



ROME FOUNDATION REPORTER

Volume 11, Issue 1, Spring 2018

Rome Foundation Newsletter

PRESIDENT'S REPORT

Douglas A. Drossman, MD
President, Rome Foundation
Spring 2018



Dear Rome Foundation Members, Friends and Sponsors,

I'm pleased to present to you an update on our current and future initiatives. The Rome Foundation has continued help promote awareness, education and newer techniques to help clinicians and investigators in gaining knowledge about GI disorders and the skills to treat them. Through our efforts, we are changing our discipline for the better and ultimately helping our patients. We are proud of our efforts and so appreciative of your support.

Here are some of the great things we've been up to over the past year:

ROME ENTERS THE DIGITAL WORLD

With the publication of 6 books, the culmination of five years of intensive work among 126 investigators in over two dozen countries, we have disseminated Rome IV knowledge around the world, selling over 35,000 books and 9,000 chapter reprints since the Rome IV launch in 2016. These products are all available in our bookstore: www.romeonline.org.

We have learned through our marketing research though, that many clinicians and scientists are moving away from hard copy books to digital platforms. To realize Rome's longstanding goal to make our information more affordable and accessible, we've introduced digital innovations that provide the same excellent content in more accessible formats.

New products and features Rome launched in 2017:

Rome IV Online. If you prefer an online reference source, we offer Rome IV Online. This contains thousands of pages of content including 50% more information than in the printed books—on a digital platform accessible for a small fee (<https://romeonline.org/romeonline-books/>). Users now may access all the texts with an easily navigable search engine, and will have access to over 700 high quality graphic images not available in the printed books. Purchasers of hard-copy Rome IV books also have discount options for purchasing the digital versions.

Rome IV Interactive Clinical Decision Toolkit. With access to both the Rome IV Diagnostic Algorithms and the Rome IV Multidimensional Clinical Profile for FGIDs (MDCP) in our toolkit, clinicians may now use this intelligent software system to navigate the complexity of FGIDs and their treatment in real time as they work with their patients. This innovative program will give access

to Rome expertise to practitioners around the world, helping them diagnose and treat patients, increase their own knowledge and credentials, and contribute to outcomes-based learning facilitated by this constantly-adapting learning system.

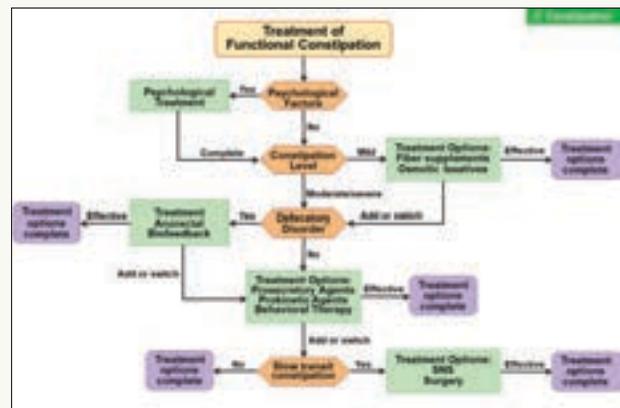


Figure 1. Rome IV Toolkit treatment pathway for treating Functional Constipation

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

Rome IV slide sets. The Rome IV slide sets (Figure 2) contain all the graphical images used in our Rome IV education materials: 1)

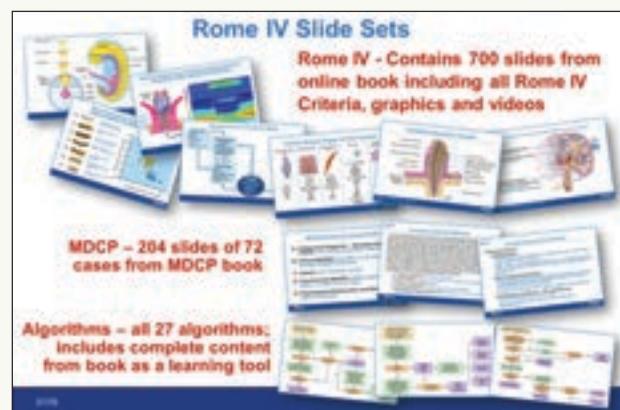


Figure 2. Rome IV slide sets

continued on page 2

Rome IV complete slide set, with images and videos from the print and online Rome IV chapters, and 58 slides of the Rome IV diagnostic criteria; 2) Rome IV MDCP slide set, containing 72 cases (2-3 slides each case) containing the history, the MDCP categories and the recommended treatments; and 3) Rome IV algorithm slide set that includes 35 slides for presentation.

Rome Foundation Social Media

We have taken advantage of popular digital media platforms to spread information on Rome IV and our initiatives. Our Rome Foundation Facebook page (<https://www.facebook.com/RomeFoundation/>), managed by Social Media Coordinator, Hayley McCorkle, is updated with Rome news and activities, live streams, and allows us to share ideas with partners. It also features a weekly video Q/A session on a challenging clinical topic, and more lighthearted posts and activities like “5 things you should know....” and “Friday Challenging Questions.” Like us now to join in the conversations.

Rome also has a twitter feed, @romefoundation, which we use to offer real-time information during lectures and symposia and also allows us to engage quickly with other organizations doing important work in the field of FGIDs. Follow us on twitter to stay up-to-date on current projects and announcements.

BOARD OF DIRECTOR CHANGES

William E. Whitehead, PhD

Rome Foundation Board of Directors, 1990-2018

Our heartfelt thanks go to Dr. William Whitehead for nearly two decades of service to the Rome Foundation and to his scientific contribution to our field. Bill joined the first Rome Working team on the classification of the functional GI disorders in 1990 and continued to serve on the board of directors—and on many Rome initiatives—until this year. **Thank you, Bill, for your contributions to GI medicine and for your service to The Rome Foundation.**

Laurie Keefer, PhD

Rome Foundation Board of Directors, 2018-

We are most pleased to welcome Dr. Laurie Keefer to the Rome Foundation Board of Directors. Dr. Keefer is Associate Professor of Medicine and Psychiatry Icahn School of Medicine at Mt. Sinai Hospital in NYC, and Director of the hospital's Psychobehavioral Research in Gastroenterology. She is well recognized in research and teaching of cognitive behavioral and other psychological treatments for IBS and IBD, and is the co-founder of Psychogastroenterology Section of the Rome Foundation. We look forward to her contributions to the Rome Foundation and the GI field in general during her term.

