic Z, Kasapi M, Jonkers DM, Garcia-Perez I, Vork L, Weerts ZZRM, et al. Gut Microbes. 2022 Jan(1):2063016

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, Mösinger M, Ruchay Z, Röcken C, Milla PJ, Das M, Böttner M, Wedel T, Schuppan D. 2019 Jul;157(1):109-118.e5.

2019

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

2018

Sara Botschuijver, MSc, (The Netherlands)
Title: Intestinal Fungal Dysbiosis Is Associated With Visceral Hypersensitivity in Patients With Irritable Bowel Syndrome and Rats. Gastroenterology 2017;153:1026–1039.

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.

RESEARCH PROGRAMS AWARDS CONTINUED...

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 highresolution manometry. Gastroenterology 2008;135:1526-33. PMID: 18722376.

2008

Krisztina Gecse, MD (Hungary)

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

Ken Heaton Award for Most Cited Paper

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

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

2023

Ami Sperber, MD, MPH

Worldwide Prevalence and Burden of Functional Gastrointestinal Disorders, Results of Rome Foundation Global Study. Sperber AD, Bangdiwala SI, Drossman DA, Ghoshal UC, Simren M, Tack J, et al. Gastroenterology. 2021 Jan;160(1):99-114.e3

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.

RESEARCH PROGRAMS AWARDS CONTINUED...

2023:
Maura Corsetti, MD, PhD (UK)
Ronnie Fass, MD (USA)

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.

2023 WINNERS

Yasmin Nasser, MD -Calgary, Canada: Mind Body Interventions: Does an integrated yoga intervention modulate gut microbial dysbiosis in IBS?

Imran Aziz, MD, PhD, Sheffield, UK: Dietary Therapies in Functional Dyspepsia: A Randomized Clinical Trial

Manik Gemilyan, MD, PhD Yerevan, Armenia: Identifying and tackling barriers to effective diagnosis and management of disorders of gut-brain interaction in Armenia.

2022 WINNERS

Heidi Stuadacher, 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 2023:

Maura Corsetti, MD
Nottingham, UK
Academic Fellow

Reuben Wong, MD
Singapore
Clinical Fellow

Agata Mulak, MD PhD
Wroclaw, Poland
Clinical Fellow

Hans Törnblom, MD, PhD
Gothenburg, Sweden
Clinical Fellow

CONGRATULATIONS TO ALL OUR IMPRESSIVE ROME FELLOWS!

Baha Moshiree, MD • USA • Carlolina Olano, MD • Uruguay • Sarah Ballou PhD • USA • Pali Hungin, MD • UK • Dan Dumitrascu, MD • Romania • Sarah Kinsinger, PhD • Darren Brenner, MD • Madhusudan (Madhu) Grover, M.B.B.S. • Albena Halpert, MD • USA • Brooks Cash, MD • USA • Shin Fukudo, MD • Japan • Fernando Azpiroz MD, PhD • Spain • Mary Joan Gerson PhD • USA • John Pandolfino MD • USA • Shirikant Bangdiwala PhD • Canada • Uday Ghoshal MD • Inda • 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 • Isreal • Lin Chang MD • USA • Laurie Keefer PhD • USA • Brennan Spiegel MD • USA • William Chey MD, AGAF, FACG • USA • John Kellow MD • Australia • Robin Spiller MD, MSC • UK • Giuseppe Chiarioni MD • Italy • Charles Knowles PsyD • UK • Vincenzo Stanghellini MD • Italy • Enrico Corazziari MD, PhD • Italy • Jeffrey Lackner PsyD • USA • Hidekazu Suzuki MD, PhD • Japan • Peter Cotton MD, FRCP • USA • Brian Lacy PhD, MD • USA • Jan Tack MD, PhD • Belgium • Michel Delvaux MD • France • Anthony Lembo MD • USA • Nicholas Talley MD, PhD • Australia • Carlo DiLorenzo PhD • USA • Rona Levy MSW, PhD • USA • Grant Thompson MD, FRCPC • Canada • Douglas Drossman MD • USA • Allison Malcolm MD, MBBS, FRACP • Australia • Kirsten Tillisch MD • USA • Grace Elta MD • USA • Fermin Mearin MD • Spain • Miranda van Tilburg PhD • USA • 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 Francisconi MD, PhD • Brazil

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

A Rome Foundation – DrossmanCare Collaboration

Douglas A. Drossman

Over the last several decades, there has been a degradation of patient and clinician satisfaction in clinical care and ultimately increased healthcare costs[1-3]. We find this to occur particularly for patients with disorders of gut-brain interaction(DGBI), formerly called Functional GI Disorders, such as IBS. The reasons include[1, 2]: 1) Clinicians are not well trained to diagnose these disorders using standards such as the Rome Criteria, and thus order tests to "rule out disease"' and this behavior is enabled by third-party payers who readily reimburse for procedures; 2) Underlying this behavior is evidence that clinicians do not understand or accept the scientific evidence for the existence of DGBIs and do not properly diagnose using Rome Criteria or effectively communicate the diagnosis using to patients which leads to patient dissatisfaction and continued doctor seeking for a diagnosis; 3) Clinicians adhere to a dualistic (i.e., organic vs. functional) perspective of illness and have difficulty caring for patients like those with DGBIs because they don't have a structural diagnosis[4]; 4) Unfortunately, when feeling ill equipped to care for these patients, clinicians may degrade or stigmatize their patients, possibly to expiate their own perceived feelings of inadequacy in their care; 5) Surveys show that patients feel degraded, and stigmatized and routinely express their dissatisfaction with the care received[5-7]; 6) The clinician's resultant lack of satisfaction can also lead to "burnout" and even malpractice suits that relate to poor patient provider communication and lack of caring; 6) In the end, all of this leads to a societal view among providers, their patients, researchers and regulatory agencies that these disorders are "second class", and ultimately this leads to a societal reduction in capabilities to help them.

Thus, the "joy of medicine" is disappearing. Doctors within academic medicine are becoming more dissatisfied with the time spent with clinical work as it has become less rewarding and meaningful. Within community practice, physicians feel besieged by the healthcare structure and process changes that reduce reimbursements and require increased time with EMR and other administrative tasks. An increasing number of physicians leave health care for other pursuits. Yet, in one survey, doctors were asked what is truly meaningful to them. They stated that it was the humanistic interactions with patients: "…when crossing from the world of biomedicine into their patient's world," We propose that effective human interaction is therapeutic for physicians and patients. The author provides the evidence for all these observations in several of his peer-reviewed publications[1, 3, 4, 8]

Given this, teaching skills that focus on the patient, including the medical interview, optimal communication methods, and patient-centered care, receive lower priority; it occupies less time in the medical school curriculum, residency training programs, and CME symposia. Educators do not seem to see the utility of patient-doctor interaction, which perpetuates this difficulty. We have heard many trainees voice that ordering studies can substitute for a good history and physical examination. "Why listen to the chest when I can get a CT scan." Yet, Sir William Osler, the Father of Modern Medicine, said: "Listen to your patient; he is telling you the diagnosis," and emphasized that 90% of diagnosis comes from the medical interview. The shifting of priorities from one-on-one interaction to test ordering occurs due to time constraints, inadequate reimbursement for these services, and the inevitable directive to obtain and enter information using the computerized electronic medical record (EMR). However, without human interaction to gather the patient's life history, personal perceptions, attitudes, and behaviors surrounding the medical data, we lose the capability to understand the complete picture of the patient's illness, make proper clinical judgments or develop a gratifying therapeutic relationship[1].

We are convinced and have demonstrated that optimizing the patient-provider relationship can improve satisfaction with care, improve clinical outcomes, and reduce unnecessary healthcare costs. These are teachable skills, with an unexpected benefit that when doctors learn and apply good

communication skills, they also like their patients and job more. Finally, the positive impact of good communication skills relates to many other critical clinical benefits: the disclosure of more meaningful information, greater patient adherence to treatment, reduced symptom severity and emotional distress, improved physiological parameters, and overall better clinical outcomes[2, 8].

For these reasons, we are committed to continuing our successful program, teaching clinicians and now patients to enhance communication skills, optimizing the patient-provider relationship for patients with DGBI, and training future facilitators in this process. By supporting this collaboration between the Rome Foundation and Drossman Care, we expect to achieve our goals as we have done in the past. There is a need for us to continue and do more.

GETTING IT DONE THROUGH OUR STRATEGIC PARTNERSHIP

The Rome Foundation and the Center for Education and Practice of Biopsychosocial Care (Drossman Care) have formed a strategic partnership thanks to previous generous support. Each entity has resources and capabilities that led to achieving the objectives of the previous proposal, as shown on our website:. https://romedross.video/2KPTYzC

Rome Foundation. The Rome Foundation will continue to be responsible for the marketing and endorsement of the products. Douglas A. Drossman, MD, the Founder, CEO, and President Emeritus, and Johannah Ruddy MEd, COO and Executive director of the Rome Foundation, facilitate the coordination of the Rome Foundation's activities in this program. The Board of directors, which contains global experts in the DGBI field, fully supports these efforts. The Rome Foundation has been the worldwide leader in educating clinicians through its resources that include 1) a network of influence via experts in the Board of Directors and other Rome Foundation members who help disseminate state-of-the-art education in DGBI, 2) an ability to reach broader clinical disciplines in addition to gastroenterologists (e.g., primary care, pediatrics, mental health providers, mid-level providers, dietitians), 3) capability to implement a broad scope of educational formats from hard copy books to online and digital learning, apps, slide sets, social media and interactive software (e.g., GI Genius Rome IV interactive toolkit). The resource base of creative leaders in the Foundation developed these products and activities as they excel in patient care, are motivated to teach, and are committed to developing long-range projects that endure. This work, managed through an efficient organizational infrastructure, can do the needed marketing and social media initiatives. Four years ago Foundation created the strategic directive to develop resources to educate clinicians on communication skills and patient-centered care. The strategic engagement with DrossmanCare followed. For all these reasons, the Rome Foundation is well poised to take on this new initiative that is consistent with its mission.

