



MSG ERC

Mycoses Study Group
Education & Research Consortium

WHAT'S NEW WITH THE MSG . . .

SPRING/SUMMER 2020 NEWSLETTER

PRESIDENT'S MESSAGE



These have been unprecedented times. No one would have predicted that we would be in the midst of a global pandemic, literally elbows deep. Kudos to the physicians, healthcare workers and especially all those infectious disease physicians, principal investigators and clinical research professionals who have risen to the occasion. We are exhausted, inspired, focused and resilient. Yet, we have all had to adjust our attentions and schedules because of this virus, something I have heard called “the COVID pivot”. Never before has the specialty of infectious disease and clinical research gotten this much public attention. One big MSGERC pivot, besides having to put some of our MSG studies on a temporary hiatus, is the need to postpone our scheduled biennial meeting from September 2020 to May 2021. In this newsletter you will see new information about those plans. We have tried to avoid dates that may interfere with other infectious disease meetings and meeting details. We are fortunate that the Hyatt Regency Tamaya was willing to negotiate a new date rather than penalize us a hefty cancellation fee. We are busily refocusing our attention to getting this

meeting back on track. We hope that you will continue to support the meeting. Your expertise and interactions at our biennial “think tank” has inspired new research directions and we know that we will have even more to share in May. This is also a time for important contributions of the MSGERC with seminal publications of the EORTC/MSGERC fungal definitions in *Clinical Infectious Diseases*; the report of the 2018 biennial meeting: a global research agenda being published in *Medical Mycology*; and new antifungal stewardship guidelines coming out in the *Journal of Infectious Diseases*. I am impressed that we have also increased our Case of the Month submissions in drfungus. Additionally, we have collaborated with Terranova Medica, LLC and Annenberg Center for Health Sciences in Eisenhower to produce our first Spanish-speaking webinar on Zoom for Latin America. We are forging new collaborations and continuing our work to further research and development in clinical mycology, scholarship, education and advocacy. We urge you to renew your memberships, bring on new members, and include junior faculty, and also attend our meeting in May! I look forward to seeing you in person soon. Please stay well!

John Perfect

MISSION & MEMBERSHIP

Our mission is to be a resource for the development, conduct, and interpretation of translational investigations in clinical mycology, to provide effective live and enduring education in clinical mycology, to promote development of the next generation of practitioners and investigators in this field, and promote advocacy for the profession and patient populations.

We thank you for your membership to the MSGERC. Many of our colleagues have been long-standing MSG members, but may or may not have become formal members of MSGERC. The MSGERC includes clinical, biotechnology and government members. Junior faculty membership is strongly encouraged. Membership dues are \$175 for a two-year membership. Current ID fellows may join at \$125 for a two-year membership. Go to MSGERC.org to join. You may use PayPal or send a check. Please update your member profile in the website. If you have difficulties, email Debbie Zaparoni at headquarters@msgerc.org.

Official member benefits include:

- *Recognition as a MSGERC member and the historic value of the group.*
- *Identification as a key opinion leader in your mycology specialization.*
- *Opportunities to serve as a subcontractor on MSGERC CME or research consultations.*

- *Recognition as a preferred investigator for mycology clinical research studies.*
- *Eligibility to vote on important MSGERC matters that are brought forth to membership.*
- *Eligibility to run for MSGERC Board of Directors and hold a leadership position helping to shape the future strategy, goals and mission of our organization.*
- *Eligibility to serve as a leader on one of MSGERC’s standing committees.*
- *Website presence.*
- *Online, searchable Membership Directory and self-management of full profile.*
- *Reduced meeting registration rates for the Biennial Meetings.*
- *Unparalleled access to a global community network of experts and renowned leaders in the mycology field.*
- *Opportunities to participate in MSG Studies.*
- *Opportunities to initiate, create and get validated “position papers”*
- *Newsletter updates and ability to join advocacy groups.*

NEWS FROM DRFUNGUS.ORG

Case of the Month Update

Drfungus.org is the key educational website for the MSGERC. We call it “your source for all things fungal”. The site features and opportunity to present cases. We use the case presentation structure modified from the [Gorgas Course](#). Include your .JPEG images as separate files.