ROME FOUNDATION RESEARCH INITIATIVE (RFRI)

With the publication of Rome IV behind us and our educational products now available we are undergoing the additional initiative to help support investigators around the world. To that end, we have initiated a project to create the Rome Foundation Research Institute (RFRI), which we envision becoming the premier research mechanism to sustain our field and better help patients.

We are pleased to have Magnus Simren MD, a recognized leader in research and treatment of FGIDs, as the Director of this

daunting and ambitious initiative. With our membership of key investigators around the world who have a record of scientific accomplishment in our field, we are well-positioned under Dr. Simren's leadership to realize our dream. We have begun to develop a database of investigators willing to participate in this research and who would be interested in funding from the RFRI institute. We can add to their resources with the results of our Global Epidemiology Study consisting of 70,000 individuals in 35 countries, and provide infrastructure for biostatistics, data analysis and clinical phenotyping to carry on future studies. With our own research instruments translated into up to 30 languages; a biobank of specimen acquisition, retrieval, and analysis; and a strong cohort of industry supporters who have expressed interest in the initiative, the RFRI is poised to become one of our most important contributions to the medical community. Planning for the structure and objectives of the RFRI are underway.

ROME FOUNDATION INITIATIVES

Rome Foundation Mentoring Program

We are pleased to offer opportunities for early-stage investigators to obtain expert consultation on research that they are developing through the continuation of last year's inaugural Annual Rome Foundation Investigator Mentoring Program. Meet this year's class at DDW in the Dogwood Room of the Marriott Marquis Hotel on Saturday June 2 from 3:30 – 5:30 PM, where awardees will present proposed research studies to experienced investigators who will review their proposals, identify pitfalls or opportunities and give advice on how to improve them. There is no age or level of training restriction and we encourage international applicants. Visit our website for more information.

Global Initiative and Epidemiology Study

Under the direction of Ami Sperber MD, we are wrapping up a five-year project collecting meaningful clinical and epidemiological data from 32 countries. The study is being undertaken using Rome IV criteria and the Rome IV Diagnostic Questionnaire along with other instruments designed for transnational research. With data collection expected to be finished by summer 2018, we will soon have the most extensive data on functional dyspepsia, IBS, and functional constipation, and other FGID issues in the world. We look forward to publications based on this data appearing as soon as 2019 and the database's inclusion in the developing Rome Foundation



Figure 3. Global Epidemiology Study Locations

continued on page 4

ROME FOUNDATION BOARD OF DIRECTORS

JUNE 2018



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Beer-Sheva, Israel



Jan Tack, MD, PhD
Leuven, Belgium

OUR MISSION IS:

“TO IMPROVE THE LIVES OF PEOPLE WITH FUNCTIONAL GI DISORDERS.”

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Research Institute database. We thank our sponsors for their support of this global initiative: **Ironwood Pharmaceuticals, Shire pharmaceuticals, Allergan pharmaceuticals, and Takeda Pharmaceutical Company.**

Rome Foundation – AGA Institute Lectureship

For the last several years the Rome Foundation and the AGA have worked together to enhance the dissemination of knowledge in the FGIDs. Beginning with the Rome-AGA Lectureship at DDW, now in its 11th year we have co-sponsored top level speakers to present “prime time” at DDW on. This year (Figure 6) we are reviewing the role of the gut microbiota as related to disorders of gut-brain interaction.

The Rome-AGA Lectureship will be held on Monday June 4 from 2:00 – 3:30 at the Washington Convention Center Room 146AB. Other collaborative activities with AGA have included the annual Research competitive awards (see above), and AGA endorsement on Rome satellite symposia. The AGA is also a participant in the Rome Foundation Advisory Council.

ROME FOUNDATION WORKING TEAM COMMITTEES

Between the work of the chapter committees (Rome I, II, III, IV), the core of the Rome Foundation’s educational activities centers on our Working Team Committees. We bring expert participants in specialized fields together to come to consensus on topics during the development of a manuscript for publication. Prior publications have included: the assessment of severity in IBS, the microbiome in FGIDs, cross cultural aspects of research in FGIDs, food and FGIDs, brain imaging, and assessment of clinical outcomes in treatment trials.

Working Team on Gut-Brain Neuromodulators for FGIDs

This team is focused on bringing attention to new ways of treating gastrointestinal pain. Their efforts have paid off with the publication of the cover article in the March issue of *Gastroenterology*: “Neuromodulators for Functional Gastrointestinal Disorders (Disorders of Gut-Brain Interaction): A Rome Foundation Working Team Report. *Gastroenterology* 2018; 154: 1140-1171. (Figure 4) <https://goo.gl/2tsgAT>



Figure 4. Cover of March Issue of *Gastroenterology*

The committee’s work will also be highlighted at a major symposium at DDW at the convention center on Saturday June 2 from 2:00 -3:30 PM in room 145A: Central Neuromodulators for Chronic GI Pain and FGIDs: A Rome Foundation Working Team Report.

Working Team on Pediatric Clinical Trials

To match our increased emphasis on the special needs of pediatric patients that was featured in Rome IV products and approaches, we have sponsored the creation 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 the committee has brought together international experts on GI disorders in pediatric patients to come together to outline procedures and assumptions for researching FGIDs in children. 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. In March, 2018, the committee met with FDA to decide whether their recommendations will be adapted by the US regulatory agency. The decision is still pending.

Working Team on Post Infection IBS

Another working team chaired by Giovanni Barbara MD has been formed to address the connection between acute infectious gastroenteritis and later functional dyspepsia and IBS. It will review literature and clinical practice, and outline areas of needed research and practical clinical guidelines.

Working Team on Brain Imaging in Functional GI Disorders

Under the leadership of Emeran Mayer and Qasim Aziz, this working group is exploring the efficacy and use of brain imaging approaches to study symptom-based disorders including chronic pain, disorders of mood and affect, and functional GI disorders. The committee is completing their work and is submitting their findings in a manuscript for peer review.