Drossman Care. Drossman Care has been responsible for creating, developing, and implementing programs in communication skills and teaching patient-centered care with assistance from members facilitators it has trained (see below) and other members of the Rome Foundation. Before entering gastroenterology, Douglas Drossman, MD, President of Drossman Care, received advanced training in communication skills from Dr. George Engel. Dr. Engel was an internist and psychiatrist who taught communication skills and developed the concept of the Biopsychosocial model9. Dr. Drossman then served as a charter member and faculty facilitator for the American Academy on Physician and Patients (AAPP), now called the Academy of Communication in Health Care (ACH): https://www.achonline.org/. This group spearheads national training programs for providers related to communication skills. For the last 40 years, Dr. Drossman has taught Communication, and patient engagement skills through various formats, including peer-reviewed publications, lectures, workshops, small group facilitative learning sessions, video production, and webinars. After leaving UNC in 2012, he developed an infrastructure to facilitate these activities: DrossmanCare (Drossman Center for Education and Practice of Biopsychosocial Care). Ms. Johannah Ruddy is secretary/treasurer of DrossmanCare and has joined Dr. Drossman in its educational initiatives. Ms. Ruddy used her evolved experience as a patient of Dr.

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

Drossman to gain insights leading her to be a nationally recognized patient advocate. She co-facilitates workshops and video productions and is a simulated patient in teaching programs and videos. Her participation in educational programs, social media, and peer-reviewed publications has impacted patients and providers.

The impact of this collaboration producing educational programs has been substantial, and they relate to increasing awareness among patients, clinicians, the pharma industry (who have provided financial support), and Society. Activities include: 1) workshops on communication skills in the US, Europe, Asia, and Latin America, 2) production of teaching and trigger videos that are used and disseminated in clinical training programs, 3) development of webinars, 4) conducting preceptorships with faculty, trainees and clinicians who visit experts to learn interview skills, 5) a large social media presence, and 6) decades of peer-reviewed publications of articles and research instruments to teach and study patient satisfaction, the patient-provider relationship, and communication skills. In recent years much of this work has been promoted through the Rome Foundation, which has yielded greater audience exposure and generated revenue for Rome.

1. Educational videos

Our video curriculum provides basic, intermediate, and advanced training in communication skills. Some industry sponsors have used the videos internally to train their staff on disease awareness, and we use them in all our workshops and training programs.

Communication 101 series (Basic). Communication 101 is an innovative video learning tool for clinicians working with patients with DGBI (see promo: https://romedross.video/Comm101ThirtySecAd) . The program leverages the expertise of 15 of our trainees, who are thought leaders in neurogastroenterology to demonstrate how they educate patients on the most common clinical issues that arise during a clinical visit. Included are 32 educational discussions covering 11 content categories. Examples include: How to explain the brain-gut axis, How to use neuromodulators, how to prescribe a secretagogue, how to recommend a brain-gut behavioral therapist, and more. Using a simulated patient visit, the speakers provide the clinical expertise to offer information clearly and concisely using practical communication methods. The interviews are brief, only 4-8 minutes, and include a detailed written statement of what was said and why. For further information, a list of all topics, and a 3-minute video explaining the program, go to: https://romedross.video/2WBhSpi.

Communication 101.5 series (Intermediate). This series provides eight 4-8 minute videos that encapsulate clinical challenges in patients with DGBI and their resolution. Included are eight seemingly complex interviews occurring during a clinic visit. See promo https://romedross.video/promo1015. The doctor uses specific methods and techniques to resolve obstacles, improve the patient-doctor interaction and result in a mutually agreed-upon care plan. 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 care plan. Examples include addressing patient demands for narcotics, explaining the value of neuromodulators when the patient is reluctant to take them, responding to the patient who wants an unneeded CT scan, and more. Clinicians can watch as a leading expert offers methods to address these interaction difficulties that lead to consensus and resolution. 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. For further information, including a listing of all eight clinical issues and a 3-minute video explaining the program, go to: https://romedross.video/com1015.

Communication 202 series (Advanced). This program offers techniques to explore and better manage deeper clinical communication issues: identifying hidden agendas, emotional handling of anger and sadness, implementing shared decision-making, addressing drug-seeking, and identifying and successfully managing a factitious illness, abuse and trauma, unresolved grief, and many other complex clinical issues. There are six common clinical vignettes, each with

Overall evaluations of the presentations in the 6 courses. % of attendees who rated each aspect of the presentations as Excellent*, averaged across all the speakers in each course.

Douglas Drossman, MD and Johannah Ruddy, M Ed

	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=26	Los Angeles Feb. 2020 N=26
Knowledge gained	90.7%	97.3%	90.6%	86.9%	84.9%	84.0%
Presentation effectiveness	91.4%	96.9%	92.9%	96.6%	87.4%	89.0%
The material presented was clear and understandable	95.4%	92.9%	91.4%	95.4%	91.5%	89.1%
The information will be useful to me in my line of work	92.5%	93.9%	95.3%	91.5%	85.6%	87.2%
The presenter seemed knowledgeable	98.7%	99.5%	97.8%	94.7%	94.1%	92.4%
The handouts provided (when available) were useful	93.0%	93.0%	92.2%	94.0%	94.9%	93.5%
The speaker met the objectives as stated	96.2%	98.6%	96.2%	90.2%	93.5%	91.9%

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

four teaching segments: ineffective and effective interview, patient's perspective, and a step-by-step critique of proper technique. -Here is the promotion video: https://romedross.video/2ZozCCu, and a link to the website explaining case vignettes: https://romedross.video/communication-202.

(Based on feedback from our educational programs, we will create new videos:

Video Library for Patients and Providers. Our video library of over one hundred 15- 20 minute educational videos informs patients and providers about the full repertoire of

DGBI and communication skills. These have greatly impacted social media sources, including Facebook, Twitter, and Linked-in. Using a simple conversational format, Dr. Drossman and Ms. Ruddy discuss various aspects of DGBI and patient-centered care and frequently invite guest visitors to interview. These videos for providers and patients cover topics that include: the patient-provider relationship, bowel disorders, chronic pain, medical and behavioral treatments, upper gut, bowel and pelvic/anorectal disorders, and pediatrics. We provide these videos as a free service on the Rome and DrossmanCare websites: https://theromefoundation.org/patient-educational-q-a/ We will continue producing these educational videos and bring in additional speakers over the next year.

2. Symposia, and webinars.

Since 2018, we have successfully held numerous national and international programs in Communication. For a complete listing of all presentations, see Appendix A. These programs are formatted, depending on the size of the audience or the time allotted, to include lectures, video presentations, discussions, small group learning, or role-play sessions. Before COVID we held 24 on-site programs in the USA at the AGA, ACG national and regional courses, American Psychosomatic Society, Rome Foundation Symposia, and at medical centers including Mt. Sinai Medical Center, Columbia University, University of Virginia, and Johns Hopkins Medical Center. Between 2018-2020 the Rome Foundation held six on-site regional courses in communication skills as part of regional CME programs. The table below shows participant feedback with the percent rating "excellent" based on a 5-point scale (Excellent, very good, good, fair, poor). We cannot rate the responses as bar graphs because the Excellent rating was so high.

isorder Conference, IBS Days in Bologna, Italy, and the World Congress of Gastroenterology in Istanbul, Turkey. After COVID began, we shifted our educational effort in 2020 to early 2022 to do online webinars and workshops. This included international programs in Sao Paulo Brazil, Santiago Chile, Bogota Columbia, Kuala Lampur Malaysia, Sendai Japan,

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

London England, Montevideo Uruguay Adelaide, Australia, and Beijing China. National programs were held virtually for the Rome Foundation, ACG FGID school, and Wake Forest/ Atrium Medical Center.

