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The Life Sciences Partnership

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THE LIFE SCIENCES VOICE

The Georgia Bio Industry E-Newsletter

Newsletter Issue: September 2017

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Georgia Bio Newsletter Credits

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National Life Sciences Partners

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PhRMA RESEARCH • PROGRESS • HOPE
Bio Business Solutions Value Through Cost-Savings

Letter from the President

Your Georgia Bio Innovation Summit team has been busy crafting another outstanding program for you for October 24th. If you are looking to maximize the value of your Georgia Bio membership, the Summit is a great place to start! We have lined up outstanding keynote speakers, including **Greg Simon, President of the Biden Cancer Initiative**, and **Kim McCleary, Acting Executive Director of FasterCures**, an organization dedicated to improvements in medical research. Ms. McCleary will deliver the luncheon keynote and then lead a discussion on patient centricity with leaders from **Amgen and the Massachusetts Biotechnology Council.**

Some new features this year include:

- **Industry Best Practices Roundtables**. Peer groups from industry will have a forum to discuss best practices, issues and challenges in closed sessions throughout the day.
- **Innovation Stage** featuring new life science inventions. Now integrated with our exhibit hall.
- **Company Investment Showcase** highlighting 8 promising Georgia companies. Winners will be selected to move on to the SEBIO and SEMDA conferences.
- **Research & Innovation track** featuring discussions on the latest scientific trends and laboratory practices.
- **"From the Trenches"** stories can be heard in our **CEO Chats** with leading Georgia bioscience executives.

Of course, the Summit also includes the best networking opportunities of the year, an exhibit hall featuring products and services to support our industry, and the ever-popular **Casino Night & Auction** benefiting the Georgia BioEd Institute. For added excitement, this year we will **stream Game 1 of the World Series** during the Casino Night.

We promise an engaging and thought-provoking day and hope you will join us.
Visit www.georgiabiosummit.org for more information.

I look forward to seeing you soon,

Russell

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The Life Sciences Partnership

GEORGIA BIO INNOVATION SUMMIT 10•24•17

BioPharma | MedTech | Digital Health

Cobb Galleria | Atlanta, Georgia

georgiabiosummit.org

Keynote Speakers:

Greg Simon

President,
Biden Cancer Initiative

Patient Advocate and visionary strategist Greg Simon is a dynamic public speaker and knowledgeable analyst of emerging trends in healthcare, information technology, innovative drug research and development and patient advocacy. His inspirational career is one of achievement and dedication.

Greg serves as the President of the Biden Cancer Initiative. He previously served as the Executive Director of the White House Cancer Moonshot Task Force, a position created by President Barack Obama and for which he was chosen by Vice President Joe Biden in March 2016.

Kim McCleary

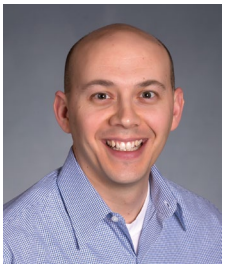
Acting Executive Director, FasterCures | A Center of the Milken Institute

Kim McCleary is Acting Executive Director at *FasterCures*, a center of the Milken Institute determined to remove barriers to medical progress. As a member of the senior management team, Kim helps define, scope and initiate new programmatic activities and strengthen existing programs for the benefit of diverse stakeholders across the biomedical research and healthcare ecosystem.

Immediately following her remarks, Kim will conduct an interview on "Engaging for Success: Patient Centricity Comes of Age" with:

Robert K. Coughlin
President & CEO, Massachusetts Biotechnology Council & Cystic Fibrosis Patient AdvocateAmgen

Jason Spangler MD, MPH, FACPM
Executive Director, Value, Quality, & Medical Policy, Amgen



Learn more and register:
www.georgiabiosummit.org

Executive Interview with InpharmD Founder

Julia A. Pendexter, Mercer University College of Pharmacy

Ashish Advani, PharmD, is a clinical associate professor of pharmacy practice at Mercer University College of Pharmacy and founder of InpharmDTM. InpharmDTM was developed to utilize technology to serve as a platform between healthcare providers (HCPs) and a nationwide network of Drug Information Centers (DICs) to promote evidence-based medical decisions.

