



## PRESIDENT'S REPORT

**Douglas A. Drossman, MD**  
President, Rome Foundation  
Senior Editor, Rome III Book

It is a great pleasure to provide you with our *Rome Foundation Reporter*. This issue provides an update on our activities over the past year and presents several new initiatives now underway to promote scientific knowledge and educational awareness in the functional GI and motility disorders. I want to thank Carlar Blackman, our newsletter editor for her efforts in producing this issue.

One of the highlights of our activities occurred on the eve of DDW 2008. We held our first Rome Foundation reception at DDW and honored W. Grant Thompson, MD, for his lifetime dedication to the field of functional GI and motility disorders. In addition we awarded a research grant (see pg. 8) and the first Ray Clouse Award for Best Research Publication (see pg. 9). Our new

educational products include the Computer Based Learning Program for Functional GI Disorders as well as a new book for primary care providers: ***Understanding the Irritable Gut***. Both are now available on our website at [www.theromefoundation.org](http://www.theromefoundation.org). It is an exciting time for the field of functional GI and motility disorders and we hope you will share in our enthusiasm to advance science and education in this field.

Our mission is: *"To improve the lives of people with functional GI disorders."*

To accomplish this we have defined two goals:

- Promote clinical recognition and legitimization of the FGIDs
- Develop a scientific understanding of their pathophysiological mechanisms to achieve optimal treatment.



## EDITOR'S REPORT

**Carlar Blackman**  
Editor, Rome Foundation Newsletter  
Administrative Director, Rome Foundation  
Managing Editor, Rome III Book

We hope you enjoy our 2<sup>nd</sup> annual *Rome Foundation Reporter* newsletter to update you on the Rome Foundation's activities and educational products.

With the facilitation of these efforts by Doug Drossman, the work of our talented and capable Board of Directors, and the administrative and business support by George Degnon and Kathy Haynes Johnson at our office in McLean, VA, our clinical and academic international experts can commit their valuable time and effort to produce valuable educational programs in the FGIDs.

Our support staff has also done a great job to bring these educational materials forward.

Jerry Schoendorf, medical illustrator, has worked countless hours with our slide committees to develop our computer-based learning program. Ceara Owre, our new graphics/website designer, has given the Foundation a public face on the internet as well as with the layout of this newsletter.

Thanks to our new Marketing and PR consultant, Ceciel Rooker, our exhibit booth at Digestive Disease Week (DDW) in San Diego far surpassed our efforts over the last few years to showcase the work of the Foundation. She has also made arrangements for the Rome Foundation to have an exhibit booth at both UEGW 2008 in October in Vienna and the 2nd Joint International Neurogastroenterology Meeting to be held in Lucerne in November 2008.

## TABLE OF CONTENTS

### PROGRAM AND PROJECT UPDATES

|                               |    |
|-------------------------------|----|
| EDUCATION REPORT              | 2  |
| ROME EDUCATIONAL PRODUCTS     | 3  |
| RESEARCH PROGRAM HISTORY      | 4  |
| RESEARCH GRANT AWARD -VARMA   | 6  |
| RAY CLOUSE BEST RESEARCH      |    |
| - GECSE, ET AL, 2008          | 7  |
| LATIN AMERICA & SPAIN ROME II |    |
| & ROME III EPIDEMIOLOGY       | 8  |
| CLINICAL ALGORITHMS FOR FGIDs | 9  |
| SEVERITY IN IBS               | 10 |
| BRAIN IMAGING IN FGIDs        | 11 |
| OUTCOMES/ENDPOINTS IN IBS     | 12 |
| OUTCOMES CONFERENCE 2009      | 13 |

### MEETING AND EVENTS

|  |    |
|--|----|
| NGM 2008 JOINT INTERNATIONAL               |    |
| MEETING - LUCERNE                          | 14 |
| NASPGHAN - SALT LAKE CITY                  | 14 |
| 8 <sup>TH</sup> INTERNATIONAL SYMPOSIUM ON |    |
| FUNCTIONAL GASTROINTESTINAL                |    |
| DISORDERS                                  | 15 |
| 1 <sup>ST</sup> ANNUAL ROME AGA LECTURE    |    |
| - GINA KOLATA                              | 15 |
| UEGW 2008 BREAKFAST SYMPOSIUM              | 15 |

### ANNOUNCEMENTS

|                                      |    |
|--------------------------------------|----|
| ROME FOUNDATION POSITION STATEMENT   | 16 |
| LETTER TO ROME FOUNDATION            |    |
| - USE OF ROME I AND ROME II CRITERIA |    |
| IN RESEARCH                          | 17 |

## Rome Foundation Organizational Chart





## ROME FOUNDATION EDUCATIONAL PROGRAM

**Lin Chang, MD**

Several Rome-sponsored educational programs have been initiated in the past 1-2 years. These include the following:

**1. Rome Computer-Based Learning Program.** In an effort to provide a comprehensive educational teaching program based on Rome III knowledge and additional information since the Rome III book was published in 2006, six committees comprised of Rome Foundation members with expertise in each of the topic areas were formed to develop the sets. The modules are: 1) Basic Science/Physiology/Pharmacokinetics, 2) Psychosocial/Quality of Life, 3) Epidemiology, 4) Diagnosis and Criteria, 5) Pediatric, and 6) Management and Design of Treatment Trials. In addition, four modules by specialty were created consisting of relevant slides from the original 6 modules. They are: 1) Primary Care/Health Care Extender, 2) Irritable Bowel Syndrome, 3) Constipation, and 4) Dyspepsia. A module on Brain Imaging in FGIDs is also under development and will be available in the fall 2008. Individual PowerPoint slides for use in presentations are also available. The Computer-Based Learning Program is completed and is available on our website, [www.theromefoundation.org](http://www.theromefoundation.org).

**2. Primary Care book.** Rome Foundation Board member, W. Grant Thompson, has written a book entitled *Understanding the Irritable Gut*, which targets primary care and other health care providers who manage patients with functional GI disorders including irritable bowel syndrome, functional dyspepsia, and constipation. The book combines scientific evidence with a practical approach and clinical experience to be a relevant and educational resource for clinicians as well as patients and the general public. Nancy Norton, the President of the IFFGD, also wrote a chapter on the patient's perspective and experience with these conditions. The book has been completed and is available on our website.

### 3. Lecture programs.

a. The first Rome Foundation-AGA Institute lecture was given at this year's Digestive Disease Week on Tuesday, May 20, 2008 at 10:30am. The speaker was Gina Kolata who is an award-winning senior science writer for *The New York Times*. Her lecture was entitled, "Lessons from Our Patients." The objectives of the lecture were: 1) to help physicians to understand the needs of patients, 2) to provide recommendations to improve the patient-physician relationship, and 3) to identify simple measures to make clinical practice more satisfying to the physician and patient.

b. NASPGHAN Pediatric FGIDs symposium 2007. The Rome Foundation sponsored and participated in a well-received symposium on the lessons learned from Rome III for pediatric gastroenterologists at the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) meeting in Salt Lake City in October 2007.

c. A Rome-sponsored symposium at the 2nd Joint International Meeting on Neurogastroenterology and Motility 2008 will be held at the meeting in Lucerne, Switzerland, on Thursday, November 6 from 1:30-3:00 pm. The symposium, "Working Towards Rome IV" will provide an update on our working team committees and how we can utilize this information as we look forward and prepare for Rome IV.

Doug Drossman will serve as moderator.

The presentations of each committee will be made by:

**Lin Chang** - "Defining symptoms and severity in FGID"

**Nicholas Talley** - "Outcome assessment in FGID"

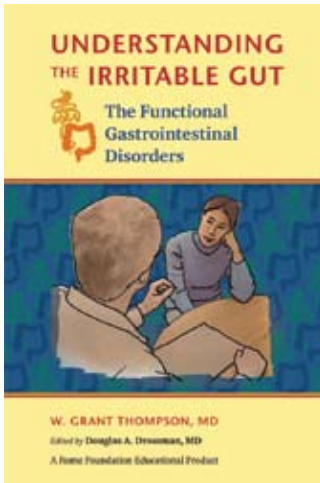
**John Kellow** - "Physiologic testing in FGID"

**Emeran Mayer** - "Brain imaging in FGID"

**4. Clinical Algorithms project.** John Kellow and Henry Parkman are co-chairing a committee to develop algorithms for clinical practice integrating the diagnostic and management strategies for evaluating GI symptoms using symptom-based Rome III criteria for FGID and physiologic testing.

**5. Possible collaboration with ePocrates®.** ePocrates® is the most commonly used handheld PDA program to access medical information. We are under negotiations to make the Rome criteria available for use on ePocrates®.

