



MARCH 2019 UPDATE

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NCBIO - Media

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NCBIO This Month

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NCBIO Executive Committee Recommends Legislative Agenda



The NCBIO Executive Committee has submitted its 2019 recommended legislative agenda to the Organization's Board of Directors. The agenda includes activities for a wide array of life science companies.

Franchise Tax Relief for Pre-Revenue R&D Companies. With key legislators in the State Senate looking hard at franchise tax reform this year, NCBIO is asking that the Assembly provide relief to early stage R&D companies. Franchise tax is paid on a company's net worth, which includes unspent cash from investors as well as other assets. The tax can be particularly significant for

NCBIO Sustaining Members

[Biogen](#)

companies that have raised later rounds of venture capital or entered the public equity markets. NC BIO is working with legislative Finance Committee leaders to evaluate mechanisms to reduce the tax burden on research and development companies that do not yet have significant product revenue.

SBIR/STTR Matching Grants. The Executive Committee also is recommending that NC BIO once again seek an increase in funding for the State's matching grant program for North Carolina companies that receive federal Phase I SBIR or STTR awards. Formally known as the One North Carolina Small Business Fund, the program received a one-time \$1 million appropriation in 2018. However, approximately \$5 million is needed to fully meet the expected demand for funding under the program. In addition, funding is needed for the Phase SBIR/STTR grant-writing stipends that are called for by the authorizing legislation. NC BIO is working with the North Carolina Board of Science Technology and Innovation, which runs the program, to seek a larger appropriation in 2019.

NIIMBL. As a member of the National Institute for Innovation in Manufacturing of Biopharmaceuticals (NIIMBL), North Carolina has committed to set aside \$2 million annually to match monies from the federal government and industry to support process innovation and workforce training for the biopharmaceutical industry. The Assembly has consistently met the State's commitment. NC BIO will be working with North Carolina State University, the state's lead NIIMBL participant, to secure program funding for 2019-21.

North Carolina Biotechnology Center. NC BIO will again be working with the North Carolina Biotechnology Center to seek adequate funding for programs operated by the Center. The Center reports that its centerpiece loan and grant programs are significantly over-subscribed. In addition, with international companies still deploying repatriated funds and savings from tax reductions, the Center's economic development and marketing programs offer opportunities to further grow the life science sector's North Carolina footprint.

Beyond these immediate legislative priorities, the NC BIO Executive Committee has recommended that the Organization's staff work with appropriate state agencies on plans to meet growing workforce training needs in the biomanufacturing and clinical research sectors. The Committee also identified wastewater management as an emerging issue for biomanufacturing companies and has directed the staff to develop proposals to mitigate challenges related to wastewater treatment and discharge. Specific recommendations for these priorities are likely to form the basis for legislative requests in the 2020 session of the General Assembly.

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Life Science Caucus Gets New Chairs, Prepares for 2019 Activities



Senators Paul Newton (R-Cabarrus) left, and Mike Woodard (D-Durham) right.

Senators Paul Newton (R-Cabarrus) and Mike Woodard (D-Durham) will be the Senate Co-Chairs of the General Assembly's 2019-21 bipartisan Legislative Joint Life Science Caucus. Newton, who co-chairs the Senate's Finance Committee, represents the State's 36th senatorial district, which includes the North Carolina Research Campus at Kannapolis. Woodard's senatorial District 22 includes much of Durham County and counts as constituents, employees from a host of life science companies.

"NC BIO congratulates these two prominent members of the State Senate and looks forward to working with them in the years ahead," said NC BIO President Sam Taylor. "We are fortunate to have these men, who are so familiar with North Carolina's life science community, to share leadership of



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the Caucus.”

Senator Newton stated, “The life science industry is a vital part of North Carolina’s economy and provides products important to the health of the people of our state. I am pleased to be Co-Chair of the Life Science Caucus and look forward to working with NCBIO and other groups in developing meetings that will help our members gain more knowledge about the industry. Later in the year, we plan to tour key companies and educational institutions to get a first-hand look at what is happening in the sector.”

