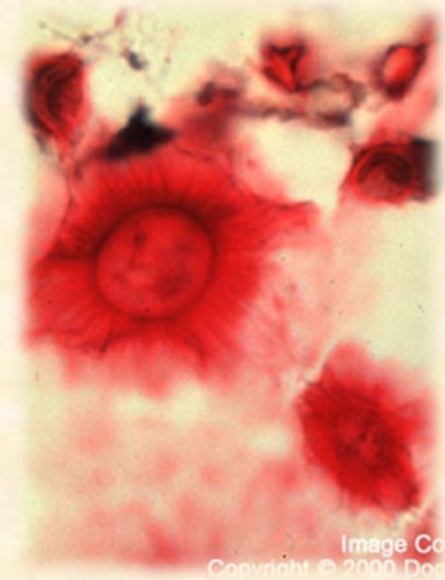


The MSG

Mycoses Study Group Quarterly Newsletter Winter 2010



Welcome to the ***Mycoses Study Group Quarterly Newsletter, winter 2010***. This newsletter is intended to keep our investigators and supporters apprised of the developments within the **MSG** and to encourage support and involvement in our ongoing activities.

I. Meetings

MSG 2010 Annual Meeting

The **MSG 2010 Annual Meeting** will be held on **April 7- 8, 2010** at the Courtyard Marriott in Downtown Philadelphia. The **CME** activity, *Innovations in Diagnosis and Treatment of Invasive Mycoses*, will be on April 7th from 3:30 – 6:30 PM and will be followed by a *MSG reception*. The business meeting with break-out sessions will be on April 8th from 8:00 – 4:00 PM. We're excited about the possibilities of new clinical trials and diagnostic studies and look forward to working with you during the meeting to further the field of mycology. See you in Philly!

Advances Against Aspergillosis

The MSG is a supporter of the AAA. During their next meeting, AAA4, which is scheduled for **February 4-6, 2010 in Rome, Italy**, a special MSG lecture will be given by Raoul Herbrecht, M.D. Be sure to visit their website to stay apprised (WWW.AAA2010.org).

MSG Reception at ICAAC: San Francisco, CA

September 12-15, 2009

The MSG 2009 Reception and Business Meeting was held on September 13, 2009 at the Grand Hyatt San Francisco Hotel located at 345 Stockton Street San Francisco, CA 94108. Attendance was at an all time high with over 100 members, affiliates, and visitors present.

II. Clinical Trials Update

MSG-01: A randomized, double-blind, placebo controlled trial of caspofungin prophylaxis followed by preemptive therapy for invasive candidiasis in high risk adults in the critical care setting.

PI: Luis Ostrosky-Zeichner

Corporate Sponsor: Merck & Co.

All 16 selected sites necessary for this study have been opened for enrollment. Currently, enrollment is at 95% completion with **211** subjects enrolled. The study is registered on Clinicaltrials.gov website.

MSG-02: Candidemia meta-analysis

PIs: Baddley, Andes, Safdar, Playford, Kullberg

Although not formally a “clinical trial”, this concept was presented and approved by the **MSG Steering Committee** and will examine the randomized candidemia treatment trials that have been completed to date. The ‘**working group**’ consists of junior investigators (John Baddley, David Andes, Nasia Safdar,) and a senior advisory group. Bart-Jan Kullberg serves as the primary senior advisor to this group, helping formulate an analysis plan, assigning responsibilities, establishing a timetable, etc. Data analysis is underway and a manuscript will be complete soon. A full presentation is expected at the **2010 MSG annual meeting**.

MSG-03: Invasive Aspergillosis Combination Study

PI: Kieren Marr

Corporate Sponsor: Pfizer

Currently, 152 total sites, 31 domestic and 121 international are participating in this pivotal trial. There have been **308** patients enrolled, 35 from the U.S. and 273 from international sites. Accrual for this study is going well and should complete enrollment earlier than scheduled.

MSG-04: Empirical Antifungal Therapy in the ICU

PI: Luis Ostrosky-Zeichner
Corporate Sponsor: Merck & Co.

