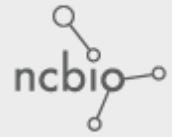




# connections newsletter



**February 2018  
UPDATE**

**Serving the NC Life  
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## NCBIO This Month

- Medical Device Tax Suspended for Two More Years
- NCBIO Life Science Forum: Privacy and Data Security, January 31
- Bold Breakthroughs Summit - Exploring Innovation in North Carolina
- Report Recommends Steps to Enhance Innovation in North Carolina
- Novel System Aims to Improve Biomanufacturing Processes
- BioNetwork Updating BioWork Training
- NCATS' Webinar on Small Business Funding, January 30
- Companies Selected to Present at CED Conference – Register by Feb. 1
- NC Ag Biotech Summit 2018, February 20-21

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- At the National Level
- Member News
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## NCBIO - Media

Find the latest news from NCBIO on the website [ncbioscience.net](http://ncbioscience.net), on [LinkedIn](#) and on Twitter at [@ncbio](#).

## NCBIO Links

- CED
- NCBIO
- NC Biotech Center
- BRITE
- BTEC
- BioNetwork
- NCBioImpact
- North Carolina  
Pharmaceutical Services  
Network

## Medical Device Tax Suspended for Two More Years



Congress has extended the suspension of the medical device tax two more years as

## NCBIO Sustaining Members



GSK

part of the Continuing Resolution that was passed to reopen government after a three-day shutdown. Without this action, medical device companies would have had to make first payments on the tax January 29th.

AdvaMed, MDMA, NCBIO and other organizations will continue to push for full repeal of the tax. "The extension is an important action for our medical device members and those companies across the country," stated NCBIO President Sam Taylor. "Obviously, full repeal remains the ultimate goal, and we will continue to push members of Congressional delegation for that action.

A survey of over 100 medical technology innovators by the national Medical Device Manufacturers Association (MDMA) showed that 88 percent of innovators would slow down hiring and/or have to eliminate jobs, and 83 percent would decrease investments in R&D if the device tax becomes effective.

NCBIO worked with MDMA and AdvaMed on this effort, making repeated contacts with North Carolina's Congressional delegation emphasizing the potential negative impact of the tax on North Carolina's economy.

Mark Leahey, President and CEO of the Medical Device Manufacturers Association (MDMA), stated, "MDMA applauds Congress for passing legislation that funds the government and reauthorizes CHIP, while protecting medical technology innovation from the destructive impact of the medical device tax. We remain committed to working with the broad, bipartisan coalition that supports a full and permanent repeal of the device tax this year so that this America's dynamic medical technology ecosystem can deliver the next generation of cures and life-saving therapies and provide the high-tech manufacturing jobs that develop them."

AdvaMed issued a statement stating that the suspension is "good news for American patients and American innovation." The association also emphasized that "[w]hile the two-year suspension is welcome, it is only an interim step toward the truly needed action by Congress to fully repeal this tax and unleash the promise of medtech innovation. We look forward to continuing to work with the Hill on a bipartisan basis to drive towards permanent relief."

For more information, contact [Sam Taylor](#) or [Brenda Summers](#) at (919) 281-8960.

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Lilly



Pfizer



We Work For Health



## NCBIO Supporting Members

Cook Medical



Merck



## NCBIO Life Science Forum: Privacy and Data Security, January 31

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Join [FUJIFILM Diosynth Biotechnologies](#), [Michael Best & Friedrich LLP](#), [Syneos Health](#) (formerly INC Research/inVentiv Health) and others in a discussion focused on privacy and data security. This Forum will be held at the North Carolina Biotechnology Center on January 31 from 11:30 a.m. to 1:30 p.m. Highlights include best practices from gathering data to sharing data, security threats and their implications, and adequate security measures and how to get better protection. The panel will be moderated by **Sean Blake**, Director of Information Services, [BioCryst Pharmaceuticals](#), and feature:

- **Brandon Champion**, Chief Information Security Officer, Syneos Health
- **Adrienne Ehrhardt**, Practice Group Chair, Privacy & Data Security, Michael Best & Friedrich LLP
- **Paulette Mara**, Partner, Michael Best & Friedrich LLP
- **Ted Midthun**, Associate Director of IT, FUJIFILM Diosynth Biotechnologies

Please mark your calendar and register for this Forum. For questions, contact [Amber Niebauer](#). Thanks to our sponsors for this event – [Donnelley Financial Solutions](#) and [Michael Best & Friedrich LLP](#).

