



connections newsletter



**DECEMBER 2019
UPDATE**

**Serving the NC Life
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Seasons Greetings



The staff members of NCBIO wish you a Happy Holiday Season. We appreciate all the support you have provided us during the 2018-19 year, and we look forward to working

NCBIO - Media

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

NCBIO Links

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NCBIO Sustaining Members

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with you on many activities to support the life science industry in 2019-2020. From all of us - Sam Taylor, Laura Gunter, Bruce Kaylos, Casey Nelson, Amber Niebauer, Brenda Summers, and John Wagner.

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Changing Landscape for Clinical Trials



Karen Makhuli (G1 Therapeutics), Matt Becker (SAS), Christina Cocciardo (PPD Inc), and Allison Kalloo (Clinical Ambassador Health)

Analytics, virtual clinical trials, more diversity in participants, adaptive designs and other topics were discussed during the NCBIO Luncheon and Forum on "Clinical Trials: Changing Landscapes and Potential Pitfalls." Panelist Matt Becker of SAS talked about the use of "real world data" and simulations to optimize patient selection and recruitment. He reviewed some of the unnecessary exclusions that prevent more people from participating in clinical trials.

Christina Cocciardo of PPD defined some of the challenges with adaptive designs and novel approaches to clinical trials, noting there is a reluctance to depart from traditional designs. She outlined ways clinical trials can provide "increasing opportunities for early patient access to new therapies."

"Optimizing Diversity in Clinical Trials" was the focus of the presentation by Allison Kalloo of Clinical Ambassador Health. She noted that increasing the diversity of participants in clinical trials can "make a measurable difference in the data you collect."

Karen Makhuli of G1 Therapeutics served as moderator for the panel discussion. For more information about the event, contact [Amber Niebauer](#).



Toni Lockett (PwC), Andy Totman (Chubb), Ken Ehemann (Wyrick Robbins), and Matt Keffer (PwC)

Thanks to [Chubb](#), [PwC](#) and [Wyrick Robbins](#) for sponsoring the event. If your organization would like to sponsor an NCBIO event in 2020, contact [Laura Gunter](#).

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NCBIO Board Members and Officers Elected



[Tom Staab, Sam Taylor and Mike McBrierty](#)

Mike McBrierty of Biogen will serve a second term as Chairman of NCBIO. Other elected officers of the organization are Sam Taylor as President, Tom Fagley of Hughes Pittman & Gupton as Treasurer and Casey Nelson of NCBIO as Secretary.

Other NCBIO members elected to serve on the Executive Committee are Chris Capel (Smith Anderson), Bill Edwards (Merz), Neal Fowler (Liquidia), Maeve Gardner (GlaxoSmithKline), Christof Jensen (UCB), Scott Kohne (BASF), Scott Sewell (Cook Medical), Tom Staab (BioCryst), Susan Thomason (IQVIA), and Tim Willis (MED1 Ventures).

Four new directors were elected to the Board of the North Carolina Biosciences Organization (NCBIO) and eight individuals were elected to another term on the Board. "We are pleased that we continue to attract directors that represent the diversity of the life science industry in North Carolina," stated Sam Taylor, President of NCBIO. "We are fortunate that leaders in our sector are willing to work with us to develop our advocacy efforts and guide programs to serve our members."

New directors are: Mike Garrett (TCG), Alex Graham (Thermo Fisher Scientific), Blake Stevens (Alexandria Real Estate Equities), and Peter Wirth (RTI International). Those elected to serve another term are: Mike Elder (Novozymes), Tom Fagley (Hughes Pittman and Gupton), Neal Fowler (Liquidia Technologies), Matthew Keffer (PwC), Scott Kohne (BASF), Russ Read (Forsyth Tech Community College), Gary Shope, and Tim Willis (MED1 Ventures).

