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**Georgia Bio Newsletter Credits**

**Layout & Distribution:** Kristen Pappaterra
Georgia Bio’s 30th year kicked off with a celebration recognizing the achievements of our companies, industry and academic leaders at the Anniversary Gala & Golden Helix Awards Dinner. The evening was our largest dinner in over 5 years and truly honored our history as well as the state’s excellence in the life sciences industry. I am personally humbled and grateful to our members and the broader Georgia community for the support shown as I assumed the helm of Georgia Bio.

Our primary goal for 2019 is to enhance the value of your membership while we continue to advance Georgia’s life sciences industry. That is why this year we launch our newest tagline: ADVOCATE. CONNECT. INSPIRE. To achieve this we are: working to better engage with policymakers on issues of critical importance to our members and have kicked off an industry PR campaign; launching quarterly member meetings, an Executive Dinner series, and expanding into new industry areas; and finally, expanding our workforce development programs, overhauling our career center, and exploring entrepreneur mentoring programs.

Next month we will begin a new strategic planning effort and invite our members to participate (contact Kristina at kforbes@gabio.org if you are interested.) We want input from our members; Georgia Bio is your organization so your input is imperative to the process.

Finally, stay tuned to additional events, news, and activities by following us at: www.gabio.org or connecting with us on Twitter, Linkedin, and Facebook. And be sure to SHARE our weekly LinkedIn posts to raise awareness of the sector.

We have an ambitious year ahead of us, but the enthusiasm from members is palpable and Georgia Bio is here to ensure the continued success of Georgia’s life sciences sector.

Sincerely,

Maria Thacker Goethe

PS: Welcome to our 10 new members who joined this quarter! What an outstanding start to 2019.

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**Don’t Miss the 2019 State of the Industry Report Launch!**

**April 17, 2019 | Breakfast Meeting**

Georgia Bio has long been a go-to source for data on the bioscience industry in our State. Do not miss this chance to network with industry leaders and learn about one of Georgia’s most innovative sectors. Welcoming:

- Lt. Governor Geoff Duncan
- Russell Allen, President & CEO, Georgia Research Alliance
- Joseph Zorzoli, Head of U.S. Government Relations, UCB, Inc.
Video Interview: “We are ultimately supporting our economy and our students in identifying high paying jobs in the life sciences sector.”

A state’s life science industry is only as robust as its available workforce. During the 2019 Georgia Bio Golden Helix Awards Gala, Chuck Fogelgren shared his thoughts on STEM education, public – private partnerships, precision medicine, data and the Georgia ecosystem.

“[Our teacher training program] is specifically designed to help prepare these students to enter the life sciences workforce with additional skills and training that they will only get in, in their classrooms in high school,” Chuck says.”Over the next year we are looking to expand this program to eight rural districts where we can provide this same high quality training to the teachers and therefore the students so that they can pursue careers in the life sciences.

“For that we’re looking for support from both industry and the state. We really see this as a partnership between the public and the private sector. We are ultimately supporting our economy and our students in identifying high paying jobs in the life sciences sector.”

[Click here to view the video interview.]

Clinical Trials in India

By Mithra Bindhu, Asiatic Clinical Research

India makes up one-sixth of the world’s population and therefore has a large portion of the world’s health problems. Many pharma and biotech companies are looking to enter the Indian market and look at the potential of higher revenues based on 1.2 B people. They are conducting trials in India not just to recruit patients but also to market the products in India. In addition to pharma/biotechs, many NGOs like Gates foundation work on specific tropical diseases like Malaria, Leishmaniasis, Tuberculosis etc.

Indian Population is polygenetic and is an amazing amalgamation of various races and cultures. There are many diverse ethnic groups among the people of India. The 6 main ethnic groups are Negrito, Australoids, Mongoloids, Mediterranean or Dravidian, Western Brachycephals and Nordic Aryans.

The Indian government has recently overhauled the approval process. CDSCO is (https://cdsco.gov.in) similar to FDA in terms of role and regulatory oversight. There are more checks and balances that have been put in for certification of sites, ethics committees and limiting # of concurrent trials by a PI. All clinical trials are registered, and information is available online at http://ctri.nic.in . Introduction of Online SUGAM portal and periodic meetings of Subject Expert Committee meetings are making approvals easier and faster. Typical approval time lines are 3-4 months. Overall - this translates to better a more predictable Clinical Trial conduct.

