

# The MSG

## ***Mycoses Study Group Quarterly Newsletter Winter 2008***

Welcome to the *Mycoses Study Group Quarterly Newsletter Winter 2008*. 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.

### *Committee Structure*

**MSG Steering Committee (SC):** The Steering Committee consists of members who are senior clinical and laboratory mycologists. The primary role of the SC is to establish the research agenda for the group and to consider specific investigator-initiated projects for scientific and biostatistical integrity, importance to the medical community, and feasibility. The SC also oversees the general direction of the MSG. Members of the SC have been asked to serve for three years.

The Steering Committee currently consists of 13 voting members, and includes the following individuals:

**Peter G. Pappas, Chair (US)**

<b>Carol Kauffman (US)</b>	<b>Jack Edwards (US)</b>
<b>Tania Sorrell (AUS)</b>	<b>John Wingard (US)</b>
<b>Jack Sobel (US)</b>	<b>Eric Bow (CAN)</b>
<b>Tom Patterson (US)</b>	<b>John Perfect (US)</b>
<b>Marcio Nucci (BRA)</b>	<b>Raoul Herbrecht (FR)</b>
<b>Emilio Bouza (SPA)</b>	<b>Thierry Calandra (SP)</b>

**Bill Dismukes and John Bennett will serve as non-voting advisors.**

**The MSG Education Committee (EC):** The function of the EC will be to develop innovative CME programs and other training activities, targeting both general and mycology-oriented audiences. These programs will be developed for variety of venues including, but not limited to traditional grand rounds, regional seminars, national/international meetings, and Web-based educational programs. Given the MSG's commitment to global education and inclusion of laboratory-based practice, we are committed to working closely with the International Society of Human and Animal Mycology (ISHAM) towards this goal. In order to avoid potential conflicts

of interest, the activities of the EC must be completely independent of the clinical trials component of the MSG.

The activities of the EC will be directed by the Chair and Co-chair, who will work closely with the EC and ISHAM to develop short and long term educational objectives, training/fellowship programs, and other educational and training initiatives.

Members of the MSG Education Committee include the following individuals:

**US:**

<b>Susan Hadley (Chair)</b>	<b>Alison Freifeld</b>
<b>David Andes (Co-chair)</b>	<b>Barbara Alexander</b>
<b>Helen Boucher</b>	<b>John Baddley</b>
<b>L. Ostrosky-Zeichner</b>	<b>Graeme Forest</b>
<b>Tom Patterson</b>	<b>Peter Pappas</b>
<b>John Bennett</b>	<b>Dimitrios Kontoyiannis</b>

**Europe:**

**Olivier Lortholary (FR)**  
**Oliver Cornely (FRG)**  
**Bart-Jan Kullberg (NETH)**

**Latin America:**

**Luis Thompson (CHI)**  
**Marcio Nucci (BRA)**

**Australia:**

**David Ellis (AUS)**

*Announcements:*

*2008 MSG Annual Meeting will be held prior to Focus on Fungal Infections 18*

The **2008 MSG Annual Meeting** will be held on **March 4<sup>th</sup> and 5<sup>th</sup>** immediately prior to **Focus on Fungal Infections 18** at the Grand Hyatt, San Antonio, Texas. The MSG meeting will start with an educational symposium on Tuesday, March 4, 2008 from 4:30-6:30 PM, followed by an informal reception 6:30-7:30 PM. The topic of the symposium will be to discuss in an open forum the most appropriate use of the currently available serodiagnostic assays for invasive aspergillosis and candidiasis. We are working towards developing this symposium into a CME accredited event. We will have a formal business meeting from 8:30am-4:30pm on March 5, 2008, to provide an update of the group's clinical, educational and administrative activities, and to discuss new proposals and initiatives. All investigators and sponsors are encouraged to attend this important meeting. A formal agenda will follow in February. If you are already planning to

attend FoFI, please try to join us for this special event. Complete details regarding the Annual Meeting will be sent in January 2008. We would especially like to thank **Mike Rinaldi** and **Elie Anaissie** for facilitating the planning process by agreeing to let the MSG Annual Meeting be held in the same venue as and immediately prior to FoFI 18.

### **Future MSG Annual Meetings**

Beginning in 2009, we will conduct the Annual MSG meeting alternately in Europe and North America. Our goal long term is to have an independent, stand-alone meeting in the US every other year, alternating with a European meeting held in conjunction with ECCMID or TIMM. While there is much work to do before achieving this ambitious goal, we believe that this approach is appropriate for the MSG, particularly as we develop a more global face. Once the dates of these future meetings are set, we'll provide these to our membership for planning purposes.

### ***ICAAC/IDSA Joint Meeting October 25-29, 2008***

The MSG is co-sponsoring several symposia at the joint ICAAC/IDSA meeting in Washington DC this fall. We'll communicate the specific topics/times for each of these symposia as they are finalized.