Senator Woodard noted, “Life science companies are an economic engine in my Senate district so I am pleased to take this leadership role to help others in the General Assembly learn more about the industry. During the Caucus meetings, I hope we can hear more about the growth of the industry and the life changing therapies that are developing in our state.”

The State House has not yet designated its Life Science Caucus Co-Chairs but is expected to make the appointments shortly.

Traditionally, the Caucus has met regularly during the legislative session to hear from life science experts and to receive updates on NCBIO’s legislative agenda. Caucus members have also held field trips to life science hubs across the state during the interim between legislative sessions. NCBIO has regularly provided support to the Caucus in the form of program recommendations and logistics for meetings and site visits.

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NCBIO Legislative Reception, March 20



2019 NCBIO Life Sciences
Legislative Reception

Wednesday, March 20
5:30 – 7:30 p.m.

Sign-up for the NCBIO Legislative Reception, March 20 from 5:30 to 7:30 p.m. Join other members and talk with legislators about workforce training, program funding, innovation and tax policy, and other topics. More than 150 NCBIO members and legislators have already registered, which features a slide show of some of the companies located across the state.

Thank you to [Astellas](#), [BIO](#), [Biogen](#), [Bristol Myers Squibb](#), [Grifols](#), [IQVIA](#), [Lilly](#), [PhRMA](#) and [Syngenta](#) for sponsoring this Legislative Reception. Learn more and register [here](#). For questions about registering, contact [Amber Niebauer](#). If you’re interested in sponsoring this event, contact [Laura Gunter](#).

The North Carolina Museum of History does not sponsor or endorse this event.

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Just a Few Days until 2019 Life Science Conference

 CED

ESTD • 1984



CED Life Science Conference

FEBRUARY 26, 2019 TO FEBRUARY 27,
2019 | RALEIGH, NC

In partnership with [NCBIO](#) and [NC Biotechnology Center](#), the 29th Annual Conference is February 26-27 at the Raleigh Convention Center. Don't miss this year's investor panel at the 2019 CED Life Science Conference featuring four of the industry's top investors from across the U.S. Hear their predictions on the direction of the Life Science Industry during a discussion moderated by Buck Phillips, CFO, and Senior Vice President of G1 Therapeutics.

Panel features:

- **Ben Auspitz**, Partner, F-Prime Capital Partners
- **Hongbo Lu**, Partner, Lilly Asia Ventures
- **Jayson Punwani**, Partner, Takeda Ventures
- **Janis Naeve**, Managing Director, Amgen Ventures

Keynote speakers include:

- **John Carreyrou**, Pulitzer Prize-Winning Journalist & Author, *Bad Blood*
- **Laura Deming**, Partner, The Longevity Fund
- **Arie Beldegrun**, D. FACS, Executive Chairman and Co-Founder, Allogene

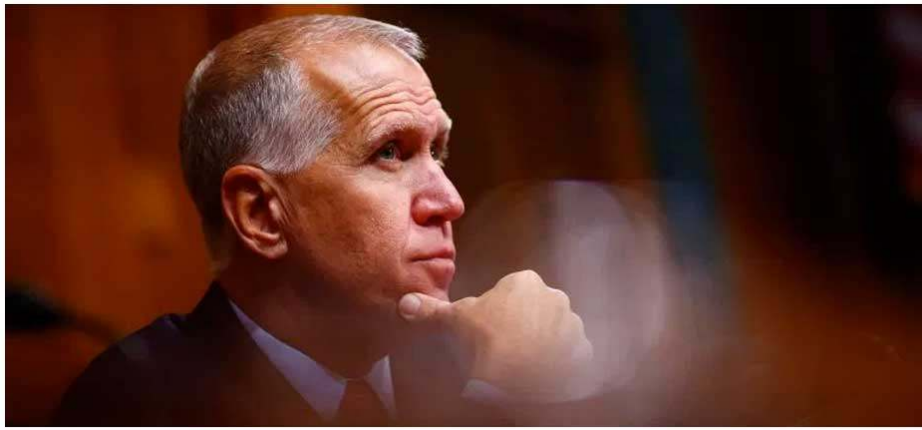
Another panel focuses on "The Journey to Becoming a Public Company," featuring Terry-Ann Burrell, Managing Director, J.P. Morgan as moderator with panel on homegrown companies: Neal Fowler, CEO, Liquidia, and Mark Velleca, M.D., Ph.D., CEO, G1 Therapeutics.