Here are videos of several of the program presentations:

- London Neurogastroenterology meeting. "Tips and Tricks on Communicating with Patients About FGIDs" https://romedross.video/Tips41
- Pan American GI Meeting In Uruguay. "Communication Skills Workshop" with Drs. Drossman, Chang, Tack and Schmulson. https://romedross.video/Tips41
- Asia Pacific Digestive Week in Kuala Lampur. We presented the same program as in Uruguay https://romedross.video/Tips41. In addition, Dr. Drossman received the 18th Panir Chelvam Award from the Society for his work in Gastroenterology: https://romedross.video/JLeeIntro
- Carlos Francisco Symposium Porto Alegre, Brazil. , "The physician-patient relationship: making it work" https://romedross.video/Brazil
- American College of Gastroenterology FGID School in St. Louis, August 13. "Optimizing Patient-Provider Communication" https://romedross.video/tips48
- Medscape – Rome Foundation online program "IBS Diagnostic Journey" with Drs. Drossman, Chang, and Heidelbaugh (primary care) released August 4. This program discussed IBS using several of our videos https://romedross.video/MedscapeIBS
- Rome Foundation Grand Rounds. "Improving the Patient-Provider Relationship with Communication Skills" This was a presentation followed by a panel discussion with Johannah Ruddy https://romedross.video/GrandRoundsComm

Later in 2021-2022, we returned to on-side educational programs, including ACG FGID school, University of North Carolina Case Western Reserve University, and Stanford Medical Center

Figure 1 shows a summary of the feedback on the most popular one-hour basic communication skills presentation at these programs over the last year.

Figure 1. Feedback from attendees on basic communication skills presentation

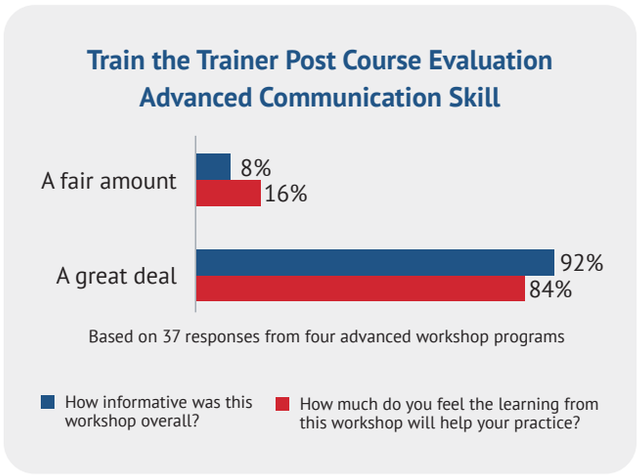
The feedback on these programs has been excellent. Below are a few of the comments:

- "Fantastic...Should be used at ACG and AGA national meetings",
- "We need this in medical school,"
- "I think it is a great demonstration of how to be sensitive and empathetic in a practical way for a brief office visit. Concrete examples of explaining things to patients and responding to their rebuttals is very helpful".
- "Thank you for sharing the links. I can disseminate to my team".
- "I see some of my own behaviors in the "how not to interact" video and this was eye opening"

3. Educational workshops for faculty and trainees at medical centers.

In addition to the shorter programs above, our third initiative is to conduct eight-hour training programs to give a deeper level of training. These programs included lectures, video discussion, role play, and small group facilitation. We conducted two full-day programs, one at Johns Hopkins Medical Center for GI faculty and another at the University of North Carolina for GI faculty and fellows. Figure 2 shows the responses from four advanced full day training programs regarding their learning in basic and advanced communication skills

Figure 2. Feedback from trainees

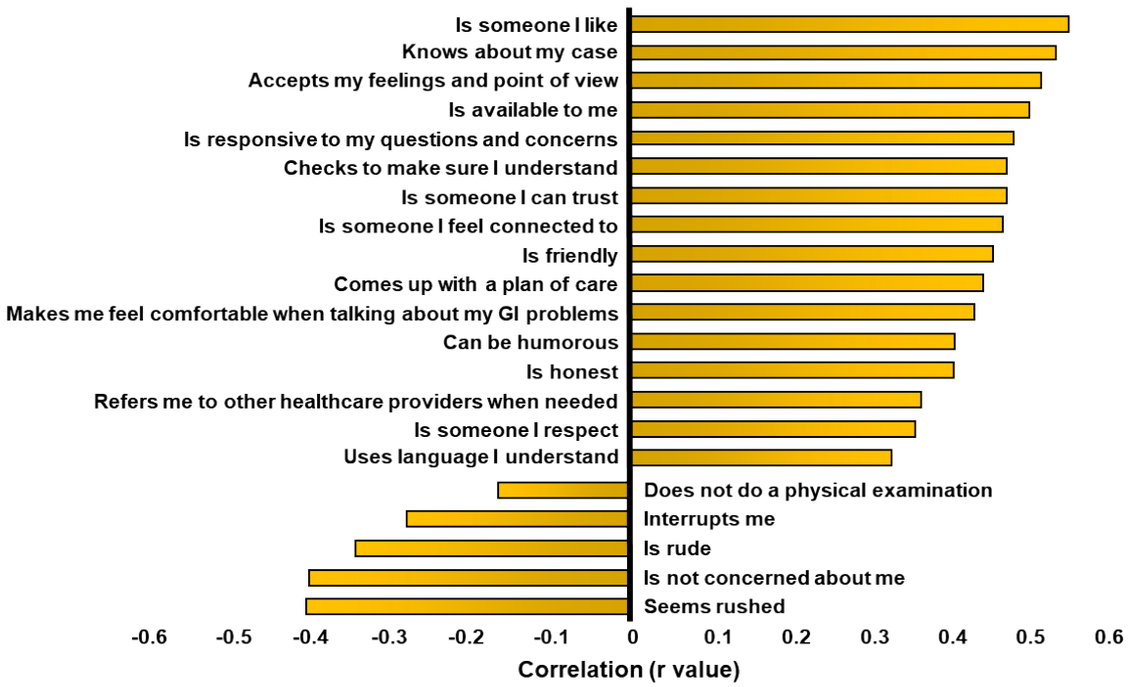


The following video shows faculty and fellows at UNC reporting their experience of their eighthour workshop: https://romedross.video/CommunicationSkillsTraining
Please review this brief video to get an overview of the content and impact of these programs on GI providers.

4. Publications on Communication and guidelines.

Peer-Reviewed Publications. In 2012 Dr. Drossman received the ACG David Sun Award for his communication skills work, subsequently published in the American Journal of Gastroenterology[8]. Until the last five years, this work was provider focused. However, with the evolution of patient-centered care and narrative medicine, Dr. Drossman joined with two of his patients, Katie[10, 11] and Johannah[12, 13], to publish companion articles with video links where the patient provides her story of the illness. At the same time, Dr. Drossman offers his perspective on the nature of the care. The next step was to give evidence to providers, patients, and Society on the deficits in our healthcare system leading to patient and provider dissatisfaction. We then published a discussion of the current healthcare system's limitations in not meeting patients' needs and possible solutions by improving communication[1]. Following this, we assembled an international group of experts to publish the Rome Foundation's Working Team Report, which includes an evidence-based review and consensus guidelines on

Figure 3 Correlation of Physician-Patient Relationship with Patient Care Satisfaction



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

communication skills[2]. A major finding of the working team was the evidence that interventions targeting patient-provider communication skills improve population health, patient experience, provider experience, and healthcare costs. Finally, we also published a study to evaluate the perceptions of GI patients attending the GI program at Johns Hopkins medical center[14]. The patients completed an online survey addressing demographic and psychosocial data, diagnosis, and two validated instruments: a Satisfaction with care scale[15] and a Physician relationship rating scale[16]. Using these data, we analyzed what factors contributed to patient satisfaction. Figure 3 demonstrates the correlations between patient views of the provider and care satisfaction. The longer the bar, the more significant the association.

Included below is a list of peer-reviewed publications on communication skills we wrote over the last 5 years.

- Feingold JH, Drossman DA. Deconstructing Stigma as a Barrier to Treating DGBI: Lessons for Clinicians. 2021. DOI: 10.1111/nmo.14080
- Drossman DA, Palsson O, Stein E, Ruddy J, Lennon AM. What Elements in the Physician- Patient Relationship (PPR) Contribute to Patient Satisfaction: Development of a Short Form PPR Patient Version (PPRS-Patient SF) Questionnaire 2021 Neurogastroenterology and Motility. DOI: 10.1111/nmo.14191
- Drossman DA, Chang L, Deutsch JK, et al. A Review of the Evidence and Recommendations on Communication Skills and the Patient-Provider Relationship (PPR): 13 A Rome Foundation Working Team Report. Gastroenterology 2021;161:1670-1688. DOI: 10.1053/j.gastro.2021.07.037
- Drossman DA, Ruddy J. Improving Patient-Provider Relationships to Improve Health Care. Clin Gastroenterol Hepatol 2020;18:1417-1426. DOI: 10.1016/j cgh.2019.12.007
- Drossman DA, Ruddy J. Communication skills in disorders of gut-brain interaction. Neurogastroenterology LATAM Reviews. 2019;2:1-14. DOI: 10.24875/NGL.19000050
- Ruddy J. From Pretending to Truly Being Ok: A Journey From Illness to Health With Postinfection Irritable Bowel Syndrome: The Patient's Perspective. Gastroenterology. 2018;155(6):1666-1669. doi.org/10.1053/j gastro.2018.11.003
- Drossman DA. From Pretending to Truly Being Ok: A Journey From Illness to Health With Postinfection Irritable BowelSyndrome: The Provider's Perspective. Gastroenterology. 2018;155(6):1664-1665. DOI: 10.1053/j.gastro.2018.11.002
- Errico K. Katie: A Patient's Perspective. American Journal of Gastroenterology. 2017;112(4):528-529. DOI: 10.1038/ajg.2017.26
- Drossman DA. Katie: The Physician's Perspective of a Young Woman's Illness Experience. American Journal of Gastroenterology. 2017;112(4):525-527. doi: 10.1038/ajg.2017.23

We plan to continue to publish peer-reviewed articles on patient-centered care and patient advocacy emphasizing communication skills based on the Rome Working Team Report findings.

