



connections newsletter



**NOVEMBER 2019
UPDATE**

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NCBIO This Month

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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 Celebrates 25th Anniversary at the Annual Meeting



NCBIO President Sam Taylor reflected on the first meeting of the organization 25 years ago, noting some of the policy issues are still the same. Current and former NCBIO Board Members along with

participants in the Annual Meeting were present for the 25th anniversary reception October 3.

NC Biotechnology Center CEO Doug Edgeton presented Taylor with an award recognizing NCBio's 25 years of service. Peter Pellerito of BIO noted the work of what he termed one of BIO's most successful state affiliates. NCBio Board member Christof Jensen with UCB presented Taylor with a framed letter from PhRMA. Staff members joined Taylor in cutting an anniversary cake, and members also enjoyed a slide show highlighting activities of NCBio.



Amber Niebauer, Laura Gunter, Sam Taylor, Casey Nelson, John Wagner, Brenda Summers and Bruce Kaylos cut the cake

[Click](#) to find out more about NCBio's past and a review of 2018-19.

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Innovation, Market Trends and More at Annual Meeting



Dr. Martin Murphy

Dr. Martin Murphy, Founding Chief Executive Officer, CEO Roundtable on Cancer and Project Data Sphere, kicked off the NCBio Annual Meeting by stating this is one of the best times "to invest time, talent and treasure in the rewarding field of health and medicine." He noted that target therapies



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such as cell and gene therapy have the potential to save lives and money.

The second keynote presentation was by Peter Meath and Lauren Ruane, J.P. Morgan's Co-Heads of Healthcare Banking, who discussed "Capital Formation and Market Trends." Meath told the audience that partnership activity was increasing in three areas; more deals, larger dollars amounts and earlier in the business cycle. "2019 had a record first quarter in both deal value and volume, continuing the positive momentum in 2018." Ruane stated that "public healthcare investors have significant cash to redeploy after recent mergers and acquisitions, which has helped drive continued strength in the healthcare IPO market."

Peter Pellerito of BIO told the crowd that BIO was actually formed in North Carolina and the first BIO convention was held in Raleigh. He added this is a challenging time for the industry with the federal initiatives on drug pricing.



Platinum and Gold Sponsors: **Front row** (L to R) VWR/David Bauer, BIO/Katrina Daiga, Novo Nordisk/Shaylah Jones, Bioventus/Vivek Munshi, Cook Medical/Scott Sewell **Middle row** (L to R) BDO/Stephen Morris, Grifols/Brian Stoker **Back row** LaSalle Group and Mentor Technical Group/Juan Pablo Gutierrez

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Panel Presentations Focus on Health Care Access and the Microbiome at Annual Meeting



Access and Availability Panel

Panelists on the “Access and Availability” panel had a lively discussion about who has access to healthcare, the cost of healthcare and prescription drugs and proposed federal policy changes. Dr. Dora Hughes with The George Washington University noted that “there is a lot of focus on health policy issues” at the federal level with at least six major proposals under consideration including drug pricing negotiations.

Vadim Lubarsky of Novartis expressed concerns about the punitive proposals regarding drug pricing and noted the current system of reimbursement was not built to accommodate cell and gene therapies and the cost of those treatments. Jeff Kiser of Aetna said the purchase of Aetna by CVS is going to result in a new approach to aligning the drug supply, insurance and medical services.

Dr. Reggie Munden discussed the pressures on medical providers and patients, noting “The poor don’t have money for treatment of pharmaceuticals...and this spirals the cycle of becoming more seriously ill, which they can’t pay for and leading hospitals to reduce or eliminates services, which can stagnate treatment advances.”

Robin Levy with the International Myeloma Foundation discussed the disparities in the reimbursement and co-pay system. IV treatments in a hospital are covered, but oral dosages of the same medicine outside a hospital are not covered or have high co-payments. The panel was moderated by Marianne Lopez, PhD, of the Duke-Margolis Center for Health Policy.

John Ryals, the former CEO of Metabolon, kicked off the Ag and Human Microbiome panel by outlining some of the history of the research on the microbiome. Anne Ballou with Premex Innovation Labs said that supporting and improving the quality of animal and plant sources can help improve human health.

Jared Jensen of AgBiome noted that the yield losses of agricultural crops is a growing concern and use of natural products such as the microbiome can have a positive impact on crop growth. Jorge Signes with the David H. Murdock Research Institute discussed the use of the plant microbiome and the diverse ecosystem around it.