Could you tell me a little about your career and leadership path within the pharmacy profession?

I graduated from UGA College of Pharmacy in 2007 and completed a drug information residency with Mercer University and Solvay Pharmaceuticals, Inc. I thought my training would mean starting my career in the pharmaceutical industry, but the timing wasn't right – not with me nor the economy, as we had just gotten into the recession and the industry represented the least stable choice at that time. Instead, I started working at Mercer's DIC in late 2007, and since I've been at Mercer University College of Pharmacy, I've never looked back. I've been driven by my passion of facilitating the practice of evidence-based medicine.

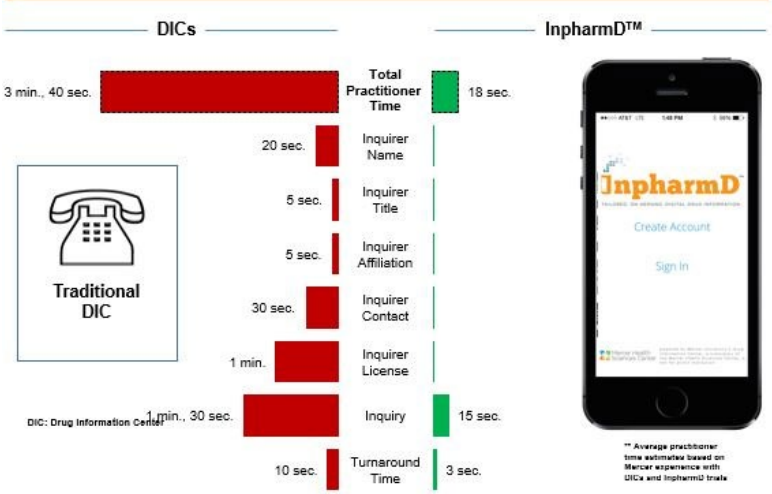
What inspired the development and launch of InpharmD?

When I first started at Mercer, I noticed their DIC was a valuable infrastructure, but operating as a call center made it a nuisance for healthcare providers to contact us with questions. (Imagine calling a taxi company before we had Uber). We'd literally time how long it took us to go through demographic questions, like name, email, etc., and it was 3-5 minutes every time – not including the time to look us up in many cases. There are more than 100 academic DICs across the country that leverage their time and resources to facilitate evidence-based decisions, but they exist as independent call centers and lack technology (like machine learning) to optimize their efforts. The idea for InpharmDTM was inspired by the realization that technology could make the most of an incredibly valuable infrastructure, the DIC. InpharmDTM is the first and only technology providing clinical decision support through a nationwide network of academic DICs. We've built InpharmDTM to meet needs of our customers – the healthcare providers who ask the app questions and the DICs that answer them. We've found technology to be useful to encourage dialogue around common questions and to help shorten answer turnaround time.

Can you describe some of the attributes that contribute to the success of InpharmD?

Clinical decisions are often based on habit, instinct, or intuition because healthcare providers don't have the time or the resources to conduct comprehensive literature searches, making evidence-based medicine impossible. InpharmDTM streamlines this process by allowing healthcare providers to submit unlimited questions 24 hours a day, 365 days a year, on campus or off, via website or app, and receive customized, evidence-based answers within a specific timeframe.

Our technology saves practitioners over 3 minutes per question, encouraging practitioners to utilize evidence more often.



Are there any new expansions or developments at InpharmDTM that you could share with me?