## PRIMARY CARE BOOK



The functional gastrointestinal disorders (FGIDs) can perplex doctors and patients alike. ***Understanding the Irritable Gut*** seeks to demystify these disorders. W. Grant Thompson, MD., explains with ease and clarity the nature, prevalence, and putative causes of these disorders that affect up to two thirds of individuals worldwide. For the first time, the information developed and assembled by

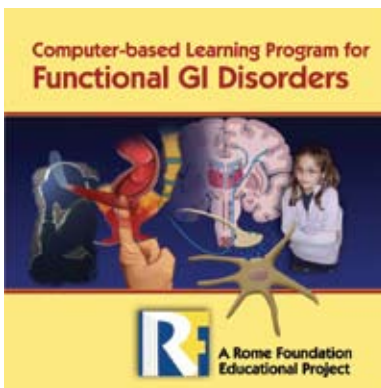
the Rome Foundation in Rome III is translated into a form that allows the identification, classification, and treatment approaches for these disorders that are geared to primary care practice. The information is presented in an easy-to-read, non-technical format that focuses on more fundamental aspects of treatment.

Dr. Thompson presents a general approach to the FGIDs with special emphasis on the all-important doctor/patient relationship. ***Understanding the Irritable Gut*** blends his professional experiences and well recognized writing talent with the information from Rome III. This book is a valuable resource for all non-gastroenterologist health care professionals, students, educated patients, and the general public.

The Rome Foundation was pleased to support the development of ***Understanding the Irritable Gut*** by Dr. Thompson who is universally recognized for his knowledge of the field and superb writing skills. We applaud Dr. Thompson for his continued dedication to the field and for this well written and informative book.

To order this book online go to [www.theromefoundation.org](http://www.theromefoundation.org).

## COMPUTER-BASED LEARNING PROGRAM



The Rome Foundation launched a project to create a graphical learning program for conveying information from the Rome III book, updated with the latest information from the scientific literature in the functional gastrointestinal disorders (FGIDs). We have now completed, for educational purposes, graphically pleasing slides for self learning and

presentations that are consistent with Rome III knowledge. In addition the project also updates this information as new scientific data has emerged since ***Rome III*** was published.

The work of the committees began during Digestive Disease Week (DDW) 2006 in Los Angeles, CA. At that time over thirty individuals working in six committees received an orientation to the expectations and standards of the project and began to identify content areas. During the summer of 2006 the committees met periodically by teleconference to continue to identify appropriate content and to modify and improve its visual presentation. The frequency of these phone meetings increased by December 2006 and early January 2007 in order to prepare for a meeting of all committees that was held on January 18-21, 2007. This meeting led to continued development of content, with additional focus on graphic presentation. The slide set committees again met at DDW in May 2007. At that time, each committee came to agreement on the content and number of slides necessary for their subject and

prepared to present and defend their work during review by all committees.

Since that time, the committees and reviewers have continued to work to complete this project. Jerry Schoendorf, our medical Illustrator has worked diligently with Carlar Blackman, the Project Coordinator, to ensure a smooth progression to the final product. The material was copy edited by Diane Feldman and all modules proofed and checked by reviewers and administration.

As a result of the hard work put into this project by all parties involved, this project has grown significantly larger than its original intent. The total number of slides from all committees is over 750, compared to the original goal of 330 slides. They include a number of animations and videos to enhance the value of the product.

There are six modules by topic which make up the full set. They include: 1) Epidemiology, 2) Basic Science/Physiology, 3) Diagnosis, 4) Pediatric, 5) Psychosocial, and 6) Management and Treatment Trials. Also available are four modules by specialty: including 1) Primary Care/Health Care Extender, 2) Irritable Bowel Syndrome, 3) Constipation, and 4) Dyspepsia.

Each module has been made into a secure format that allows for easy navigation of the material. Users will be able to browse through modules quickly with the notes readily accessible. If PowerPoint slides are needed for presentation, they can be purchased separately.

The Computer-Based Learning Program is available for purchase by download from the website or on CD. Please visit the website [www.theromefoundation.org](http://www.theromefoundation.org) for more details.





## HISTORY OF THE ROME FOUNDATION'S SUPPORT FOR RESEARCH

### William E. Whitehead, PhD

The Rome Foundation has a 9-year history of sponsoring research, which is summarized below. The goals of the research program have been three-fold: (1) to test the validity of the diagnostic criteria so that revisions to the criteria can be empirically based; (2) to increase knowledge of the prevalence and epidemiology of the FGIDs, especially in non-Western countries, in order to provide new insights into pathophysiology; and (3) to interest young investigators in research and clinical practice in the area of functional gastrointestinal disorders (FGIDs) and motility disorders.



### Enrico Corazziari, MD

#### Initial Series of Validation Study Awards – 1999

In 1998, the Rome Foundation Board decided to support research studies on the validation of the Rome I criteria in order to provide a stronger empirical foundation for the revision of the Rome criteria that was anticipated. A Request for Application was published in 1998 and five awards of approximately \$30,000 each were made in January 1999. These are listed below, together with a brief follow-up on each of them:

#### **Validation of the Pediatric Rome Criteria for Functional Gastrointestinal Disorders.**

Principal Investigator: Lynn S. Walker, PhD  
Co-Investigators: Andree Rasquin-Weber, MD, Arlene Caplan-Dover, PhD.

The investigators developed and validated a questionnaire that could be used as an aid to clinical diagnosis of all pediatric FGIDs. The Questionnaire on Pediatric Gastrointestinal Symptoms was published in 2000 and was adopted for the new Rome III criteria (QPGS-Rome III version) and published in the appendix to the Rome III book. It also led to the following publications:

Walker LS, Caplan A, Rasquin A. Manual for the Questionnaire on Pediatric Gastrointestinal Symptoms. Nashville, TN: Department of Pediatrics, Vanderbilt University Medical Center.

Walker LS, Caplan-Dover A, Rasquin-Weber, A. Questionnaire on Pediatric Gastrointestinal Symptoms, Rome III Version (QPGS-RIII). In Drossman DA, Corazziari E, Delvaux M, Spiller RC, Talley NJ, Thompson WG, Whitehead WE (Eds): Rome III: The Functional Gastrointestinal Disorders, 3rd edition. Degnon Associates, Inc., McLean, Virginia, 2006, Pp 963-990.

Walker LS, Lipani TA, Greene JW, Caines K, Caplan A, Stutts J, Polk DB, Rasquin-Weber A. Recurrent abdominal pain: symptom subtypes based on the Rome II criteria for pediatric functional gastrointestinal disorders. J Pediatr Gastroenterol Nutr 2004;39:303-4.

#### **Validation of Rome II Criteria in an Australian population-based study.**

Investigators: Philip Boyce, S. Nandurkar, and C. Burke.

The following publications resulted (in part) from this grant and informed the development of Rome II and Rome III diagnostic criteria:

Talley NJ, Boyce P, Jones M. Identification of distinct upper and lower gastrointestinal symptom groupings in an urban population. Gut 1998;42:690-5.

Boyce PM, Koloski NA, Talley NJ. Irritable bowel syndrome according to varying diagnostic criteria: Are the new Rome II criteria unnecessarily restrictive for research and practice? Am J Gastroenterol 2000;95:3176-83.

Boyce PM, Talley NJ, Burke C, Koloski NA. Epidemiology of the functional gastrointestinal disorders diagnosed according to Rome II criteria: An Australian population-based study. Intern Med J 2006;36:28-36.

#### **Validating the Rome Criteria for IBS: Should an Exclusion for Somatization Disorder be Added?**

Principal Investigator: Carol North, MD  
Co-Investigators: Ray E. Clouse, MD, David Alpers, MD.

The following papers resulted in part from this study:

Miller AR, Norch CS, Clouse RE, Wetzl RD, Spitznagel EL, Alpers DH. The association of irritable bowel syndrome and somatization disorders. Ann Clin Psychiatry 2001;13:25-30.

North CS, Downs D, Clouse RE, Alrakawi A, Dokucu ME, Cos J, Spitznagel EL, Alpers DH. The presentation of IBS in the context of somatization disorder. Clin Gastroenterol Hepatol 2004;2:787-95.

#### **Psychosocial Correlates of Dyspepsia, Non-cardiac Chest Pain and Gastroesophageal Reflux Disease.**

Principal Investigators: Francis Creed

The following publications resulted in part from this grant:

Do childhood adversity and recent social stress predict health care use in patients presenting with upper abdominal or chest pain? Anne-Marie Biggs, Qasim Aziz, Barbara Tomenson, Francis Creed. Psychosomatic Medicine. 2003. 65:1020-1028.

Biggs AM, Aziz Q, Tomenson B, Creed F. Effect of childhood adversity on health related quality of life in patients with upper abdominal or chest pain. Gut. 53(2):180-6, 2004

Fiddler M, Jackson J, Kapur N, Wells A, Creed F. Childhood adversity and frequent medical consultations. General Hospital Psychiatry. 2004; 26: 367-77.

Jackson J, Fiddler M, Kapur N, Wells A, Tomenson B, Creed F. Number of bodily symptoms predicts outcome more accurately than health anxiety in patients attending neurology, cardiology, and gastroenterology clinics. J Psychosom Res 2006; 60(4): 357-363

#### **Clinical and physiological characteristics of functional distal esophageal disorders.**

Principal Investigators: Yehuda Ringel and Charles Burnett Co-Investigators: Kenneth Jones, Nicholas Shaheen, William E. Whitehead, Ray Clouse, and Douglas A. Drossman.

