Mission: To Improve the lives of people with Functional GI Disorders

Meet the Rome Foundation

Over Two decades of Service to Patients and the Field of Functional GI Disorders

Mission: To Improve the lives of people with Functional GI Disorders
The Rome Foundation is an independent not-for-profit 501(c)3 organization that provides support for activities designed to create scientific data and educational information to assist in the diagnosis and treatment of functional gastrointestinal disorders (FGIDs). Our mission is to improve the lives of people with functional GI disorders, now called Disorders of gut-brain interaction.

For almost 3 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 FGIDs. 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, legitimation and preservation of the field of FGIDs through science-based activities. We are inclusive and collaborative, patient-centered, innovative and open to new ideas. Figure 2 shows our organizational structure.

**Goals of the Rome Foundation**

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

**Over 25 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)
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· Rome IV
· Sponsors - Information/Opportunities
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BOOKLET BY CEARA OWRE DESIGN
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 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.
Douglas A. Drossman, MD  
President, Rome Foundation  
Professor Emeritus of Medicine and Psychiatry  
Co-Director Emeritus, UNC Center for Functional GI and Motility Disorders  
UNC School of Medicine  
President, Center for the Education and Practice of Biopsychosocial Care LLC  
Drossman Gastroenterology PLLC  
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 psychosomatic (psychosomatic medicine at the University of Rochester School of Medicine and in Gastroenterology at the University of North Carolina.

In 2012, Dr. Drossman founded the Drossman Center for the Education and Practice of Integrated, LLC care as an entity to help train physicians in relationship centered biopsychosocial care with emphasis on communication skills and enhancing the patient doctor relationship. Some focus is on the care of difficult to diagnose and manage patients with functional gastrointestinal disorders 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 is on the Board of Directors of the International Foundation for Functional GI Disorders (IFFGD). He has served on three committees of the Institute of Medicine Committee on Gulf War and Health, has been an Ad Hoc member of NIH NCCAM Advisory board, and is on the NIH-National Commission on Digestive Diseases.

Dr. Drossman has written over 500 articles and book chapters, has edited seven 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 has served 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.

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) and the David Sun Award of the ACG (2012). He has also received several “Who’s Who”, “Patient Choice” and “Best Doctors” citations over the past 15 years.

Dr. Drossman’s educational and clinical interests relate to the psychosocial and behavioral aspects of patient care. He has produced numerous articles and videotapes on the biopsychosocial aspects of medical care, medical interviewing and the patient-doctor relationship, and received second prize at the 1997 AMA International Film Festival. As a Charter Fellow of the American Academy of Communication in Health Care, he facilitates workshops to develop clinical skills in physician patient communication. Since 2013 he has produced internationally over 30 workshops and webinars on communication skills. 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 for almost 25 years has served as President of the Board. He has been editor in chief of Rome I, II, and III books and currently of Rome IV published in 2016. The Rome IV project consists of 6 books available in print an e-book a set of slide sets and an electronic Rome IV educational program by subscription. Most recently he has been the editor of the Rome IV Interactive Clinical Decision Toolkit which is an intelligent software interactive program to teach diagnosis and treatment using the Rome IV database of knowledge.
Giovanni Barbara, MD
Department of Digestive Diseases and Internal Medicine
University of 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 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 Internal Medicine and Gastroenterology of the University of Bologna.

Professor Barbara’s main research interest relate to basic and clinical aspects of functional gastrointestinal disorders and neurogastroenterology, and he has authored numerous indexed peer-reviewed articles and reviews on these topics, published in various biomedical journals, including *Gastroenterology*, *Gut*, *Journal of Clinical Investigation* and *Trends in Pharmacological Science*. He is, or has been, a member of the Editorial Board of *Gut*, *American Journal of Gastroenterology*, *Neurogastroenterology and Motility*, the *American Journal of Physiology* and other international scientific Journals.

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

Lin Chang, MD, AGAF FACG

Professor of Medicine in the Vatche and Tamar Manoukian Division of Digestive Diseases and Department of Medicine
David Geffen School of Medicine at UCLA
Los Angeles, CA, USA

Lin Chang, MD, is a Professor of Medicine and Vice-Chief of the Vatche and Tamar Manoukian Division of Digestive Diseases, Department of Medicine at the David Geffen School of Medicine at UCLA. She serves as the Co-Director of the G. Oppenheimer Center for Neurobiology of Stress and Resilience at the David Geffen School of Medicine at UCLA. She is also Program Director of the UCLA Gastroenterology Fellowship Program. Dr. Chang’s clinical expertise is in functional gastrointestinal disorders. She is a NIH funded investigator studying brain-gut interactions underlying irritable bowel syndrome (IBS). Specifically, her research is focused on the pathophysiology of IBS related to stress, early life adversity, sex differences, 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 a member of the Rome Foundation Board of Directors, Chair of the Rome Advisory Council, and was a member of the Rome IV Editorial Board and Functional Bowel Disorders Committee. Dr. Chang previously served as President of the American Neurogastroenterology and Motility Society (ANMS). She is Associate Editor of *Clinical Gastroenterology and Hepatology*. She is a fellow of the American Gastroenterological Association (AGA) and was recently selected to be Clinical Research Councilor of the AGA Governing Board. She is also a fellow of the American College 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 115 original research articles, 55 review articles, and 20 book chapters on her specialty interests.
William D. Chey, MD, AGAF, FACC, FACP

Timothy T. Nostrant Collegiate Professor of Gastroenterology & Nutrition Sciences
Director, GI Physiology Laboratory
Director, Nutrition & Behavioral Medicine Program
Medical Director, Michigan Bowel Control Program
Division of Gastroenterology
University of Michigan Health System
Ann Arbor, MI, USA

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 at the University of Michigan in Ann Arbor. Following fellowship, Dr. Chey has remained at the University of Michigan, where he is currently Timothy T. Nostrant Collegiate Professor of GI & Nutrition Sciences. He has helped to found and directs a number of programs at the University of Michigan including the Nutrition & Behavioral Medicine Program and Michigan Bowel Control Program.

His research interests focus on the diagnosis and treatment of the functional bowel disorders, acid-related disorders, and Helicobacter pylori (H. pylori) infection. Dr. Chey has received funding for his research from federal and private sources.

Dr. Chey has authored more than 300 manuscripts, reviews and book chapters. He is Editor Emeritus of the *American Journal of Gastroenterology* (2010-2015), *Clinical & Translational Gastroenterology* (2011-2014). Dr. Chey is a member of the Board of Trustees of the American College of Gastroenterology. Dr. Chey joined the Board of Directors of the Rome Foundation in 2010 and is a member of the editorial board of the Rome IV criteria. He is a Counsel member of the American Neurogastroenterology & Motility Society and Advisory Board of the International Foundation of Functional GI Disorders.

He has been elected to "Best Doctors" since 2001 and “America’s Top Doctors” since 2009. In 2015, Dr. Chey was named as one of the “190 Gastroenterologists to Know” by Becker’s ASC. In 2014, Dr. Chey was inducted into the Clinical Excellence Society of the Department of Medicine, received the Dean’s Outstanding Clinician Award, and was inducted into the League of Research Excellence at the University of Michigan. In 2015, he was inducted into the League of Clinical Excellence at UM and received the Distinguished Clinician Award from the American Gastroenterological Association.

Laurie Keefer, PhD

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 [GRITT™]-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 Psychogastroenterology 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.
Dr. John Kellow is currently Associate Professor and Head of the Discipline of Medicine, Northern Clinical School, University of Sydney, and Gastroenterologist and Director of the Neurogastroenterology Unit at Royal North Shore Hospital, Sydney. Dr. Kellow graduated MBBS from the University of Sydney and subsequently received his doctorate (MD) from that university. He was made a Fellow of the Royal Australasian College of Physicians (FRACP) in 1985. Dr. Kellow was a University of Sydney Travelling Fellow at the Mayo Clinic, USA in 1984-1985, and was a Commonwealth Medical Fellow at the Royal London Hospital Medical College, UK in 1986. He is a member of the Gastroenterological Society of Australia, The American Gastroenterological Association, The American Neurogastroenterology and Motility Society, and the European Society of Neurogastroenterology and Motility. Dr. Kellow has published extensively including original research papers, book chapters and reviews. His primary and long-standing research interests are neurogastroenterology and the pathophysiology and treatment of the functional gastrointestinal disorders. He is a Board Member of the Rome Foundation, and a member of the Advisory Board of the International Foundation for Functional Gastrointestinal Disorders. He serves on the Editorial Boards of a number of international journals in gastroenterology. He has also had a long-standing interest in undergraduate and postgraduate medical education, curriculum development and assessment, and was previously Associate Dean (Assessment) Faculty of Medicine, University of Sydney.

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. In 1993 he returned to Boston and created the Motility Center which provides state of the art evaluation and care of children with motility and functional gastrointestinal disorders, offering innovative techniques and multidisciplinary approaches for diagnosis and treatment.

Dr. Nurko is a recognized leader in the field and has distinguished himself during his tenure as an academic, NIH-funded clinical researcher, teacher, and mentor. He has a long-standing interest, and dedication to patient-oriented research and has written more than 250 manuscripts, reviews and book chapters. Dr Nurko has made major contributions to the understanding of motility and functional GI disorders in children, as well as on the effect of other inflammatory or allergic conditions on the GI tract. His clinical and research interests have focused on understanding the pathophysiology and establishing the best approach and treatments for these disorders, and he has been a pioneer in the development and validation of new techniques to their study. He has participated in many National and International Committees and Task Forces to establish standards for motility procedures and training in motility. He has participated in the development 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 of the Neurogastroenterology Committee of NASPGHAN. He has been recipient of the Senior Investigator Award from IFFGD as well as the Research Mentor Award from the AGA. Recently he was portrayed in the Major Motion Picture: “Miracles from Heaven”.

Dr. Nurko has been very active in providing care and fostering education in Latin America. He works closely with minority premed students. He’s been formally recognized by the Hispanic community and received the Milagros para Ninos award for clinical excellence, and recognition from the Hispanic Chamber of Commerce, and the City of Boston for his service to the Latin community.
Max J. Schmulson W., MD

Professor of Medicine
Laboratorio de Hígado, Páncreas y Motilidad (HIPAM)
Unit of Research in Experimental Medicine
Faculty de Medicine-Universidad Nacional Autónoma de México (UNAM)
Hospital General de México
Mexico City, 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 trained in Internal Medicine. 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. While under the mentorship of Emeran Mayer at UCLA, he focused 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, the immunological factors and the microbiota/microbiome 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 90 papers on peer-reviewed journals, 4 books and 55 book chapters on Functional Gastrointestinal Disorders. In 5 opportunities he received the award “Dr. Abraham Ayala González” and the Epidemiological Research from the Mexican Gastroenterological Association. He worked in the Latin American Consensus on IBS and coordinated the Latin American Consensus on Chronic Constipation. Dr. Schmulson previously served as Chair of the Membership Committee of the Functional Brain Gut Research Group. In 2006, as a founding member of the Latin American Society for Neurogastroenterology her served as their first President. He has 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. Currently he is Founder and Co-Editor in Chief of the new journal NeurogastroLATAM Reviews.