Online registration is now closed and only on-site registration is available.

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At the National Level

Senator Tillis Leads Senate Judiciary Subcommittee on Intellectual Property



US Senator Thom Tillis (R-NC) was named Co-Chairman of the Senate Judiciary Subcommittee on Intellectual Property, which will provide a bipartisan platform to work on long-overdue IP reform. The other Co-Chair is Senator Chris Coons (D-DE). In a recent op-ed Senator Tillis wrote on how compulsory licensing proposals are counterintuitive to the goal of lowering drug prices and outlined risks US intellectual property rights face from other countries. [More](#)

Proposal to Repeal Medical Device Tax

The medical device tax is a 2.3% excise tax on the sale of most medical technologies that was enacted as part of the Affordable Care Act. Given that this tax applies to revenues, not profits, it is extremely punitive to medical technology innovators. Since the inception of the medical device tax, there has been growing bipartisan support to end this tax on innovation and it has been suspended multiple times by Congress. In 2018, the House passed a bill to repeal the tax 283-132, but the Senate failed to act.

If Congress **does not act this year**, the medical device will be reinstated in 2020, and billions of dollars will be diverted away from research and development for cures and therapies. Perhaps most concerning, the short-term suspensions limit the ability of companies to make longer term investments in new technologies and treatments without the certainty of a full repeal.

Legislation, the Protect Medical Innovation Act, will be introduced soon to repeal the medical device tax. NC BIO's Sam Taylor will discuss this proposal with the NC Congressional delegation during the AdvaMed Fly-In.

BIO Fly-In

Register Now, BIO Legislative Day Fly-In, April 3 – 4

The 2019 [BIO Legislative Day Fly-In](#) in Washington, DC is a free event hosted by BIO as a benefit of membership. NC BIO members are invited to represent your North Carolina company and meet with the Congressional delegation on key issues to the industry.

Register by March 4 and you will have the opportunity to: participate in a legislative briefing and networking reception on Wednesday, April 3, and participate in meetings with North Carolina Congressional offices on Thursday, April 4.

[Learn more](#) about the fly-in. Sam Taylor and Laura Gunter will represent NC BIO at this year's fly-in. If you would like to register, contact [Laura](#) for details.

PhRMA and BIO Statements on the Administration's Proposed Rule to Reform the Rebate System

Pharmaceutical Research and Manufacturers of America (PhRMA) president and CEO Stephen J. Ubl issued the following statement: "We applaud the Administration for taking steps to reform the rebate system to lower patients' out-of-pocket costs. Our current health care system results in patients often paying cost-sharing based on the list price, regardless of the discount their insurer receives. We need to ensure that the \$150 billion in negotiated rebates and discounts are used to lower costs for patients at the pharmacy." [More](#)

Other [groups](#) agree that the Health and Human Services Department is moving in the right direction with the recent proposal to enhance transparency in the drug distribution and rebate system. The proposal is also garnering [local support](#), and NC BIO is contacting the Congressional delegation about the reform.

BIO CEO and President Jim Greenwood said, "BIO strongly supports the goal of this proposed rule

to lower out-of-pocket costs for consumers. Every year innovative drug makers provide tens of billions of dollars in rebates to help expand affordable access to prescription medicines. But far too often these rebates are not passed along to patients and are instead used to pad the profits of middlemen. The current system creates perverse incentives that are driving the affordability crisis many patients face today." [More](#)

Report from BIO Investor Forum

A record number of investors—over 660—registered to learn about the latest biotech trends and to search for opportunities to turn technology into life-saving treatments at the BIO CEO & Investor Forum, February 11-12 in New York. More than 130 biotechnology and pharmaceutical companies delivered 13-minute pitches showcasing their pipeline, R&D activities, business objectives and investment goals. Information was also shared through face-to-face meetings scheduled by BIO's One-on-One Partnering™ system which was in full swing, scheduling almost 3,000 meetings—a record for this 21st annual event. [More](#)

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Member News

To be included in Member News, send information about your organization to [Brenda Summers](#).