Other than the huge patient population, India has enough trained and qualified medical personnel to perform clinical trials. While all medical doctors cannot conduct clinical trials, there are many who are passionate about research and understand the processes that need to be followed. India also follows the global ICG-GCP standards. The standard of care in most of the hospitals conducting the clinical research is as good as, and in some cases, better than the western counterparts.

Clinical Research is also supported by good IT infrastructure as most trials now use software for data collection and analysis. Other than standard software for clinical trial management systems, the next generation of researchers are getting innovative and using free application like WhatsApp to stay connected with the PIs and their teams to access data instantly.

Asiatic is a boutique clinical CRO headquartered in Bangalore, India with a focus on P2-P4 trials. We have been in business since 2005 and conducted trials in different therapeutic indications for pharma/ biotechs in USA and Europe. We hope to open an office in GA by Q4 2019 or early 2020. How can we assist you?

Sources:
Atlanta Science Festival Wraps Up Its Sixth Year!

By Kellie Vinal and Jordan Rose, Atlanta Science Festival

Science just exploded across metro Atlanta - with 128 public science events by 101 partners for more than 50,000 people over sixteen days.

From March 9 to 23, the Atlanta Science Festival, presented by Delta Air Lines, brought entertainment, scientific celebrations, and opportunities for curiosity-driven exploration into neighborhoods throughout the metro region. The Festival kicked off on March 9th with a “Wow in the World Pop Up Party,” featuring the insanely popular science-themed podcast “Wow in the World” live on stage. Curious kids and their grown-ups were dazzled by interactive games, skits, and music that inspired us all to ponder more deeply what wows us.

As always, the Festival offered a variety of kid-focused content as well as adults-only fun, trivia events for the competitive-minded among us, and programming to feed your every curiosity, covering everything from spirituality, insects, and stories, to goat cheese, outer space, and nano-tattoos. This year’s Festival featured some fan favorites from years past, such as “Ice Cream Science” at High Road Craft Ice Cream, “Intro to Curling” with the Atlanta Curling Club, and “Roadside Geology” with the Atlanta Geological Society and Georgia Mineral Society. Science lovers were also treated to an exciting multitude of new events covering topics never before explored, and in more Atlanta communities than ever before. The Amphibian Foundation’s “Critters & Cabernet” and Zoo Atlanta’s “Family Zoo Yoga: ‘Pandamonium Style” gave animal lovers a thrill, while sci-fi fanatics got their fix at “Science of Superpowers,” “Neuro-Engineering: Blurring the Lines Between Mind and Machine,” and “To Infinity and Beyond: Science, Fiction, and Popular Understandings of Outer Space.” Young aspiring scientists met STEM professionals and had a little science fun at “Complete the Circuit: Meet a Woman Scientist!” “Snake Day,” “Genius Camp: Makers,” and a variety of family science nights. The Festival also featured a wide variety of exciting creative and collaborative events, such as “Mathapalooza,” “Eating Bugs: A Graphic Novelist’s Perspective,” “The Astrobiology of Star Wars,” and “Science Improv”. One unique event was “Science on Stage: The Forgotten Organ,” where we heard from the minds behind last summer’s playwriting event at Emory, inspired by Ed Yong’s masterpiece I Contain Multitudes: The Microbes Within Us and a Grander View of Life. This exploration of the intersection of art, science, and creativity featured excerpts from the resulting plays written by nationally known playwrights, followed by a discussion with local scientists, the playwrights, and Ed Yong himself.

The Festival culminated with the Exploration Expo on March 23, the annual free celebration of all things science and giant outdoor party in Piedmont Park. Visitors got to touch a human brain, pet a python, squeeze into a mock MRI scanner, play robot soccer, look up their own nasal passages, excavate fossils, spin the Wheel of Bugs, touch a jet engine, and make a pollen map of Atlanta!