CASE OF THE MONTH TEMPLATE FORM:

<https://drfungus.org/case-of-the-month-template.docx>

SUBMIT TO CAROLYNN JONES BY EMAIL
JONES.5342@OSU.EDU.

We will allow cases to be accepted that have been presented as a poster or podium presentation; however, we cannot accept cases that have been previously published in a journal. You must follow the Case of the Month Template. Dr. Jose Vazquez, MD will curate cases as they are submitted.

The MSGERC Board of Directors challenged themselves to make sure we have no gaps in new

cases. A little competition goes a long way with MSG investigators and clinicians. Under the leadership of

Joe Vazquez, MD, we are exceeding goals so far with excellent cases that have been submitted by Board Members and their Junior Faculty and Fellows. We have case submissions that will take us through July 2020, but we expect to continue at this rate to make sure we keep the pace and our 2020 goal of one case per month.

We had 6 fungal cases during 2019 and so far have 7 cases submitted for 2020. Keep up the great work! We currently have a tie: Univ of Cologne, Univ of Michigan and Medical College of GA – Augusta!

Institution	2019	2020	Total
University of Cologne	0	2	2
Univ. of Michigan	1	2	3
Med College of GA- Augusta	1	2	3
Duke University	2	0	2
MD Anderson	2	0	2
Mayo	0	1	1
Total	6	7	13

Some submitters have asked how to cite these contributions. You should cite this in your CV. To illustrate, for the January 2020 case from Medical

College of Georgia- Augusta University the citation would be:

Devarapalli M, and Siddiqui B. 2020, January. "Rhino cerebral Mucormycosis." DrFungus Case of the Month. Accessed May 23, 2020. <https://drfungus.org/january-2020-case-of-the-month/>

MSGERC EDUCATION COMMITTEE REPORT

Funguscme.org

The MSGERC continues its long-standing collaboration with Dr. Lisa Tushla of Terranova Medica LLC in the production of symposia, webcasts and enduring online educational CME activities on featuring mycology presentations from the MSG Key Opinion Leaders.

Currently available via funguscme.org as an enduring CME activity is the updated New Antifungal Toolkit that provides current information about medications that are newly approved by the FDA for the management of invasive fungal infections. The new



TERRANOVA MEDICA
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2019 updates features updates on endemic mycoses including a review of Tolsura® (SUBA-itraconazole) and offers AMA PRA Category 1 credits™. Fourteen additional enduring educational offerings are available through funguscme.org, but no longer offer CME credit.

On May 6, 2020, a live Zoom webinar entitled “Actualización en Micología Medica” was launched. The activity was jointly sponsored by the Annenberg Center for Health Sciences in Eisenhower, Terranova Medica LLC and the MSGERC. The webinar is

available on demand and can be accessed at <https://funguscme.org/LatinAmerica2020/>.

This is an enduring educational activity with CMEs. This project was launched to address the unmet educational needs regarding invasive fungal and mold infections in Latin America. One objective was to address the need to unify approaches for the management of invasive fungal infection between institutions and regions. The faculty presenters for this activity were Luis Ostrosky-Zeichner, MD; Arnaldo Lopes Colombo, MD, and Francisco M. Marty, MD. This activity was made possible through financial support from Gilead Sciences, Inc. This was a highly successful event “to date, only 2 weeks after the live event, 1500 people have interacted with the curriculum across the live and on-demand activities”, commented Lisa Tushla. Luis Ostrosky-Zeichner, MD, President-Elect of the MSGERC is confident that more programming is to come.