This study formed the basis in part for the following reviews:

Ringel Y, Drossman DA. Treatment of patients with functional esophageal symptoms: is there a role for a psychotherapeutic approach? J Clin Gastroenterol 1999;28:189-93.

Ringel Y, Shaheen NJ, Drossman DA. Functional chest pain of presumed esophageal origin. Arch Intern Med 2002;162:365-6.

*continued on page 5*

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### First Cross-Cultural Study of FGID Award – 2003

In 2003 the Rome Foundation provided a \$25,000 grant to Doug Morgan, MD, MPH, for a study of the epidemiology of functional gastrointestinal disorders in Nicaragua. This was a population-based survey and nested case-control study carried out at the University of Nicaragua, Leon, Center for Epidemiology & Health (CIDS). The project involved translating the Rome II diagnostic questionnaire into Central American Spanish, validating the questionnaire, and a household survey of approximately 1600 subjects. The grant enabled Dr. Morgan to establish a long-term collaboration with the University of Nicaragua in four additional disease areas, thereby providing a platform for long term FGID research in the region. The core results of this study were presented at Digestive Disease Week 2008 (see below). The grant also facilitated the collaboration and parallel Rome II study in Mexico by Max Schmulson, MD.

Becker-Dreps S, Valladares E, Pena R, Cortes L, Morgan D., *Positive association between intimate partner violence and irritable bowel syndrome in Latina women: a population-based study in Nicaragua.* (DDW 2008).

Wurzelmann D, Pena R, Cortes L, Caldera T, Heidt P, Morgan D. *Positive association between traumatic war experiences in the Sandinista Revolution and subsequent IBS: a population-based study in Nicaragua.* (DDW 2008).

Benshoff M, Valladares E, Pena R, Cortes L, Heidt P, Cacaes M, Morgan D., *Post-infectious IBS in the "non-sterile" developing nation environment: the role of parasite burden, a population-based study in Nicaragua.* (DDW 2008).

Morgan D, Cortez L, Morales J, Torres M, Heidt P, Peña R., *A population-based study of IBS and the FGIDs in Latin America.* (ACG 2004, Interim analysis).

Lopez-Colombo A, Bravo-Gonzales D, Corona-Lopez A, Perez-Lopez ME, Cervantes-Ocampo M, Romero-Ogawa T, Morgan D, Schmulson M., *First community-based study of FGIDs México using the Rome II modular questionnaire.* (DDW 2006).

Schmulson M, Ortiz O, Santiago M, Gutiérrez G, Gutiérrez MC, Robles G, Morgan D., *Frequency of functional bowel disorders among healthy volunteers in Mexico City.* (Dig Dis 2006; 24:342).

### Second Cross-Cultural Study Award – 2006

In 2006, the Rome Foundation provided a grant of \$24,000 to a consortium consisting of Douglas Morgan (PI), Rodolfo Peña (PI for Nicaragua), Max Schmulson (PI for México), Freddy Squella (PI for Chile), and Fermín Mearin and Enrique Rey (PIs for Spain) for the Multinational Spanish translation and validation of the Rome III Diagnostic Questionnaire in Spain and Latin America. This study is ongoing. The dissemination of the validated Spanish Rome III Diagnostic Questionnaire is targeted for 2008, and the multinational FGID epidemiology studies for 2009 (see pg. 8).

### Development and Validation of Rome III Questionnaire – 2006

A major change in Rome III was the development of a diagnostic questionnaire which asked subjects to report on the frequency of occurrence of symptoms on an ordinal scale rather than responding only whether the symptom occurred at least 25% of the time on a binary Yes/No scale. The Rome Foundation board commissioned a multi-site study to develop and validate this questionnaire (\$58,978). The goals of the project were to (1) compare the psychometric properties of different response scales in order to select the best one, (2) assess the understandability of individual questions and revise them as needed, (3) identify frequency thresholds for each symptom that are clinically meaningful and that separate FGID patients from healthy controls, (4) assess the sensitivity and specificity of the diagnostic criteria and questionnaire, and (5) assess the reliability of questionnaire-based diagnoses over a two-week interval. The sites participating in the project were the University of North

Carolina (responsible for overall project management), Mayo Clinic, University of Toronto, and University of Michigan. Subjects for the study were 399 patients with clinically confirmed FGID diagnoses and 554 healthy controls. This project was completed in a 6-month period and project data were used to refine the diagnostic criteria and to finalize the diagnostic questionnaire (see Figure). The final report was published in the Rome III book, and the questionnaire and diagnostic scoring algorithm were made available on the web site, [www.theromefoundation.org](http://www.theromefoundation.org).

Figure

| Specificity and Reliability of Rome III Criteria |             |                       |
|--|-------------|-----------------------|
|  | Specificity | Test-Retest Agreement |
| IBS  | 87.8%       | 81.7%                 |
| Constipation                                     | 96.5%       | 93.3%                 |
| Diarrhea   | 99.1%       | 96.2%                 |
| Functional dyspepsia                             | 94.1%       | 84.6%                 |
| Postprandial distress                            | 99.3%       | 85.6%                 |
| Epigastric pain                                  | 100%        | 98.1%                 |
| Chronic idiopathic nausea                        | 99.1%       | 96.2%                 |

### Rome Foundation Research Committee Established – 2007

The Rome Foundation established a Research Committee in January 2007, chaired by William Whitehead and Enrico Corazziari. This committee was charged with (1) developing guidelines for an annual research award program, (2) overseeing the process of soliciting applications and reviewing them, and (3) monitoring progress of grants awarded through semiannual reports from awardees. The guidelines (approved May 2007) specify that one or more awards of up to \$50,000 will be given annually. Preference will be given to applications that (1) test the validity and/or utility of the Rome III diagnostic criteria, (2) assess the epidemiology of functional GI and motility disorders, or (3) advance knowledge of outcome assessment or trial design for FGID treatment trials. Applications will be reviewed by an independent review panel and Rome Foundation Board members are not eligible to apply.

The first award went to **Dr. Varma**, Assistant Professor of Colorectal Surgery at UCSF, for a project titled: **"Comprehensive validation of the Rome III constipation module."** (see pg. 6)

### Annual Ray Clouse Prize for Best Paper on Functional GI and Motility Disorders – 2008

In the fall 2007 the Rome Foundation established the Annual Ray Clouse Award for the best published paper on FGIMDs. Eligible papers include basic and translational research in addition to clinical, epidemiological, and outcomes research. Papers must be published or accepted for publication prior to Digestive Disease Week. Articles authored by members of the Rome Foundation Board are not eligible. Papers may be nominated by anyone, and selection is by a review committee consisting of Nicholas Talley, Enrico Corazziari, and William Whitehead. The annual prize is \$500.

The first Ray Clouse Prize for the Best Paper on FGIMD was awarded to **Krisztine Gecse** for her paper titled, **"Increased fecal serine-protease activity in diarrheic IBS patients: a colonic luminal factor impairing colonic permeability and sensitivity."** This paper was published in the journal **GUT** (see pg. 7).

## COMPETITIVE RESEARCH AWARD 2008 ROME FOUNDATION RESEARCH GRANT

*The Rome Foundation established a Research Committee in January 2007, chaired by William Whitehead and Enrico Corazziari. The Research committee is responsible for developing guidelines, overseeing the process, and monitoring progress of research grants awarded by the Foundation. One or more awards of up to \$50,000 will be given annually. Preference will be given to applications that (1) test the validity and/or utility of the Rome III diagnostic criteria, (2) assess the epidemiology of functional GI and motility disorders, or (3) advance knowledge of outcome assessment or trial design for FGID treatment trials. The first awardee is Dr. Madhulika Varma.*



### Comprehensive validation of the Rome III constipation module

**Principle Investigator: Madhulika G. Varma, MD**  
Assistant Professor,  
UCSF Department of Surgery

Dr. Madhulika Varma is a colon and rectal surgeon who specializes in fecal incontinence and pelvic floor disorders. She is a graduate of Brown University School of Medicine and completed her residency in general surgery at UCSF and a fellowship in colon and rectal surgery at the University of Minnesota. Her research focuses on constipation, fecal incontinence, and pelvic floor disorders.

**Background:** The absence of a standardized, well-validated measure of constipation severity has been a significant obstacle to research that seeks to assess treatment outcomes for constipation. Although the Rome criteria were the standard basis for identifying constipation, their inability to assess symptom severity hindered their use. The newly revised Rome III Constipation Module (RCM) assesses symptom severity and demonstrates excellent test-retest reliability and specificity of diagnostic criteria, but requires further validation testing. We developed the Constipation Severity Instrument (CSI), a reliable and valid sixteen-item measure that assesses constipation severity and identifies constipation subtypes. We propose to strengthen the validity of the RCM and CSI by comprehensively validating both instruments and comparing their ability to assess constipation severity.

**Aims:** To 1) determine convergent validity of the RCM, 2) establish criterion validity of the RCM and CSI, and 3) assess sensitivity to change validity of the RCM and CSI by using their severity scores to test the efficacy of biofeedback therapy.

