

# 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*



# ROME FOUNDATION

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.

For more than two decades, beginning with the first working team committee at Roma '88 (see figure 1), the

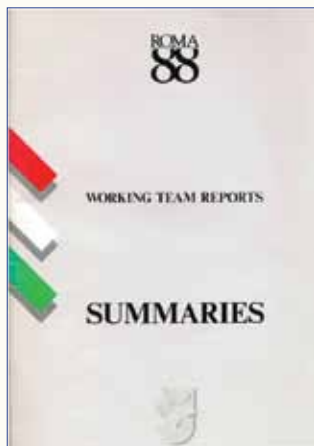


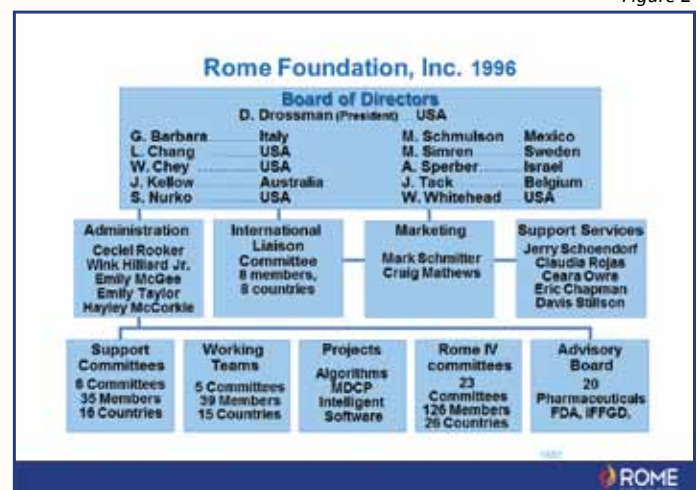
Figure 1

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, legitimization 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.

Figure 2



## GOALS OF THE ROME FOUNDATION

- 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

## 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)
- 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 (2017)

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BOOKLET BY CEARA OWRE DESIGN

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# ETHICS POLICY

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## **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 psychosocial (psychosomatic) medicine at the University of Rochester School of Medicine and in Gastroenterology at the University of North Carolina.

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

Dr. Drossman has written over 500 articles and book chapters, has edited 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 serves on six editorial and advisory boards in Gastroenterology, psychosomatic medicine, behavioral medicine, and patient health. He served 5-years as Associate Editor of the journal Gastroenterology and was the Gastroenterology Section Editor of the Merck Manual for 17 years.

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 cognitivebehavioral 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. He received the AGA Distinguished Educator Award (2004), received the American College of Gastroenterology David Sun Lecturer Award (2012), was identified as a "Best Gastroenterologist" in Men's Health (2007) and in Woman's Health (2008) and is featured as one of 12 gastroenterologists in a book "Best Gastroenterology Practices" (2007).

With regard to the Rome Foundation, Dr. Drossman was founder and currently serves as President of the Board. He has been editor in chief of Rome I, II, and III and Rome IV books and currently of Rome IV published in 2016. The Rome IV project consists of 6 books available in print and e-book form and by subscription. 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 basic science post-doctoral research fellowship in neuro-immunology at McMaster University in Canada. Currently he is involved in clinical gastroenterology diagnostic and therapeutic endoscopy, teaching and research at the Department of Digestive Diseases and Internal Medicine of the University of Bologna (AD 1088).

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

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

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



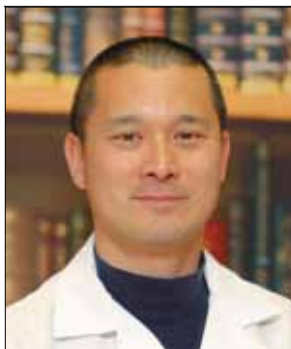
## Lin Chang, MD

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

Lin Chang, MD, is a Professor of Medicine in the Division of Digestive Diseases, Department of Medicine at the David Geffen School of Medicine at UCLA. She serves as the Co-Director of the G. Oppenheimer Center for Neurobiology of Stress and Resilience at the David Geffen School of Medicine at UCLA. This center is an interdisciplinary research and education organization, dedicated to the study of brain-body interactions in health and disease. She is also Program Director of the UCLA Gastroenterology Fellowship Program. Dr. Chang's clinical expertise is in functional gastrointestinal disorders which include irritable bowel syndrome (IBS), chronic constipation, and functional dyspepsia. She is a funded NIH-investigator studying brain-gut interactions underlying IBS. Specifically, her research is focused on the pathophysiology of IBS related to stress, early life adversity, sex differences, 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 and was a member of the Rome IV Editorial Board and Functional Bowel Disorders Committee and was the liaison for three Rome IV committees: 1) Childhood Functional Gastrointestinal Disorders: Neonate/Toddler; 2) Age, Gender and Women's Health and the Patient; and 3) Multi-Cultural Aspects of Functional Gastrointestinal Disorders committees. Dr. Chang previously served as President of the American Neurogastroenterology and Motility Society (ANMS). She is a fellow of the American Gastroenterological Association and American College of Gastroenterology, and a member of the Society for Neuroscience. Dr. Chang is a member of the FDA GI Drug Advisory Committee and the NIH Clinical, Integrative, Molecular Gastroenterology (CIMG) Study Section. She has authored more than 100 original research articles, 50 review articles, and 20 book chapters on her specialty interests.





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

**Professor of Medicine  
Director, GI Physiology Laboratory  
Co-Director, Michigan Bowel Control Program  
H. Marvin Pollard Institute Scholar  
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 Professor of GI & Nutrition Sciences. He has helped to found and directs a number of programs at the University of Michigan including the Digestive Disorders Nutrition & Lifestyle 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 member of the Counsel 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.



## John Kellow, MD

**Associate Professor and Head of the Discipline of Medicine  
Northern Clinical School  
University of Sydney  
Sydney, Australia**

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 in 1988. He was made a fellow of the Royal Australasian College of Physicians 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 disorders of gastrointestinal motility 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 and curriculum development, and was previously Associate Dean (Assessment) Faculty of Medicine, University of Sydney.





## Samuel Nurko, MD, MPH

**Professor of Pediatrics  
Harvard Medical School  
Director of the Center for Motility and Functional Bowel Disorders  
Boston Children's Hospital  
Boston, MA, USA**

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 230 manuscripts, reviews and book chapters. 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 pre-med 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 de Santa Fe de Bogota, where he then trained in Internal Medicine. After, he continued his Gastroenterology training in the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (INCMNSZ) in Mexico City, graduating with the award for the Best Residency-Graduation Thesis. He then worked in Los Angeles under the mentorship of Emeran Mayer in UCLA, focusing on the differences in symptoms, motility and visceral sensitivity of IBS patients according to the bowel habit predominance. Upon returning to Mexico he worked in the INCMNSZ for 6 years, and in 2005 he was appointed Full Professor of Medicine of the Universidad Nacional Autónoma de México (UNAM) and currently works in the Laboratory of Liver, Pancreas and Motility (HIPAM) of the Unit of Research in Experimental Medicine. Dr. Schmulson's research is focused on the epidemiology of FGIDs, 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 85 papers on peer-reviewed journals, 4 books and 55 book chapters on Functional Gastrointestinal Disorders. In 5 opportunities he has received the award "Dr.

Abraham Ayala González" and the Epidemiological Research from the Mexican Gastroenterological Association. He worked in the Latin American Consensus on IBS and coordinated the Latin American Consensus on Chronic Constipation. Dr. Schmulson previously served as Chair of the Membership Committee of the Functional Brain Gut Research Group and as Councillor as well. In 2006 he was one of the founders of the Latin American Society for Neurogastroenterology and served as the first President. He also served as Editor in Chief of the Revista de Gastroenterología de México from 2012-2014 and as Associated Editor of the American Journal of Gastroenterology from 2010-2015. Currently he is Founder and 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.



## Magnus Simrén, MD, PhD

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

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

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

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

published more than 200 original articles and also written book chapters on GI motility diseases and functional GI disorders, and is currently supervisor for eighteen PhD students and several Post-Docs. Doctor Simrén has been the President of the Scandinavian Association for Gastrointestinal Motility (SAGIM), Scientific Secretary to the Swedish Society of Gastroenterology, and a served as council member for several international organizations. He is currently the chair of the United European Gastroenterology (UEG) Scientific Committee, and a member of the UEG council. He has been working as Deputy Editor and Associate Editor of Gut (2005-2009), and Clinical Editor of Neurogastroenterology and Motility (2012-2016). Doctor Simrén received the Rising Star Award from the Association of National European and Mediterranean Societies of Gastroenterology (ASNEMGE) in 2006, and 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. 2015-2016 he was visiting research scientist at the Center for Functional GI and Motility Disorders, University of North Carolina (UNC), Chapel Hill, NC, United States, and he is now an adjunct professor at the Department of Medicine at UNC.



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

enteric nervous system, GI hormones and the control of satiation and food intake. He has published more than 6500 articles and 40 book chapters on various aspects of scientific and clinical gastroenterology.

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



## William E. Whitehead, PhD

**Professor of Medicine and OBGYN  
Co-Director, UNC Center for Functional GI and Motility Disorders  
Division of Gastroenterology and Hepatology  
UNC School of Medicine  
Chapel Hill, NC, USA**

Dr. Whitehead served on the board of the Rome Foundation since 1992. He is Chair of the Research Committee, co-chair (with Dr. Olafur Palsson) of the Questionnaire Development and Validation Committee. He is also a member of the Executive, Finance, Editorial committees, and the Steering Committee of the Global Epidemiology of Functional Gastrointestinal Disorders Study. He chaired the Questionnaire Development Committee for Rome IV and is co-chairing (with Dr. Palsson) a global validation of the Rome IV criteria in 8 countries.

He is a clinical psychologist with additional training in gastrointestinal physiology who graduated from the University of Chicago in 1973. His current academic appointments are Professor of Medicine in the Gastroenterology and Hepatology Division at the University of North Carolina at Chapel Hill, Adjunct Professor of Obstetrics and Gynecology in the Urogynecology Division, and Director of the Center for Functional Gastrointestinal and Motility Disorders.