We are proud of all our initiatives, and hope that you will continue to follow us and support our efforts. We expect to continue the many projects we have begun and hope to introduce new initiatives over time to accomplish our mission. Remember to look for us at DDW 2018 in Washington, DC in June and visit us at booth 540 for updates on many of our educational products and activities. Thank you for your continued support of our mission, and for your work in improving the lives of patients everywhere.

With all best wishes,

Douglas A. Drossman, MD
President, Rome Foundation

- UPDATE -

ROME FOUNDATION MENTORING PROGRAM



Jan Tack, MD, PhD

to young investigators who are interested in setting up research in FGIDs but who lack access to experience and guidance in this area.

The program began in 2017 with Young Investigators submitting brief outlines of research projects which were reviewed and approved by the Rome committee to present at an inaugural meeting at Digestive Disease Week 2017. The program was co-chaired by Magnus Simrén and Jan Tack and was co-organized by Dianne Bach and Michael Stolar, well-known from their past work for the AGA Institute.

To fulfill our mission to improve the lives of people with functional gastrointestinal disorders (FGIDs), one goal is to advance the scientific understanding of the pathophysiology of these disorder to optimize clinical management. This requires high quality research to enhance our knowledge. Through our Young Investigator Mentorship, the Rome Foundation provides support

Based on the originality and relevance of the proposed studies, and the potential for improvement through peer feedback, five international applicants were selected. Each briefly presented his or her project before a panel of experienced researchers in functional gastrointestinal disorders. They provided feedback, identified pitfalls or opportunities and gave recommendations to optimize study design, study conduct and define outcome parameters. The interactions were lively and feedback from the candidates confirmed the usefulness of the comments and recommendations they received.

A second call went out early 2018, from which four international applicants were selected who will present their research proposal to a slightly expanded expert panel at Digestive Disease Week 2018. In addition, the young investigators who were selected in 2017 will present a brief progress report on their research.

The mentorship program creates a unique opportunity for early stage investigators gain the tools to develop a career in the FGIDs, and also provides them the opportunity to network with experts who they can consult with during the planning, execution and analysis of studies. Based on our track record so far, we believe the Rome Foundation's Young Investigator Mentorship Program clearly fulfills a major need to help shape the future of functional gastrointestinal disorder research. Aspiring young researchers who missed this year's call should consider applying in 2019!

THE ASSOCIATES OF ROME PROGRAM HAS GROWN TO WELL OVER 2000 MEMBERS IN 84 COUNTRIES SINCE ITS INCEPTION IN 2010.

**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/.





THE ROME FOUNDATION RESEARCH INSTITUTE (RFRI)

Magnus Simren, MD
RFRI Director

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

ROME FOUNDATION RESEARCH INSTITUTE

Vision

To be the global leader in FGID research.

Mission

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

Aim

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

Implementation

Establish an international academic research initiative with leading experts, in order to facilitate global FGID research through collaboration with industrial and academic partners and with the following objectives:

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

The institute will be directed by Dr. Magnus Simrén (Research Director), who together with Drs. Jan Tack and Douglas Drossman form an executive committee who coordinate the activities in RFRI. The Executive Committee, with advice from a Research Advisory Committee, consisting of international Rome

Foundation Board Members and selected external members covering adult and pediatric clinical and translational research in FGIDs, and the Industry Council, comprised of representatives of companies that provide financial support to the RFRI. The Executive Committee will be ultimately responsible for assuring the aims and objectives of the program are achieved (Figure 5). The work within RFRI will be done on the RFRI Cores with dedicated tasks, in line with project needs. The activity of the Cores will be determined by the ongoing and expected activities and workload within the RFRI, and their composition may vary accordingly.

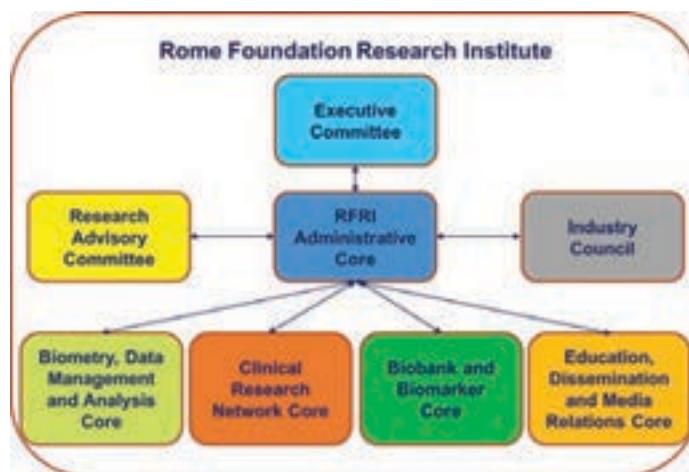


Figure 5. Organization of the Rome Foundation Research Institute

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



DOUGLAS LEVINE, MD TO BE CONSULTANT TO THE EXECUTIVE COMMITTEE OF THE RFRI

We are pleased to welcome Doug Levine, MD in his new position with the Rome Foundation. Doug is well known to all of us, and most recently has served as an ad hoc consultant to the RFRI during the early phases of development. We are thrilled to give him this more permanent role working with the Rome Foundation as we move forward with the RFRI.

Doug's career within gastroenterology and the FGIDs began when he was on the faculty in the Division of Gastroenterology at the University of Washington School of Medicine in Seattle, WA (1985-1997), where he worked as a physician and clinical investigator. He published over 200 research articles and was principal or associate investigator on more than 30 US federal grants or university contracts. After his faculty appointment, he moved into executive clinical development roles and medical affairs in the pharmaceutical industry. He was Executive Director of Strategic Development at AstraZeneca (1997-2010), Head of Medical Scientific Affairs at Ironwood Pharmaceuticals (2010-2014), and Head of Internal Medicine Global Medical Affairs at Shire Pharmaceuticals (2010-2014). His responsibilities

included the design and implementation of new organization infrastructures, operational processes, and therapy areas, R&D functions, and supervising Medical Affairs departments. Doug led three US class-leading products in Clinical or Medical Affairs roles, advised executive teams charged with industry environment initiatives (patient centricity, industry leadership, corporate reputation, health care innovation & policy), and medically managed six brand launches in US and Europe. In 2015, Doug was selected as the Industry Representative for the FDA Gastrointestinal Drugs Advisory Committee.