Yes! We're growing through our collaboration with Wellstar Health System, the largest health system in the Southeast. We now consist of four DICs providing drug information technology to 11 hospitals in the north Georgia area. This relationship allows Wellstar doctors, pharmacists, nurse practitioners, and physicians' assistants to access InpharmDTM website and app to receive customized, evidence-based answers to questions about medications and disease states.

What opportunities do you see for Georgia Bio and the life sciences industry locally?

Georgia Bio is a spring board for the growth of the life sciences industry. They offer a tool kit to scientists at any state of development of their idea, and as a result, have accelerated growth. My path is easier because Georgia is already seen as a leader in healthcare and healthcare technology, a true testament to the work of Georgia Bio. Georgia Bio enables every scientist with an idea (which I believe is 100%) has the tools he/she needs to bring it to market. I think it makes it a little clearer.

Would you like to share any advice with young professionals who are early in their career or those aspiring entrepreneurs in the pharmaceutical/healthcare industry?

Time is the only commodity we can't get more of, and we must use it wisely, especially when first beginning. It's tempting to say 'yes' to every opportunity, especially early in one's career, and think of time as a renewable resource. But, as I've progressed I've learned how incredibly important it is to be disciplined with time, focusing on that which delivers the most results. In a world of constant messaging, pop up, alerts, etc., it's really tough to do.

InpharmD™
TAILORED, ON DEMAND, DIGITAL DRUG INFORMATION

Feeding the Probiotics that Boost Your Health

Erica Bizzell, Emory University

What do your morning yogurt, the sauerkraut on your deli Rueben and a refreshing sip of kombucha have in common? All of these foods contain a healthy dose of live and beneficial bacteria known as probiotics.

The World Health Organization defines probiotics as "live microorganisms which, when administered in adequate amounts, confer a health benefit on the host." Some of the most recognized benefits of probiotics are relief from conditions such as diarrhea, inflammatory bowel disease, as well as lactose intolerance. While we know that these tiny gut-dwellers can improve our health, few of us may have ever wondered what they need to eat in order to survive.

Bacteria, including those found in probiotics, are able to feed on a number of non-digestible carbohydrates such as fiber and polysaccharides. Collectively, these bacterial food sources that promote probiotic survival in our bodies are referred to as prebiotics. Researchers have found that prebiotics, much like probiotics, can help to relieve diarrhea and IBD symptoms. Additionally, the oligosaccharides found in human breast milk serve as prebiotics that promote growth of the gut microbiome, which plays a significant role in the health of newborns.

Many research groups are currently studying the effects of combining specific probiotic organisms with their prebiotic food sources, forming what are known as synbiotics (named for their synergistic properties). In a study from the journal, Nature, published in August of 2017, Panigrahi et al. investigated the development of sepsis, which is a potentially fatal immune response, in newborns in India. The group observed that when given a synbiotic containing Lactobacillus plantarum along with the prebiotic, fructooligosaccharide, there was a 40% reduction in newborn sepsis incidence compared to a placebo group. Findings such as these highlight the potential clinical benefits of providing probiotics, along with their necessary food sources, in the form of synbiotics.

If you are wondering how you may be able to incorporate synbiotics into your diet, you are in luck! As probiotics have become a staple of sorts, there is a strong chance that you have already made your own synbiotic supplement without even knowing it. Prebiotics are found in a number of foods that many of us eat daily, such as soybeans, raw oats, garlic, and certain roots. So the next time that you eat your yogurt and oats breakfast you can rest assured that your well-fed probiotics are hard at work.

Why ACOs, Population Health Leaders, and Employers Must Engage Patients Remotely

Doug Olsen, Melon Health

Let's get to the point... the digital revolution in the U.S. began decades ago with health care being delivered almost exclusively within the physician's office, hospital, or clinic requiring patients to "commute for care". Yes, the end of Doctor "house calls" was well before the end of "disco". Thankfully, healthcare delivery started turning the tables with the use of telephonic consultations, web-based applications and remote care, although unlike other sectors of the U.S. economy, the health care industry still today has yet to realize the full potential of digital and remote health delivery.