Dr. Whitehead is a full-time clinical researcher with continuous NIH funding since 1978. Research interests include the pathophysiology and treatment of irritable bowel syndrome (IBS), fecal incontinence, and constipation. His IBS studies focus on visceral pain sensitivity, genetics, diagnostic criteria, and the co-morbidity of IBS with other somatic and psychiatric disorders. His pelvic floor research encompasses the epidemiology, pathophysiology, and treatment of constipation and fecal incontinence with biofeedback, behavioral training, and drugs. Major contributions have included randomized controlled trials (RCTs) of biofeedback for disordered defecation, proctalgia, and fecal incontinence. Services to the NIH include co-chairing an NIDDK workshop entitled "Developing a Clinical Research Agenda for Fecal Incontinence." He has served as a member of the Data Safety and Monitoring Board for the NIDDK Gastroparesis Research Network, and a member of the External Expert Panel for the NIDDK's Managing Abdominal and Pelvic Pain Research Network. Dr. Whitehead is a Master of the American College of Gastroenterology and a Fellow of the American Gastroenterological Association.



### **Eric Chapman** **Information Technology Specialist**

Eric Chapman has been working in Information Technology formally since 1999. He has worked in both the banking and medical industries. He has worked for Rome Foundation since 2007 and has been responsible for developing communication platforms and troubleshooting for the administrative group. He received a B.S. in Geographic Information Systems from Radford University in 1998.



### **Jamie DuMont** **Exhibit Manager**

Mrs. DuMont joined the Rome Foundation in 2009 to assist with exhibit booths at educational conferences. She brings over fifteen years of customer service and hospitality experience which will be utilized in her new role as Exhibit Manager. She is responsible for coordinating exhibits, welcoming visitors, sharing educational material about Rome Foundation's mission, and finding new opportunities to ensure success and expand exhibition.



### **William Hilliard, Jr.** **Director of Finance**

Mr. William "Wink" Hilliard, Jr. of Hilliard Association Management joined the Rome Foundation as its Executive Director in January 2011. In December 2016, Mr. Hilliard assumed the newly created position of Director of Finance of the Rome Foundation, where he directs the business operations and represents the Foundation in its many activities including coordinating sponsor related contracts, financial reports, fund raising, and distribution of our books and educational products.

Mr. Hilliard is a graduate of the University of North Carolina in Chapel Hill and received an MBA from the University of Virginia, where he held an academic position in Corporate and Divisional Strategic Planning. His experience has involved the management of several medical organizations including the NC Society of Anesthesiologists, the NC Society of Internal Medicine, and the NC College of Emergency Physicians. He has extensive experience in meeting management and the provision of financial services including portfolio management.



### **Hayley McCorkle** **Executive Assistant to the President**

Hayley McCorkle became a permanent member of the Rome Foundation in January 2017 as Executive Assistant to Douglas Drossman MD, President of the Rome Foundation. She'll be focusing her efforts on administrative tasks such as scheduling, planning event arrangements, preparing reports and financial data. She is also the liaison between the social media staff for both Drossmancare and the Rome foundation. Hayley is from Winterville, North Carolina and graduated from the University of North Carolina at Chapel Hill in December of 2016. At UNC, she received her BA in Exercise and Sport Science with a minor in African, African American and Diaspora Studies while playing on UNC'S Division I Volleyball team for four years.





### Emily McGee

**Project Manager**

Emily McGee has 2016 as Project Manager. She'll be focusing her efforts in several areas, including coordinating Licensing and Copyright for the Rome materials and assisting with the Global Studies initiative. 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 its 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 in public policy to provide psychiatric care to low-income populations. During his psychiatric residency at UC San Diego, Chaitanya continued to work on suicide epidemiology and also focused on mental illness among healthcare professionals. As Chief Resident, Chaitanya helped to develop an online curriculum incorporating both foundational psychiatric teachings along with current research.

Chaitanya has 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. He currently serves as the Communications Chair for the San Diego Psychiatric Society and also helps to organize their annual Continuing Medical Education (CME) event. His work with the Rome Foundation has been to serve as the Technical Consultant having worked on an iPad App for the Rome algorithms, and now facilitating the development of an interactive module to combine the diagnostic algorithms and the MDCP into one single medical guidance toolkit.



### Ms. Claudia Rojas

**Latin America 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.

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.



### Ceciel Rooker

#### Executive Director

Ms. Rooker joined the Rome Foundation in early 2008 to assist with marketing and public relations and was named Executive Director of the organization in 2016. Working with the President and the Board of Directors, she serves as a liaison with industry contacts as well as potential sponsors. She also organizes all public aspects of the Rome Foundation and coordinates Clinical Symposia, lectureships, and other major medical conferences such as at DDW and UEGW. From 2011 to 2016 she served as the Managing Editor of Rome IV. Prior to joining the Rome Foundation Ms. Rooker worked for Blackbaud, Inc., a software company which provides nonprofit management solutions, in their fund accounting product division, Financial Edge. She lives in Charleston, South Carolina with her 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.



### 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.





**Emily Taylor**  
Administrator

Emily Taylor and her husband Alex have recently moved back from Oregon, and rejoined the Rome Foundation permanently in the fall of 2015. Since then Emily has taken over coordinating the Professorship/Lectureship program and the sales of the Rome IV products. She traveled to 6 countries in 2016 to promote the *Rome IV* books at our booths all around the world. Emily graduated with a Biological Sciences degree from North Carolina State University. She is also a certified dog groomer and enjoys teaching horseback riding lessons.

## 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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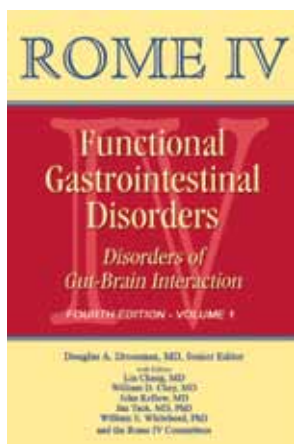
SUCAMPO AG

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### ACADEMIC ADVISORY COUNCIL

AMERICAN GASTROENTEROLOGICAL ASSOCIATION

INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS



# Rome IV Launch Continues!

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 1), 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 EDUCATIONAL MATERIALS AND RESOURCES—FOR RESEARCH, DIAGNOSIS, AND TREATMENT

Beginning with an update from the last publication 10 years ago, comes the fourth edition of our overview and diagnostic criteria for FGIDs, Rome IV Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction. With several new chapters, updates in pathophysiology and new diagnostic and treatment recommendations Rome IV is a welcome edition to aid in complete learning of the FGIDs. In addition there are 5 additional books:

**Rome IV Multidimensional Clinical Profile for Functional Gastrointestinal Disorders (MDCP)**, the second edition of our unique case-based learning module for putting the Rome approach to FGIDs care into practice we have been promoting a multicomponent approach to treatment taking 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. Now there are more than double the number of cases compared to the first edition.

**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 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 non-gastroenterological 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.

Figure 1



**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 LAUNCH FOR DDW 2017

The Rome IV launch continues in its second year with the addition of several major components beginning at DDW 2017:

**Rome IV Online Capability** will be available through e-books and through online Rome IV licensing.

- **E-books** will be available through Amazon.com and will be a way to access the print books online through a reader.
- **Rome IV Online** will allow users to access information using free-text searching across all book platforms in addition to standard access of book chapters. The entire Rome IV collection (Rome I, II), MDCP, algorithms, pediatric, primary care, and questionnaire books will be available as part of a subscription plan for one month, 6 months, 1 year or forever. In addition, there will be over 650 hyperlinked graphic images that are not available in the Rome IV printed books.

**Rome IV Slide Sets**, provide unique learning and information dissemination tools for researchers and clinicians engaging with the Rome IV criteria. Two slide sets are available:

- **The Rome IV slide set** contains up to 700 graphic images taken from Rome IV online. Each image has a text explanation of the image and references for self-learning. In addition, the slides can be used for presentation purposes.

- the **Rome IV MDCP slide set** contains 204 powerpoint slides allowing the user to present the MDCP case material at conferences and meetings for case discussion. Each of the 72 cases in the MDCP contain 2-3 slides about the clinical history, the MDCP categories and the recommended treatments.
- The **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.

**The Rome IV Interactive Clinical Decision Toolkit** is a Rome Foundation and LogicNets® Strategic Partnership that combines the content from the Rome IV Diagnostic Algorithms for Common GI Symptoms and the Rome IV Multidimensional Clinical Profile for FGIDs with an intelligent decision-support automation platform created by LogicNets. This innovative software module allows the clinician to use advanced methods to diagnose and treat FGIDs.

It 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 the constantly learning system. This program will be available through a variety of platforms and will be available by 3-year subscription.

#### MULTIPLE INTERNATIONAL SYMPOSIA TO TEACH ROME IV

Since DDW 2016, the Rome Foundation has had multiple Rome IV launch symposia at various large attendance international meetings including UEGW in Vienna, ANMS in San Francisco, and the Pan American Meetings in Cartagena Columbia, the Japanese and Asian combined Neurogastroenterology meetings in Osaka, Japan, and many national and regional meetings in Bologna and Rome, Italy; Gramado, Brazil; Mazatlan, Mexico; Beijing, China; and Tel Aviv, Israel. 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.