If you missed your chance to experience the science celebration this year, don’t panic! The Atlanta Science Festival (http://atlantasciencefestival.org) will return next March and is now producing additional opportunities for the public to engage in science learning opportunities year-round, under the name Science ATL (http://scienceatl.org). The Science Scene calendar lists events, activities, workshops, films, meetups, and other opportunities to experience science, technology, engineering and math happening across the metro area. The 5K Race Through Space on May 4th will have runners start at the Sun and travel 600,000 kilometers with each step as they whiz past the planets through a scale layout of our solar system – register today! Science ATL also offers a STEM leadership program for middle and high school students called Georgia Chief Science Officers, and a science communication fellowship for grad students. There are abundant opportunities for individuals and companies to join these efforts as volunteers, sponsors, and programming partners. Join us in our mission to bring people together through the wonder of science, and help make Atlanta a science city!

Harnessing Translational Science to Address Georgia’s Health Inequalities

Claire L Jarvis, PhD, Freelance Medical Writer

Georgia Clinical & Translational Science Alliance’s (CTSA) second annual statewide conference was held February 28 - March 1 at Callaway Resort and Gardens. The meeting drew together 250 scientists, academics and clinicians from across the state to share the latest advances in clinical and translational research.

Founded in 2017, CTSA member institutions — Emory University, Morehouse School of Medicine, Georgia Tech and UGA — aim to “leverage their complementary strengths to accelerate clinical and translational education, research, and community engagement to impact health in Georgia and beyond.”

In Georgia there exists a large disparity between the metro Atlanta area, with its high concentration of advanced medical facilities and cutting-edge research institutions, and the rest of the state, which is predominantly rural and poor. Overall, Georgia ranks as the 39th healthiest
state in USA, with high incidences of chronic diseases that particularly affect rural Black residents.

As Dr Michael Kurilla, Director of Clinical Innovation at the National Center for Advancing Translational Sciences explained in his keynote address, medical technology in large urban hospitals continues to advance, but this technology is slow to move into smaller rural hospitals, depriving rural patients of top quality healthcare.

There were many approaches to reduce Georgia’s healthcare disparities. A common approach by researchers was to connect with advocates from within underserved communities and work with them to improve local health outcomes. Dr Arletha Williams-Livingston from Morehouse School of Medicine spoke about a program that trained high school students as community health workers. Dr Priscilla Pemu, also from Morehouse, empowered community members to monitor their health and fitness using a smartphone app, aided by trained health coaches within Atlanta AME churches.

Helping vulnerable, underserved populations has its challenges. Dr Colleen Gutman at Emory explained how many Georgia adolescents infected with HIV remain undiagnosed for years while the disease progresses. Her findings suggested healthcare providers missed opportunities to diagnose these at-risk patients during routine check-ups. Dr Ofer Sadan at Emory School of Medicine spoke about the challenges of running a clinical trial in stroke critical care when consent had to be obtained from families after the patient was admitted to hospital, often through long, ambiguous consent forms.

The conference covered the full spectrum of clinical and translational research. Presentations ranged from translating basic lab science to the outcomes of large clinical trials. Attendees had backgrounds in law, public health, biomedical science, engineering and medicine.

The CTSA awarded prizes for team science to the Center for Family Research at UGA, and the Institute for People & Technology at Georgia Tech. Prizes were also awarded to the best poster presentations.

Conference attendees also had an opportunity to enjoy the scenic surroundings of Callaway Resort and Spa, located an hour’s drive south of Atlanta in Pine Mountain.

Top Issues from 2019 AdvaMed Washington Fly In and What They Mean to Georgia’s Life Science Community

Two weeks ago, Georgia Bio VP of Business Development and External Affairs Joseph Santoro participated in a Washington fly in to discuss, educate and learn from Congressional legislators, lobbyists and other industry colleagues about the medtech policy climate in the nation’s capital.

He shares with us the following top takeaways as formally shared by AdvaMed and a few brief notes about what they mean to the Georgia ecosystem.