He is a National Researcher (SNI-II) and a member of the National Academy of Medicine in Mexico. Regarding the Rome Foundation, Dr. Schmulson worked on 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 was a charter member of the International Liaison Committee serving 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 is a current member of the FGIDs Global Study Executive Committee and Co-Director of the Biobank and Biomarker Core of the recently created Rome Foundation Research Institute.

Magnus Simrén, MD, PhD

Professor of Gastroenterology
University of Gothenburg
Senior Consultant, Department of Internal Medicine
Sahlgrenska University Hospital
Gothenburg, Sweden

Dr. Magnus Simrén 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. He was visiting research scientist at the Center for Functional GI and Motility Disorders, University of North Carolina (UNC), Chapel Hill, NC, United States 2015-2016, and currently holds a position as Adjunct professor at UNC (2017-). Since 2013 he has a combined position as Professor of Gastroenterology at the University of Gothenburg, and Senior Consultant at the Sahlgrenska University Hospital in Gothenburg, Sweden.

Dr. Simrén is head of the Neurogastroenterology Unit at Sahlgrenska University Hospital. 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 240 original articles and also written book chapters on GI motility diseases and functional GI disorders, and is currently supervisor for nineteen PhD students and five 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 served as council member for several international organizations. He has been the chair of the United European Gastroenterology (UEG) Scientific Committee 2013-2017, and is currently the UEG Secretary General (2018-2021), and a member of the UEG council (2013-2021). 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 is a member of the Rome Foundation Board of Directors since 2011. 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. Dr Simren is the Research Director of the Rome Foundation Research Institute (RFRI) 2017-.
Ami Sperber, MD, MSPH
Emeritus Professor of Medicine
Faculty of Health Sciences
Ben-Gurion University
Negev, 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 continued involvement in 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 FGIDs, in particular sleep impairment and fibromyalgia, and (c) psychosocial aspects of FGIDs. 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 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. He chaired the Rome IV chapter committee on Cross-cultural factors in FGIDs. He contributed 4 cross-cultural cases to the Rome IV Multidimensional Clinical Profile (MDCP) book. He currently chairs the Executive Committee of the FGID Global Epidemiology study, which is being conducted in 33 countries around the world. He is the ongoing head of the Rome Foundation Translation Project. 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.

Jan Tack, MD, PhD
Professor and Head of Department, TARGID
University of Leuven
Head of Clinic, Gastroenterology Division
University Hospitals Leuven
Leuven, Belgium

Professor Jan Tack is Head of Clinic in the Department of Gastroenterology, a Professor in Internal 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 700 articles and more than 45 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 chief editor or editor for Neurogastroenterology and Motility, Gastroenterology, Gut and Digestion. He serves or has served as a member of the editorial board of Gastroenterology, American Journal of Gastroenterology, Alimentary Pharmacology and Therapeutics, Journal of Internal Medicine, Bailliere’s Best Practice and Research in Clinical Gastroenterology, Annals of Gastroenterology and Journal of Gastroenterology.
Advisory Council

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

MEMBERS OF THE ADVISORY COUNCIL

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Ardelyx
Commonwealth Diagnostics Intl. Inc.
Danone Nutricia Research
Genova Diagnostics, Inc.
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Mallinckrodt/Sucampo AG
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Shire Pharmaceuticals
Synergy Pharmaceuticals
Zeria Pharmaceutical Co., Ltd

ACADEMIC ADVISORY COUNCIL

American Gastroenterological Association
International Foundation for Functional Gastrointestinal Disorders
### Johannah Ruddy
**Executive Director**

Mrs. Ruddy joined the Rome Foundation as Executive Director in 2017 and works with the President and Board of Directors as the liaison with industry contacts as well as potential sponsors. Mrs. Ruddy also organizes all public aspects of Rome Foundation and coordinates the Clinical Symposia, lectureships and other major medical conferences such as DDW and UEGW. Prior to joining the Rome Foundation, Mrs. Ruddy served as the Executive Director of the American Academy of Pediatrics New Mexico Chapter and the American Heart Association, as well as other nonprofits throughout the Southwest. She lives in Wake Forest with her husband and two children.

### Mark Schmitter
**Marketing Director**

Mark is a graduate of the University of Georgia in marketing and, for the last 25 years, has worked in account management and consulted with prestigious marketing and advertising agencies like J. Walter Thompson, Saatchi and Saatchi, ICC Lowe, and Cline Davis & Mann. His expertise has been in the concept development, creation and implementation of marketing campaigns for various pharmaceutical products including those in gastroenterology and oncology as well as other medical areas.

Mr. Schmitter is continuing to create and implement strategic marketing plans for Rome IV. He is also serving as contact person for academicians and industry sponsors with regard to international translations, licensing and bulk order sales.

### Diane Cardamone
**Administrator**

Diane Cardamone began working for Rome Foundation since 2017. Her time and attention is focused on providing general administrative assistance, facilitating meetings, and planning events for annual CME programs.

Diane originated from New York. After Ohio State University and Baruch Business College, Diane began her career in NYC working in the advertising industry managing accounts for consumer products. Diane’s career shifted bringing her to working in Australia as Client Liaison.

Currently, Diane lives with her family in Raleigh, North Carolina.

### Eric Chapman
**Information Technology Director**

Eric Chapman has been working in Information Technology in higher education, banking, and medical industries since 1999. He has provided technical support for Rome Foundation since 2007.

He received a B.S. in Geographic Information Systems from Radford University in 1998.
Emily McGee  
Operation Director

Emily McGee has assisted the Rome Foundation in various capacities since 2014, becoming a permanent part of the team in fall 2016 as Project Manager. She focuses her efforts in several areas, including organizing Rome’s exhibit booths at conferences, assisting with the various copyright, licensing, and translation requests for Rome’s instruments, and acting as liaison with Rome’s numerous working committees. Emily originated from the west suburbs of Chicago, Illinois and graduated from the University of North Carolina at Chapel Hill in 2013. At UNC, she received her BA in Business Administration and Sports Administration while playing on UNC’s Division I volleyball team. Before joining the Rome Foundation, she worked in Project Management in the financial industry in Chicago, Illinois.

Ceara Curran Owre  
Web and Graphic Designer

Ceara Owre began working with the Rome Foundation in 2007. She runs her own design company, Ceara Owre Design, based in Chapel Hill, NC. Ceara received her B.A. in fine arts from St. Michael’s College, Vermont, and has studied at the Royal College of Art, London. She currently manages the Rome Foundation website and design of it’s bi-annual newsletter, Rome Foundation Reporter.

Chaitanya Pabbati, MD  
Technical Consultant, Managing Editor for Rome Foundation Interactive Clinical Decision Toolkit

Chaitanya Pabbati was raised in Seattle and completed his undergraduate studies at the University of Washington, followed by his medical training at the Mayo Clinic. During this time, Chaitanya began to engage in research in suicide epidemiology and worked on public policy to provide psychiatric care to low-income populations. While completing his psychiatric residency at UC San Diego, Chaitanya continued to work on suicide epidemiology and also focused on mental illness among healthcare professionals. He also served as the Resident/Fellow Member representative to the American Psychiatric Association for the state of California to the American Psychiatric Association, with his role focusing on increasing transparency and ease of process. As Chief Resident, Chaitanya helped to develop an online curriculum incorporating both foundational psychiatric teachings along with current research.

Chaitanya currently serves as the Communications Chair for the San Diego Psychiatric Society and also helps to organize their annual Continuing Medical Education (CME) event. He is also the medical director the VA San Diego Mental Health Intensive Case Management (MHICM) program. His work with the Rome Foundation has been to serve as the Technical Consultant having worked on an iPad App for the Rome algorithm, and then on the ROME Foundation Interactive Clinical Decision Toolkit. Chaitanya continues to provide technical updates for the Toolkit, and is also overseeing it’s continuing maintenance and development as the premier diagnostic and treatment tool for Functional GI Disorders.
Claudia Rojas
Latino Coordinator

Ms. Claudia Rojas is our administrator representative for Latin America. Ms. Rojas is originally from Cúcuta, Colombia and has enjoyed a career in the hospitality and marketing industries. She has a heart for the Hispanic community and is currently the program manager for the Center for Latino Health (CELAH), at the University of North Carolina in Chapel Hill, which she helped develop with Douglas Morgan, MD and also works with UNC TraCS and CTRC coordinating studies and clinical trials.

She serves as the translator for Rome materials into Spanish, assists with communications and membership programs (especially as they relate to the Hispanic community), and provides meeting support for Rome meetings, trade shows and exhibits.

Jerry Schoendorf
Medical Illustrator

Jerry Schoendorf is a medical illustrator and anaplastologist who has worked on many clinical teaching slide projects for the American Gastroenterological Association and on Rome II, Rome III, Rome IV and the Computer-based Learning Program for the Functional GI Disorders. He has directed and coordinated media and art departments at the Rehabilitation Institute of Chicago and at Duke University Medical Center and has recently retired from private practice in Durham, North Carolina.

Davis Stillson
Videographer

Davis Stillson is a 1977 graduate of UNC-CH with a BA focused on video production. He worked at the UNC School of Medicine for 28 years with physicians and medical educators producing over 160 videos. Davis founded Davis Stillson Associates in 2006, a video production group that focuses on videos for health, education and the humanities. Mr. Stillson has worked for the Rome foundation as a video producer/director and media consultant since 2012. He is currently working on multiple projects for the Rome Foundation to promote its agenda by creating and disseminating media for their website and YouTube channel.

