MSGERC Update
Mycoses Study Group Education and Research Consortium

MSGERC First Biannual Meeting
September 20-23, Asilomar Conference Center
Registration is now open for MSGERC’s first Biannual Meeting, on September 20-23, 2016. This meeting will be held at Asilomar Conference Facility in Monterey, CA.

MSGERC is formalizing its membership process
Please join us in our mission
msgerc.org

In the new era of translational medicine, and continuing medical education, The Mycoses Study Group Education and Research Consortium (MSGERC) has emerged as a non-profit education, scientific and charitable organization providing seamless leadership to stakeholders seeking to diagnose, prevent, treat and cure invasive fungal infections.

The consortium of MSG investigators has a long-standing reputation, commencing in 1978 as premier leaders in clinical mycology. After multi-decades as an NIH-sponsored research group, the MSGERC Steering Committee voted to restructure the group as a non-profit organization and to solicit formal memberships. You are receiving this exclusive invitation to help MSGERC finalize this process. I am personally inviting you to extend the current work and mission of MSGERC through your official membership.

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Our mission is to be a resource for the development, conduct and interpretation of innovative investigation in clinical mycology and to provide ongoing and innovative approaches to education in clinical mycology, and to train the next generation of clinical investigators in this field.
Dues are $100 per member ($75 for current ID fellows), and those signing up by April 15, 2016 will be classified as MSGERC Founding Members. The Steering Committee and Education Committee will continue as slated; however, other committees are evolving. Since this is our inaugural membership year, anyone becoming a Founding Member by April 15 will be eligible to run for the new MSGERC Board of Directors. The first MSGERC slate of candidates will be vetted and approved by the Steering Committee in early May, and members will elect the first MSGERC Board of Directors by mid-July. Lastly, MSGERC will be holding its inaugural Biannual Meeting from September 20-23 at Asilomar Conference Grounds in Pacific Grove, California and members are eligible for a reduced registration rate. Official member benefits include:

1. Recognition as a MSGERC member and the historic value of the group
2. Identification as a key opinion leader in your mycology specialization
3. Opportunities to serve as a subcontractor on MSGERC CME or research consultations
4. Recognition as a preferred investigator for mycology studies and clinical trials
5. Eligibility to vote on important MSGERC matters that are brought forth to the membership
6. Eligibility to run for the MSGERC Board of Directors and hold a leadership position helping to shape the future strategy, goals and mission of our organization
7. Eligibility to serve as a leader on one of MSGERC’s standing committees
8. Website presence
9. Online, searchable Membership Directory and self-management of full profile
10. Reduced registration rates for the first inaugural Biannual MSGERC Meeting being held at Asilomar Conference Grounds in Pacific Grove, California USA from September 20-23, 2016
11. Unparalleled access to a global community network of experts and renowned leaders in the Mycoses field.

To join the MSGERC, please complete the membership application online at [http://www.msgerc.org](http://www.msgerc.org). You may pay your membership dues online.

We are proud of the legacy of the MSG and are encouraged by our continued status within our industry and among government colleagues. You will now help us move into the next phase of the MSGERC!
MSGERC Clinical Trial Updates

MSG-03: Invasive Aspergillosis Combination Study

**PI:** Kieren Marr  
**Sponsor:** Pfizer

This trial was completed on February 22, 2011 with a total of 459 patients enrolled and 454 patients dosed. A poster was presented at ECCMID in London in April 2012. Marr K et al, *Ann Intern Med.* 2015;162(2):81-89. doi:10.7326/M13-2508

MSG-05: A re-analysis of the voriconazole versus amphotericin B followed by other licensed antifungal therapy for invasive aspergillosis trial (Herbrecht et al. *NEJM* 2002; 347: 408-15)

**PI:** Raoul Herbrecht  
**Sponsor:** Pfizer

The purpose of this project was to reanalyze the existing database from the pivotal study comparing voriconazole to amphotericin B followed by OLAT for primary treatment of invasive aspergillosis. The analysis was presented at ICAAC 2012. Herbrecht R et al., *Clin Infect Dis.* 2015 Mar 1;60(5):713-20. doi: 10.1093/cid/ciu911