**Methods:** We will assess convergent validity by correlating RCM subgroup and total scores to CSI subscale and total scores. We will establish criterion validity by using multiple regression analysis of RCM and CSI scores as predictor variables for the number of abnormal anorectal physiology test results, will correlate these scores to all testing results, and will determine threshold severity scores. We will determine sensitivity to change validity by using repeated measures analysis to assess the ability of the RCM and CSI scores to change after biofeedback and counseling for pelvic floor dyssynergia patients. Well-validated, standardized instruments of constipation severity will have significant ramifications on constipation assessment and measurement of treatment outcomes. The use of such instruments has the potential to influence health care providers' perspectives and behaviors, thus producing a significant impact on evaluation, treatment, and perhaps even clinical outcomes.





## 2008 RAY CLOUSE BEST RESEARCH ARTICLE IN FUNCTIONAL GI AND MOTILITY DISORDERS

### Ray E. Clouse, MD

*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 have left an indelible mark in the field of functional GI and motility disorders and of gastroenterology in general. The first awardee for this award was Dr. Krisztina Gecse.*



## PUBLISHED RESEARCH AWARD

***Increased fecal serine-protease activity in diarrheic ibs patients: a colonic luminal factor impairing colonic permeability and sensitivity***

### KRISZTINA GECSE, MD

*Fellow in Training  
1st Department of Internal Medicine  
University of Szeged*

Krisztina Gecse, Richard Roka, Laurent Ferrier, Mathilde Leveque, Helene Eutamene, Christel Cartier, Afifa Ait-Belgnaoui, Andras Rosztoczy, Ferenc Izbeki, Jean Fioramonti, Tibor Wittmann and Lionel Bueno  
Gut 2008 57: 591-599

**Objectives:** Diarrhea-predominant irritable bowel syndrome (IBS-D) is characterized by elevated colonic luminal serine-protease activity. The aims of this study were (i) to investigate the origin of this elevated serine-protease activity, (ii) to evaluate if it may be sufficient to trigger alterations in colonic paracellular permeability (CPP) and sensitivity and (iii) to examine the role of proteinase-activated receptor-2 (PAR-2) activation and signaling cascade in this process.

**Patients & Methods:** Fecal enzymatic activities were assayed in healthy subjects and patients with IBS, ulcerative colitis and acute infectious diarrhea. Following mucosal exposure to supernatants of control subjects and IBS-D patients, EMG response to colorectal balloon distension was recorded in WT and PAR2<sup>-/-</sup> mice and

CPP was evaluated on colonic strips in Ussing chambers. Zonula occludens-1 (ZO-1) and phosphorylated myosin light chain were detected by immunohistochemistry.

**Results:** The three-times increase in fecal serine-protease activity seen in IBS-D patients compared with IBS-C or infectious diarrhea, is neither of epithelial or inflammatory cell origin, nor is it coupled with anti-protease activity of endogenous origin. Mucosal application of fecal supernatants from IBS-D patients in mice evoked allodynia and increased CPP by 92%, both of which effects were prevented by serine-protease inhibitors and dependent on PAR-2 expression. In mice, colonic exposure to supernatants from IBS-D patients resulted in a rapid increase in the phosphorylation of myosin light chain and delayed redistribution of ZO-1 in colonocytes.

**Conclusions:** Elevated colonic luminal serine-protease activity of IBS-D patients evokes a PAR-2 mediated colonic epithelial barrier dysfunction and subsequent allodynia in mice, suggesting a novel organic background in the pathogenesis of IBS.



## ROME FOUNDATION FUNDING FOR THE ROME II AND ROME III INITIATIVES IN NICARAGUA

**Douglas Morgan, MD MPH**

*University of North Carolina, Chapel Hill*

The Rome Foundation funding for the functional gastrointestinal disorders (FGID) initiatives in Nicaragua began in 2003, as a part of the University of Nicaragua (UNAN) and University of North Carolina (UNC) collaboration. The two phases of funding have focused on the Rome II and Rome III programs. The grants have facilitated a series of investigations in the FGIDs in Nicaragua and Latin America, as well as a portfolio of scientific endeavors which promise to enhance our disease understanding, and provide significant benefit to this region of Central America.

The adult gastrointestinal diseases, including the FGIDs, are common health problems globally. Community investigations in varied racial and ethnic populations provide the opportunity to better understand the role of genetics, environment, diet, ethnicity, and psychologic factors. Population based studies in the U.S. Hispanic-Latino population and in Latin America of the gastrointestinal disease burden and the FGIDs have been surprisingly limited. The UNAN-UNC collaboration in gastrointestinal diseases will provide the first population-based data of a range of gastrointestinal diseases, with a focus on IBS and FGIDs.

The Spanish Rome II initiative involved the translation and validation of the Rome II questionnaire and subsequent population-based study of the FGID epidemiology and associated risk factors. The FGID epidemiology in Nicaragua has been shown to have important similarities and differences to developed nations and Asia. Three studies were presented at Digestive Disease Week 2008 in San Diego. These define the role of intimate partner violence, war trauma in the Sandinista Revolution, and chronic gastrointestinal infection and parasite burden.

The Spanish Rome III consortium, with Rome Foundation funding, has established the Latin America working group for the FGIDs. Specifically targeted are the translation and validation of the Rome III criteria and questionnaire, and the study of the FGID epidemiology in Latin America. The consortium includes Mexico (Dr. Max Schmulson), Spain (Drs. Fermín Mearin, Enrique Rey), Chile (Dr. Freddy Squella), and Central America (Drs. Rodolfo Peña, Loreto Cortes, Ricardo Dominguez, Enrique Martinez, Hector Blanco). The dissemination of the validated Spanish Rome III questionnaire is projected in 2008, with submissions to the American College of Gastroenterology and the Panamerican Gastroenterology Congress in Chile. Later, Fermín Mearin and Enrique Rey of Barcelona, Spain joined this multinational initiative.

**Resultant research portfolio.** Importantly, a broad portfolio of research and teaching initiatives has resulted from the initial Rome Foundation funding for the Nicaragua-UNC collaboration.

The collaborative Rome II efforts with Dr. Max Schmulson of the University of Mexico (UNAM), wherein the Nicaragua Spanish Rome II questionnaire and protocol served as templates for the investigations in Mexico.

Gastric cancer epidemiology and prevention program. The Rome Foundation FGID funding facilitated the initiation of a gastric cancer registry and epidemiology program in Nicaragua. This made possible the inclusion of Nicaragua in the "Antigua Consortium" for the prevention of gastric cancer in Latin America, with a funding submission under review with the Gates Foundation.

(Consortium: Nicaragua, Honduras, México, Chile, Colombia, Costa Rica, U.S.).

**The effect of universal infant rotavirus immunization (UIRI) in Nicaragua.** In October, 2006, Nicaragua became one of the first developing world nations to initiate UIRI with the pentavalent RotaTeq® vaccine. This study will define the current epidemiology with UNAN Faculty. The investigation grew out of the PI's (Dr. Becker-Dreps) prior incorporation into the Rome II study team (IBS – Domestic violence study), with current funding from the American Society of Tropical Medicine and Hygiene.

**Burden of diarrheal disease in the remote communities of northwestern Nicaragua.** The 'Collaborative Sahsa Health Initiative' (CSHI) is a broad collaboration involving UNAN, UNC, and Duke to address the health sector needs in the isolated Mosquitia region of Nicaragua, which was further affected by Hurricane Felix in September, 2006. The funding in 2008 includes, GlaxoSmithKline UNC-Duke Global Health Research Grant, and Carolina Center for Public Service fellowship.

**Study of endemic chronic renal disease on the Pacific Coast of Central America (Nicaragua, El Salvador, Costa Rica).** This collaboration between UNC and UNAN has grown out of GI initiatives. In western Nicaragua, renal insufficiency is the number one cause of death. Little is known about the epidemiology of this disease. Pilot funding has been successful, and NIH Fogarty funding is anticipated in 2008.

**UNC-UNAN teaching programs.** The FGID studies and resultant research portfolio have provided a series of opportunities for medical and graduate students of UNAN and UNC. The majority of involved UNC students have successfully competed for NIH STRT grants (T35 DK 007386).

The UNC-UNAN Memorandum of Understanding (MOU) was signed in April, 2008, with the visit to Nicaragua by the UNC delegation, which included UNC School of Medicine Dean William Roper. This will further advance research and teaching collaborations in many areas, including the FGIDs. The primary UNAN investigator, since inception of the FGID program, has been Rodolfo Peña MD DrPH, currently Dean of the UNAN School of Medicine.

In summary, the funding from the Rome Foundation has been instrumental in the advancement of the understanding of the FGIDs in Latin America, and has generated a broad portfolio of research which will benefit the region. Our collaborator in Nicaragua, Rodolfo Peña, has often commented: "Todo es un proceso, pero paso a paso, vamos bien." [Everything takes time, but step by step, we are doing well].