Debra Wildeman
Finance Administrator

Debra joined the Rome Foundation in 2018 as the Finance Administrator. She is a native of Huntington, New York and has worked for Citibank (Citigroup) for 23 years in NY, MD, and DC in the financial sector of the Bankcard Division. Debra moved to the Charlotte area in 2005 and has a long history of community service and work in the nonprofit arena providing financial and administrative support.
Rome IV

Provides unique, comprehensive and up to date learning tools for clinicians caring for patients with FGIDs

After five years of hard work by over 120 investigators and clinicians, Rome IV launched at the 2016 Digestive Disease Week conference (DDW 2016). Representing the collective efforts of the world’s best minds in FGIDs research and care from over two dozen countries (see Figure 3), Rome IV offers the latest update to The Rome Foundation’s acclaimed diagnostic criteria backed by a host of products designed to implement and complement our unique and effective approach to understanding and treating FGIDS. At DDW 2016 the following printed materials were made available.

Rome IV Diagnostic Algorithms for Common GI Symptoms is the second edition of our useful algorithmic approach to evaluating common GI symptoms. It is designed to aid clinicians by guiding them through a logical pathway to diagnosis. It features new sets presenting symptoms and also algorithms in pediatrics.

Rome IV Functional Gastrointestinal Disorders for Primary Care and Non-GI Clinicians provides access of Rome IV information to doctors on the front lines of clinical care as well as other nongastroenterological physicians. Indeed, the Rome Foundation philosophy and approach to FGIDs is modified into more concise information to meet the needs of the busy nonspecialist clinician.

Rome IV Pediatric Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction provides in one volume all the information that will help clinicians navigate the difficult diagnostic conditions presented by young patients and their families. The book contains the Rome IV clinical chapters, the pediatric diagnostic algorithms and MDCP cases as well as questionnaires and criteria for diagnosis.

Rome IV Diagnostic Questionnaires and Tables for Investigators and Clinicians provides the framework for further epidemiological and clinical research on FGIDs according to the Rome IV criteria. In just the last 9 months since the launch of these print books thousands have been sold internationally through individual and bulk sales. We now look forward to expanding our educational effort by utilizing other ways to educate.

Rome IV Books and Printed Educational Materials—For Research, Diagnosis, and Treatment

Rome IV Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction. The basis of our educational materials begins with this two volume set. With several new chapters, updates in pathophysiology and new diagnostic and treatment recommendations the Rome IV book set provides complete learning of the FGIDs. In addition there are 5 additional books:

Rome IV Diagnostic Algorithms for Common GI Symptoms is the second edition of our useful algorithmic approach to evaluating common GI symptoms. It is designed to aid clinicians by guiding them through a logical pathway to diagnosis. It features new sets presenting symptoms and includes pediatric algorithms.

Rome IV Multidimensional Clinical Profile for Functional Gastrointestinal Disorders (MDCP), in its second edition puts the Rome approach to FGID care into practice using a case-based learning format (72 cases). The unique multicomponent approach to treatment takes into consideration not just the diagnosis, but meaningful clinical subset information, impact of the disorder, psychosocial comorbidities and physiological features including biomarkers, all as part of a case based approach. Rome IV Diagnostic Algorithms for Common GI Symptoms is the second edition of our useful algorithmic approach to evaluating common GI symptoms. It is designed to aid clinicians by guiding them through a logical pathway to diagnosis. It features new sets presenting symptoms and also algorithms in pediatrics.

Rome IV Interactive Clinical Decision Toolkit. This intelligent software system addresses the sophistication and complexity of FGID diagnosis and treatment by interactively assisting practitioners in achieving optimal clinical outcomes, and in real time. It offers an online way to access both the Rome IV Diagnostic Algorithms and the Rome IV Multidimensional Clinical Profile for FGIDs (MDCP). But

Figure 3. Rome IV Participants

Rome IV Online. We have captured all of the Rome IV books and placed them on a digital platform www.omeonline.org/romeonline-books. For a small fee (subscriptions for 1, 6, 12 months or 10 years) the user can: 1) review thousands of pages of content, over 50% more information than in the printed books, 2) easily and intuitively navigate chapters within a book or across all books, 3) do free text searching in the entire platform using clear displays, similar to doing a google search, 4) access over 700 high quality graphic images not available in the printed books, 5) purchase and download for a nominal fee any of these images as powerpoint slides for self learning or teaching. Rome IV Online is a popular option for clinicians, investigators and institutions as it will always be password accessible on any digital platform. Discount options are available for those purchasing companion hard copy Rome IV books.

Rome IV Interactive Clinical Decision Toolkit. This intelligent software system addresses the sophistication and complexity of FGID diagnosis and treatment by interactively assisting practitioners in achieving optimal clinical outcomes, and in real time. It offers an online way to access both the Rome IV Diagnostic Algorithms and the Rome IV Multidimensional Clinical Profile for FGIDs (MDCP). But
in addition, the information is modifiable; expert clinicians from the Foundation’s Board of Directors have refined this information to fit the intelligent software platform. Furthermore, since the print books won’t be modified until Rome V, we have created the means to enhance the content of the toolkit by adding information on new scientific studies and treatments that are reviewed and vetted by Rome Foundation experts. Thus, the toolkit is a dynamic interactive tool that provides the most up-to-date clinical information, all in one place.

The program guides practitioners through a series of diagnostic and treatment pathways to offer the best clinical options (Figure 4). Navigation is very flexible, letting the user explore, select, and deselect different decision points in any order. At each decision point, users have dynamic access to relevant information and citations to confirm their conclusions or to provide enhanced guidance. Furthermore, users can work with the program in real time when caring for patients. They can enter clinical information and come back weeks later to input the clinical response and update the database, moving through new diagnostic or treatment pathways as needed. The intelligent software program also continues to learn from user input. When decision branches occur that contain uncertainties, the information is made available to the board of experts who modify the algorithm to improve its performance. We believe that this innovative 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.

**E-books through Amazon.com.** For those interested in e-books, the Rome IV product line (Rome IV volumes 1 and 2, MDCP algorithms, pediatric, primary care and questionnaire books) are available for download through Amazon ebook platforms and have within book search capability. E-books cost the same as the printed version and can be purchased individually or through bulk discounts.

**Rome IV slide sets.** The Rome IV slide sets (Figure 5) created by the Rome IV chapter committees contains all the graphical images used in our Rome IV education materials: 1) Rome IV complete slide set, with images and videos from the print and online Rome IV chapters, and 58 slides of the Rome IV diagnostic criteria 2) Rome IV MDCP slide set, containing 72 cases (2-3 slides each case) containing the history, the MDCP categories and the recommended treatments, and 3) Rome IV algorithm slide set that includes 35 slides for presentation.

Images can be purchased individually or as complete sets through our online bookstore, or individually through Rome IV online. Each multicolor image has a legend and up to date references; thus, sets are available for self-learning or for PowerPoint presentation at meetings and conferences. All printed and online educational materials will be available for bulk order at discounted prices, and Rome Foundation sponsors will receive an additional 20% off the discounted price. For further information, and to receive a listing of bulk order prices, please contact Mark Schmitter, marketing manager, at mschmitter@theromefoundation.org.

**Multiple International Symposia to Teach Rome IV**
Since the launch of Rome IV at DDW 2016, the Rome Foundation has had 26 multiple Rome IV launch symposia around the world and 132 Rome related presentations in 2017 alone! Major International meetings have been done at AGA (DDW), UEGW, ANMS the Pan American Meetings, the Japanese and Asian combined Neurogastroenterology meetings, the Brazilian Functional GI meetings, the Chinese Peking Union FGID meeting in Beijing and many national and regional meetings in Bologna and Rome, Italy; Gramado, Brazil; Mazatlan, Mexico; Tel Aviv, Israel, Veldhoven the Netherlands, Bogota Columbia, Lucknow India and Iasi Romania. Thus, we have been bringing the full complement of Rome IV educational products and resources to the international GI community to maximize our visibility and reach new audiences.

**Major Educational Symposia, Webinars and Podcasts**
A new feature this past year has been the development ourselves or with educational vendors to produce satellite symposia, webcasts and other programs with enduring digital material. This has included a simultaneous webinar for gastroenterologists in 12 Middle Eastern Countries using a sophisticated audience response system (sponsored by Acino Pharmaceuticals), webinars and satellite symposia for gastroenterologists, primary care providers (internists, NPs PAs) using case based, interactive formats (PER, Paradigm, Haymarket, Medscape), a series of regional educational programs designed to meet the needs of mid level providers (Rome Foundation), partnering with national GI organizations to do educational programs like key lectureships and webinars (AGA, ACG) and developing a series of workshops to enhance communication skills to optimize the patient provider relationship (PER).

Rome IV continues in its mission to provide unique, comprehensive and up to date learning tools for clinicians caring for patients with FGIDs.
**ROME IV CHAPTER COMMITTEES**

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<td>Guy E. Boeckxstaens, MD, PhD, Chair (Belgium) Henry P. Parkman, MD, Co-Chair (US) Fernando Azpiroz, MD (Spain) Michael Camilleri, MD (US) Sigrid Eisenbruch, PhD (Germany) Lesley A. Houghton, PhD (US) Gregor Lindberg, MD (Sweden) Daniel Sifrim, MD, PhD (UK)</td>
<td>Eamonn M. Quigley, MD, Chair (US) Giovanni Barbara, MD, Co-Chair (Italy) Christine Feinle-Bisset, PhD (Australia) Uday C. Ghoshal, MD (India) Javier Santos, MD, PhD (Spain) Stephen Vanner, MD (Canada) Nathalie Vergnolle, PhD (France) Erwin G. Zoetendal, PhD (Netherlands)</td>
<td>Michael Camilleri, MD, Chair (US) Lionel Bueno, MD, Co-Chair (France) Viola Andresen, MD (Germany) Myung-Gyu Choi, MD (Korea) Fabrizio De Ponti, MD, PhD (Italy) Anthony Lembo, MD (US)</td>
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<td>Margaret M. Heitkemper, PhD, Co-Chair (US) Lesley A. Houghton, PhD, Co-Chair (UK) Michael D. Crowell, PhD (US) Anton Emanuel, MD (UK) Albena Halpert, MD (US) James A. McRoberts, PhD (US) Brenda B. Toner, MD (Canada)</td>
<td>Ami Sperber, MD, Chair (Israel) Carlos Francisconi, MD, Co-Chair (Brazil) Xiucai Fang, MD (China) Shin Fukudo, MD, PhD (Japan) Mary-Joan Gerson, MD, PhD (US) Jin-Yong Kang, MD, PhD (UK) Max J. Schmulson W., MD (Mexico)</td>
<td>Rona L. Levy, MD, Chair (US) Lukas Van Oudenhove, MD, PhD Co-Chair (Belgium) Michael D. Crowell, PhD (US) Douglas A. Drossman, MD (US) Albena Halpert, MD (US) Laurie Keefer, PhD (US) Jeffrey Lackner, PsyD (US) Tasha B. Murphy, MD (US) Bruce D. Naliboff, PhD (US)</td>
<td>Ronnie Fass, MD, Chair (US) John E. Pandolfino, MD, Co-Chair (US) Qasim Aziz, PhD (UK) C. Prakash Gyawali, MD (US) Hiroto Miwa, MD, PhD (Japan) Frank Zeribib, MD, PhD (France)</td>
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<td>Grace H. Elta, MD, Chair (US) Peter B. Cotton, MD, Co-Chair (US) C. Ross Carter, MD (Scotland) Enrico Stefano Corazzari, MD (Italy) Pankaj Jay Pasricha, MD (US)</td>
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<td>Lynn Walker, PhD (US)</td>
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<td>Yunsheng Yang, MD (China)</td>
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<td>Paul Moayyedi, MD (Canada)</td>
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<td>Douglas Drossman, MD (US)</td>
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<td><strong>Primary Care</strong></td>
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<td>Pali Hungin, MD (UK)</td>
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<td>Niek DeWit, MD, PhD (Netherlands)</td>
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<td>Ceciel Rooker (US)</td>
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<td>Greg Rubin, MD (UK)</td>
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<td>Bohumil Seifert, PhD (Czech Republic)</td>
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<td>W. Grant Thompson, MD (Canada)</td>
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Background: Over the past 5 years the Rome Foundation has put in place a multi-faceted global initiative to implement the goals of the Foundation on a global level. This initiative is depicted in Figure 6 and described in the text below.

