



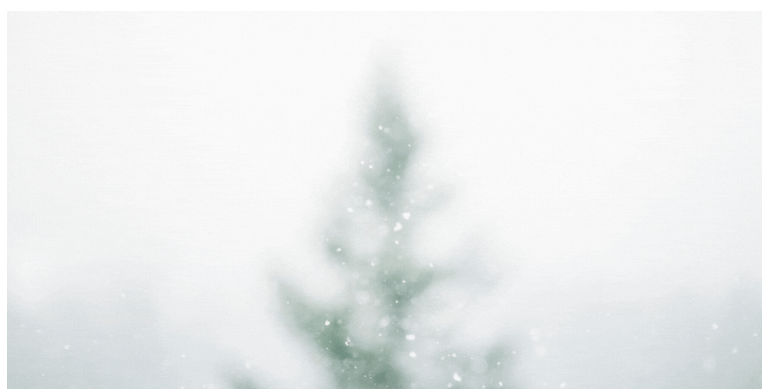
December 2021 Update
Serving the NC Life Sciences Industry

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NCBIO This Month

- State budget victories
- Federal infrastructure bill passes
- Build Back Better passes the House
- OSHA vaccine rules, TRIPS wavier on hold
- NCBIO welcomes new members

... and more



Happy holidays from all of us at NCBIO! We hope you are able to join together with family and friends and that your holidays are filled with laughter, cheer and gratitude.

Thank you for all that you have done this past year to support NCBIO as we advocate for policies and a climate in North Carolina that encourages the growth and success of our life sciences industry. I am especially gratified by our success in securing recurring NC budget dollars for the One NC Small Business program, which will help small emerging members, and I am grateful for the continued interest in North Carolina's innovative life science ecosystem by the NC General Assembly's Life Science Caucus and its chairs, Sen. Paul Newton, Sen. Mike Woodard, Rep. Donna White and Rep. Robert Reives.

I am very excited to share the news that we have hired [Natacha Janvier](#) as NCBIO's new membership director. Janvier comes to NCBIO from Eva Garland Consulting where she was the business development coordinator. Before that, she was with NCCU's BRITE for more than 14 years as a senior academic adviser and science recruiter. She also spent more than seven years as a scientist at GSK. Please look for her at upcoming events and introduce yourself.

Laura Gunter
NCBIO President

NCBIO Sustaining Members



NCBIO Supporting Members





STATE UPDATES

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

Legislature passes budget, governor signs it

Gov. Roy Cooper signed a state budget into law on Thursday, Nov. 18 after the Senate passed the bill 41-7 and the House 101-10.

The budget spends \$25.9 billion in the current fiscal year, which started July 1, and \$27 billion in the 2022-2023 year. The spending plan includes average raises of 5% over two years for teachers and other state employees, cuts individual income taxes and starts the phasing out of the state's corporate income tax.

The One North Carolina Small Business Program received a recurring appropriation of \$2 million, the first time that the program has received recurring funds, which makes it part of the base budget going forward. An additional infusion of \$3 million in nonrecurring funds for this fiscal year was also appropriated. The One NC Small Business Program provides matching funds to companies that apply for and win SBIR/STTR Phase I grant funds. Securing dependable funding for the One NC program was a priority for NCBIO this year. When applicants for these awards are asked if state matching funds are available for leveraging, they can now check yes!

The NC Biotechnology Center received funding of approximately \$17.1 million for this fiscal year and \$15.6 million for the next in a combination of recurring and nonrecurring funds. NC Biotech had not received a funding increase since 2013, so this was much needed support.

Tax changes in the 2021 state budget

Our friends at Smith Anderson have [broken down the tax changes](#) found in the 2021 state budget.

The new budget eliminates the current 2.5% [corporate income tax](#) by a phased lowering of the rate beginning in 2025. The new rates are as follows:

2021: 2.5%	2026: 2%
2022: 2.5%	2027: 2%
2023: 2.5%	2028: 1%
2024: 2.5%	2029: 1%
2025: 2.25%	2030: 0%

Under current law, the [franchise tax](#) is applied to the highest of the following three bases:

1. The taxpayer's net worth as computed in accordance with generally accepted accounting principles
2. The book value of the taxpayer's North Carolina real and tangible personal property, less outstanding debt created to acquire or improve the real property
3. 55% of the appraised value of the taxpayer's North Carolina real and tangible personal property

The budget eliminates the latter two bases with the result that all franchise taxpayers will use the net worth tax base. This is typically a benefit to those companies with facilities in North Carolina and should be an incentive when expansion plans are contemplated.

