



November 2021 Update

Serving the NC Life Sciences Industry

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NCBIO This Month

- NCBIO Annual Meeting roundup
- State budget negotiations continue
- Federal budget, infrastructure proposal cut to \$1.75 billion
- OSHA submits draft of vaccine mandate rules
- NCBIO welcomes new board members

... and more



A note from NCBIO President Laura Gunter

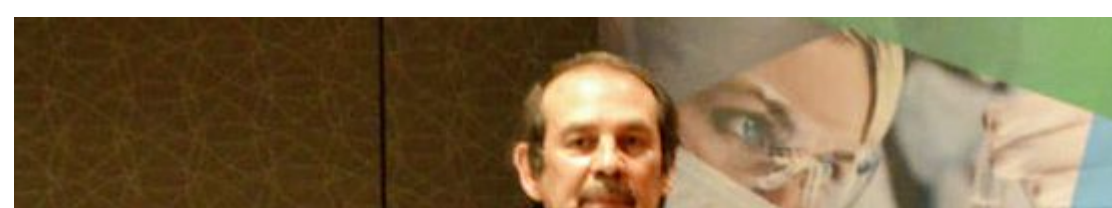
NCBIO is setting our 2022 calendar, and we are excited that easing pandemic restrictions will allow us to host in-person networking events again.

We will be continuing with popular events like our Clinical Trials, Emerging Issues, Medical Device and Lab Space Forums, in addition to hosting webinars that explore interesting and useful topics. We are particularly excited about the work we have begun on diversity, equity and inclusion that kicked off with our inaugural Roadmap to Diversity event Aug. 24 ([check it out here](#)). We are planning another event in the first quarter of next year, and we have begun working with Raleigh's The Diversity Movement to infuse DEI into our organization and help support our members.

If you would like to work with NCBIO as an event [sponsor](#), host a networking event or participate in a forum or seminar, [please let us know](#). We'd be very excited to talk about how your company can get involved in 2022.

NCBIO EVENTS

2021 NCBIO Annual Meeting returns to in-person, Samulski delivers keynote



NCBIO Sustaining Members



NCBIO Supporting Members





Jude Samulski, Ph.D., president of AskBio

Nearly 200 people attended NCBio's 2021 Annual Meeting Tuesday, Oct. 5, with almost 120 choosing to be there in person and about 75 opting to participate online.

Attendees heard discussions of drug pricing, the challenges of launching a startup, federal issues affecting the industry and the patient's role in clinical trials, as well as a powerful talk from AskBio founder Jude Samulski on the story of gene therapy in North Carolina. They also selected new board members and met the first recipients of the Samuel M. Taylor Memorial Life Sciences Scholarships.

The Annual Meeting event kicked off with a dinner Monday, Oct. 4, that featured talks on drug price fixing by U.S. Rep. Greg Murphy, M.D., and health economist David Ridley, Ph.D., the Riddick Professor of the Practice at the Duke University Fuqua School of Business.

The highlight of the 2021 Annual Meeting was a powerful presentation by Jude Samulski, Ph.D., president and chief scientific officer of AskBio, who told the story of his journey using adeno-associated virus to develop treatments for rare diseases, especially those that affect children.

READ MORE

NCBio 2021 Annual Meeting Platinum Sponsors



"We're a medical device company based in Durham, and we're a global leader in innovations for active healing. We offer products that address the growing need for clinically effective, cost efficient, minimally invasive medical treatments focused around addressing pain, bone graft substitutes and restorative technologies. We're committed to helping patients get back to living active lives." - Vivek Munshi, VP of marketing



"Cook Medical is privately held by the Cook family and is one of the world's largest medical device manufacturers. I want to mention the Samuel M. Taylor Memorial Life Sciences Scholarship, which has been established to honor our friend, past president and co-founder, Sam Taylor. We ask you or your company to consider a generous donation to this fund." Scott Sewell, VP, external affairs



"What visionary investments are we going to



What visionary investments are we going to make today that will pay off 10, 20, 30 years from now? We here bear that responsibility. Our biggest asset to date has been talent, but paradoxically, the biggest bottleneck we face right now is access to talent. At Kymanox, we're making big investments in this area, and I think we all need to work together to convert this amazing opportunity in front of us." - Stephen Perry, CEO

"As a member of NCBIO, you have access to the VWR BIO Business Solutions program. Whether you have \$5,000 a year in lab spend a year or \$20 million, you can take advantage of that program. Through that agreement, the combined lab spend is up to \$600 million so that's a lot of leverage to drive down pricing." - Jason Kempton, director of regional sales



STATE UPDATES

If you have questions or concerns on any of these topics, please contact [Laura Gunter](#).