The Rome Board of Directors of a Global Committee has established a global committee, chaired by Dr. Ami Sperber, to coordinate all activities on the global level and to collaborate with other committees established by the Board of Directors such as the Education and Research committees. The structure of the Global Committee is depicted in Figure 7.

1. International Liaison Committee (ILC) and International Associates Program
   The ILC is chaired by Dr. Uday Ghoshal from India and is composed of representatives from different regions of the world. It will now be organized on a regional basis with the following regions working semi-autonomously under ILC auspices to promote the Rome Foundation global initiative in each region:
   - Eastern Europe
   - Asia
   - Africa
   - Middle East
   - Latin America
   - Western Europe, North America, Australia/New Zealand

2. RF Translation Project
   - To provide quality, validated translations of RF material into as many languages as possible, in particular the Rome IV adult and pediatric diagnostic questionnaires, diagnostic criteria, books, clinical algorithms, multi-dimensional clinical profile (MDCP).
   - To translate other RF-copyrighted questionnaires, notably the IBS symptom severity scale (IBS-SSS), the Bristol Stool Form Scale (BSFS), the IBS-Quality of Life scale (IBS-QOL), and the Celiac Disease Quality of Life questionnaire (CD-QOL).
   - To establish regulations for the licensing and use of Rome material in the framework of academic research and commercial clinical trials.
   - The Rome IV adult diagnostic questionnaire has now been translated into close to 25 languages and “localized” for several others and the Rome IV pediatric questionnaires is being translated into several languages.

The translation project website can be seen at: www.theromefoundation.org/products/rome-translation-project/.

The following are available on the website:
   - Downloadable RF translation guidelines (updated in June 2017).
3. IBS Global Perspective Conference
This conference, initiated by the RF and organized in collaboration with the WGO, was held in Milwaukee, WI in April 2011. It was co-chaired by Drs. Sperber and Eamonn Quigley. Over 100 participants from around the world, including gastroenterologists, psychologists, nurses, and other health care providers, attended the meeting.

Among the aims of the meeting were to:
- Foster greater interest in the global aspects of IBS.
- Foster the development of cross-cultural competence in the clinical and research arenas.
- Foster international research networks and improve the quality of multinational research in IBS.

A summary of the conference was published in the Red Section of AJG (Am J Gastroenterol 2012;107: 1602–1609). The article is online at www.nature.com/ajg/journal/v107/n11/pdf/ajg2012106a.pdf.

4. RF Working Team on Cross-cultural, Multinational Research in FGIDs
This working team, chair by Dr. Sperber and comprised of 18 members and consultants from all around the world, completed its major task and published a final report in January 2014. This report is available for download at: www.theromefoundation.org/working-teams-and-committees/multinational-committee/. It has also published three scientific papers in the medical literature. Please see the section of RF Working Teams on page 30 for full details on this working team.

5. RF Asian Working Team
The Asian working team committee, chaired by Dr. Kok-Ann Gwee from Singapore and co-chaired by Dr. Whitehead, has completed an extensive literature review and is currently coordinating an Asian multinational survey to obtain data that will help in the development of the Rome IV criteria. This data will broaden understanding of FGIDs and strengthen the diagnosis and treatment of FGIDs in Asia.

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

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

6. Rome IV book chapter on Cross-cultural aspects of FGIDs
This is a new chapter, which expands on material that appeared in the Rome III book on “Gender, Age, Society, Culture, and the Patient’s Perspective in the Functional Gastrointestinal Disorders.” The chapter committee membership reflected the global membership of the Rome Foundation and the chapter drew on material provided by the Working Team. The chapter committee has completed its work and prepared the chapter for the Rome IV book, the online version of the book, and an article for the special issue of Gastroenterology devoted to Rome IV, which has already appeared.

7. Cross-cultural MDCP cases
The Rome IV book “Multidimensional Clinical Profile (MDCP)” includes four cases with a cross-cultural background and focus.

8. A Global Epidemiology Study of FGIDs
(see Figure 8 for the global study timeline)

Achieving a clear picture of the epidemiology of FGIDs is very problematic, as discussed in detail in the recent Rome Foundation working team paper published in Gut (Sperber et al. The global prevalence of IBS in adults remains elusive due to the heterogeneity of studies: a Rome Foundation working team literature review. 2016, 66:1075-1082.

The aims of the present study are to:
- To conduct a Rome Foundation-sponsored multinational, collaborative global study of the epidemiology of IBS using the Rome IV questionnaire.
- Base the study design on the recommendations of the RF Working Team on Multinational, Cross-cultural Research.

Conduct of the Study (see Figure 9 for a map of the participating countries)
- Data collection has been completed in 26 countries and is near completion in the other countries (33 in all)

Analysis of results and publication
- We have developed and disseminated a protocol document on policy for data access, statistical analyses, and publications.
- We have established three committees to conduct the three main aspects of the study once data collection is completed:
  - Publication committee
  - Database committee
  - Statistical analysis cores
- Statistical analysis core
- Regional analyses cores

Anticipated outcomes:
- A clearer picture of the global epidemiology of FGIDs, using uniform and appropriate cross-cultural research methodology.
- Enhanced understanding of FGID pathophysiology.
- Publication of the study results at the local, regional, and global levels.
- Validation of the new Rome IV diagnostic criteria
- Establishment of a RF database with 70,000 – 80,000 records from the global study with a potential for ongoing future data mining.
- Validated translations of the Rome IV adult diagnostic questionnaire into multiple languages approved by the RF for future academic and commercial research on IBS and the other FGIDs.
The International Liaison Committee (ILC) of the Rome Foundation aims to expand its activities globally to help improving the life of the patients with functional gastrointestinal disorders (FGID) and to spread the knowledge on these disorders. In 2016, Dr. Dan Dumitrascu (Romania) completed his tenure as Chair after a highly productive 4 years. Dr. Dan Dumitrascu has been succeeded by Dr. Uday C Ghoshal as Chair. The other members of the ILC of the Rome Foundation currently include Enrico Corazziari (Italy), Dan Dumitrascu (Romania), Xiucai Fang (China), Carlos Francisconi (Brazil), Shin Fukudo (Japan), Carolina Olano (Uruguay), Max Schmulson (Mexico), and Ami Sperber (Israel), to increase awareness through educational and scientific activities globally in the Eastern European, Middle Eastern, Asian-Pacific, and Latin American regions.

In the recent past, several important activities were undertaken to fulfill the aims of ILC of the Rome Foundation. A series of presentations about Rome IV were held in the Asian Pacific Digestive Disease Week (APDW) 2017 in Hong Kong. The new issues in relation to Rome IV were presented in several Asian Meetings such as in Ipoh (Malaysia), Dhaka (Bangladesh), APNM, Korea. In Brazil, the Brazilian Congress on functional bowel disease (FBD) was held in May 2018 and another pan American meeting was held in São Paulo in which Rome Foundation was represented. In Brazilian DDW held last year, several sessions on FBD were presented.

In China, meetings were held to discuss how to apply Rome IV criteria in China with Rome experts on June 2017 (Guanzhou), and in Sep 2017 (Xi’an). 16th PUMCH symposium on FGIDs and psychological disorders was held on 21th October 2017. The Chinese version of multi-dimensional Clinical Profile (MDCP) was published on July 2017.

In India, a series of regional master classes on IBS in new Rome IV era was held in Jim Corbet, Hyderabad, Delhi, Kolkata, Lucknow and major Indian Congresses such as the Annual Congress of the Indian Society of Gastroenterology, Association of the Physician of India and Indian Motility and Functional Diseases Association. Another series of IBS Master classes were held in different cities in India (Chennai, Kolkata, and Bangalore) in Nov 2017. About 2000 copies of the Rome IV books were distributed among Indian physicians and Gastroenterologists. Video lectures were also distributed among Indian physicians and Gastroenterologists.

In Bangladesh, a single day monothematic meeting and Rome Foundation-endorsed sessions during Annual Congress was organized under the Bangladesh Society of Gastroenterology in Dhaka in November 2017 and February 2018.

In Israel, several meetings were held under the auspices of the Israel Gastroenterology Association; in these meetings several key members of the Rome Foundation participated. Special training programs on FGIDs were also organized in Israel for nurses and medical students.

In Italy, in addition to several teaching programs on FGIDs, Rome IV IBS and functional constipation criteria and algorithms were distributed to more than 10,000 Italian physicians, and gastroenterologists.

In Japan, joint Conference of the Asian Neurogastroenterology and Motility Association and the Japanese Society of Neurogastroenterology and Motility was held 2017. A symposium on Clinical Practice Guideline for Irritable Bowel Syndrome and Chronic Constipation at the J-DDW in November 2018 was held in Japan. In addition, several sessions on FGIDs and Rome IV criteria were organized in various Japanese meetings.

In Romania, several sessions on neurogastroenterology were organized during the Romanian Annual Congress of gastroenterology Bucharest June 2017.

