



OCTOBER 2019 UPDATE

Serving the NC Life Sciences Industry

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NCBIO This Month

- · Sign Up Now for NCBIO Annual Meeting October 3
- · Legislative Session Continues
- · BMF Meeting Focuses on Workforce Growth
- · Career Fair for Displaced Workers
- · Social Networking Event for Potential New Members
- · NC State Receives \$27 Million Grant to Focus on Future of Biomanufacturing
- · New Degree Program in Agricultural Biotechnology

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Sign Up Now for NCBIO Annual Meeting October 3



More than 250 people have already signed up for NCBIO's 25th <u>Annual Meeting</u>, October 3 from 8:00 a.m. to 3:00 p.m. at the NC Biotechnology Center. A great line up of keynote speakers and panelists will discuss a range of life science topics. Following the morning program and lunch, we'll celebrate our 25th anniversary with a dessert reception.

NCBIO - Media

Find the latest news from NCBIO on the website ncbioscience.net, on LinkedIn and on Twitter at

NCBIO Links

CED

@ncbio.

NCBIO

NC Biotech Center

BRITE

BTEC

BioNetwork

NCBioImpact

North Carolina Pharmaceutical Services Network

NCABR

National Center for Biotechnology Workforce

NCBIO Sustaining Members

Biogen

The two keynote presentations are:

- New Innovations: Personalized Health and Cancer Treatment by Martin Murphy, Founding Chief Executive Officer, CEO Roundtable on Cancer and Project Data
- Capital Formation and Market Trends by J.P. Morgan's Co-Heads of Healthcare Banking, Peter Meath and Lauren Ruane

The Access and Availability panel will discuss how to assure patient access to novel and established therapies while controlling cost. The Ag and Human Microbiome panel will take us from acknowledging the microbiome - animal, human, and plant - to understanding how to manipulate it for nutritional and therapeutic purposes.

During the dessert reception, we will highlight accomplishments over the years with brief remarks and a slideshow. We will also recognize current and former board members for their dedication to the life sciences.

To learn more about sessions and speakers or to register, click here. If you need assistance with registration, contact Amber Niebauer.

Thank you to our current sponsors:

Platinum: BIO, Bioventus, Cook Medical, and VWR

Gold: BDO, FUJIFILM Diosynth Biotechnologies, Grifols, LaSalleGroup/Mentor Technical Group,

and Novo Nordisk

Silver: AdvaMed, Charter Medical, Office Depot, The Conafay Group, and UCB

Bronze: Business Wire, G1 Therapeutics, GSK, IQVIA Biotech, Liquidia, Mispro Biotech

Services, Nikon, Novozymes, ThermoFisher, and UniFirst/UniClean

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Legislative Session Continues



The North Carolina State House has overridden Governor Roy Cooper's veto of the General Assembly's 2019-20 appropriations legislation. The vote was taken on the morning of September 11 during what Democratic legislators had expected to be a no-vote procedural session. Democrats have decried the "surprise" vote as a deliberate deception. Republicans say that the session was never officially designated as a no-vote period. The veto override motion now goes to the Senate. Senate leaders have said they would consider the budget override after they completed the redistricting maps, which were approved last week.

Separately, a special three-judge panel of North Carolina superior court judges has held that the legislative district maps drawn by the State's General Assembly in 2017 are unconstitutional because of the level of political partisanship used to draw them. In its order, the Court directs the Assembly to redraw the districts in time for the 2020 election. Republican legislators did not challenge the order and developed new legislative district maps.

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The next steps in following up on information from the *Window on the Workplace* study were the focus of the September NCBIO Biotech Manufacturers Forum (BMF) meeting. The study indicates that North Carolina can expect 5,000 new biomanufacturing jobs in the next five years.

NCBIO President Sam Taylor said, "NCBIO will focus on identifying education and training activities that will be needed to ensure that employees and students have the skills needed and that education institutions have the resources necessary to provide the training and courses. We will be working with the companies to get subject matter experts to meet with the academic institutions to ensure we have the resources needed to meet the needs of industry."

Bill Bullock, Senior VP, Economic Development and Statewide Operations for the NC Biotechnology Center, focused on efforts to raise public awareness about the industry to get more people interested in careers in biomanufacturing. He noted that efforts will include workforce targets such as K-12, community colleges, universities, transferable and general workforce, military veterans, transitioning service members, and military spouses.