***Rome IV has launched and we couldn't be more excited!***

### CHAPTER COMMITTEES

FUNDAMENTALS OF NEUROGASTROENTEROLOGY: BASIC SCIENCE (KELLOW)*	FUNDAMENTALS OF NEUROGASTROENTEROLOGY: PHYSIOLOGY/MOTILITY-SENSATION (WHITEHEAD)*	INTESTINAL MICROENVIRONMENT AND FGIDS (CHEY)*	PHARMACOLOGICAL PHARMACOKINETIC AND PHARMACOGENOMIC ASPECTS OF FGIDS (TACK)*
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\*CHAPTER ASSOCIATE EDITOR

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

## SUPPORT COMMITTEES

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



# The Rome Foundation Comprehensive Global Initiative

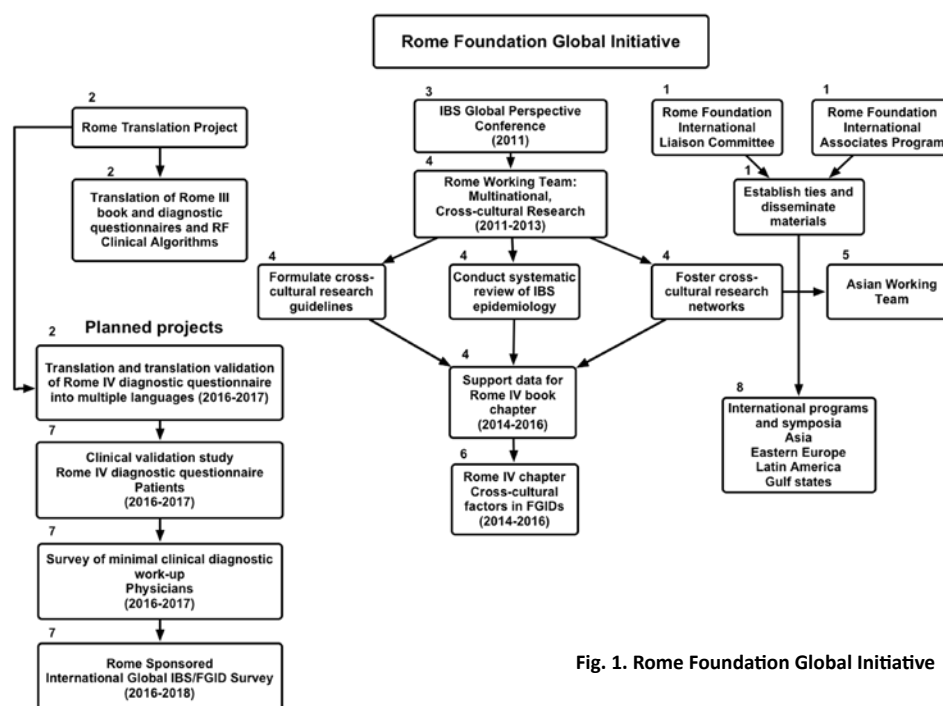


Fig. 1. Rome Foundation Global Initiative

**Background:** Over the past decade 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 the following figure (Fig. 1), which is keyed to the items below and on the following pages.

The latest development in the global initiative is the establishment by the Rome Board of Directors of 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 Fig. 2. As can be seen in this figure the International Liaison Committee (ILC), chaired by Dr. Dan Dumitrascu, now plays a central role in global projects as discussed below.

## 1) International Liaison Committee (ILC) and International Associates Program

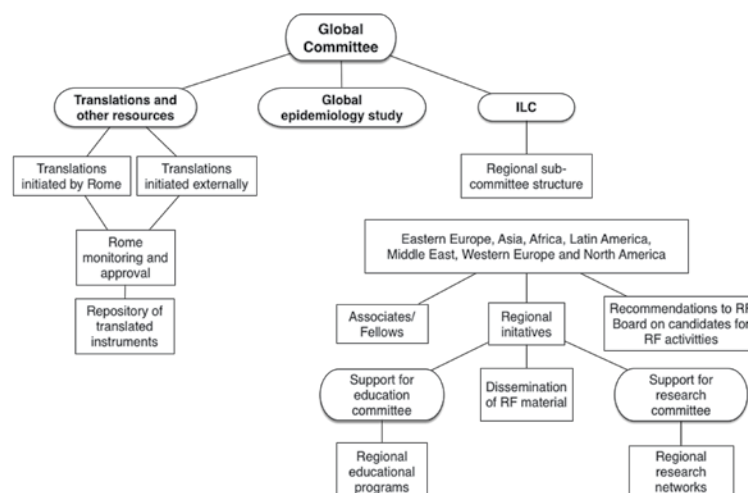
The ILC is composed of representatives from different regions of the world. It will now be organized on a regional basis with the following regions working semiautonomously under ILC auspices to promote the Rome Foundation global initiative in each region:

- Eastern Europe
- Asia
- Africa
- Middle East
- Latin America
- Western Europe, North America, Australia/New Zealand

## 2) RF Translation Project

- Provide quality, validated translations of RF material into as many languages as possible, in particular the Rome III and Rome IV books, diagnostic questionnaires, diagnostic criteria, clinical algorithms, multidimensional clinical profile (MDCP).
- Recently, other RF held questionnaires, notably the IBS-SSS (IBS symptom severity scale) and the Celiac Disease Quality of Life questionnaire (CD-QOL) are being translated into multiple languages.
- Establish regulations for the licensing and use of Rome material in the framework of academic research and commercial clinical trials.
- The Rome IV diagnostic questionnaire has now been translated into 21 languages and "localized" for several others.

Fig. 2. Rome Foundation Global Committee



The translation project website can be seen at:  
[www.theromefoundation.org/products/rome-translation-project/](http://www.theromefoundation.org/products/rome-translation-project/).

The following are available on the website:

- Downloadable RF translation guidelines (updated in February 2014).
- A table of available language versions and translation projects: [www.theromefoundation.org/products/rome-translation-project/available-translations/](http://www.theromefoundation.org/products/rome-translation-project/available-translations/).
- A request form for translated material.
- Licensing and fees information ([www.theromefoundation.org/products/copyright-and-licensing/rome-foundation-licensing-and-copyright-policy/](http://www.theromefoundation.org/products/copyright-and-licensing/rome-foundation-licensing-and-copyright-policy/)).

*Continued on page page 18*

### 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](http://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-andcommittees/multinational-committee/](http://www.theromefoundation.org/working-teams-andcommittees/multinational-committee/). It has also published three scientific papers in the medical literature. Please see the section of RF Working Teams on page 32 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

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 (E-pub ahead of publication).

The aims of the present study are to:

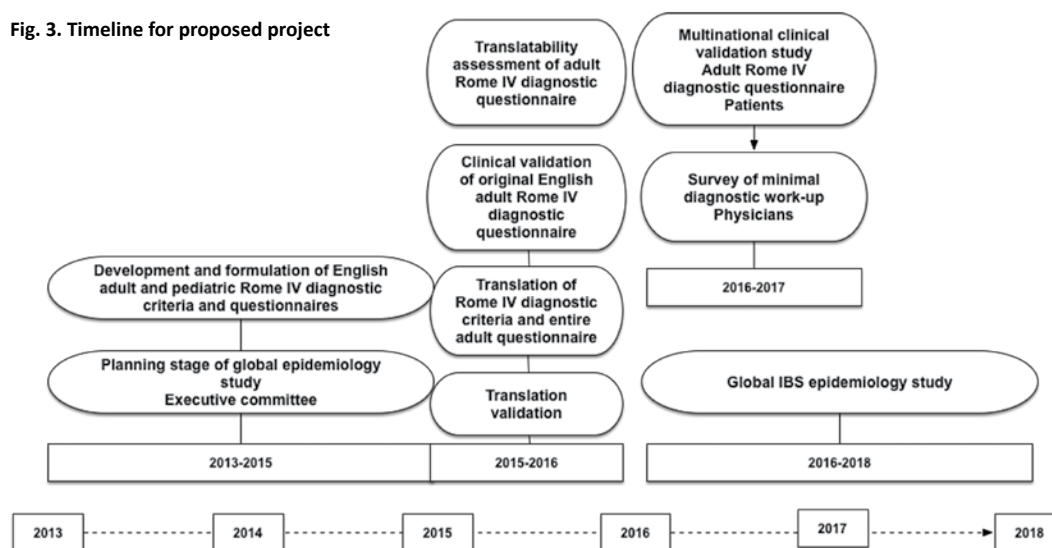
- To conduct a Rome Foundation-sponsored multinational, collaborative global study of the epidemiology of IBS using the *Rome IV* questionnaire.
- Base the study design on the recommendations of the RF Working Team on Multinational, Cross-cultural Research.

The global study will be preceded by the phases described below and depicted in the timeline in Fig. 3.

Development of the original English language questionnaire by the Rome IV questionnaire committee chaired by Dr. William Whitehead and co-chaired by Dr. Olafur Palssson.

- The original English version of the Rome IV diagnostic questionnaire has already undergone translatability assessment for 9 languages.
- The English version has been validated in a 3-country study in the US, Canada, and the UK.
- The English versions has now been translated into 21 languages and “localized” into several others. This process included cognitive debriefing for cultural validation.
- The translated versions will then undergo clinical validation in 8 countries.
- A supplemental questionnaire including socio-demographic, medical, psychosocial nutritional, hygienic, cultural and other

Fig. 3. Timeline for proposed project





information has been developed for the global study. It has been combined with the Rome IV diagnostic questionnaire to create a global study questionnaire. This extended questionnaire has also been translated into the 21 languages.

### The global study project will include:

#### Phase 1: Executive committee

An executive committee, composed of leaders in the field from around the world, has been planning this study since 2013. It has:

- Planned the overall study design and protocol.
- Determined the countries to be included in the study.
- Proposed a consortium of investigators from the participating countries.
- Included a statistician/methodologist to ensure an appropriate study design from the outset.

#### Phase 2: Translation of the Rome IV questionnaire

#### Phase 3: Conduct of the Study

- Once the translations are completed and validated the study will be conducted in 35 countries from around the world.

#### Phase 4: Analysis of results and publication

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

Validated translations of the Rome IV questionnaires into multiple languages approved by the RF for future academic and commercial research on IBS and the other FGIDs.

### THE COUNTRIES TO BE STUDIED IN THE EPIDEMIOLOGY STUDY



### 9) RF International Programs and Symposia

The Rome IV launch has taken place in multiple countries, often including lectures on the global initiative and the global study. Dr. Sperber has served as a Rome Foundation Visiting Professor in Uruguay and Brazil with a focus on the global study.