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General Assembly votes to adjourn

The House and Senate voted to officially adjourn the 2021 long session on Dec. 10, returning on Dec. 30.

The legislature will return to only address certain issues including veto overrides, conference reports, bills concerning congressional and legislative districts, legislation related to litigation of newly drawn maps and approval of appointments. House Speaker Tim Moore said that the legislature will hold no-vote sessions until December 10th. He told members that no votes would be held until at least Jan. 3.

DHHS Secretary Cohen steps down

Gov. Roy Cooper announced that Department of Health and Human Services Secretary Mandy Cohen, M.D., will step down at the end of the year.

Cohen has served as head of the Department for five years. Governor Cooper has appointed Kody Kinsley, chief deputy secretary for health, to serve as interim secretary effective Jan. 1.

Cohen was not specific about her future plans. She said she was not stepping down to seek elected office.



NATIONAL UPDATES

OSHA vaccine rules on hold, others blocked by courts

On Nov. 17, OSHA officially suspended all activities regarding the implementation and enforcement of the recent emergency temporary standard establishing the COVID-19 vaccination/testing mandate for employers with 100 or more employees. OSHA did this in response to the current injunction issued by the Sixth Circuit Court of Appeals and in recognition of the fact that the viability of the ETS will take some time to work its way through the court system and ultimately almost certainly before the U.S. Supreme Court.

A U.S. district court judge in Louisiana temporarily blocked the Centers for Medicare & Medicaid Services from enforcing its vaccine mandate for health care workers until the court can resolve legal challenges. The ruling applied nationwide, except in 10 states where the CMS was already prevented from enforcing the rule due to a prior order from a federal judge in St. Louis.

Separately, a U.S. district court judge in Kentucky blocked the administration from enforcing a regulation that new government contracts must include clauses requiring that contractors' employees get vaccinated. The contractor ruling applies in the three states that had filed the lawsuit, Kentucky, Ohio and Tennessee. This is one of at least 13 legal challenges to the regulation nationwide.

For now, employers do not need to worry about the Dec. 5 OSHA deadline (and likely the Jan. 4, 2022 deadline, as well). Employers are still free to act on their own but won't be required to comply with the OSHA ETS.

Biden signs infrastructure bill

President Joe Biden signed a \$1.2 trillion infrastructure bill into law Nov. 15. It will deliver \$550 billion of new federal investments in America's infrastructure over five years, touching everything from bridges and roads to the nation's broadband, water and energy systems.

Democrats said the legislation pays for itself through a multitude of measures and without raising taxes. However, the Congressional Budget Office found that the package would add \$256 billion to the deficit over the next 10 years.

Among other compromises, the final legislation left out \$100 billion for workforce development included in the original proposal, as well as an increase to the corporate tax rate.

Build Back Better passes House, drug-pricing provisions still problematic

The nearly \$2 trillion Build Back Better Act was passed Nov. 19 by the U.S. House of Representatives after months of negotiations between moderate and progressive Democrats

representatives after months of negotiations between moderate and progressive Democrats in the House and the U.S. Senate. The bill still contains provisions allowing Medicare Part D to "negotiate" the cost of drugs, but the current provisions are less draconian than what we saw this summer (see below).

The CBO estimates the bill will cost almost \$1.7 trillion and add \$367 billion to the federal deficit over 10 years. Adding in \$207 billion of nonscored revenue that is estimated to result from increased tax enforcement in the bill, the net total increase to the deficit would be \$160 billion.

The BBB act includes around \$5 billion in funding to support small businesses.

- Almost \$2 billion in total funding over a 10-year period to fund direct loans for the smallest businesses and government contractors under the 7(a) lending program administered by the U.S. Small Business Administration.
- \$950 million in immediate, direct fee relief for new borrowers of the SBA 7(a) and 504 loans. The funding will be available until Sept. 30, 2026, to reduce or waive fees for loans of \$2 million or less.
- \$60 million to diversify and create equity within the Small Business Investment Company program.
- \$275.9 million to enhance and improve the Community Advantage program and also provide the SBA with authority to partner with not-for-profit lenders to deliver capital through the 7(a) loan program.
- \$100 million to establish a pilot program for providing capital for cooperatives.