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Partnerships Focus of Annual Meeting Dinner



Neil Jones, Derek Norman, Tom Adams, Lauren Drowley and Charles Gersbach

NCBIO members got a chance to find out more about partnerships, acquisitions and collaborations during the Annual Meeting dinner on “Partnering 101: Tales from the Trenches.” Charles Gersbach, Co-Founder of Element Genomics and a professor at Duke University, outlined the founding and growth of the company and the decision to be acquired by UCB. He talked about the interactions with UCB in focusing on disease treatments. Lauren Drowley discussed how UCB worked to integrate the work of the scientists at Element Genomics so the innovation culture is continued within its work in the larger company.

Tom Adams of Pairwise said his company was focusing on gene editing to see beyond the impact on food to the increase of consumption of fruits and vegetables. To help with that, the company decided to partner with Bayer. Derek Norman with Venture Investments at Bayer talked about the importance of building relationships and understanding the work of the companies.

NCBIO thanks [BIO](#), [Frankel Staffing Partners](#) and [VWR, Part of Avantor](#) for sponsoring the dinner.

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Funding Options Discussed at Invest in Cures Forum

Representatives of disease foundations outlined opportunities for companies to secure funding for drug development at the Invest in the Cures event September 25th. The event was hosted by LaunchBio with BioLabs, CED, NCBIO, and the North Carolina Biotechnology Center as presenting partners.

Kirstie Keller, PhD, with the Milken Institute, discussed the organization’s report [Nonprofits: A Growing Force in Drug Development](#). Keller noted that the report says, “There is no “one-size-fits-all” model to bolster drug development; each disease-focused field has its own unique set of challenges that shift over time as the science evolves and the funding environment changes.”

- Insufficient funding for validation and translation studies
- Few medicinal chemists are integrated into academia
- Lack of drug development expertise and access to resources
- No consensus on intellectual property management
- Limited knowledge of business strategy and development
- Difficulty identifying the right partners at the right stage

Two panel sessions were also part of the event. One focused on foundation support of cancer research and a second on research in rare diseases. [More](#)

A forum on the following day looked at interdisciplinary perspectives from bench to bedside probing the barriers to therapeutic development to address the unmet needs of patients within the rare disease community. [More](#)

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NCBIO Luncheon and Forum on Clinical Trials

Join us on November 18 for a Forum on Clinical Trials: Changing Landscape and Potential Pitfalls. This forum will focus on:

- issues within the clinical space, particularly patient recruitment and diversity
- the use of analytics in managing trial sites
- how the regulatory landscape is changing in light of new therapies and rare diseases

The panel features:

- **Matt Becker**, Advisory Industry Consultant, Global Hosting and U.S. Professional Services, SAS
- **Christina Cocciardo**, Director Regulatory Affairs, Regulatory Science, PPD
- **Allison Kalloo**, President and CEO, Clinical Ambassador Health

Contact [Amber Niebauer](#) if you need help with registration or if you are interested in sponsoring this event.

Thanks to [Chubb](#) and [PwC](#) for being an event sponsor.

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Celebrating 35 Years of Life Science



From the first batches of insulin decades ago to potentially curative gene therapies today, life science has come a long way. And no place has more to celebrate than North Carolina.

The NC Biotechnology Center is celebrating North Carolina's long-term commitment to the life sciences – 35 years this year – with an event November 5. The event starts at 3:30 p.m. with an open house for programs and services. The formal program starts at 4:45 p.m. with talks from Bob Ingram, Karen LeVert, Jack Cecil and entrepreneur Aaron Lazarus. A reception will follow.

Join others in celebrating all that the life science community has created together, and the promise yet to be realized. [Click](#) to register.

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NCBiotech Awards \$1.4 Million in Grants, Loans

The North Carolina Biotechnology Center awarded 18 grants and loans totaling nearly \$1.4 million to bioscience companies, universities and non-profit organizations in the first quarter of its 2019-20 fiscal year.

The awards, made from July 1 to Sept. 30, will support life science research and technology commercialization throughout North Carolina and help companies attract follow-on funding from other sources. [More](#)

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At the National Level

Drug Pricing Debates Continue in Congress

Legislation introduced by House Speaker Nancy Pelosi (H.R. 3) is being debated by various committees in the U.S. House and is getting stiff opposition from NCBIO, BIO, PhRMA and other organizations. During the Education and Labor Committee markup of the legislation, Rep. Mark

Walker from North Carolina (R-NC 6th district) offered an amendment that would have required the GAO to conduct a study on how much R&D investment would be affected by H.R. 3, and if the findings showed a decrease by \$10 billion or more per year, the bill would not go into effect. During a Ways and Means Committee review, Congressman George Holding (R-NC 2nd District) noted that passage of the legislation would have a significant impact on bio/pharma companies in RTP.