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## Bold Breakthroughs Summit - Exploring Innovation in North Carolina January 25th

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*Business North Carolina* and America's Biopharmaceutical Companies cordially invite

you to attend a public policy forum highlighting modern medicine, medical breakthroughs and biotechnology research being conducted in and around the Research Triangle. The event is January 25th, 10:00 am - 11:30 am.

This event will feature a panel discussion on the cutting-edge biopharmaceutical innovation happening in North Carolina. Specifically, panelists will discuss some of the innovative work that GSK and others are doing to combat HIV and AIDS.

Moderator and featured panelists include:

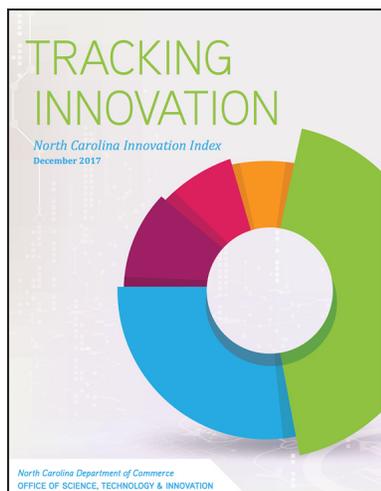
- **Sam Taylor**, President, NCPIO (Moderator)
- **Alicia Diggs**, Board Member and Secretary, North Carolina AIDS Action Network
- **Doug Edgeton**, President and CEO, North Carolina Biotechnology Center
- **Brian Johns**, Vice President, HIV Research, GlaxoSmithKline (GSK)
- **Michael Montello**, Vice President, Global Head of R&D Solutions Information Technology, IQVIA (formerly QuintilesIMS)

Please RSVP using the event page on [EventBrite](#).

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## **Report Recommends Steps to Enhance Innovation in North Carolina**

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North Carolina businesses must intensify their research and development efforts and the state must grow the share of community college and university students that earn degrees in science and engineering, according to the [2017 Tracking Innovation report](#) released by the North Carolina Board of Science, Technology & Innovation.

The 2017 report, the sixth in a series first published in 2000, rigorously evaluates the state's standing against other states in the country on measures of innovation capacity and outlines ways to advance the state's economy by encouraging and harnessing innovation.

"North Carolina has been home to many firsts, from the Wright Brothers' first flight to the invention of the barcode" said N.C. Commerce Secretary Anthony M. Copeland. "This report offers

suggestions for how to develop and encourage the next generation of innovators in our state, the people who will create North Carolina's next firsts." [More](#)

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## **Novel System Aims to Improve Biomanufacturing Processes**

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Researchers at NC State University have developed a novel approach that integrates existing technologies to improve the biomanufacturing processes used to make everything from pharmaceuticals to fuels.

“Our approach, called MIDUS control, allows biomanufacturers to collect data on their products at every stage of the manufacturing process – which offers two significant benefits,” says [John Sheppard](#), a professor of bioprocessing science at NC State and corresponding author of a journal article on the new system. MIDUS control stands for monitoring, integration, data analytics, understanding, strategy design and control.

The paper, “[Use of near-infrared spectroscopy \(NIRs\) in the biopharmaceutical industry for real-time determination of critical process parameters and integration of advanced feedback control strategies using MIDUS control](#),” is published in the December 2017 issue of the *Journal of Industrial Microbiology & Biotechnology*. Lead author of the paper is Lucas Vann, a former Ph.D. student at NC State and employee of the university’s Biomanufacturing Training and Education Center ([BTEC](#)). The work was done with support from BTEC. [More](#)

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## **BioNetwork Updating BioWork Training**

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[BioNetwork](#) is working with industry and college partners to update *BioWork*, a 16-week course that prepares learners for entry-level jobs as bioprocess technicians. The goal is to ensure the course is preparing the workforce for today’s industry needs.

BioNetwork is seeking to hire subject matter experts (SME) with biomanufacturing industry experience to serve as consultants on this project for 5-10 hours per week. As a SME, you will work with an instructional designer and a team of SMEs to design, develop, review and approve course materials. More information and the application link is available at [ncbionetwork.org/articles/consulting](http://ncbionetwork.org/articles/consulting).