MSG-06: The Phaeohyphomycosis Registry

**PIs:** Sanjay Revanker, John Baddley, Sharon Chen  
**Sponsors:** Merck, Gilead, Astellas

Enrollment began on October 31, 2012 and closed on 12/31/2015. A total of 110 cases were enrolled. The registry includes cases diagnosed between January 1, 2009 and December 31, 2015. Sixteen sites participated and enrolled cases. Sites are located in South America (1), Australia (2), and North America (13). This project prospectively identifies 110 patients from these sites and captures all relevant clinical, diagnostic, mycological and treatment/outcome information relating to this uncommon mycosis. These data will ultimately be merged with relevant data from the ongoing Fungiscope project led by Oliver Cornely in FRG. An important component of this study is that CDC has agreed to serve as specimen repository for the project, providing access to these clinical specimens by all MSG investigators.

MSG-07: Cryptococcosis Combined Analyses

**PIs:** John Baddley, Sharon Chen, Emilio DeBess, Eleni Galanis, Julie Harris, Nicola Marsden-Haug, John Perfect, Peter Phillips, Peter Pappas  
**Sponsor:** Merck

This retrospective study will evaluate archived cases of *C neoformans* and *C gattii* from UAB, Duke, Australia, BC Canada, Washington, and Oregon. Over 800 well-defined cases have been identified. UAB has obtained signed data use agreements with participating sites and has received data from each site. Data merger is complete. The analysis plan is being finalized and potential manuscripts are being discussed. Manuscript writing has begun, with final manuscript planned for early summer 2016.

MSG-08: Epidemic Mold Infections in U.S.

**PIs:** Carol Kauffman, Tom Chiller, Peter Pappas  
**Sponsors:** CDC, Gilead, Merck

MSG received funding from Merck, Gilead, and the CDC to support this project based on capturing the detailed, long-term clinical and therapeutic features of this outbreak. Data points include diagnostic, clinical, radiologic, treatment and outcomes data, and these data have assisted with defining disease management. MSG’s role has included site selection, electronic case report form development, data management and analysis. Nine sites participated with providing case data. Enrollment began in September 2013 and all data collection was complete by February 2016. Current enrollment includes 456 cases entered in the REDCap electronic database. Data is in the final stages of being cleaned and data analysis will begin this spring. A manuscript will be written by August 2016.
MSGERC First Biannual Meeting  September 20-23, 2016

The Mycoses Study Group Education and Research Consortium (MSGERC) will be holding its first Biannual Meeting in September 2016 at the Asilomar Conference Grounds in Monterey, California, USA. The purpose of this meeting will be to present the most recent and relevant data in clinical mycology, and also to create an interactive environment with experts from across the world.

In this meeting attendees will share ideas and help to establish the clinical and research priorities in mycology for the next couple of years. We have an outstanding group of speakers, and we hope to attract a large audience from the US as well as from international sites, which would also include both infectious disease fellows-in-training and younger academic physicians who are not well differentiated at this time.

We have purposefully chosen this outstanding venue and an ideal time in which to have this inaugural meeting. Asilomar is a popular and relatively remote conference facility that has been used by a number of large research-oriented groups, and is the home of the fungal genetics meeting each year. The timing of the meeting is planned so that it will occur on alternate years with the major European meeting, Trends in Medical Mycology (TIMM).

The focused approach for this meeting will concentrate key opinion leader sessions focusing on Cryptococcus, Endemic Mycoses, Aspergillus, Candida and the Mycobiome. After each set of presentations, facilitated discussions will elucidate unmet need and evolve future research concepts.

We appreciate the support of the many pharmaceutical and diagnostic sponsors and will provide venues for them to present their current pipeline and opportunities to interact with attendees.

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MSG-09: Prospective study of cryptococcosis among non-HIV infected patients

**PI:** Kieren Marr, MD  
**Sponsor:** NIAID

This observational, prospective study started enrollment of patients with cryptococcosis who are HIV negative on March 14, 2014. This study captures all relevant epidemiology, clinical and therapeutic data. In addition, immunologic and genetic studies are being performed on each study participant to explore host response to infection and genetic predispositions to disease expression. There are 23 active U.S. sites and current enrollment is 136 subjects.