John Kellow, MD

## CLINICAL ALGORITHMS PROJECT



Henry Parkman, MD

As previously reported, the Rome Foundation will be developing clinical diagnostic algorithms for the functional gastrointestinal and motility disorders. Led by John Kellow, MD, and Henry Parkman, MD, the project will summarize and update the data contained in the Rome III publication into clinical diagnostic algorithms for selected FGIDs. Recommended diagnostic decisions will be based on available evidence, where possible. The resultant algorithms should make the essentials of the Rome III FGID classification more accessible to clinicians, and provide acceptable diagnostic pathways for specific FGIDs. The project will not deal with

pathophysiology (except where clinically relevant investigations are required in the diagnostic process).

All participants (*see below*) have now accepted the invitation to develop the algorithms and held the initial planning meeting at DDW 2008 in San Diego. After working through email and conference calls, the committee will have an in-person meeting in early 2009 to review and finalize the algorithms. The process is expected to take about six months to one year from initiation to production.

**Project Administration:**

John Kellow, MD, Co-Chair  
Henry Parkman, MD, Co-Chair  
Carlar Blackman, Project Manager

***Functional Esophageal Disorders***

**Peter J. Kahrilas, MD**  
Northwestern University  
Chicago, IL, USA

**André J.P.M. Smout, MD, PhD**  
University Hospital  
Utrecht, GA  
THE NETHERLANDS

***Functional Gastroduodenal Disorders***

**Jan Tack, MD, PhD**  
University Hospitals Leuven  
University of Leuven  
Leuven, BELGIUM

**Nicholas J. Talley, MD, PhD**  
Mayo Clinic College of Medicine  
Jacksonville, FL, USA

***Functional Bowel Disorders***

**Robin C. Spiller, MD**  
Wolfson Digestive Disease Centre  
University Hospital, Nottingham  
Nottingham, UK

**W. Grant Thompson, MD**  
University of Ottawa  
Ottawa, ON, CANADA

***Functional Gallbladder and Sphincter of Oddi Disorders***

**Peter B. Cotton MD, FRCP, FRCS**  
Medical University of South Carolina  
Charleston, SC, USA

**Enrico Corazzari, MD**  
Università "La Sapienza"  
Roma, ITALY

***Functional Anorectal Disorders***

**Arnold Wald, MD**  
University of Wisconsin School of Medicine and Public Health  
Madison, WI, USA

**Adil E. Bharucha, MBBS, MD**  
Mayo Clinic College of Medicine  
Rochester, MN, USA

***Functional Abdominal Pain Syndrome (FAPS)***

**Douglas A. Drossman, MD**  
UNC Center for Functional GI & Motility Disorders  
Chapel Hill, NC, USA

**Ami D. Sperber, MD, MSPH**  
Soroka Medical Center  
Ben-Gurion University of the Negev  
Beer-Sheva, ISRAEL



Douglas Drossman, MD

As reported last year in the *Rome Foundation Reporter* Newsletter, the Rome Foundation assembled a committee to further explore the assessment of severity in functional GI disorders (FGIDs). The committee members each bring different areas of expertise to this project. Current activities include completion of the review of the literature on severity assessment, and more recently, efforts to collect new data to be published along with the literature review.

In October 2007, the Rome Foundation conducted focus groups from patients that were recruited through the efforts of the International Foundation of Functional Gastrointestinal Disorders (IFFGD) in Milwaukee. The participants filled out screening questionnaires and then were allocated into 3 groups of IBS-C, IBS-D and Mixed IBS. Doug Drossman (Chair) and Lin Chang (Co-chair) facilitated the focus groups, while Nancy Norton (President and Founder of IFFGD and member of the severity committee), Susan Schneck of the IFFGD, and Carlar Blackman took notes on

#### Committee Composition:

##### **Douglas A. Drossman, MD, Chair**

UNC Center for Functional GI & Motility Disorders  
Chapel Hill, NC, USA

##### **Lin Chang, MD, Co-Chair**

UCLA CNS: Center for Neurovisceral Sciences & Women's Health  
Los Angeles, CA, USA

##### **Nicholas Bellamy, MD, MSc, MBA, DSc, FRCP(C), FRCP, (Glas,Edin), FACP, FRACP**

The University of Queensland  
Brisbane, Qld, AUSTRALIA

##### **Hugo E. Gallo-Torres, MD, PhD, PNS**

US Food and Drug Administration  
Rockville, MD, USA

##### **Tony Lembo, MD**

Beth Israel Deaconess Medical Center  
Boston, MA, USA

##### **Fermín Mearin, MD**

Institute of Functional & Motor Digestive Disorders  
Centro Médico Teknon  
Barcelona, SPAIN

##### **Nancy Norton, BS**

International Foundation for Functional Gastrointestinal Disorders  
Milwaukee, WI, USA

##### **Peter Whorwell, PhD**

Wythenshawe Hospital  
Manchester, UK

responses from the patients participating. The sessions were also recorded. A manuscript is currently under development that will report results from these focus groups.

In addition, the committee will use data from a study that is collecting prospective data from community samples of IBS patients to determine patient reported clinical predictors of severity. This study is being conducted by Brennan Spiegel and Lin Chang at UCLA. The committee will also incorporate data being accumulated by the IFFGD and UNC to assess ratings of severity from an internet population of patients with IBS.

The committee plans to finalize the working team report before the Rome Outcomes Conference to be held on April 15-16, 2009, in conjunction with the 8th International Symposium on Functional Gastrointestinal Disorders in Milwaukee.



Lin Chang, MD

## INTERNATIONAL LIAISON COMMITTEE


Dan Dumitrascu, MD  
Cluj, Romania

Carlos Francisoni, MD  
Porto Alegre, Brazil

Shin Fukudo, MD  
Sendai, Japan

Max Schmulson, MD  
Mexico City, D.F., Mexico

The Rome Foundation has formed a new International Liaison Committee to expand our activities internationally. The Rome Foundation will be represented by charter committee members Dan Dumitrascu (Romania), Carlos Francisoni (Brazil), Shin Fukudo (Japan), and Max Schmulson (Mexico). We anticipate that this new committee will increase educational and scientific activities in the FGIDs in Eastern Europe, the Asian-Pacific, and Latin American geographical regions.

The preliminary aims of the International Liaison Committee are to: a) set up a liaison association with regional organizations, b) advise the Rome Foundation on how to implement our global activities in these regions, c) be the liaisons for such activities in their respective regions d) assist in the global dissemination of Rome materials and activities and e) help the Rome Foundation identify key individuals who could work on Rome Committees. By working together, it is likely that this committee can come up with initiatives to support, advise and promote our global outreach effort.



Emeran A. Mayer, MD

## BRAIN IMAGING WORKING TEAM



Qasim Aziz, PhD

The Brain Imaging working team, led by Emeran Mayer (Chair) and Qasim Aziz (Co-chair), was formed in 2005 to review available literature on standards for brain imaging assessment in medicine and to develop guidelines for conduct of brain imaging studies in the functional GI disorders. The document should be completed September 2008 and then submitted for publication to a peer-reviewed journal.

**Committee Composition****Emeran A. Mayer, MD, Chair**

David Geffen School of Medicine at UCLA  
Center for Neurovisceral Sciences & Women's Health  
UCLA, Los Angeles, CA, USA

**Mark Kern, PhD**

Medical College of Wisconsin  
Dysphagia Institute  
Milwaukee, WI, USA

**Bruce D. Naliboff, PhD**

David Geffen School of Medicine at UCLA  
Center for Neurovisceral Sciences & Women's Health  
Los Angeles, CA, USA

**Qasim Aziz, PhD, FRCP (London), Co-Chair**

The Wingate Institute  
London, UK

**Braden Kuo, MD**

Harvard Medical School  
Massachusetts General Hospital  
Boston, MA, USA

**Irene Tracey, PhD**

University of Oxford  
Oxford, UK

**J. Douglas Bremner, MD**

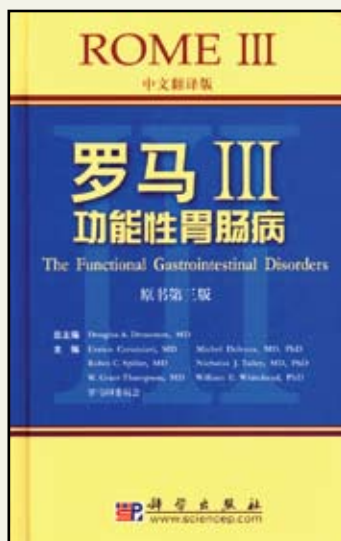
Atlanta VA Medical Center  
Decatur, GA, USA  
Emory University School of Medicine  
Atlanta, GA, USA

**Richard D. Lane, MD, PhD**

University Of Arizona  
Tucson, AZ, USA

## ROME III TRANSLATIONS

*We are pleased to report that there has been tremendous interest in the Rome III work and book internationally. This has precipitated translations of the Rome III book into other languages.*

**CHINESE**

Dr. Meiyun Ke, a Rome III committee member in China, reported that the Rome III book has had great influence in the China for both doctors and patients. She led the way with our Executive Director and publisher, George Degnon, to negotiate with Science Press in China to produce a translation of the Rome III book into Chinese. She and her team translated the book, which was sent to the publication house in December 2007, and was printed in July 2008.