Other small business-related investments include

- \$1 billion over a 10-year period to establish a national network of "uplift incubators" to assist new businesses and small government contractors with the goal of sparking economic development in underrepresented communities and
- \$200 million over 10 years to provide cash grants of at least \$100,000 to growth accelerators to expand their capabilities to assist small businesses focused on technology.

The act would provide paid leave for the first time to all U.S. workers who are new parents, dealing with their own serious medical conditions or in need of leave to care for a loved one with a serious medical issue.

The BBB act invests about \$390 billion to fund universal prekindergarten programs for all 3- and 4-year-olds and to improve access to affordable child care. The act would ensure that nearly all families of four earning up to \$300,000 would pay no more than 7% of their income on child care and provide funding for child-care providers to raise wages for their workers and add staff to serve more families.



Share this graphic and link in emails and social media for a better drug-pricing policy for patients.

Some compromise reached on drug price fixing in BBB act

The Build Back Better Act would allow the federal government to negotiate prices with drug companies for a small number of high-cost drugs covered under Medicare Part D (starting in 2025) and Part B (starting in 2027). The negotiation process would apply to no more than 10 (in 2025), 15 (in 2026 and 2027) and 20 (in 2028 and later years) single-source brand-name drugs or biologics that lack generic or biosimilar competitors. These drugs would be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The negotiation process would also apply to all insulin products.

The legislation exempts from negotiation drugs that are less than 9 years (for small-molecule drugs) or 13 years (for biological products) from their FDA approval or licensure date. The legislation also exempts "small biotech drugs" from negotiation until 2028, defined as those which account for 1% or less of Part D or Part B spending and account for 80% or more of spending under each part on that manufacturer's drugs, as well as drugs with Medicare spending of less than \$200 million in 2021 (increased by the CPI-U for subsequent years) and drugs with an orphan designation as their only FDA-approved indication.

An excise tax would be levied on drug companies that do not comply with the negotiation process. Manufacturers would face an escalating excise tax on total sales of the drug in question, starting at 65% and increasing by 10% every quarter to a maximum of 95%. In addition, manufacturers that refuse to offer an agreed-upon negotiated price for a selected drug to “a maximum fair price eligible individual” (i.e., Medicare beneficiaries enrolled in Part B and/or Part D, depending on the selected drug) or to a provider of services to maximum fair price eligible individuals (such as a physician or hospital) would pay a civil monetary penalty equal to 10 times the difference between the price charged and the maximum fair price.

[Read more from the >>
Kaiser Family Foundation](#)

WTO meeting, TRIPS discussion put off indefinitely

Due to the outbreak of the omicron variant of Covid-19, the World Trade Organization has postponed indefinitely its in-person ministerial conference that was to be held from Nov. 30 to Dec. 3 in Geneva and include further discussions of the TRIPS waiver.

Initially proposed by India and South Africa in October 2020, the TRIPS waiver would enable companies around the world to produce COVID-19 products and technologies currently protected by intellectual property rights.

As currently proposed, It would waive rules in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights that apply to patents, undisclosed information (such as information submitted to regulatory agencies or protected as trade secrets), copyright and industrial designs. And it would last for at least three years from the date the waiver is adopted and then be reviewed annually.

The TRIPS waiver is now cosponsored by 63 countries and supported by well over 100 of the World Trade Organization's 164 member states. The US signaled its support for a waiver in May (limited to vaccines) and reiterated that support as recently as Nov. 26, but it has not formally cosponsored the proposal. The European Union, the United Kingdom and Switzerland continue to oppose it, and Germany is a particularly staunch opponent.

This WTO pause is happening as two competing narratives about vaccine supplies in developing nations fight for dominance. One viewpoint accuses developed nations of hoarding vaccine supplies, not meeting commitments to deliver vaccines and doling out third doses to their citizens while most people in the developing world have not had their first. The other side points out that developing nations are struggling to store and distribute vaccines effectively, discarding millions of expired doses and postponing delivery of new supplies.

Analysis: Paper prescribing info chews up 12 million trees a year

The Environmental Paper Network has joined the [Alliance to Modernize Prescribing Information](#) and NCBI in supporting the modernization of prescribing information used by pharmacists and physicians by eliminating the paper prescribing information included in the bulk packaging of medicines. The EFN writes

"When considering that there are more than three billion prescriptions filled each year and the paper prescribing information sent to prescribers averages 30 pages in length – which is roughly 90 billion sheets of paper, the impact of this waste is significant.