**MSG-10:** A Prospective, Multicenter, Open-Label, Randomized, Comparative Study to Estimate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Oral SCY-078 vs. Standard of Care Following Initial Intravenous Echinocandin Therapy in the Treatment of Invasive Candidiasis (Including Candidemia) in Hospitalized Nonneutropenic Adults

**PI:** Peter Pappas, MD  
**Sponsor:** Scynexis

This phase 2 study is an ongoing open-label RCT. The primary focus of the trial is safety and PK; efficacy is a secondary endpoint given the small sample size (150 patients) and the trial design is a step-down strategy for candidemia. There are currently 15 active sites, 6 additional sites starting soon. 3 patients have been entered into the study, 2 have been randomized and received study medication.

**MSG-11:** Cryptococcal Infections in Non–HIV Infected Hosts: A Prospective International Study

**PI:** Peter Pappas, MD  
**Sponsor:** Gilead

This study is an international observational study, which is similar in design to MSG-09, which was originally proposed as an international study. As an international study, MSG 11 will include sites in Australia, France, Brazil, Canada, Vietnam, Taiwan and Europe. The goal is to enroll 150 non-HIV infected patients with cryptococcosis over a 24-month period. Gilead has approved the study for funding and a signed agreement is expected by March 2016. Enrollment is planned to begin late summer 2016.

**MSG-12:** Retrospective review of candidemia outcomes in a large US cohort utilizing the Premier database

**PI:** Brian Fisher, MD, Theo Zaoutis, MD, Luis Ostrosky-Zeichner, MD  
**Sponsor:** CHOP

This study was initiated by Drs. Fisher and Zaoutis at CHOP following their purchase of aspects of the Premier database. The purpose of this study is to analyze treatment and outcomes among a large cohort (approximately 2000 patients) across the US with *Candida* BSI. The first analysis is being presented at ICAAC 2015 as an abstract in clinical mycology.

**MSG-13:** A Multi-Center, Case Control Study of a Lateral Flow Assay for the Diagnosis of Histoplasmosis (2R42-AI096945-03)

**PI:** Peter Pappas, MD, William Powderly, MD  
**Sponsor:** IMMY

The MSGERC and MSG Research Central Unit have joined efforts with IMMY to develop and manage this multi-center, pre-510k case-control study to test their investigational assays for diagnosing histoplasmosis (Lateral Flow Assay and Enzyme Immunoassay). Fifteen U.S. sites have been approached for participation. Enrollment goal will be 250 separate cases (50 proven histoplasmosis cases and 50 probable). Each proven histoplasmosis case will be bundled with 2 underlying disease matched controls, and 1 control with a proven invasive fungal infection other than histoplasmosis. Sites are in the IRB and contractual phase. Enrollment is planned to begin by the end of April 2016.

**In Development:** A prospective evaluation of outcomes and economics and a registry of the T2Candida® Panel: a multi-center study.

**PIs:** Peter Pappas, MD, Kevin Geary, Eleftherios Mylonikis, Luis Ostrosky-Zeichner, Theo Zaotis  
**Sponsor:** T2

This will be an ambidirectional cohort study that will evaluate ICU patients who undergo T2Candida® testing. There will be a retrospective and prospective cohort of ICU patients and a registry for patients who received testing, but were not in the ICU.
Call for Cases: Invasive Fungal Disease Case of the Month

In 2016, the MSGERC plans an educational activity whereby our members share interesting cases in mycology. We invite you to take the lead to write up cases using a format adopted from the Gorgas Course in Tropical Medicine. We will feature these monthly on our website and drfungus.org and other educational offerings. The format for submissions will be:

- History
- Epidemiology
- Physical Exam
- Lab Exams
- Diagnosis
- Evidence-based Discussion
- Photos, Xrays

This is also an excellent opportunity for fellows-in-training. Please submit cases to jones.5342@osu.edu

MSGERC Biannual Meeting
Speakers & Topics

September 20, 2016
Keynote Speakers
- Mycology Historical Overview: John Bennett
- Mycology Today: Joseph Heitman
- Mycology Future: Arturo Casadevall

September 21, 2016
Cryptococcus
- Organisms/Biology: Tamara Doering
- Host/Pathogen: Peter Williamson
- Epidemiology: Sharon Chen
- Clinical: Tom Harrison

Endemic & Other Mycoses
- Phylogenetics: Dave Engelthaler
- Veterinary mycology: Jane Sykes
- Blasto/Emmonsia: Ilan Schwartz
- Cocci/Histoplasmosis: GR Thompson