Doug's interaction with the Rome Foundation began with his support and involvement in relation to the Rome Foundation Global Study, a 35 country five-year epidemiological project which is now in the data analysis stage. More recently, over the last year he has helped us with the creation of the RFRI, and to advise us on implementing initiatives and policies from the perspective of the pharmaceutical industry. Doug's productivity and creativity in this capacity has now led us to give him a formal position as Consultant to the Executive Committee of the RFRI.

JOIN THE ROME FOUNDATION MAILING LIST



Subscribe to our mailing list to receive the Rome Foundation's quarterly newsletter and free updates on:

- Special Announcements
- Educational product special offers
- News of upcoming events
- Quarterly e-newsletter

Under normal circumstances, emails will be sent no more frequently than once per month. Your information will be kept strictly confidential. We do not share our mailing list with other organizations under any circumstances. This list also helps us serve you better by providing us with valuable information on the visitors on our website.

Complete the form on our website to sign up
www.theromefoundation.org/resources/newsletter/ mailing-list/

ROME IV INTERACTIVE DECISION TOOLKIT

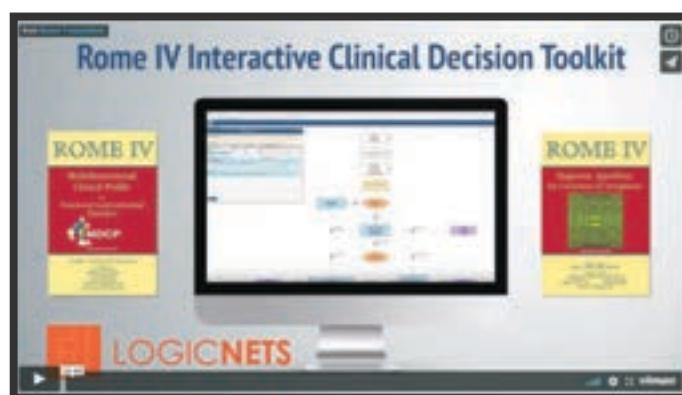
Available for Online Purchase and Use



Chaitanya Pabbati, MD
Assistant Professor, Department of Psychiatry
University of California San Diego School of Medicine
MHICM Medical Director, VA San Diego Health System
Communications Chair, San Diego Psychiatric Society

The Rome IV Clinical Decision Toolkit has now been available for purchase and use for nearly a year, and in that time we've continued to make improvements to the program. With updates coming both to the clinical information and the user interface, our program continues to adapt to meet the needs of all clinicians who care for patients with Functional GI Disorders.

One update, driven by request from users, has been to update the reference sections of the Toolkit so that each reference takes the user directly to the PubMed page. This allows are users to access primary literature directly from within the program. Additionally, we have added information related to new treatments and new biomarkers being studied for IBS-D: anti-CdtB and anti-Vinculin. This update reflects the ease of making regular clinical updates within the toolkit, improving the access to cutting-edge information for all users of the Clinical Decision Toolkit.



Additionally the Rome Foundation is finalizing the treatment algorithms for Pediatric Functional GI disorders. Spearheaded by Dr. Samuel Nurko, this new addition to the Toolkit will help cement this program as the gold standard for the diagnosis and treatment for all patients with FGIDs! Our anticipated release date is in the Fall of 2018 and this module will be incorporated into the existing toolkit at no extra charge to current users.





EARN UP TO 12 CE/CME CREDITS*

The Rome Foundation Symposium

On Functional GI Disorders

for Physician Assistants & Nurse Practitioners

A Rome Foundation Continuing Medical Education program

Learn to treat the most common gastrointestinal illnesses in your practice while earning valuable CE/CME credit. Attend our comprehensive symposium to discover new ways to treat your patients using the best, up-to-date knowledge, treatments and lifestyle changes.

Register 60 days before each symposium to receive a \$50 discount

OPTIMIZE YOUR SKILLS IN DIAGNOSIS & TREATMENTS OF FGIDS

Functional gastrointestinal disorders (FGIDs), including irritable bowel syndrome, chronic GI pain and chronic constipation, are the most commonly diagnosed gastrointestinal illnesses in GI. The Rome Foundation interactive symposium will cover the diagnosis and treatment of the most common FGIDs, featuring interactive talks by the world's leading Functional GI experts. Emphasis will be placed on the most prevalent FGID seen by clinicians, with topics chosen specifically to benefit nurse practitioners, physician assistants, dietitians and mental health professionals.

CHOOSE FROM 4 BEAUTIFUL LOCATIONS

To learn more about our symposium, see full agenda and speakers, or to register visit our website romefoundation.org/CME



October 13-14, 2018 - Santa Fe, NM
Santa Fe, Buffalo Thunder Resort

Special Room Rate of \$214 for conference. Experience one of Santa Fe's most unique golf, spa, and gaming resorts.



January 19-20, 2019 - New York, NY
Crowne Plaza Times Square

Visit Rockefeller Center, take in a Broadway show or visit world class museums.



February 9-10, 2019 - San Antonio, TX
Venue TBD

Explore the River Walk lined with restaurants, galleries and shops.



June 15-16, 2019 - Myrtle Beach, SC
Marriott Resort & Spa

Special Room Rate of \$309 for conference. 60 miles of sand, sun and ocean. Bring your family and make it a vacation!

EARN

Earn up to 12 CE/CME credits* by attending one of our comprehensive symposium.

LEARN

Learn to diagnose and treat Functional Gastrointestinal Disorders using a patient-centered approach.

MEET

Meet world-leading experts & join interactive sessions outlining the latest psycho-gastro techniques to manage GI pain & symptoms.

REGISTRATION OPENS APRIL 15: www.theromefoundation.org/cme

ROME FOUNDATION RESEARCH PROGRAM



Ray E. Clouse, MD

RAY CLOUSE AWARD

FOR BEST RESEARCH PUBLICATION ON FGIDS
AND MOTILITY DISORDERS, 2018

(best paper in our field, published in 2017)

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 GI and motility disorders and of gastroenterology in general.



Sara Botschuijver, MSc

Tytgat Institute for Liver and Intestinal Research
Academic Medical Center
Amsterdam, The Netherlands

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

Sara Botschuijver, is currently finishing her PhD at the Tytgat Institute for Liver and Intestinal Research at the Academic Medical Center in the Netherlands under the supervision of dr Rene van der Wijngaard in the neuro motility group of Wouter de Jonge.