*Continued on page 20*

**Administrative assistance for all these committees is provided by Emily Taylor of the Rome Foundation administration.**

International Liaison Committee (ILC)	IBS Global Perspective Conference	RF Working Team on Cross-cultural, Multinational Research in FGIDs	RF Asian-Rome Working Team	RF IV Global IBS - A Global Epidemiology Study	RF China Initiative
<b>Chair</b> Dan Dumitrascu, MD (Romania)	<b>Co-Directors</b> Ami Sperber, MD (Israel) Eamonn Quigley, MD (US)	<b>Chair</b> Ami Sperber, MD (Israel)	<b>Chairs</b> Kok-Ann Gwee MD, PhD (Singapore) William E. Whitehead PhD (US)	<b>Chair</b> Ami Sperber, MD (Israel)	<b>Chair</b> Lin Chang MD (US)
Enrico Corazzari, MD (Italy) Carlos Francisci, MD (Brazil) Shin Fukudo, MD, PhD (Japan) Meiyun Ke, MD (China) Max Schmulson, MD (Mexico) Ami Sperber, MD (Israel)	<b>Planning Committee</b> Lin Chang, MD (US) Douglas A Drossman, MD (US) Kok-Ann Gwee, MD, PhD (Singapore) Richard Hunt, MD (Canada) Nancy Norton (US) Carolina Olano, MD (Uruguay) Max Schmulson, MD (Mexico)	<b>Members</b> Enrico Corazzari, MD (Italy) Shin Fukudo, MD, PhD (Japan) Charles Gerson, MD (USA) Uday Ghoshal, MD (India) Kok-Ann Gwee, MD, PhD (Singapore) Pali Hungin, MD (UK) Jin-Yong Kang, MD, PhD (UK/Singapore) Rona Levy, PhD (USA) Max Schmulson, MD (Mexico) William Whitehead, PhD (USA) <b>Consultants:</b> Dan Dumitrascu, MD (Romania) Mary-Joan Gerson, MD (US) Chen Minhu MD, PhD (China) Seung-Jae Myung (Korea) Eamonn Quigley, MD (Ireland/US) Peter Whorwell, MD (UK) Katie Zarzar (US)	Young-Tae Bak, MD (South Korea) Minhu Chen MD, PhD (China) Andrew Seng Boon Chua, MD (Malaysia) Uday Ghoshal, MD (India) Sutep Gonlachanvit, MD (Thailand) Xiaohua Hou, MD (China) Ching-Liang Lu, MD (Taiwan) Hiroto Miwa, MD, PhD (Japan)	Shrikant Bangdiwala, PhD (US) Research methodologist/statistician Dan Dumitrascu, MD (Romania) Xiucai Fang, MD (China) Shin Fukudo, MD, PhD (Japan) Uday Ghoshal, MD (India) John Kellow, MD (Australia) Edith Okeke, MD (Nigeria) Eamonn Quigley, MD (Ireland/US) Max Schmulson, MD (Mexico) Peter Whorwell, MD (UK) William Whitehead, PhD (US)	William Chey, MD (US) Wenjing Ding, MD (US/China) Doug Drossman, MD (US) Meiyun Ke, MD (China) Magnus Simrén, MD, PhD (Sweden) Yunsheng Yang, MD (China)

## Summary of Rome Foundation Global Initiative

The RF is now working towards developing similar collaborations with leaders in FGIDs and gastroenterology associations in other regions of the world.

- A formal report by the working team on the methodology and conduct of cross-cultural, multi-national research in FGIDs.
- A large body of translated and validated Rome IV questionnaires and other material in multiple languages.
- A chapter in the Rome IV book on the “Cross-cultural aspects of the FGIDs”
- A global study of FGID epidemiology
- Dissemination of RF educational material throughout the world in multiple languages
- Establishment of training centers in eligible sites around the world to promote understanding of the FGIDs and the clinical application approach to their diagnosis and management.

## Copyright and Licensing

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 (available in English unless otherwise marked):

- Rome IV Adult Diagnostic Questionnaire
- Rome IV Pediatric Diagnostic Questionnaire
- Rome IV Infant/Toddler Diagnostic Questionnaire
- Rome IV Slide Set
- Rome IV MDCP Slide Set
- Rome III book (Rome III: The Functional Gastrointestinal Disorders, Third Edition, Degnon Associates, Inc., 2006) earlier editions, Additional translations - Spanish, Chinese and Japanese
- Rome III Diagnostic Questionnaires (Rome III Diagnostic Questionnaire for the Adult Functional GI Disorders, including individual modules and scoring algorithm; Rome III Diagnostic Questionnaire for the Pediatric Functional GI Disorders; Rome III Psychosocial Alarm Questionnaire for the Functional GI Disorders). Visit [www.theromefoundation.org/products/rome-translation-project/available-translations/.cfm](http://www.theromefoundation.org/products/rome-translation-project/available-translations/.cfm) to see available translations for these tools.
- Computer Based Learning Program for the Functional GI Disorders, including individual modules
- Understanding the Irritable Gut (Thompson WG, 2008)
- Clinical Diagnostic Algorithm program, including individual modules or algorithms
- Bristol Stool Form Scale (BSFS) Additional translations – Spanish, Korean, Chinese, Japanese
- Celiac Disease - Quality of Life survey (CD-QOL)
- Additional translation – Dutch, Japanese, Portuguese
- Functional Bowel Disorders Severity Index (FBDSI)
- Irritable Bowel Syndrome - Quality of Life survey (IBS-QOL) Additional translations – *Afrikaans, Arabic, Bengali, Bulgarian, Cantonese, Chinese, Czech, Danish, Dutch, Finnish, French, German, Gujarati, Hebrew, Hindi, Hungarian, Italian, Kannada, Korean, Latvian, Malay, Malayalam, Mandarin Chinese, Marathi, Norwegian, Panjabi, Polish, Portuguese, Romanian, Russian, Slovak, Spanish, Swedish, Tamil, Thai, Telugu, Ukrainian, Urdu*
- Irritable Bowel Syndrome - Symptom Severity Scale (IBS-SSS) Additional translations - Bulgarian, Chinese, Czech, French, German, Hungarian, Italian, Korean, Latvian, Norwegian, Polish, Romanian, Russian, Slovak, Spanish, Swedish
- Rating Form of Irritable Bowel Disease Patient Concerns (RFIPC) Additional translations – Afrikaans, Arabic, Bosnian, Bulgarian, Croatian, Czech, Estonian, French Canadian, German, Greek, Hebrew, Italian, Japanese, Portuguese, Romanian, Russian, Serbian, Slovak, Spanish, Swedish, Ukrainian, Turkish
- Comorbid Medical Conditions Questionnaire (CMCQ)
- Satisfaction with Care Scale (SAT-37)
- Trauma Questionnaire
- Ulcerative Colitis and Crohn’s Disease Health Status Scales (UC-CD)
- Rome III MDCP Slide Set

**Beginning in 2017, we will be adding the Rome IV questionnaire and related Rome IV products. For more information, please contact Sherita Barnes at [sbarnes@theromefoundation.org](mailto:sbarnes@theromefoundation.org).**

## International Liaison Committee

In 2008, The Rome Foundation formed the International Liaison Committee to expand our activities globally. This committee is charged to increase awareness of the functional GI disorders through educational and scientific activities in the Eastern European, Middle Eastern, Asian-Pacific, and Latin American geographical regions. In 2012, Dr. Max Schmulson (Mexico) retired as chair after a highly productive 4 years. Under his leadership several Rome Foundation educational programs were held in Latin America, Eastern Europe and Asia. Dr. Schmulson has been succeeded by Dan Dumitrascu MD (Romania). These last years were dedicated to the support and dissemination of the Rome IV working committees. Most of the committee members have been involved in the IBS epidemiological global survey project lead by Ami Sperber, but also in other working committees. The committee extended the to allow a better representation of different areas of the world. Thus, new members replaced those who quit the committee to receive other charges in the board of directors and new members have been nominated to cover areas not represented before in the committee.

During the annual meeting of the International Liaison Committee, a new chairman will start his activity, as Dr. Dumitrascu's term will come to its end. Simultaneously, some other members will be nominated or renominated.

### Committee Composition:

**Dan L. Dumitrascu, MD — Chair**  
*Romania*

**Enrico Stefano Corazzari, MD**  
*Italy*

**Shin Fukudo, MD, PhD**  
*Japan*

**Carlos F. M. Francisconi, MD**  
*Brazil*

**Uday Ghoshal, MD**  
*India*

**Meiyun Ke, MD**  
*China*

**Carolina Olano, MD, M Ed.**  
*Uruguay*

**Max J. Schmulson W., MD**  
*Mexico*

**Ami D. Sperber, MD, MSPH**  
*Israel*

During the previous years before the release of the Rome IV reports and books, the International Committee has activated for the dissemination of knowledge and awareness on functional gastrointestinal disorders worldwide. The initiative to create regional subcommittees able to intensify the Committee's activities in specific geographical areas has been elaborated and we are confident that it will continue.

The aims of the International Liaison Committee are to:

- Set up a liaison association with regional organizations
- Advise the Rome Foundation on how to implement our global activities in these regions
- Be the liaisons for such activities in their respective regions
- Assist in the global dissemination of Rome materials and activities
- Help the Rome Foundation identify key individuals who could work on Rome Committees
- By working together, this committee will identify new initiatives to support, advise and promote our global outreach effort.
- Developing regional subcommittees to better multiply the activity of the ILC members and to be close to the national or regional opinion leaders.

## Rome Foundation Working Team on Pediatric Clinical Trials

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).

Moving ahead, the committee is now undertaking the development of guidelines for pharmacological clinical trials in children with functional constipation. An initial draft is under development by the committee and will likely finalize the document later this summer.