EPN analyzed this waste through our Paper Calculator and the results were stunning. It takes 12,000,000 trees each year to produce these paper prescribing information labels, disturbing 186,000 acres of land – or 141,000 football fields. The greenhouse gas impact is the equivalent of adding 816,000 cars to our roads, year after year. The water consumption required to produce these labels is nearly 11 billion gallons, enough water to operate 7.7 million clothes washers for an entire year."

[More >>](#)



Duke's Califf nominated for 2nd stint as FDA commissioner

President Joe Biden will nominate Duke cardiologist Rob Califf, M.D., to be the next commissioner of the Food and Drug Administration, a job Califf previously held during the Obama administration.

Prior to running the agency, Califf served as the FDA's deputy commissioner for medical products and tobacco. He was a professor of medicine and a vice chancellor for clinical and translational research at Duke University before joining the FDA. He was also the director of the Duke Translational Medicine Institute and is the founding director of the Duke Clinical Research Institute.

[More >>](#)

Biden nominates chief IP negotiator

President Biden has nominated Christopher S. Wilson to be chief innovation and intellectual property negotiator in the Office of the United States Trade Representative.

[More >>](#)

NCBIO Updates



Sign up now for NCBIO's Clinical Trials Forum!

Join us virtually or **in-person** at the NC Biotechnology Center for a panel discussion focusing on the patient's experience in clinical trials. This event builds on the patient conversation from our Annual Meeting where we discussed the role of the patient in drug development. The panel discussion will be moderated by Matthew Roberts, leader, health care and public policy practice, Nexsen Pruet. Panelists include:

- Heather-Elizabeth Brown, patient;
- LaQuinta Jernigan, executive vice president, North America, mdgroup;
- Renée Leverty, program lead, stakeholder engagement, Research Together, and program lead, Duke Clinical Research Institute;
- Katie Shaw, senior director, global patient & site solutions, IQVIA; and
- Eric South, founder, Gladiator Project, and glioblastoma multiforme patient.

Thank you to [Aon](#), [Hughes Pittman & Gup-ton](#) and [Nexsen Pruet](#) for sponsoring this forum.

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NCBIO welcomes new members

At its Nov. 18 meeting, the NCBIO Board of Directors voted to accept the following new members to the organization:

- [Bavarian Nordic](#), Inc. is a fully integrated vaccines company focused on the development, manufacture and commercialization of life-saving vaccines.
- [Dean Dorton](#) is one of the largest certified public accounting and professional business advisory firms in the Southeast.
- [Istari Oncology](#) is a clinical-stage biotechnology company focused on novel immuno-oncology and immunotherapy platforms for the treatment of glioblastoma and a wide variety of tumors.
- [JC Automation Corp.](#) builds highly capable and affordable solutions for the life sciences manufacturing industry in automation, control systems integration, information

technology, system integration and regulatory compliance.

- [Jones Lang LaSalle](#) is a global commercial real estate services company with offices in 80 countries offering investment services worldwide.
- [Novex Innovations](#) is a CDMO supporting the growth and development of startups and small to medium-sized companies and fills an undeserved niche in process development, regulatory support and drive to commercialization.
- [Omar Consulting Group](#) forges and manages long-term productive relations with business alliance teams, industry stakeholders, scientists and physicians in biotech and pharma to create pathways for developing and commercializing new medical therapies.
- [Qmera Pharmaceuticals, Inc.](#) is a drug development services company targeting the pharmaceutical, biotechnology and medical device sectors.
- Ribogenics, Inc. is developing small molecule RNA medicines to treat cancer, neurological disorders and rare diseases.
- [Sanesco](#) develops clinical tools for health care providers, such as neuroendocrine analytical testing, nutritional support formulas and patient-centered clinical review.

NC colleges and universities review workforce training programs with BMF members

Representatives from the NC Community Colleges' BioNetwork, the NC Pharmaceutical Services Network, BRITE at NC Central University, NC A&T University and North Carolina State University's BTEC were all on hand Tuesday, Nov. 16, at the NCBIO Biomanufacturers Forum meeting to discuss their efforts to provide biomanufacturers with a skilled workforce and the state's citizens with access to high quality positions in the industry.