The Rome Global Epidemiology Study on FGIDs led by Dr. Ami Sperber is an important initiative that involved 33 countries. The futures goals of the Rome Foundation ILC include:

- Set up a liaison with regional organizations, which has already been initiated in some of the countries
- Advise the Rome Foundation on how to implement the Rome Foundation initiatives in these regions
- Be the liaisons for such activities in their respective Societies
- Assist in the global dissemination of Rome educational materials and activities
- Initiate multinational and cross cultural research and publication
- Motivate young researchers globally to take up research in FGIDs and mentoring them
Historically, the Rome Foundation was seminal in its efforts to develop criteria for diagnosis of the disorders of gut-brain interaction (FGIDs). The Rome criteria were rapidly accepted by all regulatory agencies for clinical trials. However, a major gap regarding clinical trials has been in the realm of pediatric disorders which have not had standard recommendations for research. Accordingly, The Rome Foundation has sponsored the development of a committee to develop guidelines for clinical trials in pediatric FGIDs. Under the leadership of Miguel Saps MD, the Rome Foundation Pediatric Committee on Clinical Trials also consisting of other expert in pediatric clinical research and study design: Marc Benninga, MD, PhD; Carlo Di Lorenzo, MD; John Lavigne, PhD; Adrian Miranda, MD; Miranda van Tilburg PhD, and Jan Taminiau, MD have undertaken this initiative. After three years of hard work, the committee in collaboration with the European Medicines Agency, completed its directive to develop a document on recommendations for clinical trials in IBS for children. It was published last November, 2016 in *Neurogastroenterology and Motility* (Saps M et al, *Neurogastroenterol Motil* 2016;28:1619-1631 PM:27477090).

As a second task of the Rome Foundation Pediatric Committee on Clinical Trials, Dr Saps invited a group of experts to provide recommendations for clinical trials for pediatric functional constipation: Marc Benninga, MD, PhD; Carlo Di Lorenzo, MD; John Lavigne, PhD; Samuel Nurko, MD, PhD, Ilan Koppen, MD, and Jan Taminiau, MD. These guidelines have been recently published in January, 2018 in *Neurogastroenterology and Motility* (Koppen IJN, Saps M, et al, *Neurogastroenterol Motil*. 2018;30(4):e13294.)

The IBS and functional constipation guidelines were presented by Carlo Di Lorenzo, MD; John Lavigne, PhD; Samuel Nurko, MD, PhD and Miguel Saps, MD at the Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics (GREAT V WORKSHOP) for Pediatric Irritable Bowel Syndrome and Pediatric Functional Constipation cosponsored by the FDA, AGA, ACG and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) on March 28th, 2018.

Moving ahead, the committee will undertake the development of guidelines for pharmacological clinical trials in children with functional dyspepsia. Beginning in 2018, this committee has been meeting with the FDA to advise them on their recommendations to provide guidelines for pediatric clinical trials.

**Rome Psychogastroenterology Group**

The Rome Psychogastroenterology Group was formed by US-based GI clinical health psychologists Laurie Keefer, PhD and Sarah Kinsinger, PhD, ABPP in 2018 based on a need to connect and support an emerging, international group of professionals interested in the clinical and scientific intersection of psychology and gastroenterology. Supported by the Rome Foundation liaison, Doug Drossman, MD and the Rome Foundation Board, our mission is to: 1) promote the use of evidence-based behavioral treatments for GI disorders internationally; 2) encourage development of interdisciplinary psychosocial GI programs in gastroenterology practices through expert consultation and lectureships; 3) connect with national and international GI organizations to enhance the visibility of GI Psychology providers and encourage collaboration; and 4) expand our field into previously under-studied areas of psychogastroenterology (e.g. inflammatory bowel diseases, chronic pancreatitis). There are several planned activities for the working group, including the development of high-quality training opportunities at national meetings or through webinars for mental health professionals interested in working with the GI population. We are also setting up opportunities to consult with gastroenterologists and administrators interested in developing a GI behavioral program at their institution. We already host an active listserv for clinical support and an online, searchable membership directory through our website. In our first year, we accrued a membership of 125 professionals from 16 countries and look forward to growing! To become a member, please email your name, credentials and contact information, and a brief bio and photo for inclusion in our membership directory to gastropsych@gmail.com.

**Aim:** To provide structure and opportunity for growth for mental health professionals around the world engaged in the research and practice of PsychoGastroenterology

**Rationale:** The first organization dedicated to training, quality improvement and promotion of research and practice in PsychoGastroenterology

**Initiatives:**
- APA endorsed training for mental health providers
- Online training videos, webinars and case conferences
- Consultations to help clinicians, investigators and administrators develop programs locally
- Visiting PsychGastroenterology Scholarships
- Database of providers for medical clinicians

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**Committee Composition:**

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<tr>
<th>Name</th>
<th>Position</th>
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<tr>
<td>Miguel Saps, MD</td>
<td>Chair</td>
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<td>Carlo Di Lorenzo, MD</td>
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<td>Marc Benninga, MD</td>
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<td>Miranda van Tilburg, PhD</td>
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**Administration:**

Laurie Keefer, PhD, Chair
Sarah Kinsinger, PhD, ABPP, Co-Chair
Douglas A. Drossman, MD, Rome Board Liaison

The first organization dedicated to training, quality improvement and promotion of research and practice in PsychoGastroenterology
Scientific developments during recent years offer the potential for our knowledge of FGIDs to expand significantly. However, research exploring these novel approaches often occurred in relatively small single-center patient cohorts in advanced research centers. The Rome consensus process, which generates the Rome criteria and Working Team Reports on specific aspects of FGIDs, readily identifies the gaps in our knowledge. Advancing the field requires standardized state-of-the-art data collection, preferably with a broad international scope. While several databases may already exist, they are usually confined to a single center and are not constituted using uniform data-collection methods. There is now a compelling need to advance the science through a research infrastructure that will integrate a well-coordinated international research program by expert investigators with creation of a patient database and biobank for prospective studies to implement advanced FGID phenotyping, identify risk factors, develop suitable biomarkers, evaluate novel or emerging diagnostic tools, guide choices of existing therapies, and advance therapeutic innovation and optimization. The Rome Foundation is uniquely able to bring in world class investigators and to recruit patients internationally using uniform validated selection criteria for conduct of research studies in FGIDs. The Rome Foundation also has a portfolio of Rome IV and other questionnaires in multiple languages and can also license from our extensive library a large variety of research questionnaires developed for and used in the FGID population.

With this as a background, the Rome Foundation is therefore developing and planning the Rome Foundation Research Institute (RFRI), to provide an infrastructure for multi-site multidisciplinary research. This has now been planned and discussed within the Rome Foundation during the last year, as well as discussed with external stakeholders with an interest in collaborative efforts in running large multinational research projects in the field of FGIDs or disorders of gut brain interaction. In January this year a planning meeting with Rome Foundation members and industry partners was held in Chapel Hill, NC, where the organization and goals of RFRI were thoroughly discussed. The work before, during and after that meeting has led to the creation of an organizational structure of the RFRI, a budget proposal and planning of several projects to be run by RFRI. At DDW in Washington this will be discussed and fine-tuned further and thereafter the plan is to launch RFRI officially and the planned activities can start.

**Mission and implementation RFRI:** The aim of RFRI is to create an international academic research institute that advances scientific understanding of the disorders of gut-brain interaction, and implementation of the aims can be seen in Table 1. Through a process of growth and gradual increase in the number, scope, and types of projects, as well as the number of centers involved in the projects, the Rome Foundation wants to advance the Research Institute to become the global leader in FGID research. The Rome Foundation believes the best opportunity for achieving these goals will be to actively collaborate with Industry, other academic non-Rome stakeholders and funding agencies.

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**ROME FOUNDATION RESEARCH INSTITUTE**

**Vision**

*To be the global leader in FGID research.*

**Mission**

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

**Aim**

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

**Implementation**

*Establish an international academic research initiative with leading experts, in order to facilitate global FGID research through collaboration with industrial and academic partners and with the following objectives:*  
1. Develop a centralized data acquisition and research coordinating center.  
2. Serve as an international clearinghouse for investigators and industry in the development, administration and analysis of clinical research in FGIDs.  
3. Develop a portfolio of current and future study protocols and an accessible database of knowledge which can be adapted to address specific questions regarding FGID pathophysiology, impact, diagnosis and treatment.

**Overall structure of RFRI:** The institute will be directed by Dr. Magnus Simrén (Research Director), who together with Drs. Jan Tack and Douglas Drossman form an executive committee who coordinate the activities in RFRI (see Figure 10). The Executive Committee, with advice from a Research Advisory Committee, consisting of international Rome Foundation Board Members and selected external members covering adult and pediatric clinical and translational research in FGIDs, and the Industry Council, comprised of representatives of companies that provide financial support to the RFRI, will be ultimately responsible for assuring the aims and objectives of the program are achieved (Figure). The work within RFRI will be done on the RFRI Cores with dedicated tasks, in line with project needs. The activity of the Cores will be determined by the ongoing and expected activities and workload within the RFRI, and their composition may vary accordingly. Three of the cores (“Biometry, Data Management, and Analysis,” “Clinical Research Network Core,” and “Biobank and Biomarker Data Core”) will be actively involved in specific aspects of protocol development and implementation, and as a consequence will
often collaborate on a given protocol. The Administrative Core will be responsible for the oversight of the RFRI which includes research, training, and education-dissemination activities, and for the overall administration of the RFRI, involving clinical services research, training, collaboration with sponsors and outside agencies, and education. The Biometry, Data Management and Analysis Core will be responsible for providing and/or ensuring the standards for high quality data management systems, quality assurance processes and statistical analytic methodology aspects for the RFRI. The Clinical Research Network Core will be responsible for providing the infrastructure and maintaining the standards for clinical investigative studies involving epidemiological, clinical, outcomes, and treatment studies. This Core serves as a clearinghouse for research and is responsible for identification and selection of study centers. The Biobank and Biomarker Core will be responsible for defining relevant biomarkers and protocols to analyze these, and for identifying centers and sites with expertise and infrastructure necessary to collect, store and analyze biological samples for large-scale multinational research project. The Education, Dissemination and Media Relations Core will serve primarily to assure quality control in the dissemination of research knowledge that is accumulated from the RFRI.

Within RFRI different studies and research programs will be initiated, with a large multicenter study aiming at defining relevant biomarkers in functional GI disorders (ROBOT – Rome foundation BiOmarker project) being one example, and a clinical trial run in primary care in Belgium (the DOMINO trial) being another. The research organization planned for our future trials with a network of international research centers is currently being implemented through our large, global epidemiology study the Rome Foundation Global Epidemiology Study. This study is currently evaluating the population prevalence of FGIDs in more than 70,000 adults in 33 countries, in addition to assessing factors associated with fulfilling diagnostic criteria for one or more FGIDs. The organization developed in this study will form the backbone of new studies within RFRI. With RFRI and the planned research activities and collaboration between experts in FGIDs across the globe as well as with external stakeholders we are confident that we will be able to improve the lives of patients with FGIDs through ground-breaking research.