NCBIO and other organizations sent a letter to House members noting among other things that, “We are deeply concerned that the proposed changes will significantly destabilize incentives to invest in research and development of new medicines, with no assurances that coverage of medicines would improve. Furthermore, this proposal would upend the successful Medicare Part D program that over 45 million people rely on today. Rather than supporting this short-sighted proposal, we believe Congress should focus on changes that prioritize patient-driven care and affordability, like requiring rebates and discounts on drugs to be shared with patients at the pharmacy counter, increasing transparency on costs for patients, and promoting value-based payment.”

BIO’s President and CEO Jim Greenwood issued the following statement after the Congressional Budget Office (CBO) released an analysis confirming that H.R. 3 will lead to fewer new medicines for patients:

“The nonpartisan Congressional Budget Office has confirmed what we have been saying: Speaker Pelosi’s reckless bill will stifle the discovery of new medicines and treatments. The same lawmakers who recently championed the bipartisan *21st Century Cures Act* are now threatening to destroy the very industry that will deliver the future cures and treatments we need. We need to accelerate the pace of cures, not create policies that ensure fewer treatments come to market as CBO cautions will happen.” For Greenwood’s full statement, click [here](#). BIO has also set up an [Action Network](#) that allows opponents of the legislation to quickly comment to members of the North Carolina congressional delegation and congressional leaders.

PhRMA has also issued statements opposing the legislation, including the following comment: “Speaker of the House Nancy Pelosi recently unveiled a radical plan that would restrict and fundamentally change how patients access medicines in the United States. It would threaten our country’s global leadership in developing innovative, lifesaving treatments and cures and force patients to face the uncertainty of a health care system where the government sets prices for critical medicines and import foreign determinations of the value of medicines.” For the full statement, click [here](#).

BIO Announces Leadership Transition



The Biotechnology Innovation Organization (BIO) announced that industry veteran Jim Greenwood will step down as President and CEO of the world’s largest biotechnology organization after the 2020 election and help transition a new leader to represent the industry globally and to defend innovation from domestic political attacks.

“I’ve been twice blessed – to represent the American people in Congress and then to represent the extraordinary scientists and entrepreneurs of the biotechnology industry,” Jim Greenwood said. “No organization has played a more powerful role than BIO in making sure government leaders embrace thoughtful policy so the science of biotechnology can march forward. I know because I was one of those lawmakers inspired by my BIO education. Through this organization, I came to see the miracles the biotech industry makes possible.” [More](#)

Push to Repeal Medical Device Tax Continues

The Medical Device Manufacturers Association (MDMA), the Advanced Medical Technology Association (AdvaMed), the Medical Imaging & Technology Alliance (MITA) and a broad coalition of medical innovators, physician inventors, patient groups, and others have sent a letter to congressional leadership urging them to permanently repeal the medical device excise tax.

“The United States is the world leader in manufacturing life-saving and life-enhancing diagnostics and treatments within an industry that is an important engine for economic growth,” the signatories wrote. “Unfortunately, when the medical device tax was in effect, it had an adverse impact on R&D investment and job creation, jeopardizing the U.S. position as a global leader in medical device innovation.”

The medical device tax is a 2.3 percent levy on the sale of nearly every medical device sold in the country—from pacemakers and stents to MRI machines and CT scanners. The tax has previously been suspended by Congress twice, but absent Congressional action the most recent suspension will expire on January 1, 2020. NCBIO supports repeal of the tax, which – if it becomes effective – will undermine jobs, patients, and important breakthroughs in medical innovation. [More](#)

MedTech Conference Continues to Grow

The MedTech Conference closed its 13th annual meeting with a record-breaking attendance of 3,320 visitors from throughout the medical device and diagnostics industry. Held at the Boston Convention and Exhibition Center, more than 1,410 companies and leaders in the medical technology industry hailing from 39 countries came to town for the three-day event.

One panel at the event focused on a merger and acquisition strategy for companies. Panelists were from Johnson & Johnson (J&J), Medtronic plc and Boston Scientific Corp. [More](#)

The 2019 EY MedTech report, *Pulse of the Industry*, was also discussed. The report indicates the “global medical technology (medtech) industry continues to grow, but its long-term growth outlook is at risk due to underinvestment in R&D and lack of collaboration between industry providers, payers and patients.” [More](#)

[Click](#) for more on the conference. Next year’s event will be held October 5-7 in Toronto, Canada.

