TENTATIVE PROGRAM SCHEDULE AS OF March 10, 2009 (To be updated as necessary)

ROME FOUNDATION

Endpoints and Outcomes Conference 2009: Optimizing Clinical Trials in FGID

April 15 - 16, 2009

Hosted by
The Rome Foundation
with unrestricted educational grants from:
Forest Laboratories, Inc.
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Takeda Pharmaceuticals, North America

The Pfister Hotel

424 East Wisconsin Avenue
Milwaukee, WI USA

ROME FOUNDATION

www.theromefoundation.org

ENDPOINTS AND OUTCOMES CONFERENCE 2009

OPTIMIZING CLINICAL TRIALS IN FGID

April 15-16, 2009

Pfister Hotel, Milwaukee, WI

This 1½ day meeting will precede the International Foundation for Functional Gastrointestinal Disorders (IFFGD) symposium (April 17-19, 2009). This Conference, an invitational gathering of invited participants, members of the Rome Foundation committees, government representatives, and participants from sponsoring corporations of the Rome Foundation, will feature keynote speakers, followed by a discussant to address key areas of concern, a panel discussion of industry, regulatory agencies and possible NIH, and breakout sessions to discuss the role of other outcome measures. Experts in the field will be invited as speakers, discussants and moderators. The content will include the published literature as well as new information collected in the past 1-2 years (e.g., from Rome working teams) which is relevant to the topics. The conference is open to industry and interested scientists and clinicians. Observers and guests are invited on a space-available basis.

Conference Objectives:

- To critically review the validity of end points that have been used to evaluate treatment efficacy in clinical trials in IBS and other FGID
- To discuss the role of outcome measures including severity, risk-benefit assessment, biomarkers, health related quality of life, and psychological symptoms
- To discuss the current and future development of meaningful and valid end points
- To provide a forum to discuss drug development and regulation amongst industry and regulatory agencies

Program Schedule

Wednesday, April 15, 2009

8:00am-8:30am Introduction and Welcome

8:00am-8:05am	Welcome	Lin Chang
8:05am-8:15am	Historical perspective, Rome Outcomes Conference, WCOG Vienna 1998	William Whitehead
8:15am-8:30am	Goals & aims of this conference	Lin Chang

8:30am-10:30am Clinical trial endpoints

Moderator: Sander van Zanten

8:30am-9:00am	Results from the Rome Endpoints/Outcomes in IBS working team	Michael Camilleri Brennan Spiegel
9:00am-9:20am	Discussant perspective to original recommendations from Rome III	Jan Irvine
9:20am-9:40am	Quantitative interpretation of outcome items (Focus groups and phase II clinical trial data)	Jeffrey Johnston
9:40am-10:00am	Feasibility of using responder definition based on primary endpoint – The experience from Japan	Kei Matsueda
10:00am-10:30am	*Discussion*	Peter Tugwell

10:30am-10:45am Break

10:45am-11:45am Meaningful outcomes for patients

Moderator: Douglas Drossman

10:45am-11:05am	Translation of outcome measures to meaningful endpoints	Donald Patrick
11:05am-11:25am	Measures of clinical benefit (MCID, MCII, etc)	Fasiha Kanwal
11:25am-11:45am	*Discussion*	Brennan Spiegel

11:45am-12:45pm Risk-benefit assessment

Moderator: William Whitehead

11:45am-12:05pm	IFFGD survey of risk-benefit assessment	Nancy Norton
12:05pm-12:25pm	Risk and medications in IBS patients	Brian Lacy
12:25pm-12:45pm	*Discussion*	Brennan Spiegel

12:45pm-1:45pm Lunch

1:45pm-2:45pm **Panel discussion: Perspectives from Industry, Regulatory Agencies and NIH about Drug Regulation and Development in FGIDs**

Moderator: William Chey

Panel: Ruyi He, Laurie Burke, and Ann Marie Trentacosti (FDA), Frank Hamilton (NIH), Sif Ormarsdóttir (EMEA), Olivier Chassany (EMEA consultant), Charles Baum (Takeda)

1:45pm-1:55pm	Perceptions of industry on drug regulation	Charles Baum
1:55pm-2:05pm	Perspective of US regulatory agencies on drug development	Ann Marie Trentacosti
2:05pm-2:15pm	Perspective of EU regulatory agencies on drug development	Sif Ormarsdóttir
2:15pm-2:45pm	*Discussion*	

2:45pm-3:35pm **Severity of FGID**

Moderator: Peter Whorwell

2:45pm-3:15pm	Update on severity assessment (Rome working team, severity focus group, FBDSI, IBS-SS)	Douglas Drossman
3:15pm-3:35pm	*Discussion*	Fermin Mearin

3:35pm-3:45pm **Break**

3:45pm-6:30pm **Breakout sessions on other outcome measures**

Moderator: Magnus Simren

3:45pm-4:05pm	Role of biomarkers	Robin Spiller
4:05pm-4:20pm	Psychological symptoms and co-morbidities	Bruce Naliboff
4:20pm-4:35pm	Health behaviors, economic outcomes, HRQOL	Brennan Spiegel
4:35pm-4:50pm	Clinical end-points for gastroparesis	Henry Parkman
5:00pm-6:30pm	Breakout groups (4 simultaneous sessions)	
	Biomarkers	Spiller/Barbara/Talley
	Psychological symptoms and co-morbidities	Naliboff/Sperber/Lydiard
	Health behaviors, economic outcomes, HRQOL	Spiegel/Streiner/Longstreth
	Clinical End points for Gastroparesis	Parkman/Revicki/Camilleri
	Discussion points	

7:00pm **Group Dinner**

Thursday, April 16, 2009

8:00am-10:00am **Presentations of breakout group discussion**

Moderator: Jan Irvine

8:00am-8:15am	Biomarkers	Spiller/Barbara/Talley
8:15am-8:30am	*Discussion*	
8:30am-8:45am	Psychological symptoms and co-morbidities	Naliboff/Sperber/Lydiard
8:45am-9:00am	*Discussion*	
9:00am-9:15am	Health behaviors, economic outcomes, HRQOL	Spiegel/Patrick/Longstreth
9:15am-9:30am	*Discussion*	
9:30am-9:45am	End-points for gastroparesis	Parkman/Revicki/Camilleri
9:45am-10:00am	*Discussion*	

10:00am-10:30am **Break**

10:30am-11:15am **End-points and outcome measures in pediatric FGIDs**

Moderator: Carlo Di Lorenzo

10:30am-10:45am	The urgent need for pediatric end-points: The scope of the problem	Jan Taminiau
10:45am-11:00am	What do we know about pediatrics and how do we go about developing pediatric end-points in FGID?	Sam Nurko
11:00am-11:15am	*Discussion*	

11:15am-1:00pm **Discussion of Outcomes Development project**

Moderator: Lin Chang

11:15am-11:45am	Patient Reported Outcomes Consortium: Proposed Framework for a Public-Private Partnership	J.R. Assenzo, PhD, Critical Path Institute
11:45am-1:00pm	*Discussion*	