Medical Device Tax – Need for Repeal

The medical device excise tax is a 2.3% excise tax on the sale of certain medical technology that was enacted as part of the Affordable Care Act. While the tax took effect in January 2013, it has been suspended twice, with the most recent moratorium set to expire at the end of the year and U.S. lawmakers are looking for a permanent repeal. U.S. Senators Pat Toomey (R-Pa.) and Amy Klobuchar’s (D-Minn.) bipartisan “Protect Medical Innovation Act” goes a step further and finally eliminates the medical device tax. When the tax was in effect between 2013 and 2015, 29,000 employees lost their jobs and industry R&D also experienced a $34m reduction in funding when the tax was in force. The American Action Forum predicts that 25,000 more jobs would be lost by 2021 if the tax is reinstated. As part of the AdvaMed DC Fly-In, Georgia Bio and other affiliates spoke on the Hill to garner support to repeal the medical device tax.

What this means to Georgia Bio members

Supporting the medical device tax repeal means employment stability and growth including investments in R&D. The life sciences, including medical device, industry in Georgia employs more than 60,000 and contributes more than $20 billion to the state’s economy (accounting for multiplier effects). This tax would stifle growth and likely prompt job loss.

Ensuring Patient Access to Critical Breakthrough Products

The breakthrough pathway proposal would establish a program of accelerated transitional coverage and payment for new technologies that offer breakthrough in the treatment or diagnosis of serious illnesses affecting Medicare beneficiaries. The Ensuring Patient Access to
Critical Breakthrough Products Act of 2019 will be introduced soon and seeks to address the issues. If the product meets the standards it would qualify for an expedited FDA review. If the therapy were eventually approved by the FDA, Centers for Medicare & Medicaid Services (CMS) would provide temporary coverage for three years.

What this means to Georgia Bio members

Making the process easier to get through FDA. This legislation has been in the works for almost two years. We support most measures that accelerate and simplify FDA review processes where appropriate. Once a bill has been introduced, there will be an opportunity for Georgia Bio and our member organizations to act. Stay tuned.

Policy Proposal to Advance Value-Based Health Care

It is widely recognized that the U.S. health care system must transition from a fee-for-service/fee-for-product payment framework to a value-based paradigm to achieve better clinical outcomes, lower costs and improve the patient experience. Value-based Arrangements (VBA’s) condition or modify payment based upon the results achieved. To promote medtech companies entry into value-based health care arrangements, AdvaMed recommends creating VBHC-specific safe harbors for: pricing arrangements, warranty, and risk-sharing arrangements.

What this means to GaBio members

While not unique to Georgia, life science companies and innovators need to be aware that if your solutions do not address a real unmet need, while improving outcomes without increasing or better reducing cost, you will likely find significant headwinds in adoption and sales in the coming years.

Related: Six issues in life science policy for the 2019 Georgia legislative session

If you would like to know more about Georgia Bio’s state advocacy and policy work, contact Joseph Santoro at jsantoro@gabio.org.

You can find our 2019 state policy priorities here.

Six Issues in Life Science Policy for the 2019 GA Legislative Session

As Georgia welcomes its new Governor and a wave of newly elected legislators, we asked Kallarin Mackey, Emory University Director of State Affairs, Government and Community Affairs and Joseph (Joe) Zorzoli, Head of U.S. Government Relations for UCB to weigh in on the state of play in life sciences policy in Georgia.

How does Georgia Bio plan to work with the incoming Governor and newly elected legislators to ensure they are aware of the important issues of the life sciences industry?

KALLARIN: It will be important to begin by educating the newly elected officials on who Georgia Bio is as an organization, the issues that are important to the membership and the impact that the life sciences industry has on our state. Georgia’s bioscience firms have grown their employment base by 10.6 percent since 2014 and employed just over 32,000 in 2016. To the point above, one of the best ways to illustrate this is by bringing legislators on site to see the work that Georgia Bio members are doing across the state. It’s important to make it personal. Seeing in person the research and innovation that Georgia Bio members engage in every day is a great way to help a lawmaker understand the impact that these companies have in their own district and across the state.

Regarding workforce development, Georgia’s life science industry is consistently seeing a shortage of employees with necessary skills to fill jobs. One example is biomanufacturing. Our research universities, through
How could Georgia Bio help support a student and workforce pipeline for the industry?