Books for Providers and Patients. Dr. Drossman and Ms. Ruddy have recently co-authored two books to help patients and providers understand DGBI and patient-centered care. The first book published in 2021 is Gut Feelings: Disorders of Gut-Brain Interaction and the Patient-Doctor Relationship. A guide for Patients and Doctors https://romedross.video/GutFeelingsWebsite. It covers the conceptual aspects of brain-gut interactions and the biopsychosocial model. Next, it catalogs the DGBI with critical pathophysiology, diagnosis, and treatment information. Finally, Ms. Ruddy tells her story of her illness with post-infection IBS and discusses the challenges she experienced by providers who were dismissive and stigmatizing. Using this experience Dr. Drossman and Ruddy teaches communication skills highlighting the patient's perspective while providing impactful methods for optimizing the patient-doctor relationship. For further information, go to:

The second book, published in 2022, is Gut Feelings: The Patient's Story. Personal Accounts of the Illness Journey https://romedross.video/patient-story builds upon the first

book by providing the narratives of 8 patients who discuss the story of their illnesses and offer insights into their care. Each story has comments by Dr. Drossman as their provider and Ms. Ruddy as a patient advocate. We recently presented a webinar where the patients discussed their accounts and received commentary from the audience: https://romedross.video/GutFeelings2Chat.

Building on the knowledge of the first two books, we plan to write a third book: Gut Feelings Gut Feelings: Achieving Patient-Centerd Care, focusing on the career development and clinical practice features of accomplished providers in DGBI. We seek to delineate the critical elements in the care process that leads to personal gratification and meaningfulness and the techniques used to achieve patient satisfaction and expertise in the field of DGBI. Some of the experts who have agreed to be an author include Lin Chang, Jan Tack, Darren Brenner, Tony Lembo, and Andrea Shin, among others.

These three books provide novel information about the field of DGBI, its providers and patients, and a clear perspective on the need for patient-centered care. We believe the books can reach a large market, including the general public, patients, and providers. The information in these books teaches the DGBI, the value of patient-centered care to optimize the patient-provider relationship. For this proposal, we request support for the publication of the third book and marketing support to assist us in the distribution of the three books.

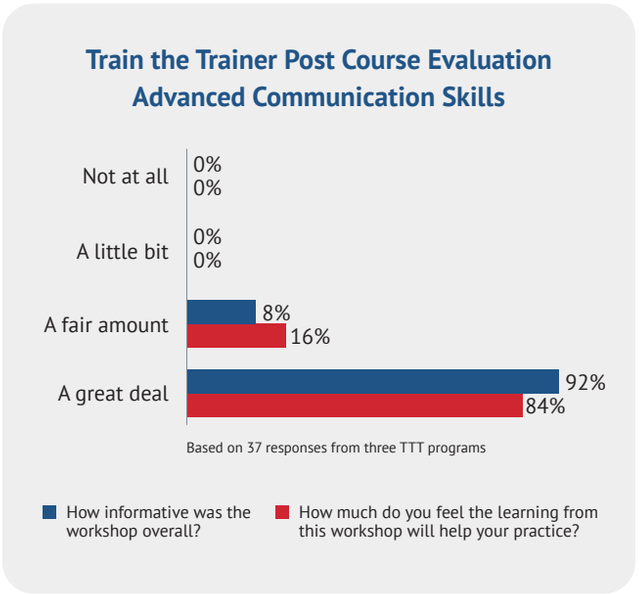
5. 1 1/2 day Train the Trainer Workshops.

We completed three Train the Trainers (TTT) programs in 2019. One was for the advanced GI faculty at Johns Hopkins, and two were for the Rome Foundation Board of Directors. Since completing these courses, they are certified to become faculty facilitators. The program consists of lectures, video demonstrations with discussion, small group teaching with patient simulators, training of group facilitation methods, and Balint-type education where clinicians share their difficulties in managing some patients. In August 2022 and February 2023 we successfully conducted our fourth and fifth Train the Trainer Programs for mid-lvel and key opinion-level participants (See Figure 4).

Figure 4. Attendees at 3rd Train the Trainer Program for mid-level KOLs in Atlanta

Figure 5 demonstrates the responses from the participants in this program relating to information gained and the degree it will help their practice.

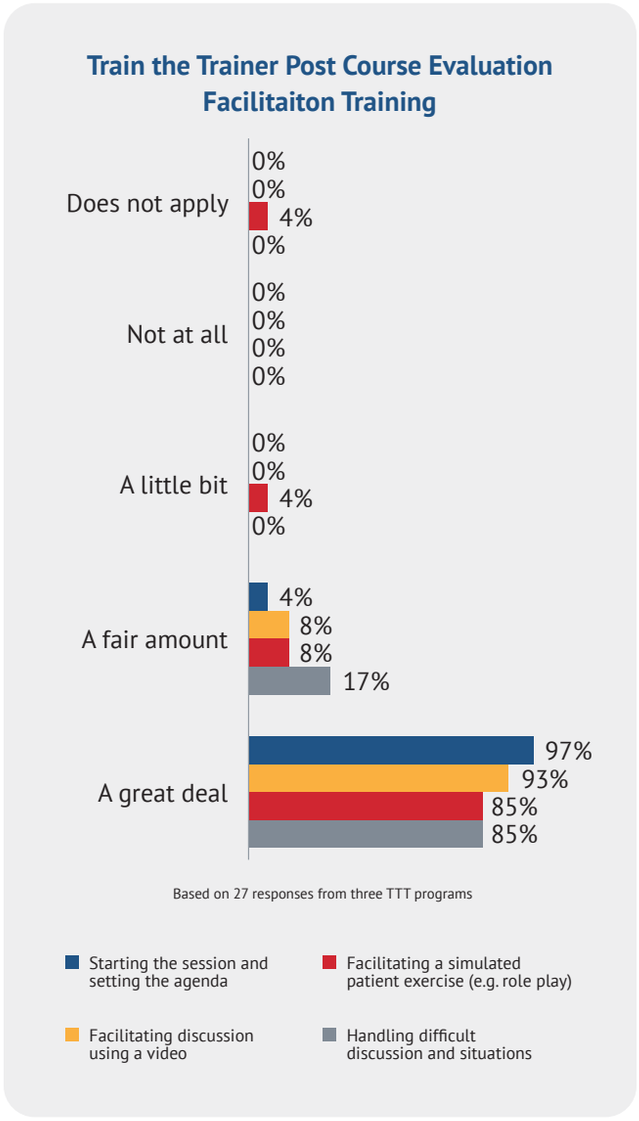
Figure 5. Train the Trainer General Post Course Evaluation Ratings



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

Figure 6 demonstrates the participant's responses to the advanced facilitation training

Figure 6. Train the Trainer Advanced Facilitation Training Ratings



6. Visiting Scholar Preceptorship Program.

For many years, gastroenterologists, trainees, psychologists, pharma executives, and mid-level providers have visited DrossmanCare to learn communication skills http://drossmancenter.com/services/mentoring- coaching/.

Subsequently, the Rome visiting scholar program instituted a program where faculty, practitioners, and trainees can see top tier programs to learn about DGBI. The visiting stopped during COVID. Now we would like to expand this program to have visitors learn communication skills at other programs involving our faculty (e.g., with Drs. Halpert, Chang, and Chey). Over the two years, there were visitors to DrossmanCare by faculty from Yale, New Haven, Ochsner clinic in New Orleans, Mt. Sinai in NYC, Yand Atrium Health in Charlotte NC.

7. Development and Distribution of a Communication skills curriculum packet for training programs and clinicians

As a means to provide educational materials for medical center and community practices, and trainees, we produced a Communication Skills Communication packet. This packet contains several of our educational materials: a) Communication 101, 101.5, and 202 videos, b) copies of the two Gut Feelings Books, c) five key research publications, d) a communication skills pocket guide, e) four video lectures and workshops. These materials can be a handy resource for educators and providers seeking to learn and teach communication methods.

8. Rome Foundation Douglas Drossman Award for Communication and Patient-Centered Care in DGBI

At the recently held 2022 Rome Foundation Board of Directors meeting, the members of the Board unanimously agreed to establish an annual award to a provider in the field of DGBI who has achieved excellence in communication skills and patient-centered care through clinical practice, teaching, and mentoring. This named award recognizes Dr. Drossman's lifetime commitment to this work area. We now believe there is a compelling need to identify individuals who have also impacted this area through their work, message others about its importance, and develop a cohort of future educators. The annual award will be $7,500.

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1. Drossman DA, Ruddy J. Improving Patient-Provider Relationships to Improve Health Care. Clin Gastroenterol Hepatol 2020;18:1417-1426.

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4. Drossman DA. Functional GI Disorders: What's in a Name? Gastroenterology 2005;128:1771- 1772.