ID in Motion (IDIM)



In September 2019, Dr. Oliver Cornely, University of Cologne launched IDIM (ID in Motion) featuring a series of short videos on infectious disease and fungal topics. With his first video featuring a talk on “Breakthrough Invasive Fungal Infections”. Since its initial launch, a series of fungal and ID topics have been launched in 44 YouTube Videos with 493 subscribers. Remarkably, half of the most recent videos were produced to explain COVID Virus and Pandemics for children with translated narrations in Spanish, Chinese, Greek, English, Farsi, Polish, Korean, Italian, Albanian, German, French. Go to [YouTube.com](https://www.youtube.com/channel/UCN-Z_1hUIaupRwMtk7uiyfw) and subscribe to IDIM Infectious Diseases in Motion.

https://www.youtube.com/channel/UCN-Z_1hUIaupRwMtk7uiyfw

PUBLICATIONS

Donnelly J P, et al Revision and update of the consensus definitions of Invasive Fungal Disease from the European Organization for Research and Treatment of Cancer and the Mycoses Study Group Education and Research Consortium. *Clinical Infectious Diseases*. Published online December 5, 2019.

Background. Invasive fungal diseases (IFDs) remain important causes of morbidity and mortality. The consensus definitions of the Infectious Diseases Group of the European Organization for Research and Treatment of Cancer and the Mycoses Study Group have been of immense value to researchers who conduct clinical trials of antifungals, assess diagnostic tests, and undertake epidemiologic studies. However, their utility has not extended beyond patients with cancer or recipients of stem cell or solid organ transplants. With newer diagnostic techniques available, it was clear that an update of these definitions was essential. **Methods.** To achieve this, 10 working groups looked closely at imaging, laboratory diagnosis, and special populations at risk of IFD. A final version of the manuscript was agreed upon after the groups' findings were presented at a scientific symposium and after a 3-month period for public comment. There were several rounds of discussion before a final version of the manuscript was approved. **Results.** There is no change in the classifications of "proven," "probable," and "possible" IFD, although the definition of "probable" has been expanded and the scope of the category "possible" has been diminished. The category of proven IFD can apply to any patient, regardless of whether the patient is immunocompromised. The probable and possible categories are proposed for immunocompromised patients only, except for endemic mycoses. **Conclusions.** These updated definitions of IFDs should prove applicable in clinical, diagnostic, and epidemiologic research of a broader range of patients at high-risk.

Pappas, PG, et al Clinical mycology today: A synopsis of the mycoses study group education and research consortium (MSGERC) second biennial meeting, September 25-28, 2018, Big Sky Montana, a proposed global research agenda. *Medical Mycology*, 14 May 2020,, myaa034, <https://doi.org/10.1093/mmy/myaa034>

"The second biennial meeting of the Mycoses Study Group Education and Research Consortium (MSGERC) took place in Big Sky, Montana, from September 25 through 28, 2018. To the clinician and clinician/educator, this meeting serves as an up-to-date review of critical issues in mycology provided by the world's leading experts. To the clinical and translational researcher, it provides an opportunity to share and discuss data, to network with other investigators, and to develop new research questions. For the trainee, the meeting serves as a clinical update, but more importantly, it provides a forum to meet with many international leading authorities in clinical and applied mycology, and to discuss career goals and research ideas. To those associated with governmental agencies such as the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the Food and Drug Administration (FDA), it provides an opportunity to share insights, perspective, and priorities with investigators and representatives from industry. As such, we believe that the MSGERC Biennial Meeting is a nexus where clinicians, trainees, researchers, industry representatives, and governmental agencies can meet to discuss each of the key issues in mycology and set the research and education agenda for the next few years in an open forum."

Johnson, M et al Core recommendations for antifungal stewardship: A statement of the Mycoses Study Group Education and Research Consortium. *Journal of Infectious Diseases*. (in press).

This manuscript offers evidence-based recommendations for best practices for antifungal stewardship using the global core elements of antimicrobial stewardship. The research synthesized the evidence by an interdisciplinary panel of members of the MSGERC resulting in key recommendations.