### ***Education Committee Up-Date***

Congratulations to **Susan Hadley** and **David Andes**, who have recently been selected by the members of the EC to serve as Chair and co-chair, respectively. I especially appreciate their willingness to offer their time and leadership to this effort, and look forward to working closely with them. They are charged with setting the Education Committee agenda for the next three years, which includes and is not limited to education symposiums, fellowship training programs, and CME events. There is much work that needs to be done, so please contact either one of them regarding possible topics for discussion and your willingness to commit to participation on any particular project.

### ***ISHAM Affiliation***

Discussions with ISHAM regarding official involvement with the group continue to move forward, although all details of formal affiliation are not yet finalized. Once consummated, this affiliation appears to be a 'win-win' situation for both the **MSG** and **ISHAM**. **MSG's** affiliation with **ISHAM** is particularly important given their long-standing involvement with CME activities internationally. **ISHAM**, traditionally a more laboratory-based group, benefits by improving their visibility and influence in the clinical mycology and general ID world. We are currently assisting in fund-raising efforts with **ISHAM** from several corporate sources for **ISHAM's** core and infrastructure support.

### ***MSG / FDA / EMEA Galactomannan Project***

The proposal for the use of galactomannan as a qualified biomarker in the context of a clinical trials for treatment of invasive aspergillosis was judged by the FDA Biomarker Qualification

Review Team to have a potentially important impact on drug development and regulatory review, and they have encouraged the **MSG** to proceed with the next step through their Pilot Process for Biomarker Qualification pathway. Since our initial discussions, the EMEA has elected to perform a joint qualification assessment together with the FDA for both serum and BAL. Johan Maertens, Paul Verweij, Barb Alexander, and Kieren Marr will continue to spearhead this effort in the US and Europe. Dr. Joe Wheat has agreed to provide invaluable assistance in the effort as well. Their leadership and the **MSG**'s supporting role in bringing this effort together is critical. FDA/EMEA are planning to review these applications in early March 2008.

### *'Dr. Fungus' Website*

The Dr. Fungus website has agreed to support the **MSG** by allowing us to post our activities via their website. The following web addresses will access **MSG** activities:

<http://mycosesstudygroup.org/> and <http://www.mycosesstudygroup.org/>

The domain - mycosesstudygroup.org - will only be visible on the initial entry page into doctorfungus.org. The **MSG** is working with the Dr. Fungus web development team to create a comprehensive overview of current and future **MSG** activities. Additional details will be provided as they evolve.

### *Clinical Trials Update*

Below are the currently approved **MSG** projects:

**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..

At this time, 14 of the 15 sites necessary for this study have been selected. Eleven sites have IRB approval, one site has submitted and awaiting IRB approval and two sites are beginning the IRB application process. The study is open for enrollment at 10 sites and **19** subjects have been 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**' will consist of junior investigators (John Baddley, David Andes, Nasia Safdar,) and a senior advisory group. Bart-Jan Kullberg will serve as the primary senior advisor to this group, help formulate an analysis plan, assign responsibilities, establish a timetable, etc.

### **MSG-03: Invasive Aspergillosis Combination Study**

PI: Kieren Marr

Corporate Sponsor: Pfizer

The **MSG** has endorsed this study sponsored by Pfizer, Inc.. **MSG** will be involved in the domestic site selection, protocol development, the Data Review Committee and DSMB, statistical analysis, and the submission for publication.

#### *Ongoing discussions*

We continue to discuss with the following companies concerning the **MSG**'s involvement in the clinical development of these compounds:

**SPRI:** oral and intravenous posaconazole for several mycoses including invasive aspergillosis, zygomycosis, the phaeohyphomycoses, and the endemic fungal infections.

**Novartis:** There was recent European Advisory Board focusing on efungimab (Mycograb); a corresponding meeting in Boston was cancelled due to weather. These discussions remain on hold at this time pending further assessment by Novartis regarding the future of this compound. The **MSG** remains quite interested in the clinical development of efungimab in the context of a large international candidemia trial.

**Merck :** Through the efforts of Luiz Ostrosky-Zeichner and other **MSG** investigators, together with the support of Merck, Inc, several sites are participating in a retrospective study of ICU patients with unexplained fever and /or presumed and possible candidiasis. This study will focus on predictive rules that may predict those patients most likely to have invasive candidiasis in the ICU setting. If successful in defining a 'predictive rule', these results could be used to identify ICU patients at highest risk for invasive candidiasis and who might benefit from empiric antifungal therapy through participation in a randomized controlled trial.

**Eisai Medical Research, Inc:** Ongoing discussions concerning the potential clinical development of ravuconazole (iv and po) for a variety of invasive fungal infections.