The Rome Foundation has a copyright policy and licensing fee schedules for usage of its copyrighted instruments and available translations. In 2010, the Rome Foundation created a copyright committee consisting of John Kellow MD, Magnus Simrén, MD, PhD, and Ami Sperber, MD. At this time we have the following instruments. Licensing and a fee schedule for use of these instruments is available through the Rome Foundation www.theromefoundation.org/products/copyright-and-licensing. Rome Foundation Industry sponsors and academic investigators are charged only a nominal administrative fee.
Rome Foundation Mentorship Program

In line with the mission of the Rome Foundation to improve the lives of people with functional gastrointestinal disorders, one of our goals is to advance the scientific understanding of their pathophysiology and optimal clinical management. This requires high quality research that enhances the state of knowledge, but many aspects remain under-studied. For young investigators who are interested in setting up research in functional gastrointestinal disorders, there is often a lack of availability of experienced guidance and mentorship. To address this need, the Rome Foundation set up a Young Investigator Mentoring Program. The program is co-chaired by Magnus Simrén and Jan Tack and is co-organized by Dianne Bach and Michael Stolar, well-known from their past work for the AGA Institute.

The program was started with a call for Young Investigators to submit brief outlines of research projects early in 2017, and had its inaugural meeting at Digestive Disease Week 2017. Based on the originality and relevance of the proposed studies, and the potential for improvement through peer feedback, five international applicants were selected. The selected applicants were emerging investigators from India, Korea, Malaysia and the United States. The selected research topics were very diverse, including the pathophysiology, diagnosis and impact of functional abdominal bloating, the use of a nutrient drink test in cyclic vomiting syndrome, the prevention of age-related loss of Interstitial Cells of Cajal, a prospective study of naturopathic approaches to IBS in academic teaching hospitals and a double blinded randomized control trial to assess the effect of improving self-efficacy on outcomes in children with functional constipation.

Each young investigator briefly presented his or her project before a panel of experienced researchers in functional gastrointestinal disorders, who provided feedback, identified pitfalls or opportunities and gave recommendations to optimize study design, conduct and outcome parameters. The interactions were lively and feedback from the candidates confirmed the usefulness of the program and a high level of appreciation of the comments and recommendations they received.

The initial success of the program in 2017 provided a substantial stimulus to continue the program at this year’s Digestive Disease Week. The young investigators who were selected in 2017 and who are attending DDW 2018 will present a brief progress report on their research. A new call for applicants went out early 2018, from which four international applicants were selected who will in turn present their research proposal to a slightly expanded expert panel. The selected applicants are young investigators from Bangladesh, Gibraltar, Japan and Mexico. Topics include the treatment of post-infectious IBS, group therapy for IBS, differences in lifestyle and FODMAP intake between chronic constipation and IBS with constipation, and management options for bacterial overgrowth.

The mentorship program creates a unique opportunity for early stage researchers to start their studies in an optimized conditions, and also provides them with a network of experts to consult during the planning, execution or analysis of studies. Based on the positive responses it generates, the Rome Foundation’s Young Investigator Mentorship Program clearly fulfills a major need and will help to shape the future of functional gastrointestinal disorder research. Aspiring young researchers who missed this year’s call should consider applying in 2019!

The Associates of Rome program has grown to well over 2000 members in 84 countries since its inception in 2010.

Members are enjoying benefits such as:
- Discounts on Rome products
- Quarterly newsletters
- Conference registration discounts
- Certificate of Association
- Specially designed Associates of Rome pin

New Associates Benefit!
All Associates of Rome are eligible to download up to 15 Rome IV slides from the Rome IV Slide Set for FREE from our website.

To join, please visit our website at www.theromefoundation.org/associates-of-rome-program/.
The Rome Foundation has carried many roles since its inception but perhaps most important is its influence on the field with regard to the genesis and maturation of functional GI disorders. 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). The Rome Foundation in developing and promoting the use of symptom based criteria have in effect created the concept of functional GI disorders, now called more appropriately disorders of gut-brain interaction\(^1\). Historically the functional GI disorders had their genesis about 25 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.
The Rome Foundation has sponsored research by young investigators since 2007. The goals of the research program, chaired by Magnus Simren MD, are two: (1) to increase knowledge of the epidemiology and pathophysiology of the functional gastrointestinal disorders (FGIDs); and (2) to interest young investigators in research and clinical practice in the area of functional gastrointestinal disorders (FGIDs) 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 award two grants of up to $50,000 annually to postdoctoral research fellows, junior faculty, or established investigators seeking to develop new areas of research.

Applications may address any aspect of functional gastrointestinal and motility disorders from basic science to clinical diagnosis, treatment, health care delivery, epidemiology, or validation of the Rome diagnostic criteria. Basic and translational research applications should describe the relevance to the diagnosis and management of functional GI and motility disorders. Applications are submitted to the AGA and are reviewed by an independent panel of AGA and Rome Foundation appointed scientists. Rome Board members are not eligible to apply. Grants awarded in previous years are as follows:

**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 MrgrpC11 in sensory afferent neurons in the GI tract.

**2017 – TWO AWARDS**

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

**Principal Investigator: Geoffrey Preidis, MD, PhD (USA)**
Title: Bile Acid Receptor Mediated Dysmotility in Protein-Energy Undernutrition.

**2016 – TWO AWARDS**

**Principal Investigator: Izumi Kaji, PhD (USA)**
Title: Enteric neural FFA3 activation regulates colonic motility.

**Principal Investigator: Ans Pauwels, MPHarmSc, PhD (Belgium)**
Title: Is refractory gastro-esophageal reflux disease a disease spanning the organic-functional spectrum? Role of visceral hypersensitivity.

**2015 – TWO AWARDS**

**Principal Investigator: Miranda van Tilburg, PhD (USA)**
Title: Validation of the pediatric Rome IV criteria.

**Principal Investigator: Madhusudan Grover MBBS (USA)**
Title: Barrier function alterations in post-infectious irritable bowel syndrome.

**2014 – TWO AWARDS**

**Principal Investigator: Stacy Menees, MD, MS (USA)**
Title: A randomized controlled trial to assess the efficacy of the low FODMAP diet in patients with fecal incontinence and loose stools.

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

**2013**

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

**2012**

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

**2011**

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

**2010**

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

**2009**

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

**2008**

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

**RAY CLOUSE AWARD FOR THE BEST PAPER**

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

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

**2018**

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

**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)

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 WINNERS
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)

2013
Mats B.O. Lowen (formerly Larsson), MD, PhD (Sweden)

2012
Nathalie Bertiaux-Vandaele, (France)
Title: The expression and the cellular distribution of the tight junction proteins are altered in irritable bowel syndrome patients with differences according to the disease subtype. Am J Gastroenterol 2011;106:2165-73. PMID: 22008894.

2011 – TWO WINNERS
QiQi Zhou, MD, PhD (USA)

Tamira K Klooger, MD (Netherlands)

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 WINNERS
Anurag Agrawal, PhD, MRCP (UK)

John E. Pandolfino, MD (USA)

2008
Kristina Gecse, MD (Hungary)

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:

2018
Doris Vandeputte, PhD (Belgium)

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)

2014 – TWO WINNERS:
Madhusudan Grover, MBBS (USA)

Natasha Koloski, PhD (Australia)
Rome Foundation/AGA Institute Lectureships at DDW

In 2008, the Rome Foundation and the American Gastroenterological Association (AGA) launched a “prime time” lecturership at DDW with the goal to have outstanding speakers present on the broader areas of health care as related to the functional GI and motility disorders.

At DDW in June 2018, we are pleased to have three speakers discuss “Gut Microbiota and Functional Gastroenterology Disorders (Disorders of Gut-Brain Interactions)”.

The talks will be:
- Post-infection Functional GI Disorders (FGIDs) with Giovanni Barbara
- Gut Microbiome-Brain Interactions: Relevance for FGIDs with Premysl Bercik
- Microbiota Modulation in FGIDs: Probiotics, Antibiotics and FMT with Eamonn M. Quigley

Previous Lectures from this series are listed below:
- 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 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” with Premysl Bercik
- 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
- 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

Rome Foundation Launches Regional CME Symposia for Nurse Practitioners (NPs) and Physician Assistants (PAs)

As the healthcare system in the United States continues to evolve, the Rome Foundation Education Chair, Dr. Lin Chang and Rome Executive Director, Johannah Ruddy have launched regional symposia aimed at providing both diagnostic and treatment education for health care providers on the most common disorders of brain-gut disorders, also known as functional gastrointestinal disorders. In 2017, Rome conducted a needs assessment among NPs and PAs and found a gap in knowledge for both diagnosis and treatment of issues such as irritable bowel syndrome (IBS), Functional Constipation, Functional Heartburn and other Esophageal Disorders. Locations for the educational symposia were chosen based on population and the number of NPs and PAs in each area for maximum impact.

Dr. Chang will head the symposia as one of 6 renowned speakers, also including Drs. William D. Chey, Doug Drossman, Laurie Keefer, and others. Accreditation for these 1½ day symposia has been provided and will include CME/CE credits for up to 12.0 hours for attendees. If you know health care providers (including NPs, PAs, dietitians, psychologists) who could benefit from these symposia, registration is only $125 per person (if registered by Aug. 1; price increases to $145.00 after Aug 1st) online at www.romefoundation.org/CME. We look forward to providing the same world class education that Rome Foundation is known for to these clinicians in practical, hands on sessions.

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<tr>
<th>Date</th>
<th>Location</th>
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<tr>
<td>October 13-14, 2018</td>
<td>Santa Fe, New Mexico</td>
<td>Hilton Santa Fe Buffalo Thunder</td>
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<tr>
<td>January 19-20, 2019</td>
<td>New York, NY</td>
<td>Crowne Plaza Times Square</td>
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<td>February 9-10, 2019</td>
<td>San Antonio, TX</td>
<td>Venue TBD</td>
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<td>June 15-16, 2019</td>
<td>Myrtle Beach, SC</td>
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Education Program

Education Committee
The Rome Education Committee, chaired by Lin Chang, MD, was formed by the Rome Foundation Board at the December 2007 strategic planning meeting to educate physicians and other health care providers about functional GI disorders (FGIDs) through a variety of approaches. Since that time, we have developed a host of educational tools and programs which reflect the latest research, engineered to guide health care providers with the most current and practical tools in the field of FGID. Some of the programs under the Education Program have included the Rome Foundation - AGA Institute Lectureship at DDW, the Regional CME Symposium for Nurse Practitioners and Physician Assistants, and various symposia and workshops. Our educational programs and tools have been updated based on Rome IV.