Poster Presentations- Jr. Faculty & Fellows

September 22, 2016
Aspergillus/Molds
- Epi/Resistance: Nathan Wiederhold
- Host/Pathogen Interaction 1: Tobias Hohl
- Host/Pathogen Interaction 2: Rob Crammer
- Clinical: Tom Walsh

Candida & Microbiome
- Fungal biofilm & Microbiome: Mahmoud Ghannoum
- Vaccine/Immunology: Jack Edwards
- Host Response: Mihalis Lionakis
- Epi/Peds/Clinical: Theo Zaoutis

Poster Presentations- Jr. Faculty & Fellows

Summary Reports
- Endemic & Other Mycoses: GR Thompson & C Kauffman
- Cryptococcus: D Boulware & J Perfect
- Aspergillus & Other Molds: T Patterson & P Donnelly
- Candida & the Microbiome: L Ostrosky-Zeichner & P Pappas
MSGERC Continuing Education Portal
funguscme.org

Educational Initiatives for 2016

The MSGERC Education Committee continues to develop live and web-based activities as part of an overall strategic educational plan. We continue to work with Terranova Medica, LLC to develop and manage our CME activity grants. This year, we plan on enhancing interactivity at our live meetings (through use of iPads) and expanding our web presence as the go-to source for all things mycological.

MSGERC 2015 Live Educational Activities:

- **May 2015 (Melbourne, Australia)** ISHAM entitled “Panel Discussion: Predicting the Future of Medical Mycology” (Non-funded, no CME, G.R Thompson, chair).

- **September 2015 (San Diego, CA)** ICAAC-ICC affiliated live CME symposium entitled, “Current Controversies in Invasive Fungal Disease Management: Predicting the Future in Medical Mycology” (Funded, CME, G.R Thompson, chair)

- **October 2015 (San Diego, CA)** ID Week-affiliated live CME symposium entitled, Optimizing Outcomes in Invasive Fungal Disease: The Interdisciplinary Approach (Funded, CME, Luis Ostrosky-Zeichner, chair)

- **December 2015 (Orlando, FL)** ASH Symposium and Enduring Activity entitled, “Invasive Mycoses in Hematologic Malignancies: Disarming the Fungal Saboteur”. (Funded, CME, Alison Freifeld, chair)

Recent Enduring CME Activities:

- Antifungal Toolkit (Update 1 launched April 2015; planned Update 2 launched September 2015)

- ICAAC/ICC and ID Week CME symposium enduring (launched January 2016)

- ID Week Enduring for Pharmacists on PowerPak: (launched February 2016)

Upcoming Enduring CME Activities:

- ASH enduring activity (launching March 2016)

- ASM Microbe Enduring Activity (Summer 2016)

- ASM Microbe Mycology Minutes™ (Summer 2016)

- ID Week enduring activity (Late 2016)

- ID Week Mycology Minutes™ (Late 2016)

New Ideas:

- ECCMID (2017)

- TIMM (2017)

- Bone Marrow Transplanters directed activities

- Hospitalist directed activities

- Lunch & Learns- Academic Onsite Live Webinars

- Case of the Month

- Exploring new venues
The findings of the 10 working groups charged with updating the EORTC/MSG definitions of invasive fungal diseases were presented at the 7th Trends in Medical Mycology (TIMM) meeting in Lisbon, which is a joint meeting of the EORTC IDG and the European Confederation of Medical Mycology (ECMM). As expected, attendance at the meeting was good and the audience was fully engaged posing very pertinent questions, which were duly noted and sent on to Prof Sharon Chen, who is acting as secretary for the project. The slides were then made available to the community at large for comment until December 31st 2015. The comments and suggestions were then compiled and sent to each chair for discussion with their own group. An online meeting with the chairs is due to be held shortly to discuss the comments and responses of the findings made so far. The next step will be to circulate the revised slides to every member of the working group for further comment. In the meantime the chairs of the EORTC Infectious Diseases group and MSGERC will collate the questions and the responses made so far to identify those that will lead to a revision of the 2008 consensus definitions. A plenary meeting will then be held in the Autumn 2016, again online, to attempt to reach a broad consensus on each of these points. If successful, the resulting revisions will then be summarized in a manuscript, which will be offered in the first instance to Clinical Infectious Disease in Autumn, 2016.