BIO Upcoming Events

Book Housing for BIO Convention 2020

Time to start your planning! Secure convenient and affordable hotel rooms for your stay in San Diego during [BIO 2020](#), June 8-11!

BIO has secured top hotels around the San Diego Convention Center for you to choose from. Book early for the best selection and price! BIO is pleased to partner with onPeak as the official, exclusive housing provider for the 2020 BIO International Convention. [Book housing](#).

BIO CEO & Investor Forum

Registration is now open for the [BIO CEO & Investor Conference](#), one of the largest investor conferences focused on established and emerging publicly traded and select private biotech companies. The event is February 10-11, 2020 in New York. [Register](#) by November 15 to get super early rates.

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Member News

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

[Aperio Clinical Outcomes](#), announced that industry veteran Jennifer Hodak has joined the company as Director of Talent Acquisition as they scale-up to support the growing needs of their pharmaceutical, biotech and medical device client base. [More](#)

[BioCryst Pharmaceuticals, Inc.](#) announced that the U.S. Department of Health and Human Services (HHS) has exercised its option to purchase an additional 10,000 doses of BioCryst’s approved antiviral influenza therapy, RAPIVAB® (peramivir injection). [More](#)

[Biogen Inc.](#) and [Eisai, Co., Ltd.](#) announced that, after consulting with the U.S. Food and Drug

Administration (FDA), Biogen plans to pursue regulatory approval for aducanumab, an investigational treatment for early Alzheimer's disease (AD). New analysis of larger dataset showed that aducanumab reduced clinical decline in patients with early Alzheimer's disease as measured by the pre-specified primary and secondary endpoints. [More](#) Biogen announced that the journal *Neuromuscular Disorders* has published data from NURTURE, the first study investigating a treatment targeting the underlying cause of spinal muscular atrophy (SMA) in infants treated pre-symptomatically. Data from the NURTURE study demonstrated that infants who initiated treatment with SPINRAZA prior to the onset of clinical symptoms attained unparalleled results compared to the natural history of the disease. [More](#)

[Eva Garland Consulting](#) (EGC) and [First Flight Venture Center](#) (First Flight) have each been awarded \$50,000 as part of the nationwide Growth Accelerator Fund competition held by the US Small Business Administration (SBA) to spur innovation in the US. [More](#)

[G1 Therapeutics, Inc.](#) announced preliminary results from a Phase 1/2a dose-escalation study of G1T48, an oral selective estrogen receptor degrader (SERD), in patients with estrogen receptor-positive, HER2-negative (ER+, HER2-) breast cancer. In the trial, G1T48 was well tolerated and demonstrated evidence of anti-tumor activity in heavily pre-treated patients. [More](#)

[IQVIA™](#) announced the launch of Orchestrated Patient Engagement (OPE), a new cloud-based software as a service (SaaS) solution that helps close the gap between life sciences companies and patients. [More](#) IQVIA and NCBio hosted a Venture Capital Networking session October 9 with a guest panel of speakers from Pappas Capital, NovaQuest Capital Management, and Hatteras Venture Partners.

[Mycovia Pharmaceuticals, Inc.](#) announced it has entered into an exclusive license and development and technology transfer agreement with Gedeon Richter Plc., based in Budapest, Hungary, to commercialize and manufacture VT-1161 in Europe, Latin America, Australia, Russia and other CIS countries. VT-1161, an oral antifungal product candidate, is currently in Phase 3 clinical trials for the treatment of Recurrent Vulvovaginal Candidiasis (RVVC), a debilitating, chronic infectious condition that affects nearly 138 million women worldwide each year. Mycovia is backed by [NovaQuest](#). [More](#)

[Novan](#) announced that the Company has received a grant from the U.S. Department of Defense's (DoD) Congressionally Directed Medical Research Programs (CDMRP) of approximately \$1.1 million as part of its Peer Reviewed Cancer Research Program. [More](#)

[Novo Nordisk](#) announced that the U.S. Food and Drug Administration (FDA) has approved Rybelsus® (semaglutide) tablets 7 mg or 14 mg for adults with type 2 diabetes that along with diet and exercise may improve blood sugar (glucose).¹ Rybelsus® is the first and only glucagon-like peptide-1 (GLP-1) analog in a pill and a new option for adults with type 2 diabetes who are not achieving their A1C goal with current antidiabetic treatment. [More](#)

[PPD](#) has been named Best CRO Provider for the second time in the last three years at the World ADC Awards. [More](#) PPD has been named a CSO50 Award winner for information security initiatives demonstrating outstanding business value and thought leadership. [More](#)