5. Drossman DA, Chang L, Schneck S, et al. A focus group assessment of patient perspectives on irritable bowel syndrome and illness severity. Digestive Diseases & Sciences 2009;54:1532-1541.

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7. Feingold JH, Drossman DA. Deconstructing Stigma as a Barrier to Treating DGBI: Lessons for Clinicians. 2021.

8. Drossman DA. 2012 David Sun Lecture: Helping your patient by helping yourself: How to improve the patient-physician relationship by optimizing communication skills. American Journal of Gastroenterology 2013:521-528.

9. Engel GL. The need for a new medical model: A challenge for biomedicine. Science 1977;196:129-136.

10. Drossman DA. Katie: The Physician's Perspective of a Young Woman's Illness Experience. American Journal of Gastroenterology 2017;112:525-527.

11. Errico K. Katie: A Patient's Perspective. American Journal of Gastroenterology 2017;112:528- 529.

12. Ruddy J. From Pretending to Truly Being OK: A Journey From Illness to Health With Postinfection Irritable Bowel Syndrome: The Patient's Perspective. Gastroenterology 2018;155:1666-1669.

13. Drossman DA. From Pretending to Truly Being OK: A Journey From Illness to Health With Postinfection Irritable Bowel Syndrome: The Provider's Perspective. Gastroenterology 2018;155:1664-1665.

14. Drossman DA, Palsson O, Stein E, et al. 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 2021:e14191.

15. Dorn SD, Morris CB, Schneck SE, et al. Development and validation of the Irritable Bowel Syndrome Satisfaction with Care Scale (IBS-SAT). Clinical Gastroenterology and Hepatology 2011;9:1065-1071.

16. Kurlander JE, Chey WD, Morris CB, et al. Development and validation of the Patient-Physician Relationship Scale among patients with irritable bowel syndrome. Neurogastroenterol. Motil

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 informatin on the 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 preseentation: 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 upto-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.

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

ROME FOUNDATION - AGA INSTITUTE LECTURE

MAY 7 AT 10:00 AM, ROOM W190A, MCCORMICK PLACE

Do changes in intestinal permeability translate into clinical symptoms and treatments in disorders of gut-brain interaction?

Disorders of gut-brain interaction (DGBI), including irritable bowel syndrome (IBS) and functional dyspepsia (FD), are among the most common gastrointestinal (GI) disorders seen in primary care and GI practices. The pathophysiology is multifactorial and not well understood. However, there is increasing evidence that patients with IBS (particularly post-infection IBS [PI-IBS] and IBS with diarrhea) and FD have increased intestinal permeability. Based on various methods of measuring intestinal permeability, there is altered expression of tight junction proteins in the small intestine and colon in patients with DGBI. Increased permeability has been associated with abdominal pain severity, visceral hyperalgesia, and overall symptom severity in IBS. Furthermore, alterations in mucosal barrier function appears to play a role in the interaction between stress, visceral hypersensitivity, altered immune function and gut microbiota in DGBI. A recent study demonstrated altered host–microbial interaction that results in increased gut protease activity that disrupts intestinal barrier function and generates visceral hypersensitivity. From a clinical practice perspective, there is growing evidence that GI symptoms correlate with alterations in intestinal permeability, that some efficacious treatments in DGBI target normalization of intestinal permeability, and that there are various methods of measuring intestinal permeability in clinical practice (and in research). These topics will be reviewed in this session.

The talks will be:

- **Mechanistic Evidence for Altered Intestinal Permeability In Food Sensitivities: FD & IBS**
  - Madhu Grover, MBBS
- **Can We Measure Intestinal Permeability in Clinical Research & Practice?**
  - Tim Vanuytsel MD
- **Implications of Targeting Intestinal Permeability on Clinical Symptoms & Potential Treatments for DGBI**
  - Lin Chang, MD

Madhu Grover, MBBS
Mayo Clinic
Rochester, MN

Tim Vanuytsel MD
KU Leuven
Leuven, Belgium

Lin Chang, MD
University of California, Los Angeles
Los Angeles, CA

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 Qurión 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 Houte • 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

RESEARCH PROTOCOLS IN GI PSYCH

Helen Burton Murray, PhD, chair
Laurie Keefer, PhD, co-chair
Brjánn Ljótsson PhD
Magnus Simrén, MD, PhD
Livia Guadagnoli, PhD

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

Gastroenterology 2022;162:300-315
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

(Neurogastronterol 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

Gastroenterology; 2021;161:1670-1688
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

FOOD AND DIET

Am J Gastronterol 2022; Vol 117
William Chey Co-Chair, Jan Tack Co-Chair
Prashant Singh, MD,
Caroline Tuck, PhD,
Peter R. Gibson, MD
Helen Burton Murray, PhD
Bethany Doerfler, MS, RD,
Kimberly N. Harer, MD, ScM
Laurie Keefer, PhD
Samuel Nurko, MD, MPH,
Marc A. Benninga, MD, PhD
Toni Solari, RD, LDN
Bruno P. Chumpitazi, MD, MPH, FACG
Heidi M. Staudacher, PhD
Chu Kion Yao, PhD
Kevin Whelan, PhD
Karen Van den Houte, PhD
Premysl Bercik, MD
Magnus Simren, MD, PhD
Stephen Vanner, MD, MSc
Hans Tornblom, MD, PhD
Victoria Tan, MD
Florencia Carbone, MSc, PhD
Anupam Rej, MBChB, BMedSci, MD, MRCP\
Michael D. E. Potter, PhD, FRACP
Nicholas J. Talley, MD, PhD, FRACP
Ayesha Shah, MBBS, FRACP, PhD
Gerald Holtmann, MD, PhD, MBA, FRACP
David Surendran Sanders, MBChB, MRCP, MD, FACG, FRCP

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
Neurogastronterol Motil 2015;27:750-763
Alim Pharm & Ther. 2014;40:1133-1145

PHARMACOLOGICAL TRIALS FOR CHILDREN - IBS
Saps, M. Chair
Neurogastronterol Motil 2016;11:1619-1631

RESEARCH PROTOCOLS IN GI PSYCH WORKING TEAM

Committee Composition

Helen Burton Murray, PhD, chair

Laurie Keefer, PhD, co-chair

Brjánn Ljótsson PhD

Magnus Simrén, MD, PhD

Livia Guadagnoli, PhD

Brain-gut behavior therapies (BGBT), the subject of a recent Rome Working Team Report (Keefer et al., 2022 Gastro), are evidence-based, non-pharmacologic interventions for disorders of gut-brain interaction (DGBI). Their mechanism of action stems from the compilation of targeted techniques that directly impact on the dysregulation of the gut-brain axis. While BGBTs have shown some of the best efficacy on the problem at hand (GI symptoms), at least when compared to rigorous psychotherapy clinical trials in depression and anxiety, their adoption in gastroenterology has been dampened by the lack of evaluative guidelines for non-pharmacological approaches to treatment. Now that there is a growing adoption of digital behavioral therapies that stem from academic, research-based clinical trials, it is critical to start to set standards for the field so that clinicians and patients can properly evaluate the potential benefit of the intervention for their specific needs.

For irritable bowel syndrome (IBS), there is robust evidence to support the efficacy for some BGBTs (self-management training, cognitive behavior therapies, gut-directed hypnotherapy and interpersonal psychodynamic psychotherapy), as well as some emerging data on how the treatments work (i.e., mediators) and for whom they may be best suited (i.e., moderators). There is also growing interest in the scalability of these therapies—with newer research on BGBTs including their translation to different treatment delivery methods (e.g., digital therapeutics).

However, trials of BGBTs have been criticized/downgraded with respect to their efficacy based on quality estimate standards that were created for pharmacologic therapy trials in the DGBI industry. We hypothesize, based on the compelling information coming out of the Rome Working Team Report on BGBT (Keefer et al., 2022 Gastro), that these drug-based methodological quality metrics may underestimate the value and fail to recognize the low risk these therapies have in the DGBI field.

To facilitate the rigor of developing, refining, testing, and implementing BGBTs, our working team aims to create clear guidelines informed by best practices recommended for the development and testing of BGBT. Our intent is that these guidelines inform both investigators and future standards on which BGBTs are evaluated in the DGBI field.

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:

Committee Composition

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- 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.

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 satiation 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

GI Genius
INTERACTIVE CLINICAL DECISION TOOLKIT

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.

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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.

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

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

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.

Committee Composition

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

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

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, andgastroenterology on the effect of enhanced communication skills andpatient-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

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FOOD AND DIET WORKING TEAM

The Rome Foundation Working Team on Food and Diet in DGBI is pleased to have its research work published in a special edition of The American Journal of Gastroenterology.

William D. Chey, MD, and Jan Tack, MD, PhD, both Rome Foundation Board members, were co-chairs of the RF Team that worked with an international group of experts to address the role of dietary therapies in DGBIs.

The Team's research presents new data that supports dietary therapies and behavioral considerations, updating previous findings published ten years ago by the prior Rome Foundation Working Team.