The group also heard a report on wastewater issues in North Carolina. For more information about the BMF, contact <u>John Wagner</u>, BMF Program Manager.

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Career Fair for Displaced Workers



NCBIO partnered with NC Works Career Center Durham and the RTP BioPharma Working Group to host a career fair for displaced workers at Merck. Employees were displaced because of a change in the mix of products due to changes in market demand. Sixteen companies participated in the event, and 75 employees turned out to talk with the companies.

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Social Networking Event for Potential New Members



NCBIO staff and board members networked with prospective members for the organization. This is one of several events the organization will hold during the next year to highlight the work and benefits of NCBIO. Thanks to Frankel Staffing Partners and Seasons 52 at Crabtree for helping host the event.

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PONC State Receives \$27 Million Grant to Focus on Future of Biomanufacturing

A new five-year project led by North Carolina State University will sponsor an international collaborative research and training program in biomanufacturing science and technology. The project – "Accelerated Innovation in Manufacturing Biologics (AIM-Bio)" – is funded by the Novo Nordisk Foundation, whose main objective is to "provide a stable basis for the commercial and research activities of Novo Nordisk and support scientific, humanitarian and social purposes."

NC State will administer the \$27 million AIM-Bio program in collaboration with the Technical University of Denmark (DTU) in Copenhagen. NC State will receive \$18 million to carry out its activities, and the remainder will go to DTU. More

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PONew Degree Program in Agricultural Biotechnology

Alamance Community College in Graham is offering the state's first and only associate's degree program in Agricultural Biotechnology. "This degree program was created to meet the need that companies have for employees trained in lab research techniques and also plant production," said Elizabeth Riley, Ph.D., department head of horticulture technology and agricultural biotechnology. "Alamance Community College is positioned in the middle of the Piedmont Triad and Research Triangle Park. There has always been a strong research presence centered around agricultural biotechnology, and that presence is continuing to grow." More

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At the National Level

NCBIO and Other Organizations Oppose Foreign Price Controls

Legislation introduced by US House Speaker Nancy Pelosi, *The Lower Drug Costs Now*, is drawing stiff opposition from the industry and from the Republicans on the House Energy and Commerce Committee, where the proposal will be considered. The plan would establish an international pricing index, penalize pharmaceutical companies for raising the price of drugs faster than inflation and a number of other provisions.

In response, all 24 Republicans on the House Energy and Commerce Committee criticized her partisan process to what has typically been, and should continue to be, a collaborative and bipartisan effort to bring down drug prices for the American people:

"We can solve this problem; we have solutions at the ready. We have advanced numerous policies aimed at lowering the costs of prescription drugs. In fact, in May, the House Energy and Commerce Committee passed bipartisan legislation to bring down prescription drug prices only to have Speaker Nancy Pelosi put politics over progress. Now Speaker Pelosi is back at it—pushing a socialist proposal to appease her most extreme members. It does not have to be this way; there are bipartisan solutions to bring down prices for patients and create real transparency and accountability for this system, "said all 24 Republicans on the Energy and Commerce Committee.

NCBIO, BIO, PhRMA and other organizations recognize it is important to make a patient's cost of drugs affordable, and it is equally important to assure patient access without damaging innovation. That's why we need you to take action.

Congress is expected to continue debating drug pricing legislation in the coming weeks. Now is the time to make your voice heard!

<u>Email</u> your elected officials and tell them to oppose importing foreign price controls into the Medicare program. Let them know that price controls are bad for seniors and bad for innovation. Urge your elected leaders to support responsible solutions that lower what patients pay out of pocket for prescription medicines and support robust biomedical innovation.

Push to Repeal Medical Device Tax Continues

AdvaMed, NCBIO, MDMA and other organizations continue efforts to repeal the Medical Device Tax. Unless Congress acts quickly, the U.S. medical device industry will face a \$20 billion tax increase when the excise tax goes back into effect Jan. 1, 2020. The tax, which was in effect from 2013-2015, proved to be a significant burden on innovative medtech companies, as it is a tax on sales – not profit – which is particularly devastating for smaller start-ups, most of which are not yet profitable.