For questions, please contact Dan McClellan at [dmcclellan@ncbionetwork.org](mailto:dmcclellan@ncbionetwork.org) or 704-922-2226.

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## **NCATS' Webinar on Small Business Funding, January 30**

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Are you an entrepreneur launching a biotech or healthcare technology business and finding the funding landscape to be complex? The National Institutes of Health’s [National Center for Advancing Translational Sciences](#) (NCATS) may be able to help through its [Small Business Innovation Research \(SBIR\)](#) and [Small Business Technology Transfer \(STTR\)](#) programs.

NCBIO and VABIO are co-hosts for a webinar, January 30th, 2-3 pm led by **Lili M. Portilla, M.P.A.**, Director, Strategic Alliances, NCATS, NIH, U.S. Department of Health and Human Services. It will feature:

- SBIR and STTR program overview
- Benefits of NCATS funding
- Tips for submitting a successful application
- Key NCATS focus areas to advance clinical research and translational sciences
- Upcoming opportunities and deadlines
- Other resources and programs, including NCATS’ [Therapeutics for Rare and Neglected Diseases \(TRND\)](#) and [Bridging Interventional Development Gaps \(BrIDGs\)](#) programs

[Register now](#) to join this webinar on January 30th

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## Companies Selected to Present at CED Conference – Register by February 1st to Save

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The Council for Entrepreneurial Development (CED) announced the entrepreneurial companies that have been selected to be featured at the twenty-seventh annual [CED Life Science Conference 2018](#), to be held February 27-28 in Raleigh. NCBIO and the North Carolina Biotechnology Center are cohosts for the event.

Twenty-eight (28) companies will present live on stage at the conference. Entrepreneurs from each of these companies will share their story and pitch their business in front of 1,000 attendees including the most active, influential investors and life science leaders from across the country. Conference attendees also will have the opportunity for in-person networking with these emerging entrepreneurs in the Innovation Room, which will exhibit at least 20 additional companies.

Running parallel to the CED Life Science Conference at the Raleigh Convention Center, Wallace H. Coulter Foundation and Duke University will be hosting the 2018 Coulter Investment Forum to spotlight life science companies representing a dozen top-tier universities from across the U.S. The Coulter Investment Forum will feature presentations from 20 companies, all from the participating universities.

To find out more about presenting companies, [click](#).

**Attendees who register by February 1 save \$75.** To learn more about the conference and register, [click](#). NCBIO Members also get a discount, email [aniebauer@ncbioscience.net](mailto:aniebauer@ncbioscience.net) for the code.

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## NC Ag Biotech Summit 2018, February 20-21

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This year's Ag Biotech Summit, through collaboration with the [Soil Health Institute](#), will highlight the impacts of soil health on plant, animal and human health, challenges faced and the responsibility needed to provide a sustainable future through soil. Emerging trends and technologies that are fostering and promoting soil health will be showcased throughout day two, ending with a not-to-be-missed closing keynote. [Click](#) for more on event and registration.

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## At the National Level

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## BIO Celebrates 25th Anniversary

Twenty-five years ago, the visionaries of two small trade groups – the Industrial Biotechnology Association (IBA) and the Association of Biotechnology Companies (ABC) – merged to form a single organization known as BIO, established on June 14, 1993. In an [interactive historical timeline](#), BIO reviews some of the policy and innovation milestones that have helped the United States build the world's strongest biotech ecosystem. The theme for BIO's 2018 International Conventional to be held June 4-7, 2018 in Boston will be "Make History."

In this [special blog](#) commemorating the Biotechnology Innovation Organization's 25th anniversary this year, BIO CEO Jim Greenwood writes about his personal experiences and his journey at BIO.

## Report on 340B Drug Pricing Program

BIO President and CEO Jim Greenwood commented on the review of the 340B drug pricing program released by the House Energy & Commerce Committee. "We applaud Chairman Walden and his colleagues on the Energy and Commerce Committee for their attention to the rapidly growing 340B program. The findings of the [report](#) reinforce the clear conclusion that the 340B program has grown far beyond its original scope, leading to growing problems with accountability and transparency. As the report makes clear, there is currently no requirement in the program for 340B covered entities to pass program savings along to uninsured patients – which many covered entities fail to do, while also failing to account for how program profits are used."