**JAPANESE**

In Japan, another Rome III member, Shin Fukudo facilitated an agreement with Japanese with Kyowa Kikaku Corporation in Japan for the translation, production, sales and distribution of a Japanese translation of ROME III. Shin Fukudo has assisted in the translation, and the Japanese version is expected to be printed either late 2008 or early 2009.

**SPANISH**

Dr. Doug Morgan, who has been responsible for developing the Spanish translation, validation and epidemiologic studies of the Rome II and Rome III questionnaires and creating a Spanish consortium to study the FGIDs, has assisted George Degnon in discussions for a translation of the entire Rome III book into Spanish. An agreement is currently under negotiation for translation of the book into Spanish for print and distribution in Mexico. There is a possibility that the distribution of the Spanish version may expand to other Spanish-speaking countries.



## ROME FOUNDATION WORKING TEAM ON OUTCOMES/ENDPOINTS IN IBS



**Michael Camilleri, MD**

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 created 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. Treatment effect will not be included in the analysis. 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 analyses will answer the following questions:

1. Are global response criteria, including adequate relief and satisfactory relief, superior to scales measuring symptom reduction for discriminating active treatment from placebo (i.e., which endpoints show the largest effect sizes)?
2. What are the placebo response rates for global response criteria relative to symptom reduction criteria?

3. Are response rates associated with global response criteria confounded with baseline symptom severity such that patients with more severe IBS show the smallest global response rates but the largest symptom reductions compared to patients with mild symptom severity at baseline?

### **Status of Committee Work**

Dr. Brennan Spiegel of UCLA, leader of the analysis team, developed a detailed proposal for the project for review by the committee. The proposal was then sent to contacts from pharmaceutical companies that have conducted large, multicenter clinical trials in patients with IBS. Along with Dr. Spiegel, the Rome Foundation has retained the services of biostatistician Roger Bolus, PhD, from San Diego, who has extensive expertise with harmonizing data from multiple trial datasets and preparing these kinds of complex analyses.

The Rome Foundation has been fortunate to gain collaboration from several companies on sharing and transferring their data on endpoints used in IBS clinical trials for this very important project. Data has been received from AstraZeneca, GlaxoSmithKline, Ironwood (formerly Microbia), Novartis, Rottapharm, Solvay. Data receipt is now closed and harmonization and analysis is underway.

The goal of the committee is to complete the analysis, prepare the manuscript for publication, and present the results at the Rome Outcomes Conference to be held Wednesday, April 15 through Thursday, April 16, 2009 in conjunction with the International Symposium on Functional Gastrointestinal Disorders in Milwaukee, Wisconsin.

### **Committee Composition:**

#### **Michael Camilleri, MD, Chair**

Mayo Medical Center  
Rochester, MN, USA

#### **Viola Andresen, MD**

Israelitic Hospital  
Hamburg, GERMANY

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

University of Michigan  
Ann Arbor, MI, USA

#### **Hashem B. el-Serag, MD, MPH**

Baylor College of Medicine  
Houston, TX, USA

#### **Sheri Fehnel, PhD**

RTI Health Solutions  
RTI International  
Research Triangle Park, NC, USA

#### **Allen Mangel, MD, PhD**

RTI Health Solutions  
RTI International  
Research Triangle Park, NC, USA

#### **Emeran A. Mayer, MD**

David Geffen School of Medicine at UCLA  
Center for Neurovisceral Sciences & Women's Health  
Los Angeles, CA, USA

#### **Brennan M. R. Spiegel, MD, MSHS**

VA Greater Los Angeles Healthcare System  
David Geffen School of Medicine at UCLA  
Los Angeles, CA, USA

#### **Nicholas J. Talley, MD, PhD**

Mayo Clinic  
Jacksonville, FL, USA

#### **William Whitehead, PhD**

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

## ROME ENDPOINTS AND OUTCOMES CONFERENCE 2009

### BOARD MEETING ON 1/26-27/08

A major initiative by the Rome Foundation is to host a consensus conference in 2009 on outcomes and endpoints in functional GI disorders (FGIDs). This will be similar to the consensus conference held in Vienna in 1998. The meeting is scheduled for April 15-16, 2009, immediately before the 8th International Symposium on Functional Gastrointestinal Disorders hosted by the International Foundation for Functional Gastrointestinal Disorders (IFFGD) and the Joint International Neurogastroenterology meetings in Milwaukee, Wisconsin.

The planning committee includes Lin Chang, MD (Chair), Douglas A. Drossman, MD, E. Jan Irvine, MD, Nancy J. Norton, Robin Spiller, MD, William E. Whitehead, PhD, and Carlar Blackman. The planning committee anticipates that participants will include academia, the pharmaceutical industry, the EMEA and FDA (and other interested regulatory agencies), and patient advocacy groups.

The conference will be held all day on Wednesday, April 15, 2009 and Thursday morning (until noon), April 16, 2009 in Milwaukee. It will be an open meeting which will last 1½ days just prior to the scientific meeting.

The Outcomes Conference will include presentations on:

- Clinical trial endpoints
- Meaningful outcomes for patients
- Risk-benefit assessment
- Severity of FGID
- Perspectives from Industry, Regulatory Agencies and NIH about Drug Regulation and Development in FGIDs

In addition, there will be brief lectures on the role of the measures below and how they might fit into clinical research in the FGIDs, after which moderated breakout groups will have further discussion. Summaries of each breakout session will be presented to the entire group.

- Role of biomarkers
- Psychological symptoms and co-morbidities
- Health behaviors, economic outcomes, HRQOL

Representatives from regulatory agencies (FDA, EMEA) and the NIH are participating in the meeting. They will participate in presentations and the panel discussion (see above). We are currently contacting representatives from the Japanese Regulatory agency as well.

The Rome Foundation is preparing for this conference through a variety of initiatives. First is the ongoing systematic review and meta-analysis of large pharmaceutical clinical trials databases by the Outcomes/Endpoints in IBS committee (see pg. 12) chaired by Michael Camilleri, MD. A number of pharmaceutical companies are cooperating with the committee by agreeing to share patient-level data from their databases. Brennan Spiegel, MD and Roger Bolus, PhD, a biostatistician, are working on harmonizing and analyzing the data.

Second, we are obtaining data regarding the issue of severity in functional GI disorders through our Severity in IBS Working team (see pg. 10) chaired by Douglas Drossman, MD and

co-chaired by Lin Chang, MD. This involves several separate analyses focused on illness severity based on data obtained from patient focus groups, a large national database of patients diagnosed with IBS coordinated by Douglas Drossman with Nancy Norton of the IFFGD, and the UCLA database of IBS patients coordinated by Brennan Spiegel, MD and Lin Chang, MD. This information will be compiled into a report and presented at the Outcomes meeting.

The Rome Foundation would like to thank our sponsors providing educational grants for the conference:

**Forest Laboratories, Inc.**  
**Ironwood Pharmaceuticals, Inc.** (formerly Microbia, Inc.)  
**Procter & Gamble Pharmaceuticals**  
**Takeda Pharmaceuticals North America**

### ROME FOUNDATION ENDPOINTS AND OUTCOMES CONFERENCE 2009 OPTIMIZING CLINICAL TRIALS IN FGID MILWAUKEE, WISCONSIN

#### DAY 1 – Wednesday, April 15, 2009

|                        |   |
|------------------------|---|
| <b>8:30 – 10:25am</b>  | <b>Clinical trial endpoints</b><br>Results from the Rome Endpoints and Outcomes working team<br>Discussant perspective to original recommendations from Rome III<br>Quantitative interpretation of outcome items<br><i>Discussion</i> |
| <b>10:25 – 10:45am</b> | <b>Break</b>  |
| <b>10:45 – 11:45am</b> | <b>Meaningful outcomes for patients</b><br>Translation of outcome measures to meaningful endpoints<br>Measures of clinical benefit (MCID, MCII, etc)<br><i>Discussion</i>   |
| <b>11:45 – 12:30pm</b> | <b>Risk-benefit assessment</b><br>IFFGD-UNC survey of risk-benefit assessment<br>Other risk-benefit surveys<br><i>Discussion</i>  |
| <b>12:45 – 1:45pm</b>  | <b>Lunch</b>  |
| <b>1:45 – 2:45pm</b>   | <b>Panel discussion</b><br>Perspectives of industry, regulatory agencies and NIH on drug regulation and development   |
| <b>2:45 – 3:35pm</b>   | <b>Severity of FGID</b><br>Update on severity assessment<br><i>Discussion</i>   |
| <b>3:35 – 3:45pm</b>   | <b>Break</b>  |
| <b>3:45 – 5:45pm</b>   | <b>Breakout sessions on other outcome measures</b><br>Role of biomarkers<br>Psychological symptoms and co-morbidities<br>Health behaviors, economic outcomes, HRQOL   |

#### DAY 2 – Thursday, April 16, 2009

|                       |   |
|-----------------------|---|
| <b>8:00 – 10:15am</b> | <b>Presentations of breakout group discussion</b> |
| <b>10:30 – noon</b>   | <b>Discussion of Outcomes Development Project</b> |

## NGM 2008, LUCERNE MEETING SPONSORSHIP

**Lucerne, Switzerland  
November 6 - 9, 2008**



The Rome Foundation is pleased to be a sponsor of the Joint International Meeting for Neurogastroenterology & Motility from 6-9 November 2008, to be held in Lucerne, Switzerland. The meeting is organized by the International Neurogastroenterology and Motility Group (INMG), Functional Brain-Gut Research Group (FBG) and American Neurogastroenterology and Motility Society (ANMS).