Legislative leader says a state budget deal is close

Four months into the fiscal year, we are seeing signs that state leaders are nearing an agreement on the state budget.

House Speaker Tim Moore said early this week that a compromise budget could be passed as soon as next week. Moore said that he, Gov. Roy Cooper, Senate leader Phil Berger, Senate Minority Leader Dan Blue and House Minority Leader Robert Reives last met Friday, Oct. 22, at the Executive Mansion to negotiate the budget. Reives is one of the co-chairs of the Legislative Life Science Caucus.

Medicaid expansion, taxes and raises are again central issues of this year's budget talks. Cooper said that he and legislators are in agreement on the "vast majority" of the budget and that taxes, health care and education are the sticking points. Moore has said repeatedly that House Republicans will not vote for Medicaid expansion in the budget. He said this week that Republicans are open to putting more money into education and that raises for teachers and state employees were still part of the negotiations.

Moore said that if there isn't a budget deal with Cooper by next week, Republicans will move ahead with passing a legislative budget. The Senate and House have each passed its own budget but have not yet passed a compromise final budget, known as the conference budget, because they have been negotiating privately with Cooper.

If there is a compromise in the coming days, there wouldn't be a budget vote until the second week of November.





NATIONAL UPDATES

Congress funds government through December

At the eleventh hour, the U.S. Senate voted to increase the debt ceiling by \$480 billion, with 11 Republicans joining Democrats in support. The Treasury Department estimates the nation will hit the new debt ceiling around Dec. 3.

President Biden announced a new framework for the Build Back Better Act on Thursday. Originally pegged at \$3.5 trillion over 10 years, the amount has been cut to \$1.75 trillion. Some of the highlights of the proposal are

- expanding access to education beyond high school by raising the maximum Pell grant, providing support to historically black colleges and universities and other minority-serving institutions;
- investing in workforce development, including community college workforce programs, sector-based training, and apprenticeships;
- expanding 10-year tax credits for utility-scale and residential clean energy, transmission and storage, clean passenger and commercial vehicles;
- extending the expanded Affordable Care Act premium tax credits through 2025; and
- establishing a hearing benefit in Medicare.

To pay for the package, the Biden administration is proposing a 15% corporate minimum tax on large corporations, a stock buyback tax and a surcharge on the top 0.02% of wealthiest taxpayers. The plan also repeals a rebate rule released under the Trump administration that sought to address Part D drug rebates that drugmakers offer to pharmacy benefit managers in exchange for participation on their formularies.

There hasn't been much movement on federal drug price setting proposals, but BIO representatives believe that drug pricing and benefit redesign is still part of the discussion on the Hill and with the White House. NCBIO is working with our national partners to continue to share important stories of individuals and small companies that will be impacted by drug pricing proposals.

Please share the graphic below (right click and Save Image As) with your networks via email, on social media, on your website or in your newsletters. Please link to <https://SaveCures.com> where individuals can send messages directly to their members of Congress.



Share this graphic and link in emails and social media.

OSHA sends vaccine rules draft to White House

The Occupational Safety and Health Administration is preparing an emergency temporary standard directing covered employers to impose President Biden's Sept. 9 executive order mandating that federal contractors and large employers require their employees to be vaccinated against COVID-19.

OSHA sent its drafted rule to the White House for review a few weeks ago, and the Office of Information and Regulatory Affairs has held meetings with multiple groups representing employers, businesses and individuals to hear their feedback.

Until the OSHA ETS has been drafted, circulated and adopted, there is no enforceable mandate requiring any employer to take any action. An ETS can go into effect on the day it is published, and OSHA has six months to follow up with a final version of the standard.

Businesses with at least 100 employees will be required to mandate that employees get vaccinated against the coronavirus or submit to weekly testing.

The mandate will likely not apply to existing government contracts. The vaccine mandate will likely apply to contract extensions and renewals, as well as to totally new contracts, but is unlikely to apply retroactively.

ultimately to apply retroactively.

Rep. David Price to retire

U.S. Rep. David Price announced his retirement, potentially opening the door for new congressional candidates in a Democratic stronghold in the Triangle. The powerful lawmaker will not run for reelection in 2022.

North Carolina’s 4th Congressional District and the state’s other political districts are being redrawn by the General Assembly. Price’s current 4th district includes Durham, Orange, Franklin, Granville and Orange counties along with parts of Wake, Chatham and Vance counties.

Price served four terms from 1987 to 1995. He lost the seat in 1994 during the Republican Revolution that saw 34 House Democrats lose reelection, but regained it in the 1996 election.