The MSG Steering Committee has approved a new clinical trial entitled “*A pilot randomized, double-blind, placebo-controlled trial of caspofungin empirical therapy for invasive candidiasis in high-risk adults in the critical care setting*”. This is a feasibility study that will assess the utility of a clinical scoring system to select ICU patients to be included in a study comparing caspofungin vs. placebo for empiric therapy for patients at high risk for invasive candidiasis. The trial will be conducted at selected international sites, and will have a target enrollment of approximately 114 patients. The study protocol has been finalized and site selection is underway. In anticipation of starting the study soon, a Web-based investigator’s meeting is planned for late February with enrollment to begin by the end of March 2010.

III. MSG / FDA / EMEA Galactomannan Project

The proposal for the use of galactomannan as a qualified biomarker in the context of a clinical trial for treatment of invasive aspergillosis was judged by the FDA Biomarker Qualification Review Team and the EMEA to have a potentially important impact on drug development and regulatory review. Johan Maertens, Paul Verweij, Barb Alexander, Kieren Marr, and Joe Wheat have spearheaded this effort in the US and Europe. Their leadership and the **MSG’s** supporting role in bringing this effort together culminated in the submission of this document to the FDA/EMEA in March 2008. Our response to the FDA’s queries was submitted in June, 2009. We are still awaiting their response.

IV. The MSG Education Committee

The EC is actively working on setting the 2010 educational agenda. We continue to work with the University of Wisconsin as the CME provider and Debra Joyce of Fallon Medica on events from 2009, but as we move forward into 2010, we will be working with Lisa Tushla and University of Nebraska to develop plans for the next 2-3 years, and to approach potential sponsors for financial support of these activities. These programs will be developed for a variety of venues including, but not limited to, support for the MSG Annual Meeting CME Program, traditional grand rounds, regional seminars, national/international meetings, support of Dr. Fungus, and Web-based educational programs.

V. Ongoing discussions

We are having ongoing discussions with the following companies concerning the **MSG’s** involvement in the clinical development of these compounds:

Novartis: These discussions remain on hold at this time pending further assessment by Novartis regarding the future of efungimab (Mycograb). If the development of this

product moves forward, the MSG remains interested in the clinical development of efungimab in the context of a large international candidemia trial.

We are also in very preliminary discussions over the further development of deferasirox (Exjade) as adjunctive therapy for zygomycosis. More in the coming months.

Merck: The impact of the Merck/Schering-Plough merger remains unclear, but as this moves forward we will provide any useful insights that pertain to the research environment. MSG 04 is approved with plans to enroll the first patient in first quarter 2010.

Basilea: Many of our members are participating in studies involving isavuconazole for the treatment of candidemia and aspergillosis. These studies are still on hold, but will likely be resume in the next few months. The MSG has not entered into any formal discussion with Basilea concerning further development of isavuconazole, but we remain very interested in this compound.

VI. MSG Administration

Administrative Structure

*Please welcome **Helen Boucher** and **Bart-Jan Kullberg**, who have agreed to participate as members of the steering committee. They will replace Jack Edwards and Emilio Bouza, who along with Jack Bennett, will both serve as non-voting advisors to the committee. Congratulations Helen and Bart-Jan!*

MSG Central Unit:

Peter G. Pappas, MD, PI
Beth Deerman, RN, Administrator
Peggy Cornelius, Financial Associate
Joyce Kanute, Administrative Assistant

MSG Steering Committee (SC):

Peter G. Pappas, Chair (US)		
Carol Kauffman (US)	Tania Sorrell (AUS)	Bart-Jan Kullberg (NETH)
John Wingard (US)	Jack Sobel (US)	Eric Bow (CAN)
Tom Patterson (US)	John Perfect (US)	Marcio Nucci (BRA)
Raoul Herbrecht (FR)	Helen Boucher (US)	Thierry Calandra (SU)

John Bennett, Jack Edwards, and Emilio Bouza will serve as non-voting advisors.

MSG Education Committee (EC):

US: Susan Hadley (Chair)

David Andes (Co-chair)

John Bennett

Alison Freifeld

Peter Pappas

Barbara Alexander

Helen Boucher

Dimitrios Kontoyiannis

Tom Patterson

John Baddley

Graeme Forest

L. Ostrosky-Zeichner

Kieren Marr

Europe: Olivier Lortholary (FR) Oliver Cornely (FRG)

Bart-Jan Kullberg (NETH)

Latin America: Luis Thompson (CHI) Marcio Nucci (BRA)

Australia: David Ellis (AUS)