Eamon Fitzmaurice, AveXis, Geoff Durham, Greater Durham Chamber of Commerce, NC Commerce Secretary Anthony Copeland, and Wendy Jacobs, Durham County Board of Commissioners.

[AveXis, Inc.](#), a gene therapy company developing treatments for rare and life-threatening neurological diseases, will create another 200 jobs as it expands its manufacturing center in Durham County according to an announcement in February. The new center was first announced in May of last year. AveXis will invest an additional \$60 million in the facility. [More](#)

[bioMérieux](#) announced the acquisition of Invisible Sentinel Inc. This company, based in Philadelphia (PA) develops, manufactures and markets innovative and user-friendly molecular diagnostic tools for the rapid, accurate and reliable detection of pathogens and spoilage organisms in food and beverage. [More](#)

[Chiesi USA, Inc.](#) has been named as a Top Employer in the United States for the fourth year in a row. The recognition is certified by the Top Employers Institute, a leading authority on identifying and measuring employment best-practices worldwide. [More](#)

The Association of Clinical Research Organizations (ACRO) announced that its Board of Directors has elected Dr. Cynthia Verst, President of Global R&D Design and Delivery Innovation at [IQVIA](#), as 2019 Chair. Alistair Macdonald, Chief Executive Officer of [Syneos Health](#), was elected as Vice Chair. [More](#)

[IQVIA™](#) announced the launch of IQVIA™ Biotech and its new approach to delivering tailored clinical and commercial solutions for small biotech and biopharma companies. This solutions suite, supported by more than 1,000 dedicated employees, will deliver simplified operating procedures, specialized teams, and services to provide a more agile way for these innovators to reach their drug development and commercialization milestones. [More](#)

[Kymanox](#) is hosting a 1-hour interactive webinar discussing auditing and gap assessments of CGMP facilities on Friday, March 8, 1:00 – 2:00 p.m. EST. Kymanox Manager of Compliance Erica Fadool

explains what makes quality audits successful and will present real-life examples from audit war-room experiences used to illustrate best-in-class practices. [Find out more and register.](#)

[MedNet Solutions](#) is continuing to provide all NCBio members with a 10% discount off the standard licensing fees and build services for any new clinical study using the *iMedNet* EDC platform. MedNet is also providing all NCBio Pharm and Biotech Member firms with a \$50,000 all-inclusive price for any new Phase 1 Clinical Study using the *iMedNet eClinical Software* platform and all NCBio medical device member firms with a \$25,000 all-inclusive price for any new Pilot Medical Device Clinical Study using the *iMedNet* EDC platform. [More](#)

[Pharmaceutical Product Development, LLC](#) (PPD) and Happy Life Tech (HLT) of China have signed an exclusive agreement to develop a distinctive service offering for the China drug-development market delivering data science-driven clinical trials and real-world evidence of drug products' effectiveness, safety and value.

[Syneos Health](#) is joining the worldwide annual observance of [Rare Disease Day](#), Thursday, February 28, by hosting a free public in-depth Rare Disease Day Symposium, from 11:30 a.m. to 3 p.m., at its new global headquarters in Morrisville. Among the groups supporting the event is the NC Rare Disease Advisory Council. [More](#)

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NCBio Member Benefits – New Discounts from NCBio Member Companies



NCBio Member Benefits

4,000 companies saved nearly \$400 million in 2018 through BIO Business Solutions®. As an NCBio member, you are eligible! This is a benefit of your NCBio membership. Review the cost-savings offered by clicking [this button](#) 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!](#)



[ShareVault](#) offers members secure, cloud-based document sharing solutions, also known as virtual data rooms, that are frequently used by organizations of all types to securely share highly confidential documents with outside parties. In contrast to consumer-grade file sharing services, ShareVault allows organizations to easily share documents with third parties, while monitoring access and maintaining control. [More](#)