SOCIAL MEDIA

Growing Fungal Awareness through Social Media: The Inaugural MSGERC TweetChat.

By: *Ilan Schwartz, MD, Chair, MSGERC Social Media Sub-Committee of the MSGERC Education Committee &Carolynn Jones, MSGERC Executive Director*

On September 24, 2019, the MSGERC launched its first "TweetChat" in tandem with educational outreach

for CDC's Fungal Awareness Week. TweetChats are an excellent way to increase visibility and awareness. "A much smaller TweetChat that a few of us participated in last year generated 613 tweets with a reach of 225,749 users and 1.2 million impressions in an hour!" says Dr. Schwartz.

MSGERC members and colleagues were invited in advance to attend. Members of the Board and Committees were sent an outlook appointment for the time of the TweetChat at 2pm EDT with specific instructions on how to create a TWITTER account (if they did not have one previously) and how to access and participate.

Some of the Twitter activity that was simultaneously ongoing was active tweeting by the CDC for Fungal Awareness Week; however, those tweets not including #OpenMyc are not included in the analytics.

Questions Issued by #OpenMyc were:

Q1: Please tell us who you are and what you do.

Q2: How/Why did you become interested in fungal disease?

Q3: What do you wish more people knew about fungal disease?

Q4: What is the most important thing we can do to prevent disability and death from fungal disease?

Q5: What challenges exist for diagnosing and treating fungal disease?

Q6: What development(s) in fungal disease research are you most excited about?

Q7: What's the biggest threat when it comes to antifungal-resistant infections?

Q8: Which #emergingfungalinfections are you keeping an eye on?

Dr. Schwartz led off the twitter session that was co-facilitated by Andrej Spec, MD, and Luis Ostrosky-Zeichner, MD.

Dr. Ilan Schwartz registered the hashtag (#OpenMyc) with *Symplur.com*, which allowed us to track use and engagement for #OpenMyc. The breakdown of participants is impressive for this first TweetChat for MSGERC.

Thank you to those MSGERC Members and Twitter Colleagues who participated. After the holidays another TweetChat was being planned; however, since then, Tweeting has been consumed with COVID-19, but we hope to have another "TweetChat" soon. Let us know if you are interested in leading one!

The Numbers:

- Number of participants (includes people retweeting): 145
- Number of original contributors (ie people composing Tweets, not just retweeting or replying): 30
- Number of original tweets: 148
- Number of total tweets (includes retweets): 480
- Potential reach (potential number of users that could have seen the hashtag): 150,446
- Potential impact (potential number of times somebody could have seen the hashtag): 642,337

IN MEMORIAL

In Memory of Dr. Claudio Viscoli



The MSGERC is saddened to report that Dr. Claudio Viscoli passed away on May 3, 2020 due to a long standing illness. “*Claudio Viscoli was one of the giants of medical mycology and a frequent collaborator of the MSGERC. His nearly 500 articles are a testament to his contributions to infectious diseases and medical mycology, but we will always remember him for his character, energy, and passion for our field*” says Luis Ostrosky-Zeichner. He was the Director of the Infectious Diseases Department of the San Martino Hospital in Genoa, as well as Professor of Infectious Diseases and the Chief of the Post-Graduate School of Infectious and Tropical Diseases at the University of Genoa, Italy. In 2018 at the 28th ECCMID meeting in Madrid, he received the ESCMID Award for Excellence. Quoting the ECSMID & ESGICH Executive Committee, “*The scientific community has lost one of the most outstanding representatives of the Italian Infectious Diseases community. We will all remember Claudio Viscoli as a*

colleague, a friend and a mentor to many, with strong opinions, great scientific integrity, intellectual curiosity and a great sense of responsibility”

Completed Studies

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 Internal 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

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 ; Herbrecht *et al.* *NEJM* 2002; 347: 408-15)