Directors continuing on the Board are: Tom Adams (Pairwise), Gray Armstrong (Pfizer), Chuck Blatchley (Grifols), Chris Capel (Smith Anderson), David Chapin (Forma Life Science Marketing), Matthew Cooke (Davis Moore), Bill Edwards (Merz), Ed Field (BioLabs NC), Maeve Gardner (GSK), Mark Harbaugh (Bioventus), Erica Jackson (K&L Gates), Christof Jensen (UCB), Ted Lithgow (Humacyte), Mike McBrierty (Biogen), Martin Meeson (Fujifilm Diosynth), Sheila Mikhail (AskBio), Kyle Rasbach (Pappas Capital), Scott Sewell (Cook Medical), Giles Shih (BioResource International), Tom Staab (BioCryst Pharmaceuticals), Susan Thomason (IQVIA), Rich West (Baebies), and Adam Zerda (BD).

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Life Science Priorities Again By-Passed in November Legislative Session

The North Carolina General Assembly has adjourned a brief November session in which it adopted new maps for the State's thirteen congressional districts. Although legislative leaders had left themselves the option to deal with other matters, including special legislation to fund portions of the state budget vetoed by Governor Roy Cooper, no such

steps were taken.

The November adjournment leaves significant portions of the Assembly's 2019-21 spending plan unenacted. Among the many provisions in veto-driven limbo are funding allocations sought by NCBIO and allied entities. These programs include:

- \$1M in non-recurring funding in both years of the 2019-21 biennium for the State's SBIR/STTR matching grant program, commonly known as the One North Carolina Small Business Program.
- \$500,000 in additional recurring funding for the North Carolina Biotechnology Center, and \$500,000 in non-recurring funding for the 2019-20 fiscal year.
- \$2M for each year of the biennium for North Carolina's participation in the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).

The legislature will have another chance to address appropriations problems in yet another session scheduled for January 14th. Unlike the November session, legislation scheduling the January session authorizes the Assembly to again consider an override of Governor Cooper's budget veto, or to take up other appropriations legislation.

Also, the January session will be open to consideration of non-appropriations legislation of interest to NCBIO, including bills addressing step therapy, PBM transparency, and coverage parity for oral cancer drugs.

Although legislative leaders have said the January session will be brief, NCBIO remains hopeful that legislators and the Governor will find a way to address both appropriations and substantive measures of importance to the life science industry.

Following adjournment of the January session, the legislature is not expected to return to Raleigh until May of 2020, in a session that would ordinarily be devoted to budget adjustments and legislation held over from 2019.

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Food Processing Plant Opens at NC Research Campus



[Officials cut ribbon for new food processing facility](#)

(Photo courtesy of Cameron Triggs)

[The NC Food Innovation Lab](#) (NCFIL) celebrated its official opening on November 14 in Kannapolis with a ribbon cutting and open house at its 16,000 sq. ft. plant-based food processing and product development facility on the 350-acre NC Research Campus in Kannapolis. NCFIL is the region's most versatile and only FDA-inspected food manufacturing pilot plant facility. It offers a range of customizable services, including product research and development; pilot plant production; training and workshops; and food industry consulting to serve a global community of growth-phase entrepreneurs, established food companies, venture capitalists and accelerators. [More](#)

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Governor Roy Cooper, Richard Staub of IQVIA and Brian O'Dwyer of Q2Solutions

[Q2 Solutions](#), a leading clinical trial laboratory services organization, will establish a new facility in Durham to help develop the next generation of precision medicines, creating 749 jobs, Governor Roy Cooper announced in November. Q2 Solutions will invest \$73 million in the project, which will grow in two phases over seven years.

"Because of our strong biotechnology talent, North Carolina has become a hub for contract research organizations of all sizes," said Governor Cooper. "In the fight against disease, innovative research companies like Q2 Solutions get the data to make life-changing drugs available to people who need it faster and safer, and we are proud of our state's role to help them do that work."