"We applaud the Committee's call for increased transparency within the program, as well as their call for Congress to clarify the program's intent and to reassess program eligibility to ensure that 340B discounts are properly serving patients and Congress's purposes in establishing the program," Greenwood said.

[Click](#) for Committee news release on report.

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## Member News

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*To be included in Member News, send information about your organization to Brenda Summers [bsummers@ncbioscience.net](mailto:bsummers@ncbioscience.net)*

[Aerie Pharmaceuticals, Inc.](#) announced that the U.S. Food and Drug Administration (FDA) has approved Rhopressa<sup>®</sup> (netarsudil ophthalmic solution) 0.02% for the lowering of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. [More](#)

[Argos Therapeutics Inc.](#) has signed a stock purchase agreement with Lummy (Hong Kong), Ltd. ("Lummy"), the Company's partner for Rocapuldence-T in China and certain other territories. The Company has agreed to issue and sell to Lummy in a private financing 7.5 million shares of the Company's common stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or similar recapitalization affecting such shares) for an aggregate purchase price of \$1.5 million. [More](#)

[Biogen](#) and Ionis Pharmaceuticals, Inc. announced that they have entered into a new collaboration agreement to identify new antisense oligonucleotide drug candidates for the treatment of spinal muscular atrophy (SMA). Biogen will have the option to license therapies arising out of this collaboration and will be responsible for their development and commercialization. [More](#)

[G1 Therapeutics, Inc.](#) was added to the Nasdaq Biotechnology Index prior to market open on Monday, December 18, 2017. [More](#)

[IQVIA](#) and Pierre Fabre Pharmaceuticals, a subsidiary of Pierre Fabre S.A. and the 2nd largest French private pharmaceutical group, announced plans to implement IQVIA's new commercial technology solution, Orchestrated Customer Engagement (OCE). The new offering, uniquely adapted for the life sciences industry, connects marketing, sales and other critical business functions, enabling all departments to collaborate more effectively and optimize customer interactions. [More](#)

[Liquidia Technologies, Inc.](#) announced the initiation of a Phase 3 clinical trial evaluating

LIQ861 for the treatment of pulmonary arterial hypertension (PAH). LIQ861, developed using [Liquidia's proprietary PRINT® technology](#), is a powder formulation of treprostinil designed for deep-lung delivery using a disposable, dry powder inhaler (DPI). PAH is a chronic, progressive disease caused by the hardening and narrowing of the pulmonary arteries, which often results in heart failure. Previously approved by the U.S. Food and Drug Administration (FDA) in oral, nebulized and parenteral formulations, treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator deficient in patients with PAH yet essential to normal lung function to regulate vessel tone. [More](#)

[Merz](#) announced that Terri L. Phillips, M.D., F.A.A.P., has been named Vice President and Head of Global Medical Affairs, effective January 2. Dr. Phillips will oversee the global medical affairs team and will be located in the Merz North America headquarters in Raleigh. [More](#)

Resolving in 2018 to eat more nutritious foods, exercise and generally make your life healthier? You are among about [twenty percent](#) of Americans vowing to do so. To help you be one of the nine percent of people who actually achieve their resolutions, scientists at the [NC Research Campus](#) share three of the top reasons you should follow through. [More](#)

[Novan, Inc.](#) has closed its previously announced underwritten public offering. The net proceeds to the company from this offering are expected to be approximately \$35.2 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company, and excluding any proceeds the company may receive upon exercise of the Warrants. [More](#)

[Pappas Capital](#) announced that Kyle Rasbach, Ph.D., PharmD has joined the firm as a partner. Dr. Rasbach was previously a Vice President with T. Rowe Price, where he was an equity research analyst responsible for pharmaceutical, specialty pharmaceutical and biotechnology investments for funds managed by T. Rowe Price, a global asset management firm. [More](#)

Pharmaceutical Product Development, LLC ([PPD](#)) and Quotient Sciences (Quotient), a drug development services organization have a new collaboration to accelerate pediatric drug development. The companies will jointly support pediatric drug development for clients from concept to market launch through a unique end-to-end service that will speed delivery of pediatric medicines. [More PPD® Laboratories](#) has been recognized as a 2018 top innovator in drug development by [CenterWatch](#), a leading publisher of clinical trials information for clinical research professionals. [More](#)