MSG-06: The Phaeohyphomycosis Registry

PIs: Sanjay Revankar, John Baddley, Sharon Chen

Sponsors: Merck, Gilead, Astellas

Enrollment began on October 31, 2012 and closed on 12/31/2015. A total of 99 cases were evaluated between January 1, 2009 and December 31, 2015. Eighteen sites participated and enrolled cases in South America, Australia and North America. This project captured all relevant clinical, diagnostic, mycological and treatment/outcome information relating to this uncommon mycosis. The specimen repository was maintained at the CDC with Confirmation and AF susceptibility performed at Wayne State. The analysis was published in October 2017 in *Open Forum Infectious Diseases*. Revankar, *et al* *Open Forum Infectious Diseases*, 4 (4) Fall 2017. Doi: <https://doi.org/10.1093/ofid/ofx200>

MSG-07: Cryptococcosis Combined Analyses (International Retrospective Cryptococcosis Case Review)

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

Sponsor: Merck, CDC

This retrospective study evaluated archived cases of *C neoformans* and *C gattii* from UAB, Duke, Australia, Canada (BC), Washington, and Oregon. Over 800 well-defined cases have been identified yielding approximately 70% *C neoformans* and 30% *C gattii*. UAB has obtained signed data use agreements with participating sites and has received data from each site. Data has been analyzed and manuscript is in progress, with a second manuscript under consideration. Publication is targeted for *Lancet*, pending.

MSG-08: Epidemic Mold Infections (Meningitis) in U.S.

PIs: Carol Kauffman, Anu Malani, 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. MSG's role included site selection, electronic case report form development, data management and analysis. Nine sites provided case data gathered over 12 months of follow up. 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 including. Final analysis is underway and a manuscript is pending.

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

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. *Spec A et al* *Open Forum Infect Dis* 2016 Dec; 3 (Suppl 1): 122 doi 10.1093/ofid/ofw194.35; Marr KA *et al.* A multicenter, longitudinal cohort study of cryptococcosis in HIV-negative people in the United States *CID*, 2019, 70(2) doi: 10.1093/cid/ciz193.

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 Non-neutropenic Adults

PI: Peter Pappas, MD

Sponsor: Scynexis

This phase 2 open-label RCT is completed. 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. Study findings were presented at ECCMID in 2017 and a manuscript is in development. This manuscript has been submitted to *Journal of Antimicrobial Chemotherapy*, provisionally accepted pending revision

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

PI: Peter Pappas, MD

Sponsor: Gilead

This international observational study is actively enrolling in Australia, Canada (BC), Europe, Taiwan, and India. Peru and France are expected to be enrolling by early summer 2019. Study design is similar to MSG-09, which was performed as a domestic US study. Thus far 60 non-HIV infected patients with cryptococcosis have been enrolled of the 100 intended over a 36-month period. This study will close for data analysis soon.

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 was to analyze treatment and outcomes among a large cohort (approximately 2000 patients) across the US with *Candida* BSI. The first analysis was presented at ICAAC 2015 as an abstract in clinical mycology. Vendetti N et al MSG12: Comparative effectiveness of echinocandins vs fluconazole therapy for the treatment of adult candidemia due to candida parapsilosis. Open Forum Infect Dis 2015 2 (Issue suppl_1) 2017, doi: 10.1093/ofid/ofv133.94; Chiotos K, et al Comparative effectiveness of echinocandins versus fluconazole therapy for the treatment of adult candidemia due to *Candida parapsilosis*: a retrospective observational cohort study of the Mycoses Study Group (MSG-12) The Journal of Antimicrobial Chemotherapy 71 (12): 3536-3539, Dec 2016.