Her PhD research was centered on the role of intestinal fungi in the irritable bowel syndrome (IBS). One of the hallmarks of IBS is visceral hypersensitivity, which is suspected to represent the pathological process behind the abdominal pain observed in most of IBS patients. The PhD research of Sara showed that fungal recognition is important in the development of visceral hypersensitivity. Because this mechanism is a novel observation, the research could open up new treatment options for abdominal pain in IBS.

Sara started her career as a technician in

biotechnology. She became aware that more in depth knowledge was needed in her profession and therefore completed the master Bio-molecular Sciences at the Vrije Universiteit in Amsterdam. This move resulted in a change of her interests towards mucosal immunity and intestinal microbiota. She has a strong analytic and scientific nature with a focus on applied science. Her interest in the human microbiome was recognized with the Microbiome Award 2016 in Amsterdam for the most original, innovative and applicable proposal that describes the use of the human microbiome. Sara's social commitment is expressed by the promotion of public awareness for the potential harmful health effects of aviation, in respect to ultra-fine particle matter emission. At home she loves to culture fungi for culinary purposes, inspired by the findings from her PhD trajectory.

ROME FOUNDATION RESEARCH PROGRAM



Ken Heaton, MD

KEN HEATON AWARD

FOR THE PAPER MOST CITED ON FGIDS AND MOTILITY DISORDERS, 2018

(most cited paper in our field, published in 2016)

The Rome Foundation established an award for the most cited paper in memory of Ken Heaton MD, former Consultant Physician at the Bristol Royal Infirmary and Reader in Medicine at the University of Bristol.



Doris Vandeputte, PhD

Department of Gastroenterology
Translational Research Center for Gastrointestinal Disorders
Leuven, Belgium

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

This article was cited 97 times.

Doris Vandeputte obtained a Master of Science in Bio-engineering Sciences in 2012 at the Vrije Universiteit Brussel, Belgium. With the support of an IWT grant, she started a PhD in the lab of Prof. Jeroen Raes at the Katholieke Universiteit Leuven and defended her work entitled 'Covariate identification in the human gut microbiome' in April 2017. During her PhD, Doris set up, analyzed, and

evaluated multiple projects and guided several master thesis students. She gained experience in microbial metabolism, ecology, statistical procedures and coding in an open-source environment. Doris is (co)-author of several papers in the gut microbiome field, published in renowned journals like *Gut* (3), *Nature* (1), *Science* (1), *Nature Microbiology* (1) and *FEMS* (1).

AGA RESEARCH FOUNDATION - ROME FOUNDATION

FUNCTIONAL GI AND MOTILITY DISORDERS RESEARCH AWARD RECIPIENTS - 2018



Faranak Fattahi, PhD

Asst. Professional Researcher
University of California San Francisco
San Francisco, CA

Title: *Modeling diabetic gastroparesis using human pluripotent stem cells*

Abstract: Gastroparesis is among the most severe and common neurodegenerative complications of diabetes mellitus. The GI is innervated by a vast network of neurons and glia that is referred to as the "enteric nervous system" (ENS). The tremendous complexity of the ENS and the unavailability of appropriate human cell-based platforms for disease modeling have profoundly limited our understanding of the molecular pathophysiology and the development of rationally-designed therapeutics for diabetic gastroparesis. As such, there is currently a huge demand for mechanistic investigation of the cellular processes that underlie the diabetic ENS damage in order to provide effective treatment strategies. We are proposing a multidisciplinary project

using a newly established framework to derive ENS lineages from human pluripotent stem cells (hPSC) to study the effects of diabetes-related stress conditions on the ENS. For the first time, this study will provide a systematic and comprehensive analysis of diabetes induced cytotoxicity in enteric neurons. The proposed biochemical, metabolomics, transcriptomics and high content drug screening experiments in hPSC-derived ENS cell types are designed to elucidate the molecular mechanisms of the disease and identify candidate therapeutic targets in parallel. These efforts will open up new avenues for development of novel treatment strategies for diabetic gastroparesis and pave the way for in-depth studies of many other enteric neuropathies in future.



Shaoyong Yu, MD

Assistant Professor of Medicine
Division of Gastroenterology, Johns Hopkins University School of Medicine
Baltimore, MD

Title: *Expression and function of an "Itch" receptor MrgprC11 in sensory afferent neurons in the GI tract*

Abstract: Visceral nociception initiated by activation of visceral afferent neurons is the most common symptom in the functional gastrointestinal disorders. At present, afferent neurons that specifically encode noxious stimuli in the GI tract are still poorly defined. In somatosensory system, the nocifensive responses are mediated by afferent C-fibers that upon activation often lead to pain (to withdraw) or itch (to remove) in order to avoid tissue damage. As a recent seminal discovery in sensory neurobiology, MrgprC11, the orthologue of human MrgprX1 that belongs to the newly discovered Mrgpr (Mas1-related G protein-coupled receptor) family, is selectively expressed in primary afferent neurons and plays a distinctive role in mediating histamine-independent itch sensation. This proposal aims to determine whether such "itch" receptor mediates functional response in C-fiber

neurons in the GI tract. Our preliminary studies demonstrate that: Mrgpr is expressed in esophageal-labeled DRG and vagal nodose-jugular ganglion (NJG) neurons; MrgprC11 selective agonist (BAM8-22) evokes action potential discharges in esophageal vagal jugular C fibers in wild type (wt) but not Mrgpr cluster knockout (Mrgpr Δ -/-) mice; and Localized application of BAM8-22 (esophageal injection) induces nocifensive response in wt but not Mrgpr Δ -/- mice. We will combine genetic and electrophysiological approaches to fully investigate, for the first time, the expression and function of MrgprC11 in afferent C-fiber neurons in the esophagus. Accomplishment the goal of this proposal will not only help to reveal a novel mechanism of esophageal nociception but also enable us to develop new target on visceral nociception in GI functional disorders.

WE ARE PLEASED TO PROVIDE SOME OF THE ARTICLES THAT HAVE BEEN PUBLISHED OVER THE LAST YEAR THAT HIGHLIGHT THE ROME CRITERIA.