[More >>](#)

NCBIO Updates

NCBIO welcomes new board members

At the Oct. 5 Annual Meeting, NCBIO members voted to accept the following new members of the organization’s Board of Directors:

- Joseph Ruiz, Ph.D., president, Enzerna Biosciences
- Marlene Sanders, associate director, government accounts, Merck
- Kseniya Simpson, Ph.D., associate, Hatteras Venture Partners
- Christine Vannais, chief operations officer, FUJIFILM Diosynth (Vannais will replace Martin Meeson for the remainder of his three-year term running through 2023.)

Additionally, the following 10 current board members are beginning a consecutive three-year term running through 2024:

- Tom Adams, Ph.D., CEO, Pairwise
- Chuck Blatchley, director of engineering, Grifols
- Christopher Capel, J.D., partner, Smith Anderson
- Matthew Cooke, partner, Davis Moore
- Alex Graham, M.B.A., vice president global sales & marketing operations, Thermo Fisher Scientific
- Mark Harbaugh, M.B.A., senior director, professional affairs, Bioventus
- Mike McBrierty, M.P.P., director, state public policy and government affairs, Biogen
- Sheila Mikhail, M.B.A., J.D., CEO, AskBio
- Kyle Rasbach, Pharm.D., Ph.D., managing partner, Pappas Capital
- Scott Sewell, vice president, external affairs and corporate compliance officer, Cook Medical

NCBIO plans diversity, equity & inclusion activities for members

Many NCBIO members participated in our very successful “Roadmap to Diversity” Forum Aug. 24. We are planning to hold another event in early March.

As an organization, NCBIO is committed to prioritizing diversity, equity, and inclusion and supporting members on their DEI journeys. Our Diversity Committee is working on a number of areas to help members with best practices. As part of NCBIO’s work, we have partnered with The Diversity Movement to help us.

Based in Raleigh, The Diversity Movement is a results-oriented, data-driven strategic partner for organization-wide diversity, equity and inclusion initiatives. Their team of experts provides a customized mix of online learning, tools, events and consulting services that help their partners create sustainable culture change and better business outcomes.

TAKE OUR DEI SURVEY

As part of the collaboration, NCBIO members can access a number of free diversity, equity, and inclusion resources offered by The Diversity Movement.

- [Blogs](#), which are updated weekly
- [Webinars](#), which are held monthly. Past recordings are available.
- [Diversity: Beyond the Checkbox](#) podcast hosted by TDM's Head of Content & Programming Jackie Ferguson and featuring a new guest on each episode
- [Whitepapers and programming guides](#), including a very useful [whitepaper on inclusive language](#)

The Diversity Movement is also currently offering their [MicroVideos](#) for business leaders and time-crunched professionals, MicroVideos will teach you how to strengthen organizational culture and practice inclusive leadership in one-to-three minute videos from business executives, certified diversity leaders and experts in inclusion.

You can also [sign up for their newsletter](#) to receive the latest updates on their free programming guides, webinars and more.



**NCBIO President Laura Gunter with Robert Voissem
and NC Community Colleges System President Thomas Stith III.**

Parents’ deaths lead Air Force vet to first Sam Taylor Scholarship, biotech career change

From flying B-52 bombers as a member of the United States Air Force to driving semis across the country, Robert Voissem has had what he calls a “colorful work history.”

It was his time taking care of his parents that led him to make another career change and pursue a degree in biotechnology at Wilson Community College.

“After my parents’ deaths, I began to explore careers that may help people live,” said Voissem. “I examined several careers, but biotechnology opened many possibilities to enhance the lives of others.”

He began his new journey toward an Associate of Applied Science in Biotechnology as one of the first recipients of the North Carolina Community Colleges’ Samuel M. Taylor Memorial Life Sciences Scholarship.

[MORE >>](#)



Rivers East Academy for Advanced Manufacturing launches

NC East Alliance and Rivers East Workforce Development Board have partnered to develop the Rivers East Academy for Advanced Manufacturing.

The Rivers East Academy is a unique multicounty solution that will comprise a three-year high school teacher externship professional learning program. It will assemble a regional network of high schools, community colleges, East Carolina University and regional industry in six counties. The six counties involved are Beaufort, Bertie, Hertford, Hyde, Martin and Pitt.

The program will train high school teachers, community college faculty and community college student “ambassadors” to work together. As teams, they will help students bridge the gap from high school to community college to career. The year-round program is a series of in-person (one-day events at respective community colleges) and virtual events (synchronous and asynchronous) that include virtual live stream events, technology partner demos, industry tours, job shadowing and career fairs.