KALLARIN: Georgia has a unique opportunity to grow its life science workforce and improve opportunities for young people in rural communities by investing in cutting-edge teacher training workshops that will provide them skills to successfully compete for jobs in the one of the highest paying career sectors. Georgia Bio is leading an effort to seek state support for rural teacher training in biomanufacturing for agribusiness, medicine, and industrial applications. The initiative will reach eight rural and under-served school districts with hands-on, life science curriculum and training for 7-12th grade teachers. The program will train 64 teachers and impact over 5,000 students. As a result, these schools districts will provide a more experienced cohort of students skilled in applicable capabilities.

On patient access, there is discussion that we could see a state waiver for Medicaid expansion this year. Do you think we are likely to see that happen this year? How does that issue impact Georgia Bio’s membership and getting patients access to cutting edge drugs on the market?

KALLARIN: The Governor has announced that he is dedicating $1 million in the FY2020 budget to develop a Medicaid waiver plan that would allow Georgia to have more flexibility in how it administers the program. We are hopeful that a waiver will expand access to care for Georgians and provide them with the drugs that they need. Another critical piece to providing patients greater access to these medications is the passage of legislation to establish clinical review criteria for step therapy protocols. This is an issue that Georgia Bio has been working on for the past few years and we are grateful to the lawmakers who have championed the issue. We hope to continue the conversation this session to seek final passage of the legislation.

Economic Development – Georgia Bio promotes tax incentives to support emerging technology companies. 28 other states have created matching grant program for recipients of National Institutes of Health SBIR (Small Business Innovative Research) and STTR (Small Business Technology Transfer) grants. Do you think Georgia should enact similar measures?

JOE: I do. It makes a lot of sense to me as we know these incentives work and helps to create and grow the health sciences ecosystem in Georgia. 28 other states have passed measures for the state to match SBIR & STTR grants.

Federal Issues. What federal issues could impact Georgia’s state policy agenda?

JOE: University Research, patient access and net operating loss. Let’s take these one at a time.

University Research – The immigration debate has already led to one government shutdown and could perhaps lead to another mid-month. Fortunately, NIH and CDC funding have already been approved for the remainder of the fiscal year, but the National Science Foundation (NSF) has not. Another shutdown when the latest funding bill expires could once again put a hold on NSF research grants.

Patient Access – Gov. Brian Kemp announced plans to apply to CMS for a waiver to expand patient access through the State’s Medicaid program. CMS has already approved more than 30 such waivers and this Administration remains receptive to such waivers. Georgia’s application details have yet to be decided, but if approved it could lead to access for many of the 500,000 uninsured who might otherwise qualify for Medicaid through a straight Medicaid expansion. Applying for a waiver is consistent with GA Bio’s support for expanding access to innovative therapies through the State’s Medicaid program.

Net Operating Loss – The Tax Cuts and Jobs Act of 2017 limited the deductibility of net operating losses (NOLs) in a way that adversely impacts Georgia’s biotech startups, especially when it comes to potential valuations. The next time Congress makes changes to the tax code, it needs to address the needs of capital-intensive biotechnology start-ups by allowing them to fundraise without sacrificing accumulated NOLs.

Why is it valuable that Georgia Bio is enhancing its policy work?

KALLARIN: The life science industry routinely reports shortages of skilled employees and without intervention, the deficit will continue to grow. It is critical for lawmakers to understand the impact that this industry has on Georgia’s economic development and the significant loss we could face if we do not continue to invest in the education and resources necessary to continue its growth trajectory. There’s tough competition for the attention of lawmakers, between healthcare, public safety, transportation and education, that Georgia Bio must put the spotlight on the life sciences industry to demonstrate that it cuts across many of these policy areas.
Please join us for an open house and reception to welcome

Dr. Grace Gowda
as the new Director

April 27, 2019 | 10:00 am – 1:00 pm

College of Pharmacy | 2530 Sever Rd
Room 165 | Lawrenceville, Georgia
UGA Gwinnett Campus

Prospective students are welcomed and encouraged to attend to learn more about the online program. Network with alumni, faculty, and staff, as well as hear Dr. Gowda’s plans for the program.