The Rome Foundation will be holding a symposium "Working Towards Rome IV," moderated by Douglas A. Drossman, MD & Lin Chang, MD.



### Working Towards Rome IV Workshop

Thursday, 6 November 2008

13:30-15:00

Auditorium

Moderator: Douglas A. Drossman, MD

### Defining symptoms & severity of FGIDs

Lin Chang, MD

David Geffen School of Medicine at UCLA  
CNS: Center for Neurovisceral Sciences & Women's Health  
Los Angeles, CA, USA

### Outcome assessment in FGID

Nicholas J. Talley, MD, PhD  
Mayo Medical Center  
Jacksonville, FL, USA

### Physiological testing in FGID

John Kellow, MD  
University of Sydney  
Royal North Shore Hospital  
St. Leonards, NSW, AUSTRALIA

### Brain imaging in FGID

Emeran A. Mayer, MD  
David Geffen School of Medicine at UCLA  
CNS: Center for Neurovisceral Sciences & Women's Health  
UCLA, Los Angeles, CA, USA

## ROME FOUNDATION CO-SPONSORS NASPGHAN SYMPOSIUM

On October 24, 2007, in Salt Lake City, Utah, as a part of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) annual meeting, a special single topic symposium entitled "New Insights into Childhood Functional Abdominal Pain Syndrome (FAPS) and Irritable Bowel Syndrome (IBS): A Multidisciplinary Approach," was held.

Rome members who presented at the symposium include Marc Benninga, Carlo Di Lorenzo, Doug Drossman, Jeff Hyams, Paul Hyman, Nick Talley, Lynn Walker, and Jackie Wood. The symposium addressed a wide range of topics in the childhood functional gastrointestinal disorders including the role of early life and psychosocial factors, basic science and physiological mechanisms, genetics, and the future of research in the area. In addition, the symposium included a session providing insights from other specialties similar to the FGID's like migraine, chronic fatigue, fibromyalgia, and autonomic dysfunction. Jackie Wood delivered a keynote presentation on basic mechanisms of IBS, while Nick Talley gave another keynote presentation on the role genetics in the field.

The full-day symposium, chaired by Carlo Di Lorenzo, MD of Ohio State University and Samuel Nurko, MD, MPH of Harvard Medical School was jointly sponsored by the Rome Foundation, Nationwide Children's Hospital, Procter & Gamble, NIDDK, TAP Pharmaceutical Products, Inc., and the Pediatric Group. The symposium was a great success with over 350 registrants in attendance.



*From left to right: Jackie Wood, Nick Talley, Sam Nurko, Paul Hyman, Carlo Di Lorenzo, Carlar Blackman, Doug Drossman and Jeff Hyams*



## FIRST ANNUAL ROME FOUNDATION-AGA LECTURESHIP HELD AT DDW 2008



**Gina Kolata**  
Senior Science Writer  
New York Times

*The Rome Foundation held the First Annual Rome Foundation-American Gastroenterological Association (AGA) Lectureship at the Digestive Disease Week (DDW) 2008 meeting in San Diego, on May 20, 2008.*

The speaker was Gina Kolata, Senior Science Writer for the *New York Times*. Ms. Kolata has an undergraduate degree in microbiology, a master's degree in applied mathematics, and studied molecular biology at MIT. She previously worked as a writer for *Science*. She has reported on broad environmental and medical topics including breast cancer, the medical and legal issues surrounding silicone breast implants, experimental AIDS drugs, abuse, obesity, diet and health, relationship of environment and cancer, and cloning.

Dr. Douglas Drossman and Dr. Lin Chang moderated the session.

**The title of the lecture was: "Lessons from our Patients"**

**The objectives were:**

1. to help physicians to understand the needs of patients
2. to provide recommendations to improve the patient-physician relationship, and
3. to identify simple measures to make clinical practice more satisfying to the physician and patient.

## 8TH INTERNATIONAL SYMPOSIUM ON FUNCTIONAL GASTROINTESTINAL DISORDERS

**April 17-19, 2009**  
**Pfister Hotel**  
**Milwaukee, Wisconsin**

This CME accredited symposium will be held April 17-19, 2009, at the Pfister Hotel, Milwaukee, Wisconsin. It is jointly sponsored by the University of Wisconsin School of Medicine and Public Health and the International Foundation for Functional Gastrointestinal Disorders, in cooperation with the Functional Brain-Gut Research Group. A global audience of clinicians and investigators will gather to exchange information on the latest advancements in the areas of functional gastrointestinal and motility disorders. The symposium will offer a format of plenary sessions, interactive workshops and mini symposia on both adult and pediatric disorders - from basic science to clinical applications.

View a video about the meeting at:

[www.iffgd.org/site/news-events/events/professional-symposia/](http://www.iffgd.org/site/news-events/events/professional-symposia/).

For registration information contact:

Terese Bailey,  
Office of Continuing Professional Development in Medicine and Public Health  
2701 International Lane, #208  
Madison, WI 53704,  
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fax (608) 240-6040  
email: [tmbailey@wisc.edu](mailto:tmbailey@wisc.edu).

For further information contact:

Cara O'Brien, IFFGD  
phone: 414-964-1799  
email: [cobrien@iffgd.org](mailto:cobrien@iffgd.org).

THE ROME FOUNDATION  
WILL BE SPONSORING A  
BREAKFAST SYMPOSIUM  
AT UEGW IN  
VIENNA, AUSTRIA  
ON  
OCTOBER 20, 2008  
7:00 - 8:00 AM

### Meet the experts

*How I manage a difficult patient with ...*

- Recurrent belching with Andre Smout, MD, Utrecht, The Netherlands
- Bloating with Peter Whorwell, MD, Manchester, UK
- Chronic diarrhoea following a bout of acute gastroenteritis with Robin Spiller, MD, Nottingham, UK

Chairmen: Enrico Corazzari & Fernando Azpiroz

**Time:**  
Monday  
October 20, 2008  
7:00 - 8:00 AM

**Location:**  
Room L  
on the green level  
of the  
Austria Center  
Vienna

*Sponsored by the Rome Foundation*



16th United European Gastroenterology Week - 18 - 22 October 2008 - ACV - Vienna - Austria



# THE ROME FOUNDATION POSITION STATEMENT 2008

## Who are we?

- The Rome Foundation is a non-profit international organization directed by a board of independent members of scientists and clinicians active in academic, publishing and scientific societies.
- The Rome Foundation facilitates research and educational activities consistent with their mission "to improve the lives of patients with functional GI disorders" and its goals. Activities are proposed and approved by the members of the Board.

## How do we function?

- The Rome Foundation activities are conducted by a Board of Directors. Board members are selected according to guidelines related to gender and geographical diversity, academic performance, international recognition and ability to work in a group environment.
- The Administrative support structure consists of: a) an executive home office that handles fiduciary, sponsorship and legal responsibilities, b) an administrative office that handles board membership and scientific activities, c) a marketing and development office and d) support personnel who when needed work under the direction of these 3 offices.
- The Rome Foundation selects committee members and activities similar to the National Academy of Sciences in the USA.
  - Activities are prioritized by consensus of the Board with advice from consultants as needed.
  - Committee members are selected by the Board based on their qualifications to do the required work according to established guidelines.
  - The Rome Foundation is not a membership organization. It does not compete for members with other groups in the field of functional GI and motility disorders, nor does it compete with activities of these groups.
- The Rome Foundation seeks to collaborate with and support membership organizations that share similar goals:
  - Promote clinical recognition and legitimization of the functional GI disorders
  - Develop a scientific understanding of their pathophysiological mechanisms to achieve optimal treatment.
- The Rome Foundation has set as a directive to provide administrative and/or financial support for activities in collaboration with other organizations. Previous organizations for which support has been provided include: AGA, NASPGHAN, The Joint Neurogastroenterology and Motility Meetings, IFFGD and others.