[More >>](#)

Member news briefs

To be included in member news, send information about your organization to [David Etchison](#).

BD has received expanded 510(k) clearance from the FDA for its Rotarex atherectomy system, allowing it to be used for treatments inside peripheral arteries that have stents, stent grafts and native or artificial bypasses. [More >>](#)

BioAgilytix Labs, LLC. signed a formal, worldwide partnership agreement with global contract research organization Clinical Trial and Consulting Services. [More >>](#)

BioDelivery Sciences International, Inc. appointed John Golubieski as chief financial officer. Golubieski brings to BDSI more than 30 years of financial and operational experience and will serve as a member of the company’s executive leadership team. [More >>](#)

Cambrex Corp. plans to invest another \$30 million and hire 78 more employees to expand the production capabilities of its High Point campus. [More >>](#)

Chiesi USA joined the Durham Bulls to present donation checks of more than \$4,000 to three Triangle-area nonprofits – Inter-Faith Food Shuttle, Children’s Flight of Hope and Activate Good. [More >>](#)

FUJIFILM Diosynth Biotechnologies held a groundbreaking ceremony to celebrate the start of its large-scale cell culture expansion project, the largest in North America, in Holly Springs. [More >>](#)

IQVIA announced the opening of a state-of-the-art, 160,000-square-foot lab facility for its Q2 Solutions subsidiary located on the new IQVIA Innovation Park Campus in RTP. [More >>](#)

Locus Biosciences has entered a credit facility with Hercules Capital, Inc. of up to \$25 million to expand the clinical-stage biotechnology company’s drug discovery platform and in-house manufacturing. [More >>](#)

Mayne Pharma announced that the FDA has approved LEXETTE® (halobetasol propionate) foam, 0.05% for the treatment of plaque psoriasis in patients 12 years and older. [More >>](#)

Novozymes and Anuvia Plant Nutrients have joined forces to develop a range of combined biotechnologies that will reduce the need for synthetic fertilizers in commercial agriculture. [More >>](#)

PPD, Inc. is the recipient of the 2021 Eagle Award from the Society for Clinical Research Site for its commitment to advancing clinical research professionalism through strong site partnerships. [More >>](#)

PPD, Inc. was named “Clinical Research Company of the Year” at the 2021 PharmaTimes Clinical Researcher of the Year International competition in London. In addition, PPD clinical researchers won individual gold, silver and bronze awards. [More >>](#)

Sage Therapeutics, Inc. and **Biogen Inc.** announced new data from the LANDSCAPE and NEST clinical development program evaluating the efficacy and safety of zuranolone for the treatment of major depressive disorder and postpartum depression. [More >>](#)

SAS and **Pappas Capital** are joining forces to help advance the state as a global leader in agricultural technology by providing select NC agriculture and food startups with guidance and executive leadership from Pappas and access to industry-leading analytics software, data science expertise and cloud services from SAS. [More >>](#)

Seqirus was received a multiyear, \$34.95 million BARDA contract to develop two influenza A (H2Nx) virus vaccine candidates for assessment in a Phase 1 clinical study with the goal of helping to safeguard communities in the event of an influenza pandemic. [More >>](#)

StrideBio, Inc. achieved several significant operational milestones, including the hiring of StrideBio’s 100th team member, completion of its 6,700 square-foot in-house GMP-grade manufacturing facility, and the addition of a 15,000 square foot expansion of its laboratory and office spaces. [More >>](#)

Events



Registration is now open for 2022 BIO Partnering @ JPM! January 10-14 | San Francisco, CA & Virtual

BIO One-on-One Partnering has many features to help you make strategic connections, including:

- Robust search so you can quickly find the companies and contacts that matter
- Easy-to-use time zone features, embedded video conferencing and automated calendar updates
- Scheduling features that will allow you to book meetings in your own physical or virtual space, or take advantage of BIO-provided virtual meeting links through Zoom
- Extended access to the system for a year after JPM Week for follow-up

Whether you are attending JPM Week virtually, in person, or both, you can use BIO One-on-One Partnering to simplify your experience. Don't miss this opportunity to directly connect with partners, industry leaders, and supporters.

REGISTER NOW



MDMA Reimbursement & Health Policy Conference

Join MDMA online Nov. 9-10

Reimbursement and market access strategies have become critical to medical technology companies of all sizes, and this conference will deliver insights and feature panels on coding, coverage, and payment as well as private payers, Administrative updates and more. A dynamic group of policy makers and speakers will interact with attendees during informative sessions and discuss the latest reimbursement challenges and issues facing the medical device industry.