So how do we leverage digital technology to improve outcomes, reduce costs and extend care beyond the physical setting? By engaging patients remotely with the right information, at the right time, along with education, support, resources and tracking they'll want to use daily. Patients are consumers now, and consumers that are treated poorly by a business are more likely to complain, especially in today's era of "give us your feedback". Successful engagement will result in more positive patient feedback, better self-management, higher levels of satisfaction and you guessed it, healthier and happier participants.

For ACOs, population health organizations, and employers, there's additional benefits when implementing remote health care engagement that help the bottom line, which include:

- Well-engaged patients result in better adherence to prescribed care plans and goals
- Simpler communication between patients and health teams reduces complications (Especially given that 36% of the adult U.S. population has basic or below basic health literacy levels)
- More comprehensive information via patient-generated health data (PGHD) in the form of manually entered tracking data, biometrics and wearables (ie physical activity, weight, food diary, mood diary, glucose, medication adherence)
- Ability to engage participants anonymously in a private online peer support community
- There are many financial incentives for better outcomes and satisfaction measures that can be attained by remotely engaging patients in self-care to augment care team support.

Let's embrace the digital health revolution by deploying remote patient engagement tools placing the patient's care plan, coaches, resources and support crew at their fingertips.

The Importance of Teaching Biological Statistics

Darian Williams, PhD Candidate, Molecular Systems and Pharmacology, Emory University

In recent years, there has been an increasing importance applied to the use of statistics in biological research, and more specifically, the correct use of statistics. Graduate students are now being required to take biological statistics courses when almost a decade ago, these classes were never offered. So why has there been this shift in mentality towards a process that is often viewed as a minor component of research? The answer is that weak statistical analysis has been implicated to be one of the major factors contributing to scientific irreproducibility (Hayden, 2013). According to Hayden, one-quarter of studies that meet the commonly used statistical cutoff (a p-value of <0.05) may be false, i.e., a false-positive.

There are multiple reasons for this, one being that a 5% chance of a result being due to chance is not stringent enough to conclude a result is actually statistically significant. The other reason, that is more likely to be the bigger concern, is p-hacking. P-hacking occurs when a researcher runs one statistical analysis on their data, such a Student's T-test, and obtains a p-value that is greater than 0.05. Because the data is not significant, the researcher then decides to run a different statistical test on the same data set to obtain a p-value that is less than 0.05. What this does is introduce bias into data that often ends up being published; sometimes so much so that future data synthesis may lead to flawed conclusions.

Unfortunately, the large incidence of p-hacking and publication bias is most likely due to the nature of current scientific practices. Most prestigious journals are known to disproportionally publish statistically significant data and most employers are known to only hire candidates that are able to publish in journals with high impact factors. While these practices are unlikely to change in the near future, there are certain methods of attempting to stop the problem at the root; with one of the best being to educate students about the correct use of statistics early on. For example, students taught about pre-hoc vs post-hoc analyses will learn that planning which statistical analysis to perform before conducting experiments will greatly reduce the amount of bias introduced into their research. These classes will also introduce students to GraphPad Prism®, which is the most commonly used tool for performing statistical analyses and generating publication-quality graphs.

After my experience this past year in the Statistical Design and Analysis of Experiments course at Emory University, I strongly believe this or a similar course should be required for all graduate students involved in biological research.

Hayden, Erika Check. "Weak statistical standards implicated in scientific irreproducibility." Nature News 10 (2013).

Georgia BioEd Institute Provides Laboratory Supplies to 78 Classrooms

As the school year begins, we are wrapping up our latest round of Equipment Depot events that have provided 78 schools with free laboratory supplies to help prepare 12,000 students for careers in the life sciences. Many thanks to our partners at VWR, Omega Biotek, Thermo Fisher Scientific, and Emory University for donating this round of supplies! Our goal is to expand our operations statewide via fulfillment center and shipping solutions. Find out how you can help here.