Rome in Clinical Practice and Outcomes

Aziz I, Palsson OS, Tornblom H, Sperber AD, Whitehead WE, Simren M. The Prevalence and Impact of Overlapping Rome IV-Diagnosed Functional Gastrointestinal Disorders on Somatization, Quality of Life, and Healthcare Utilization: A Cross-Sectional General Population Study in Three Countries. *Am J Gastroenterol*. 2018;113(1):86-96. Epub 2017/11/15. doi: 10.1038/ajg.2017.421. PubMed PMID: 29134969.

Drossman DA. Improving the Treatment of Irritable Bowel Syndrome With the Rome IV Multidimensional Clinical Profile. *Gastroenterol Hepatol (N Y)*. 2017;13(11):694-6. PMID: 29134969.

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Working Group Reports

Drossman DA, Tack J, Ford AC, Szigethy E, Tornblom H, Van Oudenhove L. Neuromodulators for Functional Gastrointestinal Disorders (Disorders of Gut-Brain Interaction): A Rome Foundation Working Team Report. *Gastroenterology*. 2018;154(4):1140-71 e1. PMID: 29274869.

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Pediatric

Robin SG, Keller C, Zwiener R, Hyman PE, Nurko S, Saps M, Di Lorenzo C, Shulman RJ, Hyams JS, Palsson O, van Tilburg MAL. Prevalence of Pediatric Functional Gastrointestinal Disorders Utilizing the Rome IV Criteria. *J Pediatr*. 2018;195:134-9. PMID: 29398057.

Zeevenhooven J, Koppen IJ, Benninga MA. The New Rome IV Criteria for Functional Gastrointestinal Disorders in Infants and Toddlers. *Pediatr Gastroenterol Hepatol Nutr*. 2017;20(1):1-13. PMID: 28401050; PMCID: PMC5385301.

Validation of Rome Criteria

Aziz I, Palsson OS, Tornblom H, Sperber AD, Whitehead WE, Simren M. Epidemiology, clinical characteristics, and associations for symptom-based Rome IV functional dyspepsia in adults in the USA, Canada, and the UK: a cross-sectional population-based study. *Lancet Gastroenterol Hepatol*. 2018;3(4):252-62. PMID: 29396034.

Clevers E, Whitehead WE, Palsson OS, Sperber AD, Tornblom H, Van Oudenhove L, Tack J, Simren M. Factor Analysis Defines Distinct Upper and Lower Gastrointestinal Symptom Groups Compatible With Rome IV Criteria in a Population-based Study. *Clin Gastroenterol Hepatol*. 2018. PMID: 29510215.

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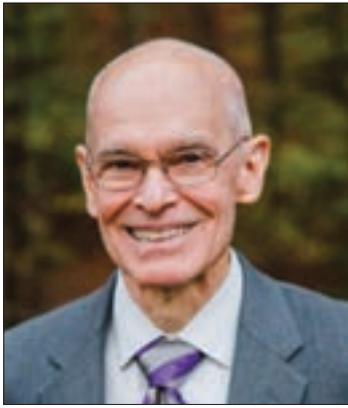
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Vork L, Weerts Z, Mujagic Z, Kruijmel JW, Hesselink MAM, Muris JWM, Keszthelyi D, Jonkers D, Masclee AAM. Rome III vs Rome IV criteria for irritable bowel syndrome: A comparison of clinical characteristics in a large cohort study. *Neurogastroenterol Motil*. 2018;30(2). Epub 2017/08/15. doi: 10.1111/nmo.13189. PubMed PMID: 28804974.

BOARD OF DIRECTOR CHANGES

Dr. William Whitehead Retires From The Rome Foundation Board After More Than 25 Years Of Service

By Olafur Palsson, Psy.D



At the upcoming Rome Foundation meeting at DDW in Washington DC in June, Dr. William (Bill) Whitehead will finish his

long tenure of service as a member of the foundation's Board of Directors. He has been a constant presence and major influence in the work of the Rome Foundation for more than 25 years.

Bill is a clinical psychologist and Professor of Medicine (Digestive Diseases) and Adjunct Professor of Obstetrics and Gynecology at the University of North Carolina. He is a career researcher who has had continuous NIH research funding for more than fifty years (since 1977!) and has been one of the leaders in the field of functional GI disorders for decades. For most of his career, he has focused his investigative efforts on anorectal and functional bowel disorders, and in particular on constipation, fecal incontinence and IBS. His research studies have principally aimed at enhancing understanding of key psychological and physiological mechanisms that play a role in lower GI functional disorders, examining the overlap and comorbidities of functional GI disorders, and improving outcomes for hard-to-treat GI disorders through behavioral treatment. Among his most influential scientific contributions have been early studies of visceral pain sensitivity (he was a pioneer in barostat measurement), studies elucidating family influences on gastrointestinal symptoms through learning and modeling, key studies on biofeedback treatment for fecal incontinence and constipation, major publications on somatization in functional GI disorders, and detailed investigations of how symptoms behave over time in IBS.

Bill co-founded the UNC Center for Functional GI and Motility Disorders in 1994, and co-directed it with Doug Drossman until 2011. He has been the Center's Director since that time. In close collaboration with Doug, he made the Center one of the principal powerhouses in the U.S. in research and education on functional GI disorders.

In addition to directing a highly productive research, clinical care and education team at UNC, Bill has been tireless in mentoring and educating young people in the field throughout his career. A large number of residents, fellows and junior faculty in gastroenterology, psychology, and urogynecology have grown into competent investigators under his tutelage, amplifying his impact on the field of functional GI research. Bill is also a uniquely prolific collaborator. He has established and maintained very active joint research efforts across the country and across the world with other influential investigators, each of which

have yielded numerous important publications: These include collaborations with Rona Levy's team in Seattle, Shin Fukudo's team in Japan, Magnus Simren's team in Sweden, Giuseppe Chiarioni in Italy, Paul Enck in Germany, and Reuben Wong in Singapore.

Bill joined the Rome Foundation Board of Directors in 1992, having already been involved in committee work with the organization for a while. He participated actively in the creation of every iteration of the Rome diagnostic criteria, from Rome I to Rome IV, and has helped shape the evolving thinking about functional GI disorder through his many roles within the foundation.

One of Bill's most notable contributions to the Rome Foundation's mission has been his steadfast emphasis on scientific validation of the Rome criteria. He personally led the way in this by carrying out formal validation studies of the Rome III and Rome IV criteria, as well as by publishing factor-analysis studies and studies of the overlap between Rome diagnostic entities that have helped support the validity of the criteria and highlight remaining issues for refining them further.

