Cumulative Overview of MSGERC Protocols

August 1, 2013

Concept Name	Study Number; Protocol Chair(s)	Concept/ Protocol Status	Study Status / Comments
A randomized, double-blind, placebo controlled trial of caspofungin prophylaxis followed by pre-emptive therapy for invasive candidiasis in high-risk adults in the critical care setting.	**MSG -01** Dr. Ostrosky-Zeichner	The concept was re-reviewed and approved by the MSG Steering Committee November 20, 2006.	**Comparative arms**: Caspofungin vs. placebo **Sponsor:** Merck, Inc. Enrolled 222 subjects from 16 participating centers. A manuscript has been written and was submitted to CID in June 2013. Previous journals that rejected the manuscript include NEJM and The Lancet.
Concept Name	**Study Number; Protocol Chair(s)**	**Concept/ Protocol Status**	**Study Status / Comments**
Outcomes of infection by non-albicans species of candida compared with *C. albicans:* A patient level meta-analysis.	**MSG -02** Dr. Andes	Reviewed and approved by the MSG Steering Committee May 14, 2007.	**Sponsor:** Astellas Pharma, U.S., Inc. The manuscript was published by Clinical Infectious Diseases 2012;54(8):1110-22.

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A prospective, randomized trial comparing the efficacy of anidulafungin and voriconazole in combination to that of voriconazole alone when used for primary therapy of proven or probable invasive aspergillosis.	**MSG-03** Dr. Marr	Reviewed and approved by the MSG Steering Committee July 12, 2007	**Comparative arms:** Voriconazole + placebo **vs.** Voriconazole + anidulafungin **Sponsor:** Pfizer, Inc. Enrollment completed on February 22, 2011 with 459 subjects enrolled of which 454 were dosed. The manuscript was rejected by NEJM. The manuscript is being submitted to another journal in the near future.
Concept Name	**Study Number; Protocol Chair(s)**	**Concept/ Protocol Status**	**Study Status / Comments**
MSG-04 (Merck Caspofungin Protocol 067): A Pilot, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Caspofungin Empirical Therapy for Invasive Candidiasis in High-Risk Patients in the Critical Care Setting	**MSG-04** Dr. Ostrosky-Zeichner	Reviewed and approved by the MSG Steering Committee June 9, 2009	**Comparative arms:** Caspofungin vs. Placebo **Sponsor:** Merck, Inc. As recommended by the Data Monitoring Committee and the Steering Committee, the study closed due to low enrollment. Enrollment - Start date: 1/24/2011; End date: 5/9/12 Enrollment goal: 114 subjects Final enrollment: 15 subjects There are no plans for data presentation at this time.

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Recategorization of the cases of the Global Comparative Aspergillus study - A project of EORTC / MSG collaborative analysis	**MSG-05** Dr. Herbrecht	Reviewed and approved by the MSG Steering Committee on August 16, 2010.	**Comparative arms:** Not applicable **Sponsor:** Pfizer, Inc. DRC review and analysis have been completed. A manuscript is in preparation.
Concept Name	**Study Number; Protocol Chair(s)**	**Concept/ Protocol Status**	**Study Status / Comments**
A Case Registry of Patients with Phaeohyphomycosis	**MSG-06** Drs. Revankar, Baddley, & Chen	Reviewed and approved by the MSG Steering Committee on September 3, 2010.	**Sponsors:** Gilead, Merck, Astellas Eleven sites are actively enrolling and three sites are in the IRB approval and contract negotiation stage. Enrollment began on October 31, 2012. Current enrollment is 22. Enrollment goal: 150 subjects.

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Epidemiology, risk factors, treatment, and outcome of patients with cryptococcosis: a retrospective, combined analysis comparing *C. neoformans* and *C. gattii*	**MSG-07** * See proposed sites and investigators	Reviewed and approved by the MSG Steering Committee on May 14, 2012.	**Sponsors:** Merck Case merger is in progress. Analysis is planned for late 2013. ***PROPOSED SITES AND INVESTIGATORS** *British Columbia* BCCDC: Eleni Galanis, Laura MacDougall UBC: Peter Phillips *Washington, USA* Washington State Department of Health: Nicola Marsden-Haug *Oregon, USA* Oregon State Department of Health: Emilio DeBess, Mathieu Tourdjman *Alabama, USA* UAB: Peter G. Pappas, John Baddley, Kyle Brizendine *North Carolina, USA* Duke University Medical Center: John Perfect *Georgia, USA* CDC: Julie Harris, Ben Park, Rachel Smith *Australia* University of Sydney: Tania Sorrell, Sharon Chen

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Defining the clinical, diagnostic, treatment, and outcomes among patients with epidemic mold infections in the US following contaminated methylprednisolone injections	**MSG-08** Dr. Pappas	Reviewed and approved by the MSG Steering Committee on November 7, 2012.	**Sponsors:** Gilead, Merck, and the CDC Site selection and contract negotiation is underway. Enrollment is planned to begin late summer 2013.