## What are our activities?

- **Classification and Criteria for the FGIDs.** Historically the Rome Foundation emerged in the field of functional gut disorders at the time when there was no consensus on the definitions and classifications of the FGIDs. There was no common language for research and teaching. Similar to the Diagnostic and Statistical Manual (DSM) for Psychiatry, the Rome organization set up a classification system and criteria for clinical syndromes that were consistent with clinical observation. A consensus ("Delphi") process eventually changed to more evidence based methods for classification and criteria that were based on epidemiological and clinical studies.
  - The clinical syndromes that exist are meant to be a common language for the standardized selection of patients to be included in different types of research studies. They have evolved based on scientific evidence and a process is in place for change of the criteria or classification as new data emerges.
  - The groups of patients defined by clinical criteria are designed to be consistent with the conditions that patients present to their physicians; the disorders are heterogeneous and may include distinctive subgroups with different pathophysiological mechanisms. The subgroups with a common pathophysiology can be identified by research studies and become the target for specific treatment trials.
  - Hence, drug development should be supported by active research programs and follow a series of steps:
    1. characterization of the drug mechanism of action.
    2. among a group of patients defined by clinical criteria, identification of the specific subgroup with a common pathophysiological mechanism that can be corrected by the drug.
    3. a therapeutic trial in this specific subgroup of patients.

Until pathophysiologic mechanisms and biomarkers are available, the Foundation acknowledges that entry criteria for clinical trials in some of the FGIDs may be based on clinical criteria alone.
- **Educational programs and materials.** To fulfill our goals, several educational activities exist which include written material such as the Rome III or primary care books, educational slide programs, lectureships and symposia and support for such activities with other organizations. Recently the Foundation is increasing its efforts to provide world-wide educational activities.
- **Support for research.** With reduced availability of support for research another initiative is to recognize and support research in the functional GI and motility disorders. This includes awards for outstanding publications, research grants and fellowship training.
- **Collaboration.** The 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 current and developing associations are with the IFFGD, FBG, FDA, and AGA

## LETTERS

*To the Rome Foundation:*

*I would like to share an issue that has raised some concerns lately. As the Rome Criteria have evolved from Rome I to Rome III, we are starting to see in meetings as well as in reviewers from peer reviewed journals, criticism when data or research on FGID is presented without using the latest available criteria. For example, if a paper is submitted on patients with IBS, and they are not classified using the Rome III criteria because the study was done or started when Rome I or Rome II criteria were available, a comment from the reviewers may be "Why didn't the authors diagnose the patients according to Rome III?" or "Will the data hold up if patients are diagnosed according to the new Rome III?"*

*Although it is interesting to see if the results change according to the newer criteria, we will not change the FGID diagnosis of our clinic nor our research patients only because they were given using the previous available Rome II or I criteria. This issue is even more important in non-English speaking countries where it takes longer to use the most recent criteria because of the process of translation and validation. I am concerned that we may hear these comments more often as new criteria becomes available.*

*Anonymous*

**ANSWER:**

Thanks for your thoughtful comments. This is an understandable concern that the Rome Foundation has recognized, so we are glad to provide an opportunity to clarify this issue.

The Rome Criteria were designed originally for the selection of patients of clinical studies and has been used increasingly in clinical practice. Validation studies exist that support its accuracy (1) though more are needed. Nevertheless, no diagnostic criteria are "etched in stone" and they require ongoing appraisal and modification over time as new scientific data relating to the pathophysiology of these disorders may affect diagnoses. As a result, the Rome Foundation when moving from Rome I to Rome II and continuing with Rome III, has established and published strict guidelines for modifying existing criteria (2). In effect, we are no longer modifying criteria solely by consensus; the committees are required to provide an evidence-based rationale for changes. For example, the Rome II criteria removed the bowel symptoms of diarrhea or constipation from the stem criteria for IBS that existed with Rome I, and this change continues with Rome III. This change was based epidemiologic factor analysis studies

by Whitehead, et al (3;4) who showed that the diarrhea and constipation clusters were distinct from the IBS stem of "abdominal pain associated with change in bowel habit and/or relief with defecation". Similarly, the decision to subcategorize functional dyspepsia into epigastric pain syndrome (EPS) and postprandial distress syndrome (PDS) was based on emerging data from Tack et al.(5-7) showing physiologic distinctions for these two conditions. This change helps to improve the prior difficulty in clinical trials with the heterogeneity of functional dyspepsia, though is still permitted in clinical practice as an umbrella term. We acknowledge that further validation for all criteria is needed, and we are actively support this through our Research Grant Program: [www.theromefoundation.org/research](http://www.theromefoundation.org/research).

With regard to your question, in most all cases when Rome criteria have been revised or updated, the changes are almost always refinements or "fine tuning" of what previously existed rather than redefinitions. Conceptually the changes do not lead to the selection of a different cohort of patients. For example, as noted above, the change for IBS to eliminate bowel subsets does not change the existing cohort of patients with bowel dysfunction who are classified as IBS based on the stem criteria; in effect the modification for Rome II and III now permit sub-typing of this cohort which is relevant for clinical trials. The same is true for functional dyspepsia, the "umbrella" classification for EPS and PDS. As a result, the Rome Foundation clearly states (8) that the use of previous Rome criteria is acceptable for clinical research when the newest criteria (in this case Rome III) is not available. This is supported by recent data indicating high levels of agreement between Rome II and Rome III in a patient study population (9). For these reasons, we feel it justified to support an author's ability to publish a study using earlier criteria when the newest criteria were not yet available when the study began.

Your comment regarding the challenges of translating newer criteria is one that we recognize and are hoping to address through some new initiatives for the Foundation to support cross-cultural translations of the criteria. Some of this has been done in a joint effort by Drs. Schmulson, Morgan and Mearin for the Spanish speaking countries and other groups are working in the translation into Portuguese, Chinese, and Japanese. We are eager to support others looking to translate, validate or in any way study the applicability of the Rome Criteria in research and clinical practice.

**Rome Foundation****Reference List**

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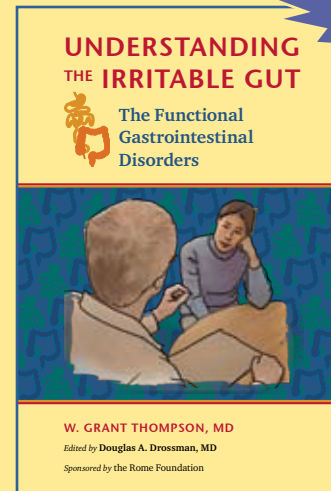


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*Improving the lives of people with functional gastrointestinal disorders*

## Understanding the Irritable Gut

For the first time, the information of the functional GI disorders as developed by the Rome Foundation is presented in an easy to read, non-technical format — ideal for non-gastroenterology health care professionals, students, educated patients, and the general public.



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## Computer-based Learning Program for Functional GI Disorders



## Computer-Based Learning Program for Functional GI Disorders

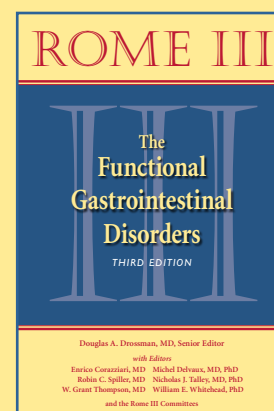
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## FAREWELL TO W. GRANT THOMPSON, MD

W. Grant Thompson, MD, Professor Emeritus (Medicine), University of Ottawa was honored at DDW 2008 on Saturday evening, May 17, 2008, for his contribution to the field of functional GI disorders. He has presented over 200 scientific or educational reports in 5 continents and is the author of 7 highly regarded books in the field of functional GI disorders (FGIDs). Dr. Thompson is also the author of 280 scientific and lay articles dealing mainly with gastrointestinal illnesses and serves on several international committees concerned with the classification and diagnostic criteria for the FGIDs including his work as a Rome Foundation Board member. Notably Dr. Thompson was honored at DDW 2008 on the 30<sup>th</sup> anniversary of the seminal paper that described

the first set of diagnostic criteria for IBS, the Manning Criteria. Dr. Thompson is retired from clinical practice, but remains active consulting in clinical trial design, medical education, medical legal work and writing about the FGIDs.

As a founding member of The Rome Foundation, and a member of the Board, he will be greatly missed.

### CECIEL T. ROOKER



Ceciel joined the Rome Foundation in March 2008 as a consultant for Marketing and Public Relations. She has a background in management and has been instrumental in the development of the newly designed exhibit booth, which premiered at DDW 2008. She has also created the variety of flyers, brochures, giveaways and handouts to assist with the marketing of our programs as well as the educational products.

Ceciel lives in Raleigh, NC with her husband Michael Daughtry and their three children, Tomoko, Meiko, and Yoshiko.

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## 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 clinical recognition and legitimization of the functional GI disorders
- Develop a scientific understanding of their pathophysiological mechanisms to achieve optimal treatment.



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From left to right: (Front row) Carlar Blackman, Nick Talley, Doug Drossman, Bill Whitehead; (Back row) John Kellow, Robin Spiller, Michel Delvaux (2001-2006), W. Grant Thompson, Enrico Corazzari, Lin Chang, and George Degnon

(below: Fernando Azpiroz, MD, PhD, Board Member; Jerry Schoendorf, Medical Illustrator; Kathy Haynes Johnson, Administrator; Ceciel Rooker, Marketing and PR. not shown: Ceara Owre)



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