Bill's devotion to the field and to the Rome Foundation has led him to volunteer to be involved in many different aspects of the foundation's work. In addition to being on expert working teams defining the diagnostic criteria for anorectal and bowel disorders, he chaired the Questionnaire Development Committee for Rome III and Rome IV, was the sole Western member of the Rome Asian Working Team that endeavored to expand research and understanding of functional GI disorders in Asian countries, and participated actively on a committee defining standards for functional GI treatment trials. More recently he has chaired the Rome Foundation's research and finance committees and been a member of the executive committee.

Bill remains a very active investigator, and will undoubtedly continue to make his mark on the field in multiple ways through his publication and continuing studies. He is presently launching a large multi-center NIDDK-funded trial in collaboration with other prominent Rome Foundation members (Satish Rao and Adil Barucha). This ambitious project, which Bill leads and initiated, examines the relative benefits of biofeedback, sacral nerve stimulation, and bulking agents injections for treatment of fecal incontinence. The findings will almost certainly have a significant impact on future therapeutic approaches for that problem.

The Rome Foundation would like to thank Bill for his numerous years of invaluable service to the organization, and wishes him much success and satisfaction in his continuing professional and personal endeavors.



Rome Foundation Welcomes Newest Board Member, Laurie Keefer, PhD

The Rome Foundation board of directors is pleased to announce the addition of our newest board member, Laurie Keefer, PhD. Dr. Keefer, joins the Board as its first GI Health Psychologist. Dr. Keefer is an Associate Professor of Gastroenterology and Psychiatry at the Icahn School of Medicine at Mount Sinai in New York City. Dr. Laurie Keefer is an academic health psychologist and the Director for Psychobehavioral Research within the Division of Gastroenterology. She specializes in the psychosocial care of patients with chronic digestive diseases,

specifically inflammatory bowel diseases such as Crohn's or Ulcerative Colitis.

Dr. Keefer's clinical and research interests in the area of IBD disease self-management, gut-directed hypnotherapy, resilience, the psychosocial care needs of emerging adults with chronic disease and cognitive-behavior therapy makes her a highly sought after speaker and mentor. She chairs the Psychogastroenterology Section within the Rome Foundation and is on the Council of the American Neurogastroenterology and Motility Society.

ROME 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. Licensing and a fee schedule for use of these instruments is available through the Rome Foundation www.theromefoundation.org/products/copyright-and-licensing. Rome Foundation Industry sponsors and academic investigators are charged only a nominal administrative fee.

| NAME OF INSTRUMENT (NICKNAME OF INSTRUMENT) | AVAILABLE LANGUAGES |
|--|--------------------------------------|
| Rome IV Diagnostic Questionnaire for Adults (R4DQ) | 40+ languages and localizations |
| Rome IV Diagnostic Questionnaire on Pediatric Functional Gastrointestinal Disorders – Child (R4PDQ) | English, Spanish, Danish |
| Rome IV Diagnostic Questionnaire for Pediatric Functional Gastrointestinal Disorders – Toddler (R4PDQ-toddler) | English |
| Guidelines for Involvement of Mental Health Professional | English |
| Bristol Stool Form Scale (BSFS) | 60+ languages and localizations |
| Celiac Disease - Quality of Life Survey (CD-QOL) | English, Dutch, Japanese, Portuguese |
| Functional Bowel Disorders Severity Index (FBDSI) | English |
| Irritable Bowel Syndrome- Quality of Life survey (IBS-QOL) | 20+ languages and localizations |
| Irritable Bowel Syndrome - Symptom Severity Scale (IBS-SSS) | 50+ languages and localizations |
| Rating form of Irritable Bowel Disease Patient Concerns (RFIPC) | 20+ languages and localizations |
| Comorbid Medical Conditions Questionnaire (CMCQ) | English |
| Satisfaction with Care Scale (SAT-37) | English, Dutch, Japanese, Portuguese |
| Trauma Questionnaire | English, Dutch, Japanese, Portuguese |
| Ulcerative Colitis and Chron's Disease Health Satus Scales (UC-CD) | English |



UPDATE FROM THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS (IFFGD)

SPRING 2018



By Tegan Gaetano

IFFGD was founded in 1991 by one person struggling with the challenges posed by a chronic gastrointestinal (GI) disorder. Since then, we have worked to raise global awareness of the prevalence and burden of these conditions; reduce the stigma often associated with symptoms; provide accessible information to patients, their family members, and the public; and encourage and support research into diagnostic pathways, treatments, and cures. These efforts have been made possible through the collaborative energies and contributions of many. We are grateful for the Rome Foundation's continued support of our mission and for their work on behalf of all those affected by chronic GI disorders.

Awareness

While the general public is becoming more familiar with disorders of the GI tract, much about the symptoms, diagnosis, and treatment of these conditions remains unknown, and myths and misconceptions are common among patients as well as the public. IFFGD currently sponsors three health observances on the U.S. National Health Observances calendar: IBS Awareness Month in April, Gastroparesis Awareness Month in August, and GERD Awareness Week during the week of Thanksgiving in November. By doing so, we seek to broaden understanding of the needs of these patients and encourage open dialogue among patients, healthcare professionals, and the public. We invite you to join us in recognizing these health observances.

Research

IFFGD first offered Research Awards in 2003 and has provided a total of 31 awards to researchers from around the world. These awards recognize the accomplishments of young investigators engaged in significant research in the field of digestive diseases. We are excited to announce the winners of our 2018 Research Recognition Awards at Digestive Disease Week (DDW) in June.

Advocacy

IFFGD continues to champion the needs of the digestive health patient community in Washington by educating key decision makers in Congress and at federal agencies about the needs of the millions of Americans affected by chronic GI disorders. Earlier this year, IFFGD Executive Director and President,

Ceciel T. Rooker, presented on the patient experience at the Great 5 Public Workshop on pediatric IBS and pediatric functional constipation cosponsored by the U.S. Food and Drug Administration (FDA) in association with leaders in the field of digestive diseases. This workshop represents an ongoing effort by the FDA to facilitate open dialogue between the FDA and all stakeholders. We were grateful for the opportunity to bring the patient voice to this important gathering.