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 FGIDs. We approached Pali Hungin, MD, a leading expert in the primary care of FGIDs, has led our educational materials for primary care. The Rome Foundation Primary Care Committee published two articles on how nongastroenterologists see FGIDs and the Rome IV primary care book. 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 MDCP is a unique learning tool which redefines the way clinicians can care for their patients who have even the most complex functional GI disorders. The Rome Foundation had over 30 original MDCP cases published in our 1st edition book. We updated these cases and added additional ones based on the Rome IV diagnoses in our 2nd Edition book. These MDCPs, which covers the full spectrum of functional GI disorders from mild to severe, are meant to be clinically valuable to students, practitioners in gastroenterology and primary care, health care extenders, or anyone who treats patients with FGIDs. After completion of these case exercises, the reader will be well prepared to address the full spectrum of treatment options available to help our patients. The Rome Foundation gathered the world’s leading experts to create an intuitive learning model that incorporates how good clinicians approach treatment of these disorders. The key factors are organized into a simple and logical 5-component framework. Using this information, we provide a treatment plan uniquely targeted to the patient.

Lecture Programs
The Rome Foundation sponsors a variety of lectures and professional meetings. Since 2008, we have an annual Rome-AGA Institute lectureship at DDW as well as Rome Symposia at Conferences around the world. As we completed Rome IV, we had many Rome symposia that were focused on the new Rome IV information as part of our Rome IV launch. Our International Visiting Professorship and Lectureship Program was conducted in 2015-2017 (see below). This unique program allows key experts to disseminate the new knowledge of FGIDs at a global level. We are also starting a Regional CME Symposium for Nurse Practitioners and Physician Assistants which is described further below.

Rome Foundation International Program for Visiting Professorships and Lectureships
The Rome Foundation’s visiting professorship (usually 2-3 days) and lectureship (1-2 days) program was created to improve knowledge on functional GI disorders. Speakers were internationally recognized in their areas of expertise, and selection is based on matching selected topics with the speakers. Over the past 2 years, these lectureships were successfully conducted internationally at many medical centers, academic programs, community hospital programs and “gut clubs”.

Rome Foundation Regional CME Symposium for Nurse Practitioners and Physician Assistants
The Rome Foundation has launched regional symposia aimed at providing both diagnostic and treatment education for clinicians on the most common brain-gut disorders. In 2017, Rome conducted a needs assessment among NPs and PA’s and found a gap in knowledge for both diagnosis and treatment of issues such as IBS, Functional Constipation, Functional Heartburn and Esophageal Disorders. Experts in the FGID field will give didactic lectures on these topics. In addition, there will be interactive workshops on patient-provider communication skills and a case-based session using the MDCP and interactive toolkit. Starting in the fall of 2018, there will be four regional meetings that were selected based on the number of NP’s and PA’s in each area for maximum impact.

Rome IV Interactive Clinical Decision Toolkit
The Rome Foundation in partnership with LogicNets®, the developer of an intelligent decision-support automation platform produced the Rome IV Interactive Clinical Decision Toolkit. This new intelligent software system addresses the sophistication and complexity of FGID 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. The interactive toolkit is now being incorporated into our educational conferences.

Rome IV Slide Sets
The Rome Foundation has developed over 800 images and slides for Rome IV and additionally a Rome IV Multi-Dimensional Clinical Profile (MDCP) slide set. The slides include notes and references covering the information provided in the Rome IV book. Designed by the world’s leading experts in functional GI disorders, the program allows for self-learning and presentations using the most up-to-date information. Purchase the entire slide set collection, specific modules by topic, or individual slides. They are available exclusively from the Rome Foundation website.

Website
In 2016 we updated and redesigned our website to provide more educational information to the public and health care professionals. Visitors can view our news and updates, order our educational products, download the Rome IV criteria, download the Rome III and IV Questionnaires and electronic scoring in SAS, learn about our research grant program and educational programs, view videos of the communication skills workshop, and learn about meetings and events. Visitors may also join our mailing list or become an Associate to receive periodic updates on Rome Foundation activities and our quarterly e-newsletters.

WWW.THEROMEFOUNDATION.ORG
Working Team on Gut-Brain Neuromodulators for FGIDs (Disorders of Gut-Brain Interaction)

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

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

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

Committee Composition:
- **Douglas A. Drossman, MD**, Chair  
  (Gastroenterology, Psychiatry/Psychosomatic Medicine)  
  *US*
- **Jan Tack, MD, PhD**, Co-Chair  
  (Gastroenterology, Gi physiology)  
  *Belgium*
- **Alex Ford**  
  (Gastroenterology, Meta-analysis)  
  *UK*
- **Eva Szigethy**  
  (Psychiatry)  
  *US*
- **Hans Ford Tornblom**  
  (Gastroenterology)  
  *Sweden*
- **Lukas Van Oudenhove, MD, PhD**  
  (Psychiatry)  
  *Belgium*
Rome Working Team

Post-Infection IBS

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

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

Update: The manuscript is under review at Gastroenterology.

Rome Working Team

The Role of Brain Imaging in Functional GI Disorders

Since the last Brain Imaging Working Team report published in 2009 (Neurogastroenterol Motil 2009;21:579-596), there has been an exponential growth in publications related to brain imaging approaches to study symptom based disorders, including chronic pain, disorders of mood and affect and functional GI disorders. In addition to the traditional fMRI and PET approaches, there also has been a dramatic expansion of imaging technologies (including resting state, structural, diffusion tensor imaging, MR spectroscopy, optical imaging, magnetic encephalography) and analysis strategies (including multivariate, connectivity, machine learning). The integration of insights gained from brain imaging data with those obtained from a) peripheral biological investigations and b) epidemiological and psychosocial studies has been slow.

The Working Team has reviewed and published findings from the fields of chronic pain, disorders of mood and affect and FGIDs, identify the key relevance of these findings for a better understanding for the pathophysiology of FGIDs, for biomarker identification and for a better understanding of pharmacological and non-pharmacological treatment approaches. Emphasis has been placed on identifying clinically relevant applications of the knowledge gained from these studies in terms of a better understanding of the pathophysiology of FGIDs, and in terms of the development and assessment of more effective treatments. Based on these insights, the Team has made recommendations for future study design to address gaps in current knowledge. The committee is completing their work and is submitting the manuscript for peer review.

Update: The manuscript is under review at Gastroenterology.
Rome Foundation - Asian Neurogastroenterology and Motility Association Working Team

The Rome - Asian working team was established in 2010 as a partnership between the Asian Neurogastroenterology and Motility Association (ANMA) and the Rome Foundation with the goals of developing culturally sensitive translations of the Rome III Diagnostic Questionnaire and carrying out a multinational survey of functional gastrointestinal disorders in Asia. The co-chairs of the working team were Kok-Ann Gwee (Singapore) and William Whitehead (U.S.A.), and the secretary was Andrew Chua (Malaysia). Other members of the team were Chen Min-hu (China), Hou Xiao-hua (China), Hiroto Miwa (Japan), Uday Ghoshal (India), Sutep Gonlachanvit (Thailand), and Bak Young-tae (Korea). The goals of the survey were to examine the appropriateness of the Rome III criteria for Asian patients and to broaden the understanding of FGIDs and strengthen their diagnosis and treatment in Asia.

Specific Aims:
1. Design a transnational survey for China, Taiwan, India, Japan, South Korea, Thailand, Malaysia, Singapore, Philippines, and Indonesia.
2. Develop and validate translations of survey instruments in target languages with guidance from Dr. Ami Sperber of the Rome Foundation.
3. Carry out a survey of patients with any FGID diagnoses presenting to primary and secondary care centers across multiple sites in Asia.
4. Understand the symptom presentation and diagnostic challenges, with a view to presenting recommendations appropriate to Asia.

Current Status:
The survey was completed in October 2013. A total of 1805 patients were recruited. The following two papers resulting from this study have been published.


Additional papers describing the survey findings are in preparation.

Cross-Cultural Multinational Research

The working team on Cross-cultural, Multinational Research in the Functional Gastrointestinal Disorders has completed its work. The final report of the working team is available as a downloadable pdf file at www.theromefoundation.org/working-teams-and-committees/multinational-committee/.

The final report relates to:
Methodological issues in multinational research:
  - Study design
  - Potential research areas
  - Availability and development of appropriate study instruments
  - Translation and validation of study instruments
  - Subject recruitment
  - Culturally appropriate endpoints and outcomes

Fostering of multinational research
  - Development of research networks
  - Formulation of multinational research guidelines for FGIDs
  - Collaboration with pharmaceutical companies and regulatory Agencies

In addition the working team has published two papers and a third one is now in submission. The two published papers are:


View online here - http://www.mindbodydigestive.com/pdf/Schmulson_Four_country_comparsion_NGMearly_view-2.pdf


The third paper, currently in submission, is a systematic review of IBS prevalence around the world.
Background:
A number of factors have been suggested to play a role in the pathogenesis of IBS including disturbed motility, the brain-gut axis, genetic factors, impaired gut barrier function, immunologic dysregulation, the gut microbiome, and psychosocial factors. More recently, there has been increasing attention on the role of food in IBS. Patients have long associated their IBS symptoms with the ingestion of certain foods, combinations of foods, or a meal itself. In fact, more than 60% of IBS patients report worsening of symptoms after meals; 28% of these within 15 minutes after eating and 93% within 3 hours. Unfortunately, the relative lack of empiric data proving a causal link or consistently documenting symptom improvement has caused health care providers to view dietary interventions with skepticism. Further, gastroenterologists and primary care providers receive virtually no structured training in dietary interventions for IBS. This lack of enthusiasm for dietary counseling has increasingly caused providers to be misaligned with their patients who commonly ask for more holistic solutions for their IBS symptoms. Out of desperation, many providers recommend or passively stand by as their patients empirically attempt various dietary manipulations, such as the elimination of fatty foods, fruits, gluten, milk/dairy products, or modifying dietary fiber content. This haphazard approach leads to inconsistent results which can be frustrating for both patients and providers.

It is now clear that a number of disorders and diseases can masquerade as or exacerbate the symptoms of IBS. For example, few clinicians would dispute that celiac disease and lactose intolerance are important considerations in patients presenting with IBS symptoms. However, these two well defined disorders likely represent the tip of the iceberg as it pertains to the role of food in IBS. For these reasons, the Rome Foundation has decided to formulate a multidisciplinary group to carefully evaluate the evidence which supports a role of food in the pathogenesis and management of FGIDs.