NCBIO members receive a \$100 discount on registration. Contact [Amber Niebauer](#) for the discount code.

MORE INFO



Professional Development Training at BTEC

The Biomanufacturing Training and Education Center at NC State is resuming its professional development program. Make plans to join them next year for an exciting lineup of learning experiences. In addition to familiar favorites, they are launching five new hands-on courses:

- [Analytical Methods for Gene Therapy Vector Characterization and Testing](#)
- [Analytical Methods for Raw Materials Testing](#)
- [Automation, Process Control, and Real-time Monitoring of Yeast Culture](#)
- [Biopharmaceutical Lyophilization and Spray Drying](#)
- [Protein Precipitation and Crystallization](#)

See the full schedule of [2022 professional development courses](#) and act quickly as space is

limited, and courses are filling fast!

Online opportunities for distance learning

To complement its hands-on courses, BTEC is offering three new virtual courses in 2022.

- [Introduction to Chemical Modification of Protein Therapeutics](#), on-demand format
- [Latest Trends in Downstream Biopharmaceutical Processing](#), on-demand format
- [Upstream Production Process Development for Biopharmaceuticals](#), hybrid format with live sessions

In addition, a newly revised version of the online [Fundamentals of Biomanufacturing course](#) is now available on a year-round basis.

If you're interested, ask [Erica Vilsaint](#), BTEC's coordinator of professional development programs about how to register and what discount options are available as soon as possible.

NCBIO calendar

- [Negotiating SPAC Deal Terms](#) hosted by BIO (11/3/2021)
- [Triangle Global Health Virtual Annual Conference: Reframing Global Health in a Changing World](#) hosted by Triangle Global Health Consortium (11/4/2021)
- [Larger than Life Science: Measuring and Tracking the Competition](#) (11/4/2021)
- [Reimbursement & Health Policy Conference](#) hosted by MDMA (11/9/2021 to 11/10/2021)
- [Tax Consideration for Chapter 11 Bankruptcy Proceeding: Best Practices for Corporate Executives](#) hosted by ShareVault (11/9/2021)
- [Spotlight on Cybersecurity with the FBI](#) hosted by NC TECH (11/10/2021)
- [The Untapped Talent Pool Part II](#) hosted by NCEast Alliance and EDPNC (11/10/2021)
- [BIOMARKERS: Improving Patient Access to Targeted Cancer Therapies](#) hosted by CSBA (11/16/2021)
- [8th Annual Women in Bio with HBA Joint Networking Event](#) (11/17/2021)
- [Women in Law Inclusion & Equity Virtual Summit \(East\)](#) featuring Womble Bond Dickinson (11/17/2021)
- [Attracting VCs: How to Stand Out from the Crowd](#) hosted by LaunchBio (11/17/2021)
- [First Flight & Innovation: Celebrating the First 30 Years](#) hosted by First Flight Venture Center (11/19/2021)
- [BTEC Analytical Methods for Raw Materials Testing](#) (12/1/2021 to 12/3/2021)
- [How to WIN SBIR/STTR Grants Educational Seminar](#) hosted by First Flight (12/2/2021)
- [BTEC Protein Precipitation and Crystallization Course](#) (12/14/2021 to 12/16/2021)



BIO Business Solutions Highlights

BIO Business Solutions provides significant cost savings to NCBIO member companies on a wide variety of products and services, including lab supplies, insurance, shipping, office supplies and more.

The BBS team continuously works to offer competitive pricing and favorable terms so you can focus on your organization's core mission. With almost \$724 million in purchasing power, the BIO Business Solutions program helped over 4,600 member companies save more than \$590 million in 2020.

All the heavy lifting is done for you.

For all the latest news, promos and event information, follow [BIO Business Solutions on LinkedIn](#).

Check out a few of the newer partner programs



simplifies how R&D organizations access scientific literature, such as peer-reviewed journal articles, book chapters, patents and other content.



helps to provide small employers (generally between 2-99 employees) quality group medical benefits at competitive pricing.



is a corporate credit card for the life sciences and is designed to empower its life sciences customers to spend less time on end of month closes and more time on life changing R&D. This card offers its customers streamlined reporting functions, tailored rewards such as 3x points multipliers on lab equipment and much more.



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Pre-configured and validated eQMS



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- ✓ Pre-Configured Workflows (10 different)

✓ Full Software Integration

✓ Track and Manage Requests

✓ And More!

✓ Pre-Configured Workflows (10 different)

✓ Cloud-based access

✓ Integrated Reporting and Dashboards

✓ Fully Validated System (IOPQ)

✓ And More!

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NC BIO Partners

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