GEORGIA BIOED Institute

New ShareVault White Paper: " What's the role of Non-Immuno Oncology in an Immuno Oncology World?"

This white paper discusses the role of non-immuno-oncology therapies for cancer in a world where immuno-oncology is playing a greater role.

The clinical success of checkpoint inhibitors has made Immuno-Oncology an amazingly "hot" area for pharmaceutical and biotech deal making. With checkpoint antibodies seen as backbones for combination therapy in cancer, many in Oncology are asking:

· What is the role of non-IO in an IO world and can you partner a non-IO opportunity?
· Is there still room for new anticancer agents that are not working in IO models?
· Are drug candidates evaluated with the assumption that everything will eventually be used in combination with IO agents? Or are there indications or mechanisms for which IO will never be important? Should I pursue combinations with IO?
· What kinds of mechanisms are attractive in non-IO? What data and models will big pharma want to see? Do I need to run experiments with their molecule? Are there certain tumor types that are particularly attractive?
· Is it too late to try to compete in the crowded space of combination with PD1 antibodies? What other IO agents are likely to backbones of oncology franchises?
· What will make my non-IO drug candidate compelling for partners and investors?

ShareVault®
Share documents. Simply, securely.

Download the white paper at this link.

2017 MedTech Conference

The MedTech Conference powered by AdvaMed is the leading gathering in North America of global medtech executives with regulatory, reimbursement, business development, legal, IP, marketing, quality, compliance, HR and other key responsibilities. Along with industry leaders, the international conference attracts business development professionals, investors, policy-makers, members of the media, legal experts, consultants, distributors, and other important stakeholders. More than 2,500 attendees will network, conduct business, gain access to capital and share insights in San Jose, Calif. from September 25-27. The conference also features world-class plenary speakers, networking, and business development opportunities. Visit www.themedtechconference.com to learn more.

Become an Advocate for Biotechnology

Learn more about key policy issues affecting biotechnology in Washington, D.C., and state capitals around the country. With the unpredictability of the federal level coupled with the increasingly hostile state legislatures, it is vital that the biotechnology industry amplify its voice on the federal, state and local levels. Become an advocate for biotechnology by joining BIO Action today. Now, more than ever, we need your voice! Text BIO to 52886 or visit BIO's website.

Bio Biotechnology Innovation Organization

GT Alum Leads Company Developing a Novel Technology to Deliver Therapy to Hard-to-Reach Targets in the Body

Benjamin Shapiro, an alum of the Georgia Institute of Technology (Bachelor of Science with highest honors, 1995) is leading a team at Otomagnetics LLC (www.otomagnetics.com) to commercialize a novel drug delivery technology. The technology works like a syringe, but instead of a needle there is a magnetic field that transports bio-degradable therapeutic nano-particles through tissue barriers to the targets behind them. "There are many targets in the body that are not reached by current medical care, or would otherwise require invasive procedures or surgeries to reach. Our pre-clinical testing demonstrates that we can deliver therapy to those targets non-invasively, without needles or surgery" explains Dr. Shapiro.

The team at Otomagnetics includes engineers, chemists and biologists, clinicians, business development and regulatory experts. The 'magnetic injection' technology(pre-clinical) has been shown to deliver therapy (drugs, proteins, or genes) to compartments of the ear, into eyes, and through the skin, without needles or surgery. It is being developed to deliver therapy to the cochlea, to the middle ear to treat recurrent or chronic middle ear infections without tympanostomy tube surgeries (the most common pediatric surgery in the United States), and to deliver therapy into the eye without needle injections (e.g. for macular degeneration). Shapiro credits his original training at Georgia Tech for enabling the invention and development of the technology: "I got my start in research at Georgia Tech. That was the first time I got into a research lab environment, and had a chance to find new answers to open questions. Working with the professors and students at Georgia Tech, that was the foundation".