Article titles in this special edition include:

- Evidence-Based and Emerging Diet Recommendations for Small Bowel Disorders
- Pediatric Aspects of Nutrition Interventions for Disorders of Gut-Brain Interaction
- Psychological Considerations in the Dietary Management of Patients With DGBI
- Evidence-Based and Emerging Dietary Approaches to Upper Disorders of Gut–Brain Interaction
- The Role of Food in the Treatment of Bowel Disorders: Focus on Irritable Bowel Syndrome and Functional Constipation
- Mechanisms Underlying Food-Triggered Symptoms in Disorders of Gut-Brain Interactions
- Optimal Design of Clinical Trials of Dietary Interventions in Disorders of Gut-Brain Interaction
- The Role of Food in the Treatment of Bowel Disorders: Focus on Irritable Bowel Syndrome and Functional Constipation
- Prashant Singh, MD, Caroline Tuck, PhD, Peter R. Gibson, MD and William D. Chey, MD (2022). American Journal of Gastroenterology, 117:947–957.
- The Role of Food in Disorders of Gut-Brain Interaction: Introduction to a Rome Foundation Working Group Series William D. Chey, MD and Jan Tack, MD, PhD (2022). American Journal of Gastroenterology; 117:935–936.

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- Psychological Considerations in the Dietary Management of Patients With DGBI, Helen Burton Murray, PhD, Bethany Doerfler, MS, RD, Kimberly N. Harer, MD, ScM and Laurie Keefer, PhD (2022). American Journal Gastroenterol;117:985–994.
- Pediatric Aspects of Nutrition Interventions for Disorders of Gut-Brain Interaction, Samuel Nurko, MD, MPH, Marc A. Benninga, MD, PhD, Toni Solari, RD, LDN and Bruno P. Chumpitazi, MD, MPH, FACG (2022). American Journal Gastroenterol; 117:995–1009.
- Optimal Design of Clinical Trials of Dietary Interventions in Disorders of Gut-Brain Interaction, Heidi M. Staudacher, PhD, Chu Kion Yao, PhD, William D. Chey, MD and Kevin Whelan, PhD (2022). American Journal Gastroenterol; 117:973–984.
- Mechanisms Underlying Food-Triggered Symptoms in Disorders of Gut-Brain Interactions, Karen Van den Houte, PhD, Premysl Bercik, MD, Magnus Simren, MD, PhD, Jan Tack, MD, PhD and Stephen Vanner, MD, MSc (2022). American Journal Gastroenterol; 117:937–946.
- Evidence-Based and Emerging Dietary Approaches to Upper Disorders of Gut–Brain Interaction, Jan Tack, MD, PhD, Hans Tornblom, MD, PhD, Victoria Tan, MD and Florencia Carbone, MSc, PhD (2022). American Journal Gastroenterol; 117:965–972.
- Evidence-Based and Emerging Diet Recommendations for Small Bowel Disorders, Anupam Rej, MBChB, BMedSci, MD, MRCP, Michael D. E. Potter, PhD, FRACP, Nicholas J. Talley, MD, PhD, FRACP, Ayesha Shah, MBBS, FRACP, PhD, Gerald Holtmann, MD, PhD, MBA, FRACP and David Surendran Sanders, MBChB, MRCP, MD, FACG, FRCP (2022). American Journal Gastroenterol;117:958–964.

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

Drossman, D.A., Tack, J., 2022. Rome Foundation Clinical Diagnostic Criteria for Disorders of Gut-Brain Interaction. Gastroenterology 162, 675–679.. doi:10.1053/j.gastro.2021.11.019

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.[19–23] 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%.[24] 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.[25]

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.[26,27]

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[1] 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.

ROME FOUNDATION

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.**

[1]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).16 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.[28]

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. [20–24,29] 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.[30] 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.[31] 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).[32] Furthermore, the Rome IV criteria use bothersomeness for some diagnoses like functional dyspepsia.[33] 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.[16] 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.[1,16,24,31] 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.

ROME PARTNERS PROGRAM

The Rome Foundation Partner's Program is designed for physicians and other allied health care providers (NPs and PA), primarily early to mid-career, who are involved in Neurogastroenterology or are considering this area of specialization. Our goal with this program is to provide a forum for these providers and also to provide support in a variety of means, through specialized educational opportunities, networking events both in person and virtually throughout the year, mentoring from senior members of the Rome Foundation and collaborative research opportunities. This program is chaired by a quartet of mid-level clinicians who are rising leaders in the field and who have the vision to help Rome Foundation reach out and meet the needs of the next generation.

This program will begin accepting applications for membership in January, 2024 and will host their inaugural membership meeting and reception at DDW, 2024. Please watch the Rome Foundation website for updated information and membership application.

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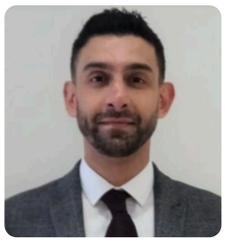

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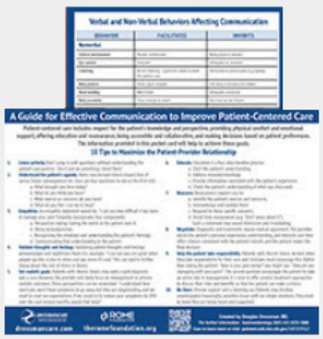
Diagnostic Pocket Cards



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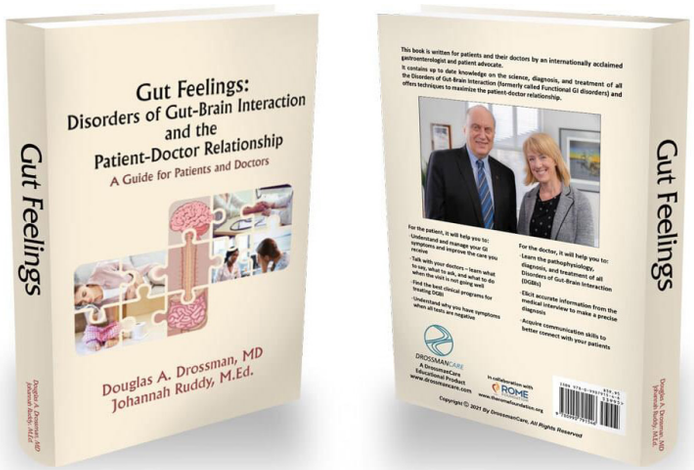
GUT FEELINGS BOOK

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



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

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

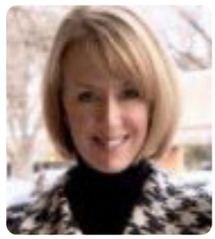
PART 2: The Disorders of Gut-Brain Interaction (DGBI)

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

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

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

Douglas Drossman, MD



Johannah Ruddy M.Ed

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 mytime 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

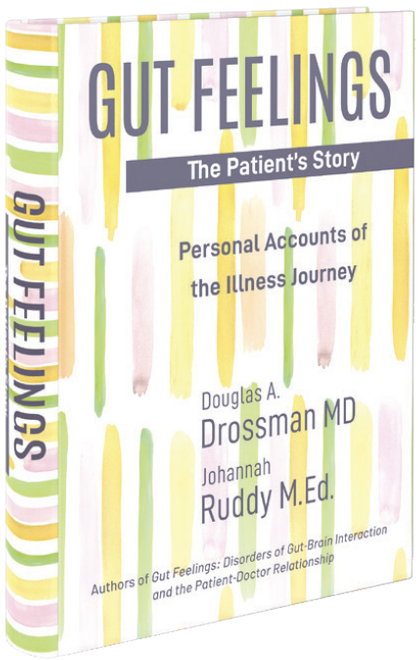
"In the most difficult time of your illness, the illness might seem like a curse, but as you heal, you can use it to help you connect with others and learn to truly advocate for yourself."

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

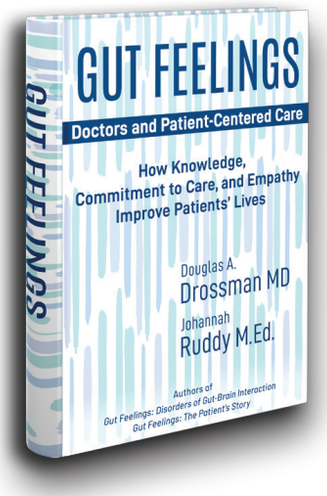
Optimal care of DGBI is a collaboration where patient and provider achieve mutual goals: The provider elicits the patient's illness experience and applies that knowledge along with the science of neurogastroenterology to select diagnostic strategies and optimize treatment. The patient communicates to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



Gut Feelings:
Doctors and Patient-Centered Care
A Guide for Patients and Doctors

by Douglas A. Drossman MD and Johannah Ruddy M.Ed.

Learn from Key Opinion Leaders About
What Makes Good Doctors Great in the Field of DGBI



This book "closes the loop" on the Gut Feelings series.

- The first book covered the clinical aspects of DGBI (Disorders of Gut-Brain Interaction) and the importance of good communication skills for achieving an effective patient-provider relationship.
- The second book covered eight patient stories, and their illness experiences.
- Now, this third book describes the key factors that makes these doctors successful and why their patients value them.

The book series *"Gut Feelings"* is authored by
Douglas A. Drossman MD and Johannah Ruddy M.Ed.