We continue to advocate for an expanded research portfolio for chronic GI disorders at the National Institutes of Health (NIH), FDA, and other agencies through The Functional Gastrointestinal and Motility Disorders Research Enhancement Act (H.R. 1187), the first federal bill focused on these conditions. H.R. 1187 will expand research opportunities to improve basic understanding of these conditions and their underlying mechanisms, so that both diagnosis and treatment can advance. IFFGD has worked to get this budget-neutral legislation in front of Congress for many years on behalf of the digestive health community – children, adults, veterans, patients, care givers, healthcare providers, and many more. We encourage you to urge your House Members of Congress to cosponsor this important legislation.

IFFGD Update

We are excited to welcome two new members to the IFFGD team. In October, IFFGD brought on board Emily Taylor as Programs Assistant. Prior to joining IFFGD, Emily worked for the Rome Foundation. During her time at the Rome Foundation, she managed the International Visiting Professor and Lecturer Program as well as assisted with other Foundation projects. More recently, IFFGD welcomed Jamie DuMont as Project Manager. Jamie joins IFFGD after almost 20 years at Blackbaud, the leading software company providing solutions for non-profit organization, and brings with her a focus on building projects that heighten awareness and bolster education.

We invite you to stop by our booth (#536) at DDW in June where we will be sharing some of our new projects and initiatives. We look forward to continuing our work to improve the lives of people around the world affected by chronic GI disorders and appreciate your many contributions on behalf of this patient community. Thank you for your dedicated efforts.

THE STANDARD FOR FUNCTIONAL GI

Rome Foundation has made available its entire Rome IV educational resources in digital format, allowing users to access all Rome IV educational materials from any device with Internet access.

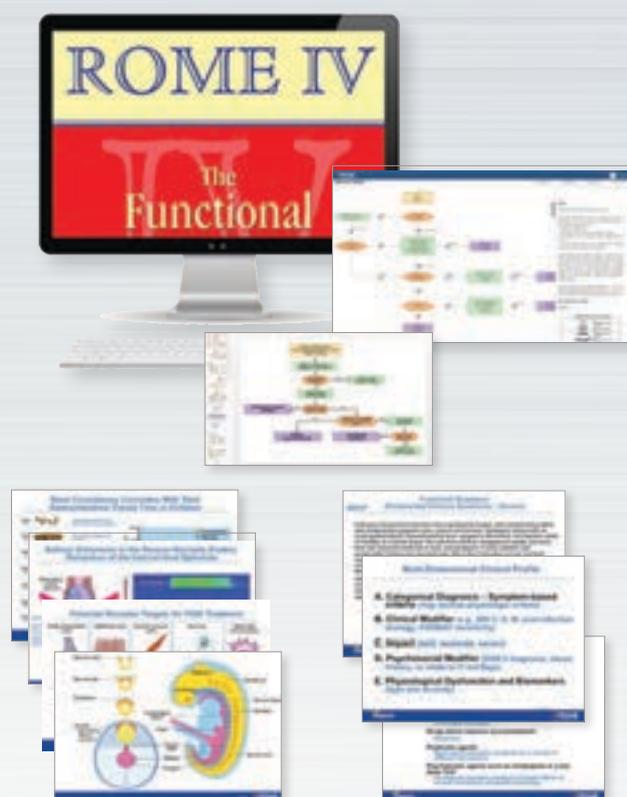
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- **Rome IV Algorithms Slide Set** with 35 slides, including text from the book to supplement and explain each slide
- **Rome IV MDCP Slide Set** with over 200 slides for MDCP cases
- **e-books** available in Kindle format on Amazon



Rome IV Books

- Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction:
 - Volume I: the core science and foundation for FGIDs
 - Volume II: the clinical information for 33 adult and 17 pediatric FGIDs and diagnostic criteria
- Multidimensional Clinical Profile for Functional Gastrointestinal Disorders (MDCP): a case-based learning module for multi-component treatment of over 70 complex cases
- Diagnostic Algorithms for Common GI Symptoms: guides clinicians through the maze of diagnostic studies
- Diagnostic Questionnaires and Tables for Investigators and Clinicians: for performing clinical trials and other studies in English-speaking countries
- Pediatric Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction: includes all the above books Pediatric content in one volume
- Functional Gastrointestinal Disorders for Primary Care and Non-GI Clinicians: the most common FGIDs with diagnosis and treatment for non-GI professionals

Rome Foundation – AGA Institute Lectureship at Digestive Disease Week 2018 Gut Microbiota and Functional GI Disorders (Disorders of Gut-Brain Interactions)



Giovanni Barbara, MD
University of Bologna
Italy

*Post-Infection Functional
GI Disorders (FGIDS)*



Premysl Bercik, MD
McMaster University
Canada

*Gut Microbiome-Brain
Interactions: Relevance
for FGIDs*



Eamonn M. Quigley, MD
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USA

*Microbiota Modulation in
FGIDs: Probiotics,
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THE ROME FOUNDATION



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



- Rome IV Pediatric Functional Gastrointestinal Disorders – Disorders of Gut-Brain Interaction (First Edition)
- Rome IV Functional Gastrointestinal Disorders for Primary Care and Non-GI Clinicians (First Edition)

INFORMATION ON THE ASSOCIATES OF ROME AND FREE ENROLLMENT

LOOK FOR OUR BOOTH AT THESE UPCOMING CONFERENCES

BRAZILIAN CONGRESS OF FGIDS

Sao Paulo, Brazil
May 11-12, 2018

IBS BOLOGNA DAYS 2018

Bologna, Italy
May 17-19, 2018
www.ibsdays2018.it

AAPA 2018

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

DDW 2018

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

FNM 2018

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

ACG 2018

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

UEG WEEK 2018

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

APDW

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



ROME FOUNDATION SPONSORS



ABOUT THE ROME FOUNDATION

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. Over the last 20 years, the Rome organization has sought to legitimize and update our knowledge of the FGIDs. This has been accomplished by bringing together scientists and clinicians from around the world to classify and critically appraise the science of gastrointestinal function and dysfunction. This knowledge permits clinical scientists to make recommendations for diagnosis and treatment that can be applied in research and clinical practice.

The Rome Foundation is committed to the continuous development, 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.

The goals of the Rome Foundation are to:

- 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

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