Read more and access a recording of the meeting [here](#).

Member news briefs

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

AskBio's Co-founder and CEO Sheila Mikhail has been named national Entrepreneur of the Year by Ernst & Young, the accounting and business services firm. [More >>](#)

BioAgilytix officially closed the purchase of 360biolabs, which expands BioAgilytix's capabilities into first-in-human trials, early-phase clinical trials and adds additional capacity. [More >>](#)

BioAgilytix has been named to the Triangle Business Journal's Fast 50 List highlighting the fastest-growing private companies in the Triangle for the eighth time. [More >>](#)

BioCryst Pharmaceuticals, Inc. received \$350 million in new funding to further advance BCX9930, BioCryst's oral Factor D inhibitor and support additional investment in the global launch of ORLADEYO (berotralstat), a prophylactic hereditary angioedema therapy. [More >>](#)

Biogen has set an industry record as the most frequently recognized biotechnology company on the Dow Jones Sustainability World Index, earning recognition for the ninth consecutive year, more than any other biotechnology company. [More >>](#)

Biogen announced that the European Commission has granted marketing authorization for VUMERITY (diroximel fumarate) to treat adults with relapsing-remitting multiple sclerosis. [More >>](#)

Biogen's Head of Pharmaceutical Operations and Technology, Alphonse Galdes, Ph.D., called for companies to take action and treat the climate crisis like it is a health crisis. [More >>](#)

Chiesi USA promoted Polly Petrino to vice president, finance to lead during an important time of projected future growth. Petrino will lead the finance, administrative and contracting teams. [More >>](#)

Kymanox has hired Tony Perry as its chief financial officer responsible for all aspects of the company's financial strategy and operations, including accounting and financial reporting, mergers and acquisitions, treasury, tax, risk management, and budgeting and planning. [More >>](#)

IQVIA was judged a Leader by International Data Corporation in its 2021 MarketScape focused on the Worldwide Life Science Sales and Marketing Business Process Outsourcing Pharma space. [More >>](#)

Mycovia Pharmaceuticals has hired Trish Dixon as its senior director of marketing.

PPD, Inc. earned numerous honors at the 2021 PharmaTimes Clinical Researcher of the Year. The American Association of Pharmaceutical Manufacturers (AAPM) named PPD as one of the top 100 pharmaceutical manufacturers in the world.

year- in the Americas competition. Two PPD teams won gold, one team won silver and another team took home bronze. PPD clinical researchers also won silver and bronze awards in various individual categories. [More >>](#)

PPD, Inc. was named “Best Vaccine CRO of the Year” at the Asia-Pacific Vaccine Excellence Awards 2021 for its strong presence, extensive experience and quality delivery in the Asia-Pacific region. [More >>](#)

Events

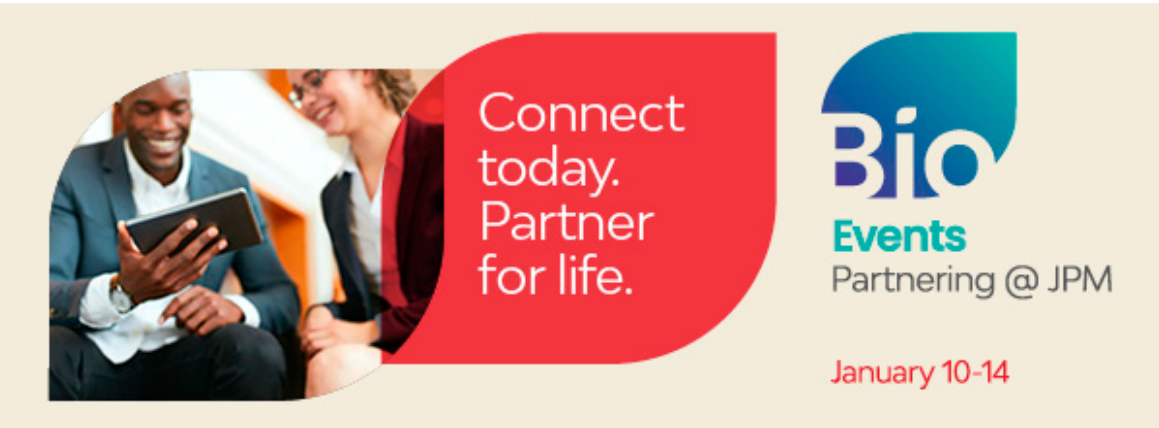


AdvaMed Cybersecurity Summit taking place virtually Dec. 6-7 | 12 - 3 p.m. ET

This year's AdvaMed Cybersecurity Summit features experts from across the medical device and healthcare cybersecurity landscape who will help you navigate this complex threat environment and the FDA regulatory requirements that continue to evolve. This year's [agenda](#) is filled with timely sessions and dynamic speakers from FDA and Industry. Register now to take advantage early bird pricing!