Q2 Solutions, a joint venture of [IQVIA](#) and [Quest Diagnostics](#), offers end-to-end laboratory services and secure, enterprise-wide biospecimen and consent management solutions. [More](#)

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[Venture Connect](#), **March 17-19, 2020**, plans to highlight 135 of the Southeast's most notable Tech and Life Science companies in three days. If you have been to the CED Tech Venture or the CED Life Science Conference - you know they always bring you the best of the best. This year you can find companies presenting in three primary categories: Life Digitized, Business Optimized and Life Improved. This will cover B2B companies, B2C companies and traditional life sciences. [Applications are open now](#), and the deadline to submit applications is **December 5**. J.P. Morgan is the headline sponsor for the event. [More](#)

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Sponsorships for the 2020 NCBiotech Company Directory are closing soon! The printed directory is one of NCBiotech's most popular publications, and a sponsorship is an opportunity to build brand awareness for your company to a local, national and global

audience. For more information, contact [Lori Melliere](#) or learn more [here](#).

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NCBIO Welcomes New Members

The NCBIO Board of Directors approved 17 new members to the organization at the November meeting.

- [21MedTech](#) is a medical technologies company offering new, highly advanced biomedical materials for regenerative medicine, drug delivery and 3D manufacturing.
- [Adare Pharmaceuticals](#) is a global specialty CDMO focused on oral dosage form technologies, development and manufacturing for the pharmaceutical, animal health and OTC markets.
- [Breakthrough BioAssets](#) is a life sciences and technology company that performs operating and asset validation activities from concept phase to full-scale commercialization.
- [CSC Leasing](#) helps companies obtain the equipment they need to achieve their business goals, at the lowest possible cost.
- [CureDuchenne](#) breaks the traditional charitable mold and is a recognized as the global leader in research, patient care and innovation for improving and extending the lives of those with Duchenne muscular dystrophy.
- [Deloitte](#) provides industry-leading audit, consulting, tax, and advisory services. Its network of member firms spans more than 150 countries and territories.
- [DPS Group Global](#) is a global consulting, engineering and construction management company, serving industries around the world.
- [Enzerna Biosciences](#) is focused on developing gene therapies for neurodegenerative disorders such as Huntington's Disease.
- [Gemelli Biotech](#) supports the discovery of novel diagnostics and therapeutics for the human microbiome by bringing biotechnology innovations to market in a fiscally responsible and socially conscious way.
- [Grant Engine](#) helps life sciences companies access grants and identifies the funding programs that best match a company's business needs.
- [Invicro](#) applies resources to answer complex questions with industry leading imaging biomarkers, core lab services, advanced analytics and software solutions across all drug phases and therapeutic areas.
- [KriGen Pharmaceuticals](#), an India-based injectables maker, is establishing a cGMP-compliant formulation manufacturing facility in Lillington, that will manufacture a wide range of injectables using aseptic filling/terminal sterilization, as applicable.
- [LaSalle Group LLC](#) is a business-consulting firm with experience in North and Latin America helping clients increase efficiency, reduce operational costs, and create a culture of continuous improvement.
- [Lee & Associates](#) offers a comprehensive range of commercial real estate services delivered by local market experts with a depth of resources.
- [Mentor Technical Group](#) provides a complete portfolio of technical support services and flexible solutions to the top life science manufacturers.
- [PROTECS, Inc.](#) is a full-service project and construction management company that will transform the speed, cost effectiveness and quality of project delivery throughout every stage of your project's lifecycle.
- [Statera Environmental](#) offers a unique passive sampling exposure assessment technology that provides an unprecedented comprehensive picture of chemical exposure.

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At the National Level

Drug Pricing Will Harm Industry According to Report



Speaker Nancy Pelosi's *Lower Drug Costs Now Act of 2019*, H.R.3, could result in at least 56 fewer new medicines for patients over 10 years, according to a [new analysis](#) from economic consulting firm Vital Transformation. The study examined the impact of foreign reference pricing provisions in H.R.3 on treatments and cures from small, emerging U.S. biotech companies that rely on venture capital to finance their research and development. The analysis was commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Innovation Organization (BIO) and the Council of State Bioscience Associations (CSBA).