### Committee Composition:

**Miguel Saps, MD, Chair**  
*(USA)*

**Marc Benninga, MD**  
*(Netherlands)*

**Carlo Di Lorenzo, MD**  
*(USA)*

**Adrian Miranda, MD**  
*(USA)*

**John Lavigne, PhD**  
*(USA)*

**Jan Tack, MD, PhD**  
*(Belgium)*

**Jan Taminiau, MD, PhD**  
*(Netherlands)*

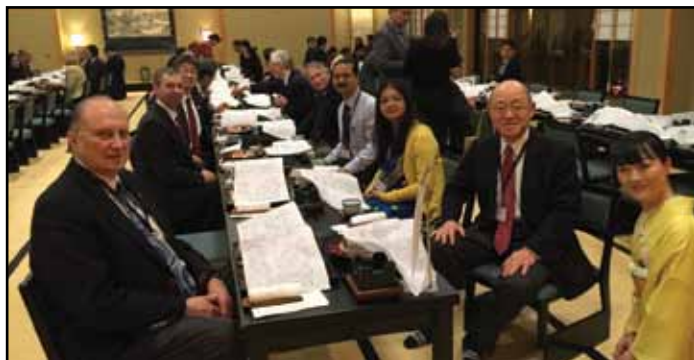
**Miranda van Tilburg, PhD**  
*(USA)*



# Rome IV Launch Committee

The release of the Rome IV criteria in May 2016 marked the culmination of an international, multi-year effort to provide evidence based reviews addressing the latest basic, translational, and clinical science as well as updating the diagnostic criteria for disorders of gut-brain interaction. The release of Rome IV has been met with international enthusiasm. The Rome IV Launch Committee has assisted in the orderly dissemination of information about the Rome IV Diagnostic criteria. In 2016, the Launch Committee focused on developing programs to help clinicians understand the key changes in diagnostic criteria from Rome III to Rome IV. Launch Committee programs were featured in 16 programs in 10 countries, educating tens of thousands of gastroenterologists. The Rome IV criteria were prominently featured on the programs of major international GI meetings including Digestive Diseases Week, United European Gastroenterology Week, Romanian and Central European Neurogastroenterology Society, Japanese and Asian Neurogastroenterology Societies, Pan American Meetings, Brazilian GI Society, and the Annual Meeting of the American College of Gastroenterology.

The Launch Committee will remain active in 2017, although our focus will undoubtedly evolve over time. While programs addressing the diagnostic criteria will remain a mainstay for meeting programming, the Launch Committee is now offering new programs to help learners understand other elements of the Rome IV package including the multi-disciplinary clinical profile or MDCP, the clinical algorithms, and the Interactive Clinical Decision Toolkit, an interactive online intelligent software program. To date, the Launch Committee's efforts have been focused primarily on gastroenterologists. Recognizing that the potential importance of the Rome IV criteria to a wide range of providers including primary care physicians, nurse practitioners, physician's assistants, and nurses, the Launch Committee hopes to partner with appropriate stakeholders to address each group's unique educational needs.



FEATURED AT THE JAPANESE AND ASIAN NEUROGASTROENTEROLOGY MEETINGS IN OSAKA OF WHICH OVER 300 GASTROENTEROLOGISTS ATTENDED THROUGHOUT ASIA WERE TWO SYMPOSIA HIGHLIGHTING THE NEW KNOWLEDGE FROM ROME IV.



DOUGLAS DROSSMAN, CARLOS FRANCISCONI, MARIA HELENA FRANCISCONI, AND BILL CHEY AT THE NGM MEETING GRAMADO, BRAZIL. THIS EVENT IS PART OF THE ROME IV LAUNCH PROGRAM.



AS PART OF THE ROME IV LAUNCH DR. DROSSMAN ALSO DISCUSSED HOW TO IMPROVE THE PATIENT PROVIDER RELATIONSHIP THROUGH EFFECTIVE COMMUNICATION SKILLS



AMI SPERBER AT THE 2017 INNOVATIONS IN GASTROENTEROLOGY MEETINGS IN TEL AVIV, ISRAEL.



THE PEKING UNION MEDICAL COLLEGE HOSPITAL SYMPOSIUM HELD IN NOVEMBER, 2016 HIGHLIGHTED THE LAUNCH OF THE CHINESE ROME IV BOOK. INCLUDED HERE ARE THE MEMBERS OF THE CHINESE TRANSLATION TEAM HEADED BY DR. XIUCAI FANG (FAR LEFT) AND GUEST SPEAKERS FROM THE ROME FOUNDATION BOARD OF DIRECTORS LIN CHANG MD (WHITE COAT) AND NEXT TO HER DOUGLAS DROSSMAN MD.

## Rome Criteria: Setting the Stage for Research in the 21st Century

The Rome Foundation has carried many roles since its inception but perhaps most important is its influence on the field 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 1, we define disorders based on evident pathology (organic GI disorder), altered motility (motility disorder) or symptoms

	Organic GI disorder	Motility disorder	Functional GI disorder
Primary domain	Organ morphology	Organ function	Illness experience
Criterion	Pathology (disease)	Altered motility	Symptoms
Measurement	Histology Pathology Endoscopy Radiology	Motility Visceral sensitivity	Motility Visceral sensitivity Symptom Criteria (Rome) Psychosocial
Treatment options	Medications Surgery Ther. endoscopy	Pro / anti-kinetics Surgery Pacing/Stimulator	Pro / anti-kinetics Antinociceptives Antidepressants Behavioral Pro / antibiotics
Examples	Esophagitis Peptic ulcer IBD Colon cancer	Diffuse esoph. spasm Gastroparesis Pseudo-obstruction Colonic inertia	Esophageal chest pain Functional dyspepsia IBS Functional constipation

Figure 1

(functional GI disorder). Functional GI disorders, now called more appropriately disorders of gut-brain interaction<sup>1</sup>, are diagnosed by Rome criteria which are usually symptom based. Historically the functional GI disorders had their genesis about 25 years ago (Figure 2) when a symptom based classification system developed.

While gastrointestinal symptoms have been reported by individuals for millennia, the classification into syndromes first began with research on GI motility in the 1940's and 1950's. At this time notable GI physiologists like Stuart

Wolf and Tom Almy<sup>2,3</sup> attempted to correlate gut motility changes with symptoms. Motility research was dominant in the latter half of the 20th century. However by the late 1980's it was becoming evident that motility alone was not sufficient to explain GI symptoms or symptom based disorders. A breakthrough occurred around 1990 with two new entries into the field. First was the research by William Whitehead<sup>4, 5</sup>, Emeran Mayer<sup>6</sup>, and others who began to report the concept of visceral hypersensitivity, i.e., characterizing pain reports by what later was recognized as augmented afferent signaling rather than motility. The second was the classification system for functional GI disorders published in 1990<sup>7</sup> which evolved into the Rome Criteria. This symptom based classification categorized patients with various symptom patterns into diagnoses that were amenable to many re-search models as shown in Figure 2. This has had a major impact on our scientific understanding of these disorders. Currently the Rome criteria are used by regulatory agencies, investigators and clinicians around the world.

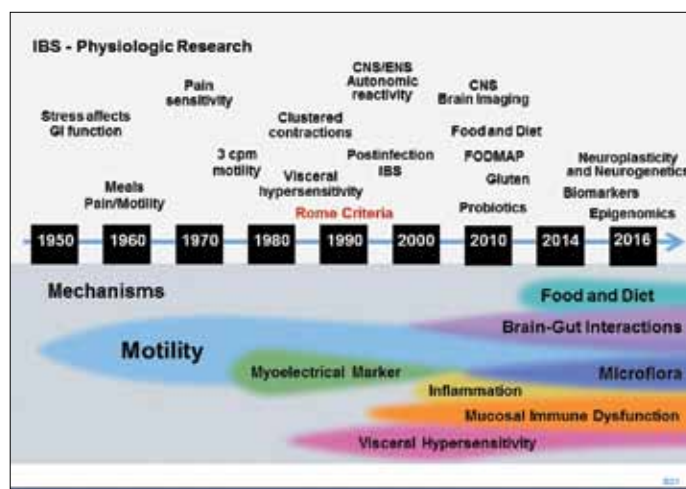


Figure 2

### REFERENCE LIST

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



# Research Program

The Rome Foundation has sponsored research by young investigators since 2007. The goals of the research program, chaired by William Whitehead, PhD, and Uday Ghoshal, 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:

### 2017 – TWO AWARDS

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

Title: *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:

### 2017

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

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



2016

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

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

2015

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

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

2014 – TWO 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)**

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

2013

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

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

2012

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

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

2011 – TWO WINNERS

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

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

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

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

2010

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

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

2009 – TWO WINNERS

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

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

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

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

2008

**Krisztina Gecse, MD (Hungary)**

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

**KEN HEATON AWARD FOR MOST CITED PAPER**

The Rome Foundation also offers a \$1000 prize for the most frequently cited research paper on functional gastrointestinal and motility disorders. This award is named in honor of the late Kenneth Heaton for his ground-breaking contributions to the development of positive diagnostic criteria for irritable bowel syndrome (the Manning Criteria) and the pathophysiology of constipation (the Bristol Stool Scale). Dr. Heaton (1936 - 2013) was a Consultant Physician at the Bristol Royal Infirmary, and Reader in Medicine at the University of Bristol. The Rome Foundation Board of Directors selects this paper based on the Science Citation Index, and the winner is announced at Digestive Disease Week. Articles on functional gastrointestinal and motility disorders published from January to December in the penultimate year before DDW and indexed in PubMed will be evaluated. Note that there is a one-year lag between the publication of the paper and its consideration for the prize; this is to allow enough time for the paper to be recognized and cited. This \$1000 prize will be presented at the Rome Foundation Reception at DDW. Previous winners of this award are listed below:

2017

**G De Palma, (Canada)**

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

2016

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

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

2015

**Jessica Biesiekierski, PhD (Australia)**

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

2014 – TWO WINNERS:

**Madhusudan Grover, MBBS (USA)**

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

**Natasha Koloski, PhD (Australia)**

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

## Rome Foundation/AGA Institute Lectureships at DDW

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

At DDW in May 2017, we are pleased to have three speakers discuss “Applications of novel diagnostic modalities in the diagnosis, pathophysiology and treatment response of functional GI disorders”.