Key Questions to be addressed:
Members of the working group will be charged with addressing a number of key questions as outlined below. Whenever possible, the working group will try to conduct a systematic review of the literature to identify the best possible evidence to answer each of the key questions. The same set of questions will be applied to the most prevalent FGIDs including GERD/heartburn, functional dyspepsia, irritable bowel syndrome, bloating, diarrhea and constipation.

1. **Physiology of food’s effects in the GI tract:**
   - How does the GI tract handle food?
   - How does the GI tract sense nutrients?
   - Consequences of nutrient sensing on perception?
2. **Pathophysiology:**
   - Is nutrient handling different in FGIDs?
3. **Food intake and symptoms in FGID:**
   a. Does food intake exacerbate symptoms in FGID and if so, by what mechanism/s?
   b. Is food intake altered in patients with FGID?
   c. Can food challenges be used to measure symptom patterns and severity in FGIDs?
      - Reflux provocative meals in GERD
      - Nutrient challenge tests in FD
      - Meal-related symptom measurements in FD and gastroparesis
      - Meal-related exacerbations in IBS and bloating
   d. Can changes in food intake be used to improve symptoms in FGIDs and if so, by what mechanism/s?
   e. Can specific nutritional interventions (“functional foods”) be used to improve symptoms in FGIDs and if so, by what mechanisms?

Result:
The Committee has generated a series of articles on the role of food in FGIDs which were published in the American Journal of Gastroenterology in May 2013. The Role of Food in the Functional Gastrointestinal Disorders: Introduction to a Manuscript Series. Am J Gastroenterol 2013; 108:694–697; doi:10.1038/ajg.2013.62;
The pathogenesis and pathophysiology of patients with functional gastrointestinal disorders remains incompletely understood. During the last years, the role of intestinal microbiota in the development of functional gut problems has received great interest, with a steadily increasing numbers of research projects assessing this. For instance, it has been convincingly demonstrated that one of the most well established risk factors for developing IBS is having a bacterial or viral gastroenteritis. However, why some, but definitely not all, subjects with a gastroenteritis go on to develop longstanding symptoms, whereas others regain their gut health within a week, is not altogether clear. Moreover, there are also suggestions that patients with IBS have abnormal composition of the colonic bacterial flora, as well as controversial findings that small intestinal bacterial overgrowth is a major factor in IBS. New treatment options for functional GI disorders based on these findings have also appeared, such as non-absorbable antibiotics, and prebiotics, probiotics and synbiotics. Even though these findings are very intriguing and of great interest for researchers in the field, their relevance of some of these is unclear. Especially, their potential implications for the daily care of our patients are not well established.

The specific goals of the Working team were:
- To critically review the existing literature on the role of gut microbiota in functional GI disorders (FGIDs), with focus on clinical and translational aspects. This included the relevance of post-infectious IBS, alterations in composition of small and large intestinal microflora in FGIDs, the clinical usefulness of antibiotics and probiotics in FGIDs, as well as a thorough review on the basic/translational science literature with potential clinical relevance for this group of patients. A specific focus was on new methodology to assess the relevance of gut microbiota in FGIDs and potential drawbacks and pitfalls with previously used methods.
- Based on the literature search, provide recommendations how to implement the current knowledge into clinical practice, in order to improve the health of our patients.
- To give recommendations for future work in order to improve the current knowledge on the role of gut microbiota in functional GI disorders.

The report summarizing the work of the group was published in *Gut* in January 2013.

Severity in IBS

Measuring severity in functional GI disorders (FGIDs) is necessary to guide diagnostic evaluation, risk assessment, and treatment decisions. However, there has been a dearth of consensus regarding severity in irritable bowel syndrome (IBS) and other FGIDs. In late 2005, the Rome Foundation assembled a working group to develop guidelines for severity assessment in FGID. This committee was comprised of members with different areas of expertise but with a mutual interest in severity and in establishing clear health outcomes assessment. In 2011 the committee members published a document that summarized the literature on the concept of severity in IBS, its methods of assessment as well as guidelines for future work in this area.

Guidelines for Brain Imaging in the FGIDs

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

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

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

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

The journal article was published in *Neuropathology & Motorility, May 2009.*

Because of the complexity of the functional gastrointestinal disorders, it has been difficult over the years to determine which outcome measures and endpoints should be used in clinical trials of pharmaceutical agents. Some trials have used a global relief measure as a primary endpoint, while others have focused on symptom improvement.

The Rome Foundation has approved initiative for a strategic group to explore the behavior of different outcome measures and endpoints that have been used in large clinical trials for irritable bowel syndrome. This effort is consistent with the Rome III Design of Treatment Trials documents that recommend additional research to address outcomes and endpoints in the functional gastrointestinal disorders.

**Brief Summary of Plan**

**Aims**

To conduct a systematic review and meta-analysis of the psychometric and performance characteristics of primary endpoints used in large multicenter therapeutic trials for irritable bowel syndrome using pharmacological approaches, specifically:

1. global assessment of relief
2. adequate or satisfactory relief of IBS pain or discomfort
3. integrative symptom severity scores

The results of this study were published in *Gastroenterology*, December 2009.

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.


As with earlier book editions beginning in 1994, the Rome IV textbook is a comprehensive update of knowledge in FGIDs 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.

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**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 FGIDs; 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 FGIDs from esophagus to anorectum, as well as a newly developed chapter on centrally mediated disorders of gastrointestinal pain. For each FGID 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 FGIDs. 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 FGIDs 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.
The MDCP redefines the ways in which clinicians can care for patients having even the most complex functional GI disorders. The 2nd edition is a case-based learning module that updates the content of the first MDCP book published in 2015. There are over 70 cases, more than double that in the first edition, and all cases are revised to meet the Rome IV diagnostic standards.

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 IV chapter committees, who revised the previous cases to meet Rome IV guidelines 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. Thus, this 2nd edition truly addresses the full depth and breadth of clinical decision-making for FGIDs. Furthermore, we have added 18 pediatric cases (neonate-toddler and child-adolescent) and 4 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. The 1st edition of the book was translated into Spanish, and the MDCP concept has been promoted by academic organizations including at the AGA's Annual Freston conference (article in AGA Institute’s GI & Hepatology News) and at two webinars sponsored by the ACG (ACG-sponsored webinars).
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 neonates-toddlers and children-adolescents.

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

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.
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 FGIDs. We approached Pali Hungin, MD, a leading expert in the primary care of FGIDs, 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 FGIDs, 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 FGIDs, 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 FGIDs 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 FGIDs: 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 FGIDs. The book concludes with the comprehensive list of the Rome IV FGIDs and their diagnostic criteria.
The Rome Foundation maintains a major commitment to the creation and dissemination of good research in the field of FGIDs. 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 FGIDs 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 FGIDs to help clinicians decide when to refer patients for mental health treatment, and 3) the diagnostic questionnaires for pediatric FGIDs 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.
The field of pediatric FGIDs has grown over the last two decades, and for this reason we have decided to publish a separate book on pediatric FGIDs, 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 FGIDs relative to his or her specialty.

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.

**ROME IV ONLINE SUBSCRIPTION**

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**ROME IV Slide Sets**

**Rome IV MDCP Slide Set**
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.

**MDCP slide set of 204 images $29.95/set**

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

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

**Rome IV Diagnostic Algorithm Slide 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

**Slide set of 35 images $29.95/set**

**ROME IV Interactive Clinical Decision Toolkit**

**Rome – LogicNets Collaboration**
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.

**Interactive Clinical Toolkit: $149.95 (1 year license)**

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.
THE ROME FOUNDATION

ENCOURAGES YOU TO VISIT OUR EXHIBIT BOOTHs AT CONFERENCES AROUND THE WORLD

NOW AVAILABLE

- Rome IV Online subscription
- Rome IV Interactive Clinical Decision Toolkit
- e-books through Amazon.com
- Slides sets: Rome IV, MDCP and Diagnostic Algorithms
- Rome IV volumes I and II
- Rome IV Multidimensional Clinical Profile for Functional Gastrointestinal Disorders (MDCP Second Edition)
- Rome IV Diagnostic Questionnaires and Tables for Investigators and Clinicians (First Edition)
- Rome IV Diagnostic Algorithms for Common GI Symptoms (Second Edition)

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

INFORMATION ON THE ASSOCIATES OF ROME AND FREE ENROLLMENT

LOOK FOR OUR BOOTH AT THESE UPCOMING CONFERENCES

**BRAZILIAN CONGRESS OF FGIDs**
Sao Paulo, Brazil
May 11-12, 2018

**IBS BOLOGNA DAYS 2018**
Bologna, Italy
May 17-19, 2018
www.ibsdays2018.it

**AAPA 2018**
New Orleans, LA
May 19-23, 2018
www.aapa.org

**DDW 2018**
Washington, DC
June 2-5, 2018
www.ddw.org

**FNM 2018**
Amsterdam, Netherlands
August 29-Sept. 1, 2018
www.fnm2018.org

**ACG 2018**
Philadelphia, PA
October 5-10, 2018
www.acgmeetings.gi.org

**DDW 2018**
Washington, DC
June 2-5, 2018
www.ddw.org

**UEG WEEK 2018**
Vienna, Austria
October 20-24, 2018
www.ueg.eu/week/

**APDW**
Seoul, Korea
Nov. 15-18, 2018
www.apdw2018.org
Collaboration

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

- Promote global recognition and legitimization of FGIDs
- 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 and Focus Med-Ed.

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.

![Sponsor Logos]

Benefits of Rome Foundation Sponsorship include the following:

- Participation in annual advisory meetings of the Rome Foundation Advisory Council
- Opportunity to make presentations at Rome Foundation Advisory Council meetings
- Free use of Rome IV questionnaires beginning in 2018
- Pre-publication access to Rome IV manuscripts
- Acknowledgment on publications and projects
- Collaboration on educational activities of interest
- Opportunity to sponsor and participate in Rome Foundation activities

- Opportunity to sponsor research grants through the Rome Foundation
- Opportunity to sponsor and participate in symposia and meetings
- Discounts on Bulk Orders
- Discount at Rome conferences
- 5 copies of all books
- Newsletters and other mailings
- Invitations to Rome Reception at DDW
- Certificate and pins

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 and Focus Med-Ed.
MISSION - TO IMPROVE THE LIVES OF PEOPLE WITH FUNCTIONAL GI DISORDERS