The Senate and House have both previously passed repeal legislation with strong bipartisan majorities. Members of Congress from both parties joined together in late 2015 to suspend the tax from 2016 through 2017 and again in 2018 to delay it through 2019. The suspension of the tax has resulted in improvements to the ecosystem in the short-term and has enabled companies to reinvest in research and development, make new hires and provide new benefits to their employees like companywide raises and increased 401(k) matches. Still, companies are holding off on long-term investments to prepare for the possible reinstatement of the tax at the end of this year. Fortunately, there continues to be overwhelming bipartisan support for full repeal of the medical device tax in Congress.

NCBIO members are encouraged to contact members of the Congressional delegation and urge repeal of the tax.

Upcoming National Events: NCBIO Members Can Get Discounts



Tell Your Story at BIO

Call for Sessions is now open for the 2020 BIO International Convention. Does your company have a compelling story to tell about new, innovative research or projects? Do you want to showcase your expertise or latest findings in front of 17,000+ innovators in biotechnology and life sciences?

This is your chance to submit topics that go beyond and paint a vision for the global biotechnology industry's future in San Diego, June 8-11, 2020. The submission timeline is **September 12 - October 10, 2019**. All session applications must be submitted by the deadline, October 10, 2019, at 5:00 PM ET.

BIO Investor Forum Next Month in San Francisco

Less than a month until the <u>BIO Investor Forum</u>, October 22-23, in San Francisco. This international biotech investor conference focuses on investment trends and opportunities in life sciences. Find out more about <u>registration</u>.

BIO Patient & Health Advocacy Summit - October 30-31

Attend the 2019 BIO Patient and Health Advocacy Summit to discuss timely policy issues and share best practices for interactions with the patient advocacy community. Learn from and network with key stakeholders in the healthcare ecosystem, patient advocacy groups, policymakers, and more on October 30-31, 2019 in Washington, DC.

Program Topics

- · Practices and Principles: Navigating the FDA
- Closing the Gap: Partnering to Invest in Areas of Unmet Need
- 2020 Election: Impact on Patient Access
- Patient Access to Innovative Therapies and the Future of the US Healthcare System

View the program and register.

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To be included in Member News, send information about your organization to Brenda Summers.

<u>AgBiome, Inc.</u> has received Phase II grant funding from the Bill & Melinda Gates Foundation to continue the discovery of microbes that target sweet potato weevils (SPW) and to move lead strains into early product development for future deployment to smallholder farmers in African nations. <u>More</u>

<u>Asklepios BioPharmaceutical, Inc. (AskBio)</u> has acquired the technology assets of RoverMed BioSciences. RoverMed developed nanotechnology cargo delivery of therapeutics into the nucleus of diseased cells without affecting healthy cells. <u>More</u>

Baebies SEEKER was installed for the first time outside the U.S. More

Biogen Inc. announced that it has been ranked the #1 biotechnology company on the Dow Jones Sustainability World Index (DJSI World) for the fourth time, after being the first U.S.-based biotech company to ever make the list in 2013. More Biogen is highlighting new data that demonstrates the potential benefits of treatment with TYSABRI® (natalizumab), PLEGRIDY® (peginterferon beta-1a) and AVONEX® (interferon beta-1a) in specific multiple sclerosis (MS) patient populations. More

<u>Hughes Pittman & Gupton</u>, LLP (HPG), has been named to *INSIDE Public Accounting's (IPA)* 2019 Best of the Best Accounting Firms list. HPG was also named to IPA's Top 200 Firms list for the second time. More

Evidera, a business unit of PPD, has entered into an exclusive collaboration agreement with Clinical Study Support, Inc. (CSS), a subsidiary of Shin Nippon Biomedical Laboratories Ltd. (SNBL), extending both organizations' capabilities to deliver more robust consulting and analytical capabilities and creating a more complete geographic customer solution for clinical, real-world and patient-centered research. More Harbour BioMed (HBM), a global clinical-stage biopharmaceutical company, and PPD announced a strategic collaboration to develop HBM's innovative therapeutics in the fields of oncology and immunology. More

<u>RFPi Inc.</u> has received a grant from the National Institutes of Health to develop a novel, imagingbased medical device that health-care providers could use to test asymptomatic patients at risk for peripheral arterial disease. <u>More</u>

<u>Smith Anderson</u> partners Rose Kenyon and Caryn McNeill were honored with *North Carolina Lawyers Weekly's* prestigious 2019 "Women of Justice" awards. <u>More</u>

Syneos Health announced the launch of Deployment Solutions, which provides customizable, scalable field-facing programs integrating promotional and educational subject matter experts, including reimbursement and access managers, Medical Science Liaisons (MSLs), nurse educators, sales teams, contact center specialists, medication adherence professionals, and hybrid experts. More