John Pandolfino, MD



Robin Spiller, MD



Emeran Mayer, MD

### The talks will be:

- *EndoFLIP for Functional Esophageal Disorders* with John Pandolfino
- *Magnetic Resonance Imaging of the Intestine in IBS and Chronic Constipation* with Robin Spiller
- *Novel Brain Imaging Techniques in IBS* with Emeran Mayer

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

- **2016:** “Overview of Rome IV: Changes in Criteria and New Educational Concepts” with Douglas A. Drossman. “Functional Gastrointestinal Disorders” with Nicholas J. Talley. “Lower Gastrointestinal Functional Bowel Disorders” with Fermin Mearin
- **2015:** “Clinical Practice and Research for FGIDs in the Technology Era”. “Clinical practice in a social media environment” with Ryan Madnick MD; University of North Carolina; “Use of health information technology in clinical practice” with William D. Chey MD; University of Michigan; “How health information technology on the internet can be used in clinical research” with Patrick Furey; ConsumerSphere
- **2014:** “Understanding and Treating the Brain’s Contribution to Pain”: “Central mechanisms of pain” with Irene Tracey, PhD; Oxford Centre for Neuroethics; “Behavioral interventions for pain management” with Laurie Keefer, PhD; Northwestern University; “Centrally targeted pharmacotherapy for chronic abdominal pain” with Douglas A. Drossman, MD; Center for Biopsychosocial Patient Care and UNC
- **2013:** “The Role of Food Sensitivities and Microbiota in Functional GI Disorders” with Sheila Crowe, MD from the University of California in San Diego, CA; “Food sensitivities and food allergies: The clinical perspective” and Kevin Whelan, PhD from King’s College, London; “Understanding the mechanisms underlying the interaction of food and gut microbiota in FGIDs”
- **2012:** “Intestinal Permeability: Does it Explain the Symptoms of Functional GI Disorders?” with Giovanni Barbara, MD from the University of Bologna; “Regulation of Intestinal Permeability in Health and Disease” with Alessio Fassano, MD from the University of Maryland and “Esophageal Permeability: Does it Explain the Symptoms of NERD?” with Roy Orlando, MD from the University of North Carolina at Chapel Hill
- **2011:** “The Role of Neurogenesis in the Brain” with Tarique Perera MD from Columbia University in NYC and “The Role of Neurogenesis in the Enteric Nervous System and its Implications for Functional GI Disorders.” with Michael D. Gershon MD from Columbia University in NYC
- **2010:** “Understanding Gut Microbiota: A New Era in Gastroenterology.” with Dr. Erwin G. Zoetendal from Wageningen, Netherlands
- **2009:** “Motility Assessments for Functional GI Disorders: How far does it get us?” with Dr. Juan-R. Malagelada, Professor of Gastroenterology at Hospital Universitari Vall d’Hebron in Barcelona
- **2008:** “Lessons from our Patients” with Ms. Gina Kolata, Science Writer for the New York Times

THE ASSOCIATES OF ROME PROGRAM HAS GROWN TO WELL OVER 1900 MEMBERS IN 84 COUNTRIES SINCE ITS INCEPTION IN 2010.

*Associates*  
OF ROME

### 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/](http://www.theromefoundation.org/associates-of-rome-program/).



# 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 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 Rome Foundation - AGA Institute Communication Skills Workshop, and various symposia and workshops. We have recently focused and updated our educational programs 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, 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 non-gastroenterological providers who see patients with these disorders

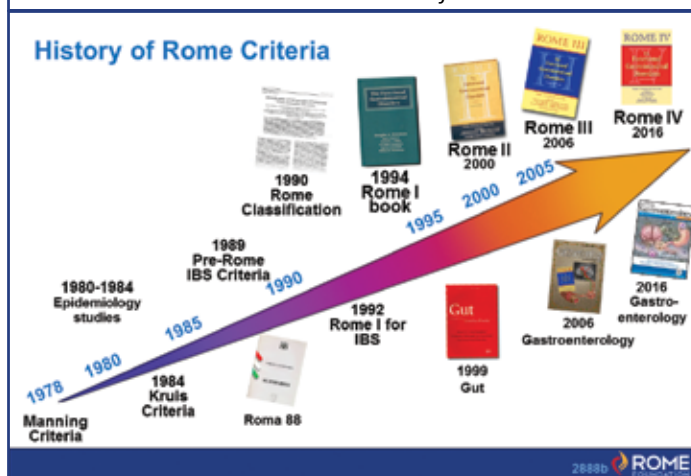
## **Multi-Dimensional Clinical Profile**

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 have now 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.

## **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 are internationally recognized in their areas of expertise, and selection is based on matching selected topics with the speakers. Where there is interest in hearing the latest on functional GI and motility disorders, we invite all medical centers, academic programs,

## *Educational Products and Publications of the Rome Foundation*



community hospital programs and “gut clubs” to apply.

## **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.

## **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.

## **Lecture Programs**

The Rome Foundation sponsors a variety of lectures and professional meetings. We have an annual Rome-AGA Institute lectureship at DDW as well as Rome Symposia at Conferences around the world. In addition, we launched our International Visiting Professorship and Lectureship Program in 2015. This unique program allows key experts to disseminate the new knowledge of FGIDs at a global level. Currently, our Rome symposia are focused on the new Rome IV information as part of our Rome IV launch.

## **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.

# ROME FOUNDATION INTERNATIONAL PROGRAM FOR VISITING PROFESSORSHIP 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 are internationally recognized in their areas of expertise, and selection is based on matching selected topics with the speakers. Where there is interest in hearing the latest on functional GI and motility disorders, we invite all medical centers, academic programs, community hospital programs and "gut clubs" to apply.



## ADDRESSING CRITICAL NEEDS IN FUNCTIONAL GI AND MOTILITY DISORDERS (FGIDs)

- Over the last 10-15 years, the FGIDs have become a major research area within gastroenterology due to technological advances and growing knowledge related to mucosal immune dysfunction, bacterial flora, braingut interactions and newer treatments.
- The FGIDs are the most common GI disorders seen by gastroenterologists and primary care physicians, yet medical school curricula and post graduate training are unable to keep up with advancing knowledge in their diagnosis and treatment.
- Educators possessing the knowledge needed to teach the research and clinical care are limited to a small number of clinical experts who are concentrated at major medical centers.
- The numbers of visiting professorships are diminishing due to increasingly rigorous guidelines that limit industry from supporting such activities. As a result current educational programs may be restricted to local or regional speakers who may not be as up to date on newer content areas.

## RATIONALE

- As an academic organization that develops educational materials (e.g., Rome III book, slide sets, research questionnaires, video training, workshops) for the FGIDs, the Rome Foundation is in an ideal position to take responsibility for programs to teach clinicians and trainees.
- The members of the Rome Foundation are selected for their expert knowledge and are the key opinion leaders in research and clinical care of the FGIDs.
- Because the Rome Foundation members develop the research agenda and the clinical guidelines for these disorders, they are highly capable of developing a curriculum for learners that includes the most up to date knowledge as well as current and soon to be developed recommendations for patient care.
- As an international non-profit academic organization with high credibility in the field, Rome Foundation sponsored visiting professorships fill the gap in knowledge of functional GI disorders in the academic and practice community.
- The proposed multi-sponsored programs are not subject to the restrictions on content imposed upon promotional talks. As such, these programs provide a true state of the art update by the world's leading experts on FGIDs.
- Due to its international structure, the Rome Foundation provides visiting professorships and other educational programs on a global level.



## VISITING PROFESSORSHIP AND LECTURESHIP

**WE HAVE DEVELOPED A SERIES OF VISITING PROFESSORSHIPS AND LECTURES FOLLOWING TWO MODELS:****THE ROME FOUNDATION VISITING PROFESSORSHIP**

Top tier investigators and clinicians within the Foundation visit an academic medical center for a period of 1-3 days to provide a variety of activities: a) medical and/or gastroenterology grand rounds, b) clinical case conferences with trainees, c) individual advisory meetings with young aspiring faculty and trainees seeking to develop a career in the FGIDs, d) workshops or other more intense training programs in their area of expertise if requested. The Foundation advertises and then solicits applications from medical centers. We then identify the best speaker who meets that institution's specific educational needs.

**THE ROME FOUNDATION VISITING LECTURESHIP**

This is usually a 1-day visit either to an academic program or large clinical practice program, gut club or community oriented educational venue. The speaker might give a

grand rounds to an academic program, a round table or a lecture to a community educational venue or gut club. It may be possible to link presentations (e.g., a GI grand rounds in daytime and community gut club in evening) over a 24 hour period.

**PAST PROGRAMS**

In 2015, a total of 8 Visiting Lectureships and 4 Visiting Professorships were organized generating more than 30 presentations across 5 different continents. For 2016, the programs grew to 15 and included many more international visits including China, Brazil, Uruguay, Leuven, Italy, Australia, and Norway. With the recognition of the program and the high interest in the Rome IV criteria, the number of activities is expected to be substantially higher in 2017. So far 2 Visiting Professorships have been completed, and 7 more are scheduled.

**SELECTION COMMITTEE**

William D. Chey, MD, Co-Chair (USA)

Jan Tack, MD PhD, Co-Chair (Belgium)

Magnus Simren, MD PhD (Sweden)

Douglas A. Drossman, MD (USA)

## Rome Working Team

## Working Team on Gut-Brain Neuromodulators for FGIDs (Disorders of Gut-Brain Interaction)

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A major area in the care of patients with FGIDs involves treatment of gastrointestinal pain. The pathophysiological basis for the pain extends on a spectrum from increased peripheral signaling due to increased motility and visceral hypersensitivity, to central pain due to inadequate downregulation of incoming visceral signals or central hypersensitivity. The use of centrally targeted medications (gut-brain neuromodulator) 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.

### The objectives of this working team will be to:

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

### Committee Composition:

Douglas A. Drossman, MD (Gastroenterology, Psychiatry/Psychosomatic Medicine), US, Chair  
 Jan Tack, MD, PhD (Gastroenterology, GI physiology), Belgium, Co-Chair  
 Alex Ford (Gastroenterology, Meta-analysis), UK  
 Eva Szigethy (Psychiatry), US  
 Hans 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.