For more information, please contact
Arvinder Makkar at amakkar@uga.edu
Upcoming Events

2019 BIO Legislative Day Fly-In
April 3-4, 2019

Neo-Biz Solutions: Tour of Georgia at Emory University
April 4, 2019

2019 SEMDA MedTech Conference
April 8, 2019

Mobile to Multiplex: Accelerating Innovation in Global Diagnostics
April 11, 2019

GA Bioscience & Health IT Career Fair
April 12, 2019

The AgLanta Conference 2019
April 14-15, 2019

World Vaccines Congress Washington
April 14-17, 2019

Small Dinner with Michael Fisher, Director at GCMI
April 15, 2019

2nd International Conference on Biotechnology
April 15-16, 2019

Georgia Bio Member Meeting: State of the Industry
April 17, 2019

Soft Lithography for Microfluidics - IEN Short Course
April 18-19, 2019

2019 Southeast Regional Annual Regulatory Career Day
April 24, 2019

Welcome New Members

- ACS BrightEdge
- Analytics-Shop USA LP
- Antios Therapeutics
- Asiatic Clinical Research
- Ernst & Young LLP
- Genologue
- Innovetica
- Newton County of Economic Development
- Ogilvy Health & Wellness
- Strategic Relevance
NCATS SBIR & STTR Funding Opportunities Are Available

The NIH National Center for Advancing Translational Sciences (NCATS) is seeking applicants for its small business funding opportunities through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. NCATS offers annual funding for the development of innovative tools, technologies and intervention (drug, device, diagnostic) platforms that would support the creation of novel therapeutics.

NCATS has released a new SBIR contract solicitation to support small businesses interested in developing innovative health technologies. The standard deadlines to submit an application for open NCATS SBIR and STTR Omnibus Solicitation are April 5, 2019; September 5, 2019; and January 5, 2020.

For more information about NCATS, its SBIR and STTR programs, and upcoming funding opportunities, visit the Small Business Opportunities page. If you have general questions about the NCATS SBIR and STTR program or want to discuss potential project ideas and related questions, email NCATS-SBIRSTTR@mail.nih.gov.

GeoVax, Inc. Seeking Pre-Clinical Service for Immunogenicity Testing

GeoVax is developing an MVA and Vaccinia virus vector-based vaccine against HPV related cancer. The company is seeking a pre-clinical research service provider who can test the vaccine in vivo in C57BL/6 mice to determine the immunogenicity of the vector-based vaccine. Please contact Mugdha Vasireddi mvasireddi@geovax.com for more information.

Spring 2019 IEN Soft Lithography for Microfluidics Short Course | April 18th & 19th

The Institute for Electronics and Nanotechnology (IEN) at Georgia Tech will offer a short course on “Soft Lithography for Microfluidics” on April 18 & 19, 2019. This course module is designed for individuals interested in hands-on training in the fabrication of microfluidic devices using the soft lithography technique. This 2 day intensive short course will be structured to assume no prior knowledge of the technologies by the participants. The course agenda is evenly divided between laboratory hands-on sessions, including SU-8 master mold creation using photolithography and PDMS device fabrication in the IEN cleanroom, and supporting lectures. The goal for this course is to impart a basic understanding of soft lithography for microfluidic applications as practiced in academia and industry.

Target Audience:
This short course is open to off-campus researchers from academia, industry and government laboratories/organizations and is not limited to current Georgia Tech students or IEN users. Anyone who is interested in starting research in the area of microfluidics or PDMS device fabrication is invited and strongly encouraged to participate.

Rates:
*rates include lunch on both days*
Georgia Tech Rate: $150
Academic and Government Rate: $300
Industry Rate: $600

Registration:
Due to the nature of the lab portion of the course, registration has a maximum of 15 participants. Your registration is not guaranteed until full payment is received. If you wish to charge the course to an IEN Cleanroom account, please contact us immediately so that we can provide the proper forms, and so that we may notify the PI or accounts representative. Credit cards are the only payment option for people outside Georgia Tech. Once you submit your registration, follow the appropriate links in your confirmation email. A waiting list of overflow registrants will be maintained in case of cancellations.

Register for the course here.
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