Dr. Drossman is an internationally recognized scientist, clinician, and educator in DGBIs and communication skills training. He is Professor Emeritus of Medicine and Psychiatry in Gastroenterology from the University of North Carolina, CEO and President Emeritus of the Rome Foundaton, and President of DrossmanCare, which develops training programs in communication skills. He treats patients with complex DGBIs in his gastroenterology practice.

Douglas A. Drossman MD, Co-Author

Ms. Ruddy is a highly recognized patient advocate with a career background in healthcare nonprofit organizations. She is the COO and Executive Director of the Rome Foundation and is on the Board of Directors of DrossmanCare. Her social media presence is well recognized, and she has published peer-reviewed articles in scientific journals on patient advocacy. Ms. Ruddy works with Dr. Drossman in facilitating communication skills training programs internationally.

Johannah Ruddy, MEd, Co-Author

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.

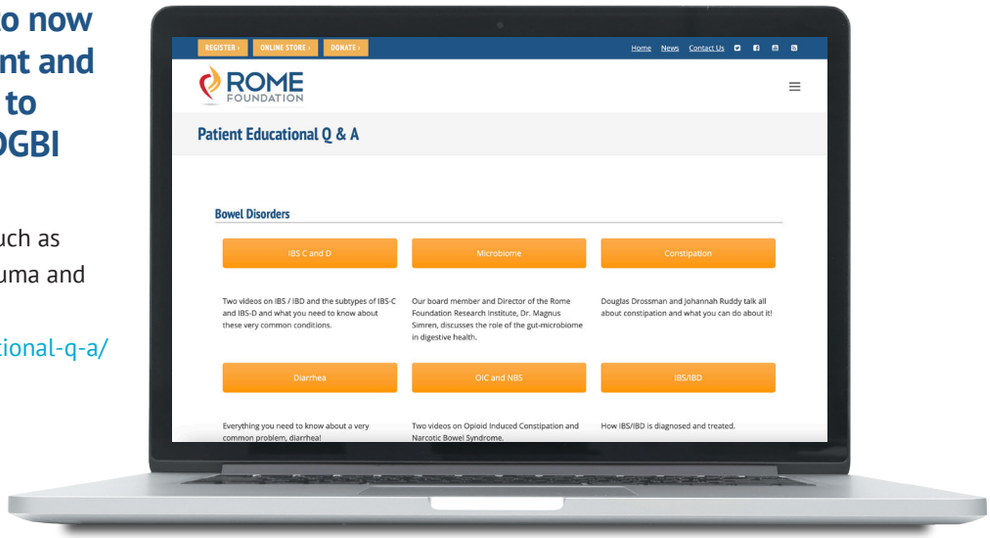
- **Graded educational program from basic to advanced**
- **Build your communication skills as you move from one module to another**
- **Learn at your own pace while you gain more and more advanced skills**
- **Earn 9 CME credits for completing all the programs**
- **101 tells you what you need to say 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/



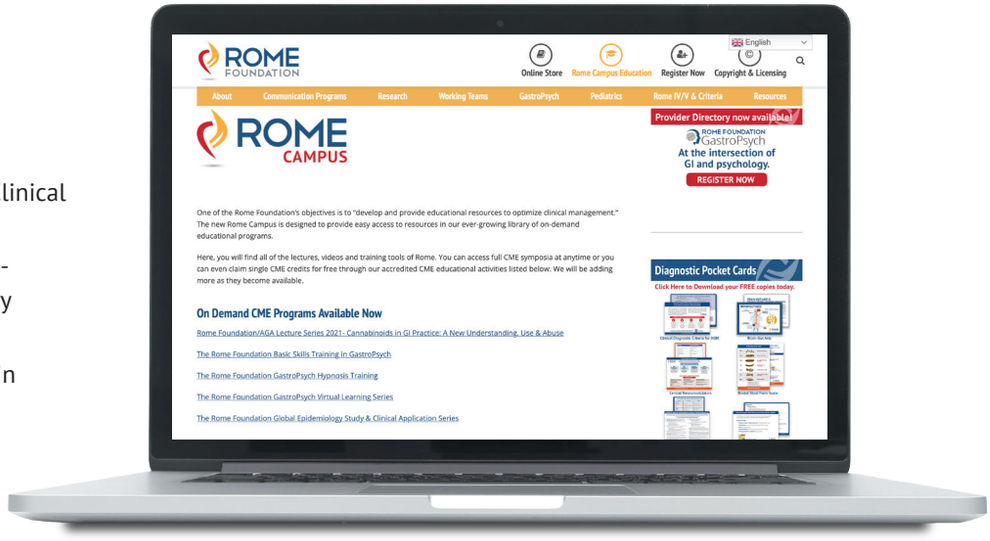
ROME CAMPUS

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

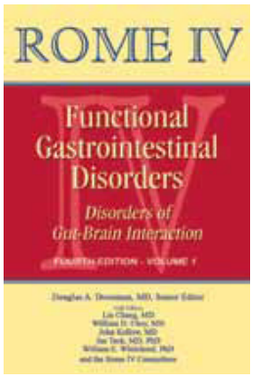
- 2022 Rome Grand Rounds sessions
- 2022 Rome Pediatric DGBI Symposium
- The Rome Foundation Global Epi Study & Clinical Applications Symposium
- The Rome Foundation Educational Program- Diagnosing and Treating DGBI in the Primary Care Setting
- The Rome Foundation Basic Skills Training in GastroPsych
- The Rome Foundation GastroPsych Hypnosis Training



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.



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

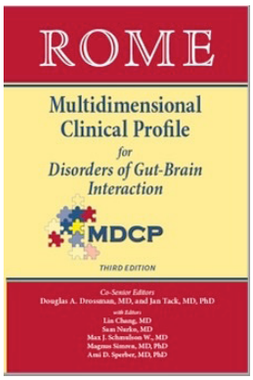
Rome IV Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction (Fourth Edition)

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

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

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

Volume II provides the key clinical information on 33 adult and 17 pediatric DGBIs from esophagus to anorectum, as well as a newly developed chapter on centrally mediated disorders of gastrointestinal pain. For each DGBI we provide recent information on the epidemiology, pathophysiology, and psychosocial aspects along with evidence- and consensus-based recommendations on diagnosis and treatment. Volume II also contains new information and the revised Rome IV diagnostic criteria for adult and pediatric DGBIs. Also there are appendices that contain key reference information including the Rome IV diagnostic criteria tables, a comparison of the Rome III and Rome IV criteria, a flowchart to assist in the biopsychosocial assessment of patients with DGBIs and how to treat or when to seek a mental health consultant. There are also the validated Rome IV pediatric and adult questionnaires criteria for epidemiological and clinical research.



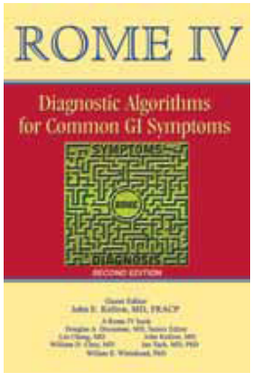
Soft cover or e-book $49.95

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

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

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

We accomplished this task in a short time by acquiring the expertise of our Rome Board Members, who revised the previous cases and added newer diagnostic entities (such as OIC—opioid-induced constipation, narcotic bowel syndrome, cannabinoid hyperemesis syndrome, and esophageal reflux hypersensitivity) and who also provided additional cases to increase the variety of clinical presentations that occur in real-life practice, often with dual or multiple diagnoses including post-COVID-19 infection and ARFID. Thus, this 3rd edition truly addresses the full depth and breadth of clinical decision-making for DGBIs. Furthermore, we have updated all 18 pediatric cases (neonate-toddler and child-adolescent) and the multi-cultural cases where sociocultural influences affect symptom presentation, and where treatment must be geared to the patient's cultural perspective. In this way, any diagnosis, for example, IBS or dyspepsia, has multiple clinical cases ranging from mild to severe, with or without associated comorbidities or sociocultural influences or with psychological comorbidities. As before, the MDCP identifies and classifies five components of every case scenario that include the categorical Rome diagnosis (Category A), additional subclassifications leading to more specific treatments (Category B, e.g., IBS-D or IBS-C, EPS or PDS), the personal impact of the disorder on the patient (Category C), psychosocial influences (Category D), and physiological abnormalities or biomarkers (Category E). This framework is intuitively clear and the organizational approach is both pragmatic and useful.



Soft Cover or e-book $39.95

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

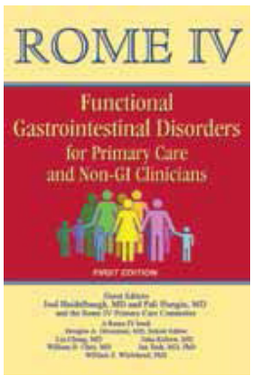
The diagnostic criteria, designed primarily for research, has a limited role in clinical practice. Patients don't go to doctors complaining of IBS, or sphincter of Oddi dysfunction; they present with symptoms of abdominal pain, nausea, vomiting and constipation, among others. Accordingly, the Foundation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

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

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



Soft Cover or e-book $24.95

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

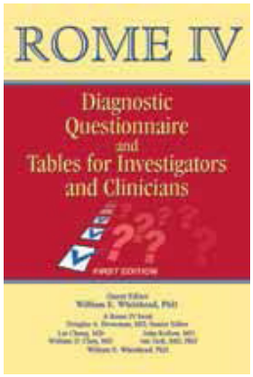
As noted, one of the Rome IV initiatives was that of reaching a larger audience of non-gastroenterologists. We have partnered with leaders in the primary care field to create a primary care book, co-edited by Joel Heidelbaugh, MD, and Pali Hungin, MD.