### Committee Composition:

Giovanni Barbara, Chair (*Italy*)  
 Madhusudan Grover, Co-Chair (*USA*)  
 Premysl Bercik (*Canada*)  
 Maura Corsetti (*UK*)  
 Uday Ghoshal (*India*)  
 Lena Ohman (*Sweden*)  
 Mirjana Rajilić-Stojanović (*Serbia*)

## 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.

### Committee Composition:

Emeran Mayer, MD, Chair (*US*)  
 Qasim Aziz, MD, Co-chair (*UK*)  
 David Borsook MD, (*US*)  
 Sigrid Eisenbruch, MD (*Germany*)  
 Lisa Kilpatrick, PhD (*US*)  
 Jennifer Labus, PhD (*US*)  
 Petra Schwienhardt, MD (*Canada*)  
 Irene Tracy, PhD (*UK*)  
 Lukas Van Oudenhove, MD (*Belgium*)

## 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.

Ghoshal UC, Gwee KA, Chen M, Gong XR, Pratap N, Hou X, Syam AF, Abdullah M, Bak YT, Choi MG, Gonlachanvit S, Chua AS, Chong KM, Siah KT, Lu CL, Xiong L, Whitehead WE. Development, Translation and Validation of Enhanced Asian Rome III Questionnaires for Diagnosis of Functional Bowel Diseases in Major Asian Languages: A Rome Foundation-Asian Neurogastroenterology and Motility Association Working Team Report. *J Neurogastroenterol Motil*. 2015 Jan 1;21(1):83-92. doi: 10.5056/jnm14045. PMID: 25537673; PMCID: 4288097.

Rahman MM, Ghoshal UC, Rowshon AH, Ahmed F, Kibria MG, Hasan M, Gwee KA, Whitehead WE. Translation and validation of enhanced Asian Rome III questionnaires in Bengali language for diagnosis of functional gastrointestinal disorders. *J Neurogastroenterol Motil* 2016;22:240-70. PMID:26690730

Additional papers describing the survey findings are in preparation.

### Committee Composition

Kok Ann Gwee MD, PhD  
*Chair*  
*Singapore*

William E. Whitehead, PhD  
*Co-Chair*  
*USA*

Young-Tae Bak, MD  
*South Korea*

Minhu Chen MD, PhD  
*China*

Andrew Seng Boon Chua, MD  
*Malaysia*

Uday C. Ghoshal, MD  
*India*

Sutep Gonlachanvit, MD  
*Thailand*

Xiaohua Hou, MD, PhD  
*China*

Ching-Liang Lu, MD  
*Taiwan*

Hiroto Miwa MD, PhD  
*Japan*

## 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/](http://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:

**Schmulson M, Corazziari E, Ghoshal UC, S Myung S-J, Gerson CD, Quigley EMM, Gwee K-A, Sperber AD (2014) A four-country comparison of healthcare systems, implementation of diagnostic criteria, and treatment availability for Functional Gastrointestinal Disorders. A Report of the Rome Foundation Working Team on Cross-Cultural, Multinational Research. *Neurogastroenterology and Motility* 26:1368-1385.**

View online here - [http://www.mindbodydigestive.com/pdf/Schmulson\\_Four\\_country\\_comparison\\_NGMearly\\_view-2.pdf](http://www.mindbodydigestive.com/pdf/Schmulson_Four_country_comparison_NGMearly_view-2.pdf)

**Sperber AD, Gwee KA, Hungin AP, Corazziari E, Fukudo S, Gerson C, Ghoshal UC, Kang J-Y, Levy RL, Schmulson M, Dumitrascu D, Gerson M-J, Chen M, Myung S-J, Quigley EMM, Whorwell PJ, Zarzar K, Whitehead WE. (2014) Conducting multinational, cross-cultural research in the functional gastrointestinal disorders: issues and recommendations. A Rome Foundation working team report. *Alimentary Pharmacology and Therapeutics* 40:1094-1102**

View online here - <http://onlinelibrary.wiley.com/doi/10.1111/apt.12942/abstract>

The third paper, currently in submission, is a systematic review of IBS prevalence around the world.

# Food and Diet Committee

## ROME FOUNDATION WORKING TEAM ON THE ROLE OF FOOD IN FUNCTIONAL GI DISORDERS

### 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:

- Does food intake exacerbate symptoms in FGID and if so, by what mechanism/s?
- Is food intake altered in patients with FGID?
- 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
- Can changes in food intake be used to improve symptoms in FGIDs and if so, by what mechanism/s?
- 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;

### Committee Composition

William D. Chey, MD  
Michigan, USA  
Co-Chair

Jan Tack, MD, PhD  
Leuven, Belgium  
Co-Chair

Fernando Azpiroz, MD, PhD  
Barcelona, Spain

Sheila Crowe, MD  
California, USA

Shanti Eswaran, MD  
USA

Peter Gibson, MD  
Australia

Sue Shepherd, PhD  
Australia

## The Role of the Intestinal Microbiota in FGIDs

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.

Simrén M, Barbara G, Flint HJ, Spiegel BM, Spiller RC, Vanner S, Verdu EF, Whorwell PJ, Zoetendal EG; *Rome Foundation Committee. Intestinal microbiota in functional bowel disorders: a Rome foundation report. Gut* 2013 Jan;62(1):159-76)

### *Committee Composition*

#### **Chair**

Magnus Simrén, MD  
Gothenburg, Sweden

#### **Co-Chair**

Giovanni Barbara, MD  
Bologna, Italy

#### ***Clinical:***

Peter Whorwell, PhD  
Manchester, UK

Robin Spiller, MD  
Nottingham, UK

Brennan Spiegel, MD  
Los Angeles, CA, USA

#### ***Translational:***

Stephen Vanner, MD  
Kingston, Canada

Elena Verdu, MD, PhD  
Hamilton, Canada

#### ***Basic/Microbiology:***

Erwin Zoetendal, PhD  
Wageningen, Netherlands

Harry Flint, PhD  
Aberdeen, UK



## 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.

The article was published in the *American Journal of Gastroenterology*. Drossman DA, Chang L, Bellamy N, Gallo-Torres H, Lembo A, Mearin F, Norton N, Whorwell P, Severity in Irritable Bowel Syndrome: A Rome Foundation Working Team Report. *Am J Gastroenterol* 2011;106:1749-1759.

### Committee Composition

Douglas A. Drossman, MD, Chair Chapel Hill, NC, USA	Anthony Lembo, MD Boston, MA, USA
Lin Chang, MD, Co-Chair Los Angeles, CA, USA	Fermín Mearin, MD Centro Médico Teknon Barcelona, Spain
Nicholas Bellamy, MD, MSc, MBA, DSc, FRCP(C), FRCP, Brisbane, Qld, Australia	Nancy Norton, BS Milwaukee, WI, USA
Hugo E. Gallo-Torres, MD, PhD, PNS Rockville, MD, USA	Peter Whorwell, PhD Manchester, UK

## 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 *Neurogastroenterology & Motility*, May 2009.

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

### Committee Composition

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Mark Kern, PhD Medical College of Wisconsin Dysphagia Institute Milwaukee, WI, USA
Braden Kuo, MD Harvard Medical School Massachusetts General Hospital Boston, MA, USA
Richard D. Lane, MD, PhD University Of Arizona Tucson, AZ, USA
Bruce D. Naliboff, PhD David Geffen School of Medicine at UCLA Center for Neurovisceral Sciences & Women's Health UCLA Los Angeles, CA, USA
Irene Tracey, PhD University of Oxford Oxford, UK

## Outcomes/Endpoints in Pharmaceutical Clinical Trials

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.

**Brennan Spiegel, Michael Camilleri, Roger Bolus, Viola Andresen, William D. Chey, Sheri Fehnel, Allen Mangel, Nicholas J. Talley, and William E. Whitehead. Psychometric Evaluation of Patient-Reported Outcomes in Irritable Bowel Syndrome Randomized Controlled Trials: A Rome Foundation Report, Volume 137, Issue 6, December 2009, Pages 1944-1953.e3**

### **Committee Composition**

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William Whitehead, PhD  
Co-Director of the Center for Functional  
GI & Motility Disorders  
University of NC at Chapel Hill  
Chapel Hill, NC, USA

# Rome IV Educational Books

THE ROME IV EDUCATIONAL MATERIALS INCLUDE SEVERAL BOOKS, EACH SERVING DIFFERENT PURPOSES. THEY ARE AVAILABLE AS HARD COPY BOOKS AND AS PART OF THE ROME ONLINE SUBSCRIPTION:

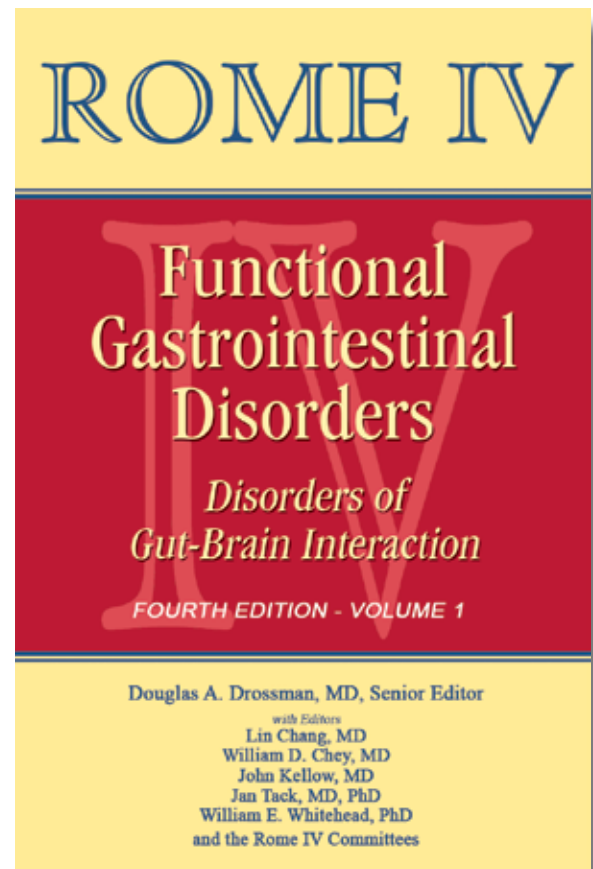
## ***Rome IV Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction*** (Fourth Edition).

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

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.