<u>TransEnterix, Inc.</u> announced the company's Senhance Microlaparoscopy 3 mm instruments is a recipient of the 2019 Innovations of the Year award from the Society of Laparoendoscopic Surgeons (SLS). <u>More</u>

vTv Therapeutics Inc. presented additional positive data from its phase 2 Simplici-T1 study in

North Carolina Events of Interest

Invest in Cures Forum September 25

Representatives from eight disease foundations will present a deep dive into their approaches to accelerating treatments for patients, including investing in startups through venture and social impact funds. The program *Invest in Cures* includes one panel focused on cancer and a second on rare diseases, as well as a report from the Milken Institute's Center for Strategic Philanthropy on how foundations are translating science into products and services that advance human health.

The forum is September 25, 3:00 – 6:00 p.m. at the North Carolina Biotechnology Center. The event is hosted by LaunchBio. Presenting partners are BioLabs, CED, NCBIO, and the North Carolina Biotechnology Center.

Invest in Cures is part of a 2-day session at the North Carolina Biotechnology Center highlighting rare diseases. On September 26, UNC's Catalyst for Rare Diseases and the Rare Disease InfoHub will present a forum bringing together stakeholders to discuss policy affecting progress in advancing research and treatment. Click for more information.

IQVIA Biotech and NC Venture Capital Firms Networking Reception

Join IQVIA Biotech, NCBIO and other local colleagues for a networking reception at IQVIA's RTP Office on October 9 from 5:00-7:00 p.m. Enjoy an evening with a guest panel of speakers from Pappas Capital, NovaQuest Capital Management, and Hatteras Venture Partners as they offer insight into VC fundraising and how to better position company assets. After the presentations, there will be a reception and networking opportunity to speak with your local colleagues and the speakers. Register to attend.

To support our local community, IQVIA Biotech also requests that each attendee please bring an item found on the Ronald McDonald House <u>website</u>. IQVIA Biotech will have collection bins set up where these items can be dropped off and will donate these to the Ronald McDonald House to support local families in need. **Questions?** Please email <u>Andrew Langley</u>.

Livestream of BARDA Event at First Flight Venture Center

First Flight Venture Center will be livestreaming day one of BARDA Industry Day 2019 on October 15. BARDA will be broadcasting topics on U.S. government medical countermeasure priorities highlighted by exciting speakers and interesting content! Register here.

In other news, First Flight Venture has been awarded a \$125,000 grant by the U.S. Small Business Administration (SBA) Federal and State Technology (FAST) Partnership Program. First Flight, for the second year in a row, is one of just 24 recipient organizations recognized nationwide that provide support to science-focused entrepreneurs developing innovative and disruptive technologies.

Disability Summit October 24

Join other life science companies and affiliates for the "Working Beyond Barriers: Leveraging Inclusion to Drive Behavior and Culture and Change Disability Summit," at Biogen's 5000 Davis Drive campus, October 24. The session is in partnership with Access Ability. This is a chance to share best practices for organizations at various levels and create a successful blueprint to engage with hiring managers to increase employment for people with disabilities.

Keynote speaker is John Register, Paralympic Athlete and Military Veteran. Event highlights include:

- ERG/BRG Best Practices Panel
- Sourcing Top Talent including People with Disabilities
- Facilitated Round Tables
- Key Take-A-Ways
- Establish an Active Consortium

Register or for more information contact, accessability@biogen.com.

Bull City Biotech Summit October 29

The 3rd annual Bull City Biotech Summit hosted by Durham Tech will be held October 29, 8:00 a.m. – 12:30 p.m. at the NC Biotechnology Center to connect with local industry, academia, and community leaders, and explore opportunities for partnerships and collaboration to attract, develop, and retain skilled biotech talent in Durham.

Featured speakers will share updates and provide connections to local programs and resources available to your organization, including:

- · Advanced training programs in biotechnology and advanced manufacturing
- Customized training
- Funding to offset training costs
- · Apprenticeships and internships
- · Recruitment and placement success stories

NCBIO, NC Biotechnology Center and BRITE are partners for the event. Register or contact Ingrid Charles at charlesi@durhamtech.edu for more information.