Research and development at the company has been supported by major grants from the National Institutes of Health, by investments from the Action on Hearing Loss in the UK, the State of Maryland (where the company is based), and by a physician backed investment group (http://www.prweb.com/releases/2017/07/prweb14538821.htm). Otomagnetics is first focusing on conditions of the cochlea and middle ear (hearing loss, tinnitus, middle ear infections) and of the eye (macular degeneration), for which magnetic injection has shown strong therapeutic benefit in pre-clinical studies. Each of these conditions affects millions of patients every year. "Our goal is simple" says Shapiro who in 2006 was selected to the Council of Outstanding Young Engineering Alumni for Georgia Tech, "we want to use engineering to address pressing unmet clinical needs and improve the lives of patients".

Forward-Looking Statements

This press release contains "forward-looking statements" concerning the development of the company's products, the potential benefits and attributes of such products, and the company's expectations regarding its prospects. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements. These statements are made as of the date of this press release. Actual results may vary. Otomagnetics undertakes no obligation to update any forward-looking statements for any reason.

Featured New Member: Innovation Compounding

Innovation Compounding has been providing compounding services for ten years to physicians, clinics, and patients nationwide. Their staff of health care professionals are ready to counsel practitioners and patients alike. Innovation Compounding is here to listen to you, answer your questions, provide recommendations, and provide you with not only medication, but also the knowledge to reach your desired health goals. Their practice is designed around thier mission of advocating people to find a healthier, better way of life.

Learn more here.

Upcoming Events

Small Dinner Series with William Hamilton
September 5, 2017

Bench to Business: Session 4
September 8, 2017

Medtech Women @ SEMDA
September 12, 2017

1st Annual Water Technology Innovation Conference
September 12, 2017

State of the Industry Population & Digital Health
September 12, 2017

BioBash at Clearside Biomedical
September 14, 2017

2017 Triple Negative Breast Cancer Int Conference
September 18-20, 2017

Careers in Life Sciences Series
September 19, 2017

The MedTech Conference (formerly AdvaMed)
September 25-27, 2017

RESI Boston 2017
September 26, 2017

BioPharm America 2017
September 26-27, 2017

Bench to Business: Session 5
September 29, 2017

Boehringer Ingelheim Industry Tour
October 4, 2017

World Vaccine Congress
October 10-12, 2017

Careers in Life Sciences Series
October 17, 2017

BioNetwork 2017
October 23-25, 2017

Casino Night
October 24, 2017

2017 Georgia Bio Innovation Summit
October 24, 2017

BIO-Europe 2017
November 6-8, 2017

5th Annual UGA Medical Device Regulations Conference
November 7-8, 2017

World Orphan Drug Congress Europe
November 13-15, 2017

Careers in Life Sciences Series
November 14, 2017

SEBIO Investor & Partnering Forum
November 14-16, 2017

Welcome New Members

Innovation Compounding
Powers Regulatory Consulting
Spectrum Science Commmunications
Tula Executive Search

STATE OF THE INDUSTRY

Population Health and Digital Health

On behalf of
The Metro Atlanta Chamber Bioscience Leadership Council (BLC) Chair,
Valerie Montgomery Rice, M.D.
President and Dean
Morehouse School of Medicine
I would like to invite you to the BLC meeting on

Tuesday, September 12
9 - 10:30 AM

Morehouse School of Medicine
720 Westview Dr. SW, Atlanta, GA 30310

Please register online at www.metroatlantachamber.com

SPEAKERS:

Valerie Montgomery Rice, M.D.
President and Dean
Morehouse School of Medicine

Todd Haedrich
Vice President and General Manager
athenahealth

Greg Vaughn, M.D.
Spencer Stuart's Healthcare Practice

Jayne Morgan, M.D.
Director of Cardiovascular Research
Piedmont Health Institute

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