"This report reaffirms just how destructive Speaker Pelosi's extreme drug pricing plan will be for patients and their families," said BIO's President and Chief Executive Officer Jim Greenwood. "It's imperative that we work to make the medicines of today more affordable, and it's immoral to delay or deny the discovery of new cures and treatments for devastating diseases such as Alzheimer's and Parkinson's."

Stephen Ubl, President and Chief Executive Officer of PhRMA said, "We have made tremendous progress in the fight against disease, but there is still a long way to go. Instead of blowing up the entire health care system and giving up the search for future innovation, let's focus on practical reforms such as capping out-of-pocket costs, making patients' monthly costs more predictable, sharing negotiated savings with patients, enhancing competition from generic medicines and promoting value-based contracts." [More](#)

A column by former Duke professor Henry Grabowski points out the importance of private investment and innovation in developing breakthrough medicines. [More](#)

Efforts Continue to Repeal Med Device Tax by Year End

As Congress prepares to address end-of-year spending decisions and other initiatives that are set to expire if not acted upon, the Advanced Medical Technology Association (AdvaMed) released survey results showing that reinstatement of the medical device excise tax would bring job losses as well as declines in investment in research and development.

"We've seen it before. We'll see it again," said Scott Whitaker, President and CEO of AdvaMed. "A \$20 billion tax increase on the industry will have serious consequences on employment and investment. The last time this tax was in effect, we saw nearly 29,000 jobs lost, and we could face even greater losses if Congress does not stop this tax from returning." [More](#)

The Medical Device Manufacturers Association (MDMA) is also working aggressively on the issue and urging companies and individuals to [contact members of Congress](#).

Upcoming Events – National Partners

MedTech Innovator Now Accepting Applications for MedTech Conference

Applications are now being accepted for [MedTech Innovator 2020](#). This is a unique opportunity for start-ups and emerging growth medical technology companies to gain access to industry stakeholders such as Baxter, BTG, HOYA, Maxim Ventures, Johnson & Johnson, Olympus, NIPRO, W.L. Gore and RCT Ventures. Deadline to apply is January 17, 2020. [More](#)

BIO One-on-One Partnering™ @ JPM

BIO is providing resources to help you make the most of the 2020 JPM week, January 12-16 in San Francisco!

Complimentary access to BIO One-on-One Partnering: With nearly 1,500 participating companies and 2,000 users in 2019, BIO One-on-One Partnering will help you identify prospective partners, schedule meetings, and make the deals that drive our industry. [Apply here](#).

BIO CEO & Investor Forum - February 10-11

Now in its 22nd year, the BIO CEO & Investor Conference is one of the largest investor conferences focused on established and emerging publicly traded and select private biotech companies. Experience the best of biotech with two-days of productive partnering meetings with institutional investors, industry analysts, and senior biotechnology executives, in one location.

Fireside chat features Dr. Michael Morrissey, President and CEO, Excelixis. View the [schedule of events](#) and proposed educational topics. To learn more visit bio.org/ceo or download the [conference brochure](#).

[Registration](#) is open! **Sign up before December 31** for discounted rates.

Start-Up Stadium Applications for BIO 2020

[Submit your application today](#) to be featured in Start-Up Stadium at the [2020 BIO International Convention](#), June 8-11, in San Diego!

This innovative program is designed to provide start-up companies with the opportunity to access key members of the investment community, venture philanthropy groups, strategic partners, and non-dilutive capital at the world's largest biotechnology event. Applications close March 27 and final applicants notified by April 13.

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Member News

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

[AccuGenomics](#) received a NIIMBL grant to develop a test kit—AccuKit—that streamlines adventitious agent screening while directly ensuring every target is measured with the required sensitivity. The company will partner with [North Carolina State University](#), [Celgene Corporation](#), and [Merck](#) to advance its MRL-4 level technology to MRL-6. [More](#)

[Aerie Pharmaceuticals, Inc](#) announced the European Commission (EC) has granted a marketing authorization for Rhokiinsa® (netarsudil ophthalmic solution) 0.02% for the reduction of elevated intraocular pressure in adult patients with primary open-angle glaucoma or ocular hypertension. [More](#)

[AgBiome](#) was featured recently on the UNC-TV program "Sci NC". They spoke with The COO of AgBiome Innovations, Toni Bucci, who was interviewed along with several scientists involved in a variety of research projects. Check out the [video](#).