ShareVault will host a [Best Practices for Fundraising and M&A Due Diligence](#) web panel, **March 21st, 2019 at 2:00 p.m.** The panel will feature legal, financial, and technological perspectives from a trio of experienced business experts. Here's a short list of what they'll dive into:

- Importance of establishing goals & objectives early in the process
- How to get the right people to ask the right questions in advance
- Creative deal structures to bridge valuation gaps between buyers & sellers
- How to avoid cramming and back-peddling in the midst of diligence and negotiations
- How to avoid cultural clashes, litigation, and epic losses
- Plus, much more

If you can't attend the live presentation, register anyway, and ShareVault will send you the recording

when it becomes available. [Register today.](#)



[UniFirst](#), a leading supplier of workwear programs for businesses big and small since 1936, provides a range of apparel from traditional uniforms and industrial wear to protective clothing and “corporate casual” attire. UniFirst also offers various floorcare and restroom products. [More](#)

[UniClean](#), a division of UniFirst Corporation, is a leading cleanroom services provider that supplies, launders, and services the work clothing of employees who manufacture sensitive medical, electronic, and pharmaceutical products in “ultra-clean” production environments (cleanrooms). UniClean operates ISO 3 and ISO 4 facilities that service the United States and Canada. [More](#)

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Calendar

To view full calendar, [click](#).

[CED Tech Conference 2019](#)

Monday Feb 25, 2019 - Tuesday Feb 26, 2019

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[FuseCR Fast Track to Clinical Research Careers: Trial Integrity](#)

Monday Feb 25, 2019

... [read more](#)

[Durham Tech Cell and Tissue Culture Techniques](#)

Monday Feb 25, 2019

... [read more](#)

[CED Life Science Conference 2019](#)

Tuesday Feb 26, 2019 - Wednesday Feb 27, 2019

... [read more](#)

[Government Affairs Reception](#)

Wednesday Feb 27, 2019

... [read more](#)

[The Future of AgTech & Ag BioTech, RTP - A Conversation with the Community](#)

Wednesday Feb 27, 2019

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[Durham Tech Cell and Tissue Culture Techniques](#)

Wednesday Feb 27, 2019

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[Rare Disease Day Symposium](#)

Thursday Feb 28, 2019

... [read more](#)

[Durham Tech Cell and Tissue Culture Techniques](#)

Monday Mar 4, 2019

... [read more](#)

[2019 Pharma Conference: Back to Basics: The Pharmaceutical Industry](#)

Tuesday Mar 5, 2019 - Wednesday Mar 6, 2019

... [read more](#)

[Durham Tech Molecular Biology Techniques](#)

Tuesday Mar 5, 2019

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[Durham Tech Cell and Tissue Culture Techniques](#)

Wednesday Mar 6, 2019

... [read more](#)

[LaunchBio: Larger than Life Science - Think Outside](#)

Thursday Mar 7, 2019

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[Durham Tech Molecular Biology Techniques](#)

Thursday Mar 7, 2019

... [read more](#)

[Kymanox Webinar Series: Auditing and Gap Assessments](#)

Friday Mar 8, 2019

... [read more](#)

[Durham Tech Cell and Tissue Culture Techniques](#)

Monday Mar 11, 2019

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[Durham Tech Molecular Biology Techniques](#)

Tuesday Mar 12, 2019

... [read more](#)

[Durham Tech Cell and Tissue Culture Techniques](#)

Wednesday Mar 13, 2019

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**[2019 SciTech Lecture Series: Consumer
Medicine-Democratizing Health Care Decisions](#)**

Thursday Mar 14, 2019

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[Durham Tech Molecular Biology Techniques](#)

Thursday Mar 14, 2019

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[Durham Tech Cell and Tissue Culture Techniques](#)

Monday Mar 18, 2019

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[Durham Tech Molecular Biology Techniques](#)

Tuesday Mar 19, 2019

... [read more](#)

[NCBIO Legislative Reception 2019](#)

Wednesday Mar 20, 2019

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