**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.

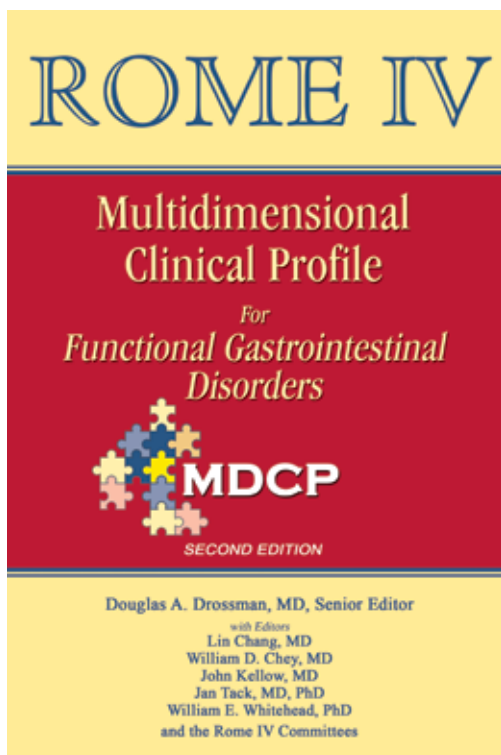
**Volume II** provides the key clinical information on 33 adult and 17 pediatric FGIDs from esophagus to anorectum, as well as a newly developed chapter on centrally mediated disorders of gastrointestinal pain. For each FGID we provide recent information on the epidemiology, pathophysiology, and psychosocial 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.



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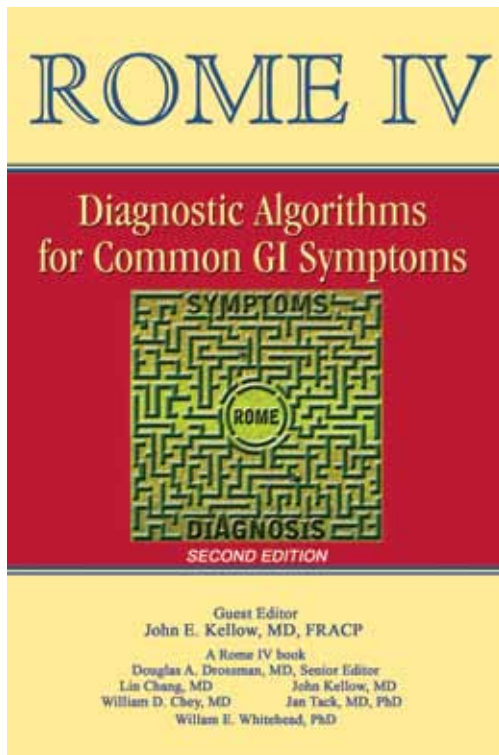
## ***Rome IV Multidimensional Clinical Profile for Functional Gastrointestinal Disorders: MDCP*** (Second Edition)

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).





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## ***Rome IV Diagnostic Algorithms for Common GI Symptoms***

(Second Edition)

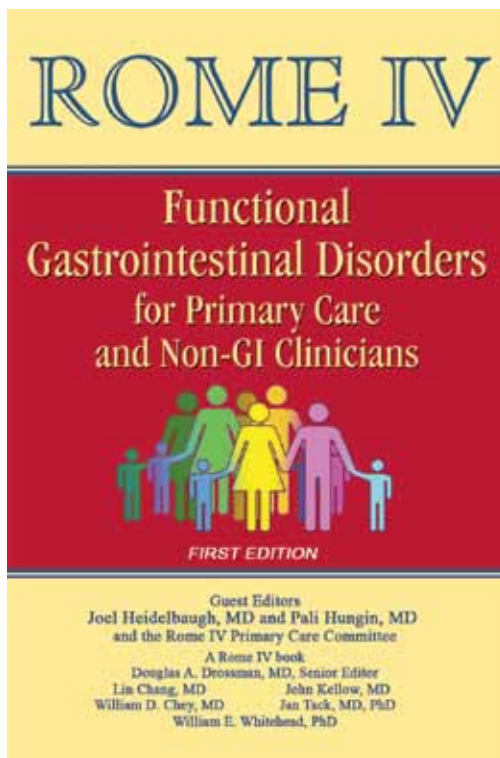
The diagnostic criteria, designed primarily for research, has a limited role in clinical practice. Patients don't go to doctors complaining of IBS, or sphincter of Oddi dysfunction; they present with symptoms of abdominal pain, nausea, vomiting and constipation, among others. Accordingly, the Foundation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

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

This 2nd edition, with guest editor John Kellow, MD, was developed concurrent with that of the Rome IV book. Thus we called upon the Rome IV chapter committee members to accomplish this update and revision with the creation of new algorithms, all consistent with Rome IV diagnostic guidelines and criteria. Now there are 19 algorithms for adults, and 10 for neonates, toddlers, children and adolescents. The book is organized into 8 separate chapters that cover the symptom presentations of the primary GI regions in adults (esophagus, gastroduodenal, biliary, bowel, anorectal and centrally mediated abdominal pain) as well as the symptom presentations in 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.



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## ***Rome IV Functional Gastrointestinal Disorders for Primary Care and Non-GI Clinicians***

(First Edition)

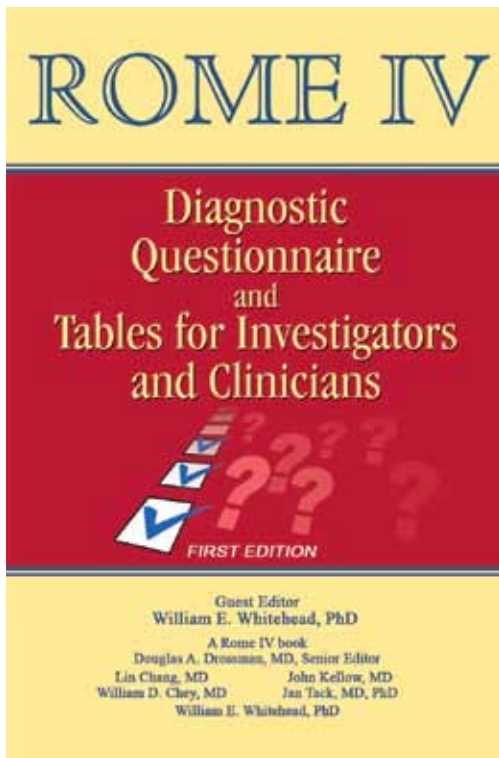
As noted, one of the Rome IV initiatives was that of reaching a larger audience of non-gastroenterologists. We have partnered with leaders in the primary care field to create a primary care book, co-edited by Joel Heidelbaugh, MD, and Pali Hungin, MD.

For many years, the Rome Foundation has heard from primary care physicians that our educational materials are “too complex, cumbersome, and not efficient” for practical day-to-day use. Taking this as a challenge, in 2010 the Board of Directors prioritized the effort to find ways to learn more about how primary care physicians understand and approach diagnosis and treatment of 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 children/adolescents, 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.



## ***Rome IV Diagnostic Questionnaires and Tables for Investigators and Clinicians***

(First Edition)

The Rome Foundation maintains a major commitment to the creation and dissemination of good research in the field of 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.

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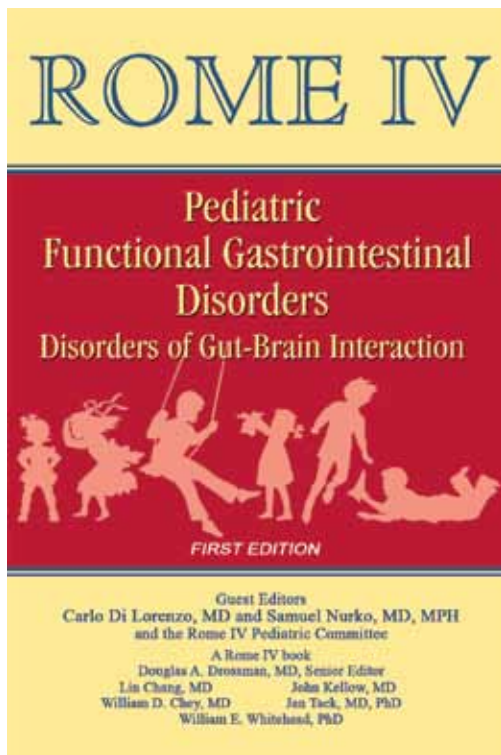
To maintain this initiative for Rome IV, we developed an extensive multinational program to first create the Rome criteria through our Rome IV chapter committees, and, in

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.



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## ***Rome IV Pediatric Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction***

(First Edition)

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.

## **ROME IV ONLINE SUBSCRIPTIONS**

A *major* enhancement to our educational program will be to provide all books online on a subscription basis, allowing the individual to do free-text searching across all book platforms. For example, searching “functional dyspepsia” will lead to links in the Rome IV books, algorithms, MDCP, pediatrics and primary care.

We believe that this will be a very popular option for clinicians and investigators as it will always be accessible through a password and can be purchased with several options.

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The MDCP is an effective educational tool not only for case-based self-learning but also for presentation at conferences. We are providing approximately 150 PowerPoint slides for the MDCP cases.

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The online version of the Rome IV book contains over 650 graphic images. We have also compiled these images into an educational slide program. Each image has a legend and reference for self-learning or for PowerPoint presentation at meetings.

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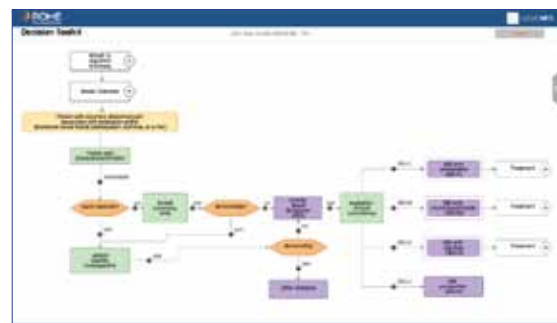
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### ***Rome – LogicNets Collaboration***

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.

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.



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[www.laspgan.org](http://www.laspgan.org)

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[www.aafp.org/events/fmx.html](http://www.aafp.org/events/fmx.html)

### ACG 2017

Orlando, FL  
October 13-18, 2017  
[www.gi.org](http://www.gi.org)

### UEG WEEK

Barcelona, Spain  
Oct. 28- Nov. 1, 2017  
[www.ueg.eu/week](http://www.ueg.eu/week)

## 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 IV and Rome Foundation Sponsors

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

Benefits of Rome Foundation Sponsorship include the following:

- Participation in annual advisory meetings of the Rome Foundation Advisory Council
- Opportunity to make presentations at Rome Foundation Advisory Council meetings
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