[Baebies](#) has released a white paper on approaches to minimize blood loss in critically ill newborns and children. [More](#)

[BD](#) along with Check-Points Health B.V., announced that FDA 510(k) clearance was obtained for a molecular screening test for antibiotic-resistant carbapenemase-producing organisms (CPOs) on the fully-automated [BD MAX™ System](#). [More](#)

[BioCryst Pharmaceuticals, Inc.](#) announced the completion of an underwritten public offering of 43,620,690 shares of its common stock, including 5,689,655 shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares. [More](#) BioCryst announced that it has licensed commercialization rights in Japan to Torii Pharmaceutical, Co. for BCX7353, an oral, once-daily treatment for the prevention of hereditary angioedema (HAE) attacks. [More](#) BioCryst also announced 48-week results from its APeX-S and APeX-2 trials and comprehensive market research which support the significant commercial opportunity for oral, once daily BCX7353 in HAE. [More](#)

[Biogen Inc.](#) and Alkermes plc announced that the U.S. Food and Drug Administration (FDA) approved VUMERITY™ (diroximel fumarate), a novel oral fumarate with a distinct chemical structure, for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary

progressive disease. [More](#) Biogen also announced the enrollment of the last patient in the global Phase 3 STAR clinical study, which is evaluating the investigational gene therapy timrepigene emparvovec (BIIB111/AAV2-REP1) for the treatment of choroideremia (CHM). CHM is a rare, degenerative, X-linked inherited retinal disorder that leads to blindness. [More](#)



[G1 Therapeutics](#) recently held a ribbon cutting for its new facility in Frontier RTP. CEO Mark Velleca cuts ribbon to the 700 Park Drive office.

[Lindy Biosciences](#) in collaboration with [Genentech](#) and [NC State University](#) has received a NIIMBL award to develop a novel dehydration technology (Microglassification™) that will enable preservation of biologics at multiple points in downstream purification, eliminating process flow interruptions and allowing quick response to changing demand. [More](#). Lindy Biosciences also received the Initial Funding Award from SEBIO at the annual conference in November. [More](#)

[Locus Biosciences](#) was named one of the CNBC Upstart 100. [More](#) Locus has also been named as one of the Fierce 15 by *FierceBiotech*. [More](#)

[Merz](#) announced plans to reorganize into three independently operating businesses: medical aesthetics, therapeutics and consumer care. Merz Aesthetics global management team will now be based in Raleigh. As part of this reorganization, Bob Rhatigan has been appointed global chief executive officer of Merz Aesthetics, assuming responsibility for all aspects of the global aesthetics business. [More](#)

[Novozymes'](#) Board of Directors has appointed Ester Baiget as President and CEO of Novozymes from 1 February 2020. She will succeed Peder Holk Nielsen who, as previously announced, will be leaving Novozymes in early 2020. Ms. Baiget is currently business president for Dow's Industrial Solutions business unit and a member of the executive leadership team. [More](#)

[PPD](#) has launched PPD's [SiteCoach](#), providing advanced clinical research training, coaching and support to physicians, hospitals and academic institutions that are new to clinical research. [More](#) PPD, has confidentially submitted a draft registration statement on Form S-1 with the Securities and Exchange Commission (the "SEC") relating to the proposed initial public offering of the parent company's common stock. [More](#)

[RTI International](#) announced a follow-on investment in PierianDx to help empower leading health institutions and diagnostic laboratories to build world-class precision medicine programs. [More](#)

[Syneos Health](#) has released a report on "Real World Value: Advancing Payer Understanding of RWE in Rare Disease." [More](#) Syneos Health and AiCure, an AI and advanced data analytics company, announced a novel strategic partnership to drive faster, smarter trials to optimize patient engagement. [More](#)