INC Research/inVentiv Health has changed its brand identity to [Syneos Health, Inc.](#), effective January 4. The word Syneos (pronounced SIN-ee-ohs) communicates the value of synchronizing clinical and commercial capabilities to accelerate customer performance. "Syneos Health fully expresses our value proposition – that is, our ability to deliver integrated end-to-end solutions and create new paths for our customers to develop and commercialize their therapies," said Alistair Macdonald, Chief Executive Officer of Syneos Health. [More](#) Also, Syneos Health has released its inaugural Commercial Trends Forecast. [More](#)

[Syngenta](#) and NRGene, the premier genomic big data company, have continued to advance their cooperation in breeding and trait discovery in key crops. Syngenta has licensed NRGene's GenoMAGIC™, a cloud-based big data analytics platform, to evaluate, predict, compare and select the best genetic makeup for crop molecular breeding and genomic selection. [More](#)

[TCG](#) welcomes Dean Gray as its newest partner. Dean is a global business executive with over 25 years of leadership in turning innovation into value for life science companies in the U.S, Europe, and Asia. Prior to joining TCG, Dean was a principal at Appareo LLC, a life science consulting firm specializing in market analysis and go-to-market strategy development. Previously he held senior roles with Heidelberg Engineering, an ophthalmic imaging company. [More](#)

"2017 was a transformational year for [TransEnterix](#) that included the commencement of U.S. Senhance commercialization and progression towards the global commercialization of SurgiBot," said Todd M. Pope, President and CEO at TransEnterix. "We are very excited about the opportunity that lies ahead in 2018 as we look to build upon our momentum and drive the global adoption of the Senhance." [More](#)

[vTv Therapeutics Inc.](#) announced that vTv Therapeutics LLC has entered into a global licensing agreement with Reneo Pharmaceuticals, a privately-held biotechnology company focused on developing treatments for orphan diseases. [More](#) vTv Therapeutics

LLC has entered into a licensing agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("Huadong Pharmaceutical"), a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (SZSE: 000963.SZ), for rights to develop and commercialize vTV Therapeutics' GLP-1r agonist program in China and other Pacific Rim countries. [More](#)

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## Member Benefits

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[BIO Business Solutions](#)<sup>®</sup> provides NC BIO members with numerous discount prices. BIO Business Solutions<sup>®</sup> aggregates the purchasing power of over 3,000 biotech companies from North America. Find out more about [NC BIO discounts](#).

One discount partner is [American Laboratory Trading](#) (ALT), an Agilent Technologies Channel Partner, is a customer-focused, full-service provider of premium refurbished lab equipment and asset management services for the life sciences. With sales, service, and warehouse facilities on both coasts, ALT stocks more than 12,000 instruments ranging from small benchtop accessories to robust triple quad mass spectrometers - all carefully refurbished and delivered with a one year warranty. The local contact is Amy Bunn, Account Executive 919-436-3977 or [abunn@alt-inc.com](mailto:abunn@alt-inc.com). You can also contact Jayson Bernstein, President, 860-691-2213 or [jayson@alt-inc.com](mailto:jayson@alt-inc.com).

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## Calendar

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

### [Bold Breakthroughs Summit: Exploring Innovation in North Carolina](#)

Thursday Jan 25, 2018

... [read more](#)

### [Webinar: National Center for Advancing Translational Science \(NCATS\) - SBIR and STTR Programs](#)

Tuesday Jan 30, 2018

... [read more](#)

### [NC BIO Life Sciences Luncheon and Forum: Privacy and Data Security](#)

Wednesday Jan 31, 2018

... [read more](#)

### [LaunchBio's "Larger Than Life Science" Monthly Networking Event](#)

Thursday Feb 1, 2018

... [read more](#)

### [NC CEO Forum 2018 Healthcare Summit](#)

Monday Feb 12, 2018

... [read more](#)

**[BIO CEO & Investor Conference](#)**

Monday Feb 12, 2018 - Tuesday Feb 13, 2018

... [read more](#)

**[NCBiotech Ag Biotech Summit 2018](#)**

Tuesday Feb 20, 2018 - Wednesday Feb 21, 2018

... [read more](#)

**[CED Life Science Conference](#)**

Tuesday Feb 27, 2018 - Wednesday Feb 28, 2018

... [read more](#)

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