[Syneos Health®](#) announced that the Company was awarded the Society for Clinical Research Sites (SCRS) Eagle Award in the CRO category for a third consecutive year. [More](#) Syneos Health® also announced the launch of *Why We Resist: The Surprising Truths About Motivating Behavior Change*. Leveraging collective knowledge across the clinical to commercial continuum, *Why We Resist* translates the complex field of behavioral science into actionable insights and tools to enable healthcare brands to optimize patient reach and engagement. [More](#)

[TCG](#) Partner Nat Bowditch participated in the Medical Japan Conference in Tokyo, October 23-25. For more than twenty years, TCG has assisted medical device companies in Europe and Asia to successfully enter and grow in the United States. [More](#)

[ZenBio, Inc.](#) has been awarded a Phase II SBIR grant from the National Institutes on Aging to develop stem cell-derived extracellular vesicles as a therapy for chronic non-healing wounds in the elderly. [More](#)

Events of Interest

Bioprocess Workshop at BTEC

Join others at BTEC at NC State University, November 6, 11:30 AM to 2:30 PM for a complimentary Bioprocess Workshop hosted by Eppendorf North America.

Topics include:

- Implementation of an Affordable and Scalable Manufacturing Strategy for Gene Therapy

- A Beginner's Guide to Bioprocess Modes – Batch, Fed-Batch, and Continuous Processing
- Develop Robust, Scalable and Transferable Processes More Quickly with Kaiser Raman

[Click here for more information and to register.](#)

FDA-PDS Symposium VIII November 11 at Stanford

CEO Roundtable on Cancer's Project Data Sphere® (PDS), in partnership with the FDA, founded a series of symposia devoted to areas fertile for fresh attention in the realm of cancer clinical trials. This year's FDA-PDS Symposium VII will focus on the development of machine learning algorithms, based on computerized tomography (CT) images, to improve the efficiency and consistency of CT tumor measurements and to augment/eliminate the adjudication of CT readings. Hosted by Stanford University School of Medicine, the Symposium will focus on PDS' Images and Algorithms Program devoted to machine learning image-recognition algorithms.

It will also be offered through a live webcast for those unable to travel to Stanford. To register and find out more, [click here](#).

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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!](#)



Business Wire

Why still use a commercial newswire?

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BIO members can save a minimum of 10% on all news release distribution circuits and more when you bundle in any additional Business Wire services.

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Airgas

In pharmaceuticals, biotech, and life sciences, discovery and invention are daily priorities...

...and efficient and cost-effective innovation is critical for growth and continued success. BIO's preferred partner, Airgas Healthcare, an Air Liquide company, specializes in improved laboratory safety, gas purity, minimizing gas consumption AND is offering BIO members 10%-25% off all while enhancing analytical productivity. The BIO-Airgas member benefits include:

- 10% to 25% discounts on cryogenic equipment, gas distribution equipment and safety products
- Hotlist of medical-grade nitrogen, helium, argon & carbon dioxide, plus custom offerings tailored to specific member needs
- Customized product service agreement for renewal, removal, and remedy terms and guaranteed price savings option
- National sales and support combined with local industry specialists to assist your business
- Full supply mode services: Cylinders, Dewars, Microbulk, Bulk and Pipeline, and Dry Ice services

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](#).

[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

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[NC CEO Forum: "Leading in a World of Disruptive Technologies"](#)

Tuesday Nov 5, 2019

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[NCBiotech's 35th Anniversary Celebration](#)

Tuesday Nov 5, 2019

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[SEBIO Investor and Partnering Forum 2019](#)

Wednesday Nov 6, 2019 - Thursday Nov 7, 2019

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[LaunchBio: Larger than Life Science "Front and Center"](#)

Thursday Nov 7, 2019

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[Annual NCRAF Roundtable Dinner](#)

Thursday Nov 7, 2019

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[Brewer's Ball Celebrating the Triangle's Finest](#)

Friday Nov 8, 2019

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[Artificial Intelligence in Tumor Imaging: Needs, Opportunities & Challenges](#)

Monday Nov 11, 2019

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[ACS CAN North Carolina Research Breakfast](#)

Tuesday Nov 12, 2019

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[15th Annual Personalized Medicine Conference](#)

Wednesday Nov 13, 2019 - Thursday Nov 14, 2019

... [read more](#)

[NCBIO Forum on Clinical Trials: Landscape and Pitfalls](#)

Monday Nov 18, 2019

... [read more](#)

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