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 childrenadolescents, 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



Soft Cover or e-book $34.95

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

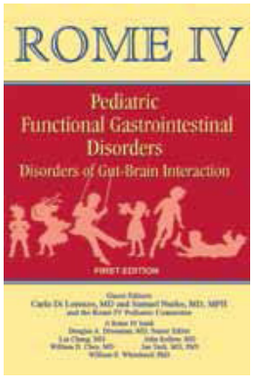
The Rome Foundation maintains a major commitment to the creation and dissemination of good research in the field of DGBIs. To properly study patients having these disorders we need to identify them in as precise a way as possible. Hence, we have proposed, created and disseminated the use of diagnostic 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.

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.



Soft Cover or e-book $59.95

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

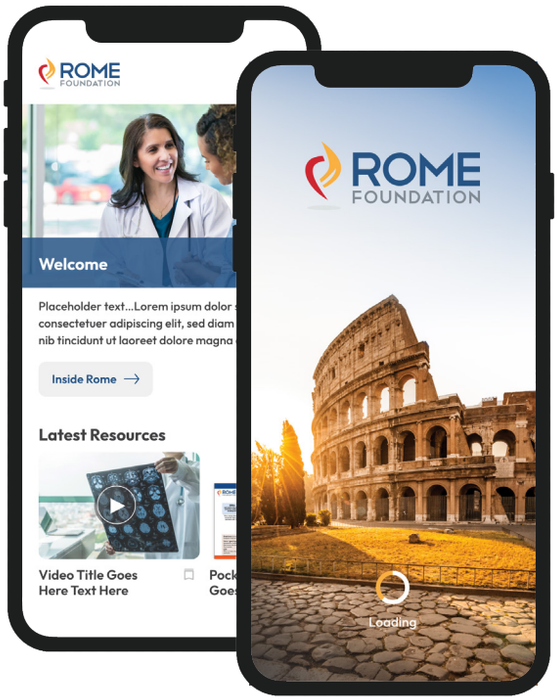
The field of pediatric DGBIs has grown over the last two decades, and for this reason we have decided to publish a separate book on pediatric DGBIs, which is extracted from the main Rome IV chapter material. This book has an introduction by co–guest editors Samuel Nurko, MD (chair of the Neonate-Toddler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

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.

Rome IV Online Subscriptions

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

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

Rome IV Online Subscription Bulk Order Pricing

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

EDUCATIONAL PRODUCTS

Rome IV Slide Sets

Rome IV MDCP Slide Set

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

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

Rome IV Slide Set

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

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

Rome IV Diagnostic Algorithm Slide Set

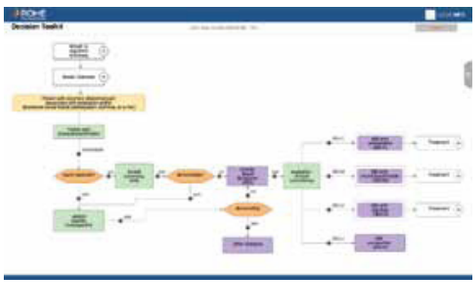
Slide set of 35 images $29.95/set

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

GI Genius Interactive Clinical Decision Toolkit

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

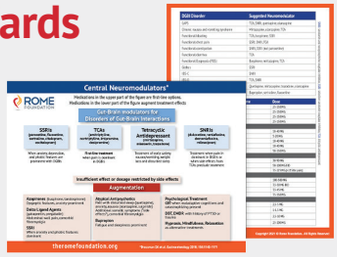
3 month trial subscription - $29.95 | Renew annually for $89.95



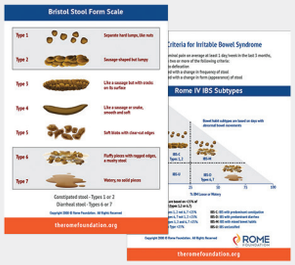
Participants learn interactively. The program responds to input by the clinician and then interactively guides practitioners through optimal diagnostic and treatment pathways. The intelligent software also continues to learn. User input is retained and catalogued. When decision branches occur that contain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

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 te 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

Pommunication 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**

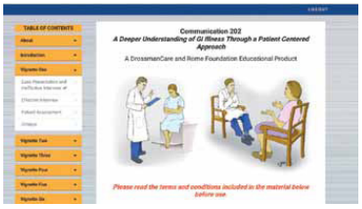
COMMUNICATION 202

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** 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
Gary M. Mawe, PhD **Co-chair** **Beverley Greenwood, PhD** **Co-chair** Stuart Brierley Brian Gulbransen Gerard Clark Kara Margolis Art Beyder	**Lesley Anne Houghton, PhD, FRSB, RFF, AGAF, FACG- Co-Chair** **Roberto DeGiorgio- Co-Chair** Guy Boeckxstaens John F Cryan Tim Vanuytsel Phil Dinning Mauro D'Amato Bill Hasler	**Eamonn M Quigley, MD** **Madhusudan Grover, MBBS** Giovanni Barbara Bruno Chumpitazi William D. Chey Christine Feinle-Bisset Harriett Schellekens	**Michael Camilleri, MD** **Giovanni Sarnelli, MD, PhD** Colin Howden Beverley Greenwood van Meerveld Angelo Izzo Viola Andresen Karen Jones	**Albena Halpert, MD co-chair** **Margaret Heitkemper, PhD, RN co-chair** 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**
Gerald J Holtmann, MD, PhD, MBA **Reuben K. Wong, MD** Xiucai Fang Uday Ghoshal Justin Lee Agata Mulak Purna Kayshap	**Rona L. Levy, MSW, PhD, MPH** **Sigrid Elsenbruch, PhD** Sarah Ballou Laurie Keefer Lukas Van Oudenhove Miranda VanTilburg Dipesh Vasant	**John E. Pandolfino, MD** **Sabine Roman, MD PhD** Ronnie Fass Shobna Bhatia Edoardo Savarino Frank Zerbib Prakash Gyawali	**Vincenzo Stanghellini, MD** **Hans Tornblom, MD, PhD** Nick Talley Hidekazu Suzuki Florencia Carbone Jan Tack André Smout Bill Hasler	**Anthony Lembo, MD** **Maura Corsetti, MD, PhD** 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
Qasim Aziz, PhD **Shin Fukudo, MD, PhD** Douglas A. Drossman, MD Eva Szigethy Lukas Van Oudenhove Adam Farmer Asbjorn Drewes	**B. Joseph Elmunzer, MD, MSc** **Enrico Stefano Corazziari, MD** Grace Elta Marianna Arvanitakis Emily Winslow Roberto De Giorgio Andrea Laghi	**Satish S. C. Rao, MD, PhD, FRCP** **Emma V. Carrington** Adil Bharucha Allison Malcolm Jose Remes-Troche Ugo Grossi Leila Neshatian	**Marc A. Benninga, MD** **Rachel Rosen, MD, MPH** Usha Krishnan Christophe Faure Nathalie Rommel Osvaldo Borelli Alan Silverman Michiel van Wijk Carlos Velasco	**Carlo Di Lorenzo, MD** **Miguel Saps, MD** Annamaria Staiano Nikhil Thapar Miranda Van Tilburg Shaman Rajindrath Katja Kovacic Arine Vlieger Bruno Chumpitazi	**Greg Sayuk, MD, MPH** **Alex Ford, MD** 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***
Laurie Keefer, PhD Brjánn Ljótsson, PhD Douglas A. Drossman, MD Sarah Ballou, PhD Sigrid Elsenbruch, PhD Gisela Ringstrom, PhD	**Douglas A. Drossman, MD** Lin Chang, MD Johannah Ruddy, MEd Albena Halpert, MD Alex Charles Ford, MD Kurt Kroenke, MD, MACP Samuel Nurko, MD, MPH Jill Deutsch, MD Julie Snyder, PsyD Ami Sperber, MD, MSPH	**William D. Chey, MD, AGAF, FACG, FACP** **Jan Tack, MD, PhD** Steve Vanner Bill Chey David Sanders Jan Tack Heidi Staudacher	**Jan Tack, MD, PhD** **Nicholas Talley, MD** 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	**Magnus Simren, MD, PhD** **Giovanni Barbara, MD** 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**
Anthony Lembo, MD Vipul Jairaith, MD Eric Shah, MD, Prashant Singh, MD Jan Tack, MD, PhD Daphne Ang, MD Oliver Chassany, MD, PhD Miguel Saps MD	**Ami Sperber, MD, MPH** Kant Bangdiwala PhD Oli Palsson PsyD Xiucai Fang, MD	**Laurie Keefer, PhD** **Sarah Kinsinger, PhD** Giuseppe Chiarioni Bonney Reed Sarah Ballou Livia Guadagnoli Liesbeth Ten Cate	**Joel J. Heidelbaugh, M.D., FAAFP, FACG** 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	**Brian E. Lacy, MD, PhD** **Olafur Palsson, PsyD** 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