Cystic Fibrosis Foundation Holds Fall Event to Benefit Patients

This fall the Cystic Fibrosis Foundation (CFF) through its <u>Triangle's Finest</u> program to benefit patients with cystic fibrosis will host several events. The <u>Brewer's Ball</u> on November 8 will celebrate the Triangle's finest young professionals.

ACS CAN NORTH CAROLINA RESEARCH BREAKFAST

ACS CAN (American Cancer Society Cancer Action Network) will hold its 10th annual Research Breakfast on Tuesday, November 12. The Honorary Hosts, North Carolina's three NCI-designated Comprehensive Cancer Centers (Duke, Wake Forest, and UNC-Lineberger), will join a panel to discuss barriers and promising practices to patient enrollment in therapeutic clinical trials, especially focusing on disparate populations and underserved communities. Industry leaders and government officials will join the program and highlight the importance of clinical trials as an integral part of the healthcare system.

<u>Click</u> to register. If you would like to sponsor the event or get more information, contact Christine Weason at christine.weason@cancer.org.

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9 BIO Business Solutions



Last year BIO saved 4,200 companies nearly \$460 million through BIO Business Solutions with volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more.

NCBIO members, you are eligible! This is a benefit of your NCBIO membership. Review the cost-savings offered by clicking here and choose the programs you're interested in. Email biobusinesssolutions@bio.org with your choices and they will get you started. For all the latest news, promos, and event information, follow BIO Business Solutions on LinkedIn!

Upcoming Webinars

Free Webinar Hosted by BIO and Scientist.com

September 25, 1:00 - 1:45 p.m.

Biotechnology Leaders:

Are You Using Good Data to Help Drive Therapeutic Decisions?

Attendees will learn how to use the Trial Insights digital solution to help guide data-driven decision making, including how to:

- Quickly assess the landscape for industry peers, existing partners and potential collaborators for a given disease, therapy or biomarker
- Identify "up and coming" key opinion leaders, track their progress and connect with them at any stage of your study
- Pinpoint investigative sites for any disease, therapy or biomarker within 200 miles of

Register and get more information.

Aon/Sidley Webinar

Life Sciences Securities Class Action Update:

Legal and Risk Best Practices for Life Sciences Companies

Tuesday, October 1, 2019 | 1 PM EST | CLE Credit Pending

In this webinar, Aon/Sidley will discuss:

- Overview and analysis of trends in decisions involving life sciences companies with products at two distinct stages of development – pre- and post-FDA approval and takeaways that can help guide disclosure approaches
- Recent cases and what those reveal about the events that can draw a lawsuit
- Insight into the D&O insurance underwriters' reaction to the volatile life science shareholder litigation landscape

Register for the webinar:

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Webinar for Biotechnology Leaders: Are You Using Good Data to Help Drive Therapeutic Decisions?

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Invest in Cures & Rare Disease Forum

Wednesday Sep 25, 2019

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Invest in Cures & Rare Disease Forum

Thursday Sep 26, 2019

... read more

2019 SciTech Lecture Series - Age and Sex: Implications for Regenerative Medicine Applications

Thursday Sep 26, 2019

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NCBIO Annual Meeting 2019

Thursday Oct 3, 2019

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LaunchBio: Larger than Life Science

Thursday Oct 3, 2019

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BTEC Hands-On Single-Use Processing for Biopharmaceuticals Tuesday Oct 8, 2019 - Thursday Oct 10, 2019 ... read more **Triangle Global Health Annual Conference** Wednesday Oct 16, 2019 ... read more **Clinical Trial Supply East Coast 2019** Wednesday Oct 16, 2019 - Thursday Oct 17, 2019 ... read more **NCRAF Seminar** Thursday Oct 17, 2019 ... read more **Funding Success - Mitigating Venture Financing Risks** Thursday Oct 17, 2019 ... read more BTEC Applied Principles and Techniques of Depth Flow Filtration (DFF) and Tangential Flow Filtration (TFF) for BioPharm Downstream Purification Tuesday Oct 22, 2019 - Friday Oct 25, 2019 ... read more **Biogen AccessAbility Disability Summit** Thursday Oct 24, 2019 ... read more **Bull City Biotech Summit 2019** Tuesday Oct 29, 2019 ... read more **BIO Patient and Health Advocacy Summit** Wednesday Oct 30, 2019 - Thursday Oct 31, 2019 ... read more 2019 SciTech Lecture Series: The Ingredients for Innovation in Clinical Research

Thursday Oct 31, 2019

... read more

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