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

Ongoing Studies

MSG-15: SUBA-itraconazole vs conventional itraconazole for endemic mycoses: randomized, open-label international study

PI: GR Thompson, MD, Peter Pappas, MD, Andrej Spec, MD

Sponsor: Mayne Pharmaceuticals Pty Ltd

Actively Enrolling. This prospective, multi-center, randomized, open-label parallel arm study involving patients with proven or probable invasive endemic fungal infection evaluates pharmacokinetics, safety, efficacy, tolerability and health economics of oral SUBA-itraconazole compared to conventional itraconazole. Currently 71 subjects have been enrolled at 12 sites. <https://www.clinicaltrials.gov/ct2/show/NCT03572049>.

MSG-16: Natural History of Antifungal Failure in IC in the US: A multicenter Study (NATURE-US)

PI: Luis Ostrosky-Zeichner, MD

Sponsor: Scynexis, Inc.

The aim of this study is to describe the frequency and reasons for antifungal failure as well as current treatment strategies and outcomes for enrolled subjects. The study will include both retrospective and prospective cohort

PI: Peter Pappas, MD, Andrej Spec, MD

Sponsor: IMMY/NIH Small Business Grant

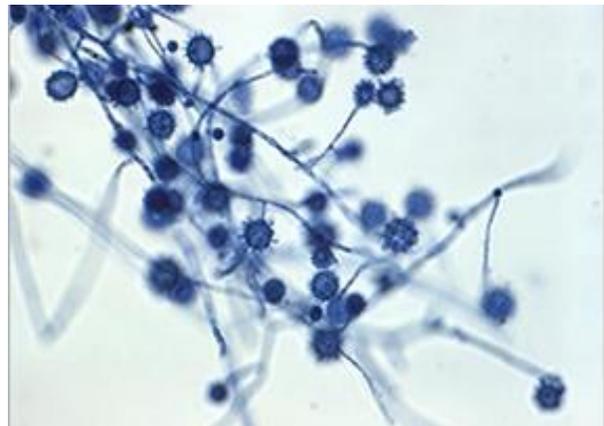
The MSGERC and MSG Coordinating Center have joined efforts with IMMY to develop and manage this multi-center, pre-510k case-control study to test investigational assays for diagnosing histoplasmosis (Lateral Flow Assay and Enzyme Immunoassay). This study closed in April 2018 with 164 evaluable subjects including cases and controls. Specimens were processed at the IMMY laboratory in Oklahoma. Clinical data was captured using the REDCap electronic database. **No publication.**

MSG-14: Prophylaxis Surveys

PIs: John Baddley, MD, Tom Patterson, MD, Oliver Cornely, MD, Julian Lindsay, MD; Orla Morrissey, MD; Eric Bow, MD; and Ricardo LaHoz, MD

Sponsor: Mayne Pharma Pty Ltd.

A survey of physicians to determine current treatment patterns and challenges to treatment across patient populations including Lung Transplant, Lymphoma and BMT/HSCT. To date over surveys have completed: Lung 52 of 124 recipients; Lymphoma 23 of 423 recipients; HSCT 100 of 148 recipients. The survey is hosted on REDCap and data analysis will be completed April 2019. Abstract presented at TIMM 2019.



observations at approximately six sites in the US. A total of 36 of 120 subjects with culture-proven Candidemia or invasive candidiasis with suspected antifungal therapy failure will be included. 2 sites are pending startup. Medical records will be used to examine demographics, risk factors, treatment data, hospital metrics, severity of illness and clinical outcomes. Study is managed by UT-Houston.

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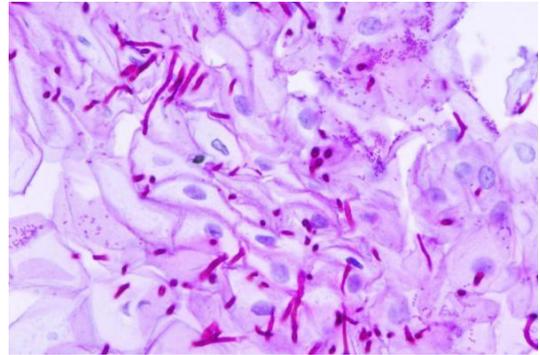


Let's Connect

In addition to our repertoire of completed and ongoing studies, the MSGERC is continuing to work with MSGERC affiliated biotechnology sponsors and MSGERC investigators. We were contracted by Minnetronix Medical to assist with protocol development for an upcoming study of an innovative technology product Neurapheresis™ Therapy, a minimally invasive procedure to filter CSF.