[TCG](#) Partner Ken West presented the company's new service for international companies who are thinking of entering the US market at the 2019 MEDICA TECH FORUM in November in Dusseldorf. [More](#)

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Last year, more than 4,300 companies using BIO Business Solutions® saved over \$430 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!](#)



Clean Harbors

New and Improved Waste Removal Benefits for BIO Members

BIO has just renegotiated with Clean Harbors for new and improved benefits for members! With Clean Harbors, members eliminate significant liability and potential compliance issues by dealing directly with the owner of disposal facilities AND benefit from enhanced pricing and terms:

- Pre-negotiated Not-To-Exceed competitive rates
 - Lab Pack Disposal starts at 35% off
 - Reduced Recovery Fee
- Free site consultation, waste stream review and record keeping, regardless of company size
- Full online services capability (track waste, manage profiles, view reporting, download biannual report data, etc.)
- Recommendations for staff training to ensure compliance with applicable state and federal laws.
- Robust recycling and sustainability capabilities applicable for waste and unused products.

[Learn More](#)



ShareVault

Introducing the new ShareVault

Turn Intelligence into Insights Due diligence is a critical part of acquiring or selling an asset or stock. It's the process of "kicking the tires" and "looking under the hood" in an effort to thoroughly evaluate the underlying financial and material risks, liabilities and other unknown attributes that lie under the surface. It's the responsibility of a business to assess that it is what it says it is... [Continue reading.](#)

UniClean

Avoiding the Hidden Costs in Uniform Inventory Management

Cut Down on Lost and Damage Rates and Replacement Charges BIO's preferred partner for cleanroom services, UniClean, offers members uniform and facility services savings of 30-50% and access to a more efficient and accurate inventory management system with UHF chip technology.

UniClean merchandise is coded with unique barcodes and equipped with a UHF chip to support a strengthened proactive inventory management program:

- Provides easily identified Shortages and Usage Rates
- Decreased lost and damage rates with customers compared to competitors' rates of 25% to 35%
- No hidden replacement charges
- Allows the customer to take comfort in the fact that nothing is being kept, lost, or hidden

ABOUT BIO BUSINESS SOLUTIONS

BIO Business Solutions® is the largest cost savings purchasing program for the biotech industry, operated by the Biotechnology Innovation Organization (BIO). BIO leverages the purchasing power of the industry to negotiate with top suppliers to secure exceptional savings, favorable terms, and superior service for members. BIO Members can participate for no charge as a benefit of their membership and to save on items they need to run a successful biotechnology enterprise.

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Calendar

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

[NCBiotech Ag Tech Professional Forum December 2019](#)

Thursday Dec 5, 2019

... [read more](#)

[LaunchBio: Larger than Life Science - Big Holiday Party](#)

Thursday Dec 5, 2019

... [read more](#)

[First Flight's How to Win SBIR/STTR Grants Seminar \(Wilmington\)](#)

Thursday Dec 5, 2019

... [read more](#)

[2019 SciTech Lecture Series: The Necessary Interdependency Between Basic Research and Novel Healthcare Products](#)

Tuesday Dec 10, 2019

... [read more](#)

[NCRAF Seminar](#)

Thursday Dec 12, 2019

... [read more](#)

[LaunchBio: Larger than Life Science](#)

Thursday Jan 2, 2020

... [read more](#)

[NC Chamber Economic Forecast Forum](#)

Tuesday Jan 7, 2020

... [read more](#)

[First Flight's How to Win SBIR/STTR Grants Seminar](#)

Wednesday Jan 8, 2020

... [read more](#)

[J.P. Morgan Healthcare Conference](#)

Monday Jan 13, 2020 - Thursday Jan 16, 2020

... [read more](#)

[BIO CEO & Investor Conference](#)

Monday Feb 10, 2020 - Tuesday Feb 11, 2020

... [read more](#)

[CED Venture Connect 2020 Summit](#)

Tuesday Mar 17, 2020 - Thursday Mar 19, 2020

... [read more](#)

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