Originally approved for post-aneurysmal subarachnoid hemorrhage patients, this study seeks to explore clearance of fungus from the CSF.

We have resubmitted an R24 grant for the development of a protocol for a Phase II clinical trial with ATI-2307 (Appili, Inc.) in patients with *Candida auris* or antifungal resistant *Candida* spp. We are assisting in the development of a Phase II protocol design for pneumocystis prophylaxis (60 Degree



Pharma). On the advocacy front, 2 pilot videos are in production that includes interviews with patients with invasive fungal diseases. We hope this will evolve as the MSGERC Series “Face of Fungal Infections” to be featured on the MSGERC YouTube channel and on the msgerc.org website.

How do clinical studies become designated as an MSG Study?

The MSGERC is often approached by industry partners to confer on the development of new clinical trials. Master Services Agreements (MSA) and Statements of Work are negotiated between MSGERC and the study sponsor (biotechnology generally). Our services may be consultative for developing a study synopsis, a full study protocol, and other services, such as the Data Review Committee and Statistical Reporting. Sometimes sponsors want to contract us for Clinical Operations, such as site selection, CRF and database development, site monitoring, regulatory affairs and safety tracking. Clinical operations are not performed by MSGERC, but rather are subcontracted to the MSG Central Unit at University of Alabama at Birmingham, administered by Alisa Peinhardt. Other institutions may also contract with our biotechnology partners to perform multi-site Clinical Operations. For instance, the University of Texas, Houston is managing the Clinical Operations of the NATURE study (MSG #16).

To be designated as an MSG study (MSG Study #), generally the MSG must have major input into study development and the conduct of the study at MSG sites; however, often those studies are managed by pharmaceutical sponsors (IND holder) and other contract research organizations. These studies are submitted to the MSG Scientific Committee for

review, comment and approval to be designated as an MSG study. Such designation indicates that the study is a substantial contribution to clinical mycology, addresses an unmet need and has other important opportunities to the field.

MSGERC is involved with multiple levels of study consultation in addition to basic science and laboratory services:

- Input into protocol design and methods
- Statistical methods, analyses and reports
- Case Report Form design
- Clinical Operations
- Data Review Committees (DRC)
- Protocol and grant writing
- Publications
- Site selection
- Regulatory Advising (NIH, FDA)
- Continuing Medical Education



POSTPONED DUE TO COVID-19!

The MSGERC 3rd Biennial Meeting, Clinical Mycology Today 2020 which was originally scheduled to take place on September 22-25, 2020 is being postponed due to COVID-19. We have moved our meeting date to May 18-21, 2021 and continue to plan to meet at the Hyatt Regency Tamaya, Albuquerque, New Mexico, USA. We are presently working on securing confirmations for our previously scheduled speakers for these new dates. We are also actively seeking sponsorship. In keeping with our acquired Zoom skills, we will also explore options to live stream some of meeting. The unique aspect of this meeting is the coming together of fungal experts and colleagues, to discuss the science, the trends, and new possibilities. Through these collaborative conversations, we reach great convergence of ideas and future research agendas. Please check the MSGERC.org website for detailed information.

Now May 18-21, 2021



The Video Recordings from the 2016 and 2018 Clinical Mycology Today meetings are found on the MSGERC YouTube Channel (https://www.youtube.com/channel/UCBIAV_cS7pCsf6q2huEf00g) and are also accessible through the MSGERC.org website. Proceedings from the 2018 meeting are now published. (See Publications).

Biennial Meeting Committee

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John Perfect
Barbara Alexander
Marisa Miceli
Oliver Cornely
Sharon Chen
Tom Chiller
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