Contact [Amber Niebauer](#) to get 10% off registration fees!

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NCBIO members save on BIO One-on-One Partnering!

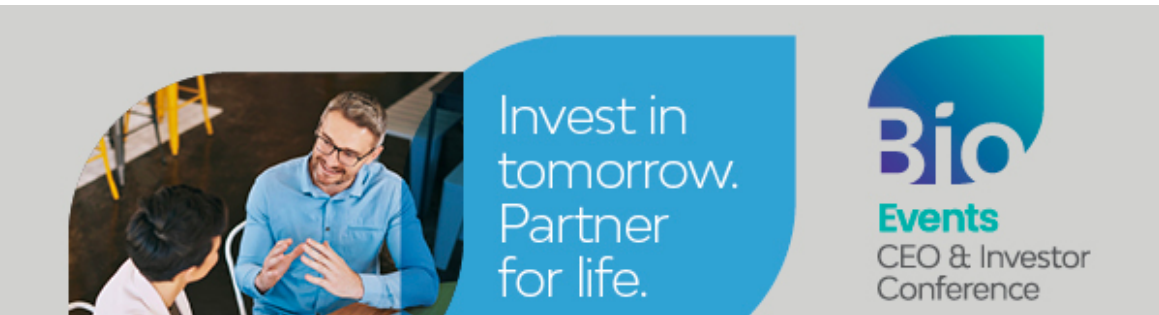
As an NCBIO member, you can save \$100 on BIO @JPM. BIO One-on-One Partnering has many features to help you make strategic connections, including:

- 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 allow you to book meetings in physical or virtual space or take advantage of BIO-provided virtual meeting links through Zoom; and
- 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.

Contact [Amber Niebauer](#) to get \$100 off the registration fee.

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BIO is Bringing Partnering, Networking & Learning Back to NYC

Join BIO from Feb. 14-17 for the 2022 BIO CEO & Investor Conference. It's a vital opportunity for meaningful networking and important programing about topics that matter.

- Powered by BIO One-on-One Partnering: one of the most advanced and easy-to-use partnering platforms to maximize your connections, whether in-person or virtually
- Policy: Implications of Biden administration health-care policy initiatives on biotech
- Business: ESG investor expectations as well as IPO and SPAC trends
- Innovation: Oncology therapeutic frontiers on the latest trends in deal-making, clinical innovations and US Congressional agenda for biotech

REGISTER NOW

NCBIO calendar

- [BTEC Analytical Methods for Raw Materials Testing \(12/1/2021 to 12/3/2021\)](#)
- [Understanding Commercialization Within Biopharma: Live Online Course hosted by BIO \(12/1/2021 to 12/2/2021\)](#)
- [How to WIN SBIR/STTR Grants Educational Seminar hosted by First Flight \(12/2/2021\)](#)
- [2022 State of States: Policy Priorities & Updates hosted by Bristol Myers Squibb \(12/2/2021\)](#)
- [Growing Trust in Innovation hosted by BIO \(12/2/2021\)](#)
- [Leveraging JPM Week to Achieve Business Development Goals \(12/2/2021\)](#)
- [GET2KNOW NC TECH \(12/3/2021\)](#)
- [Cybersecurity Summit hosted by AdvaMed \(12/6/2021 to 12/7/2021\)](#)
- [NCBIO Clinical Trials Forum \(12/8/2021\)](#)
- [What Federal Contractors Need to Know For 2022 AAP Compliance hosted by Smith Anderson \(12/8/2021\)](#)
- [From Deal Announcement to De-SPAC Process hosted by BIO \(12/9/2021\)](#)
- [BTEC Protein Precipitation and Crystallization Course \(12/14/2021 to 12/16/2021\)](#)
- [Clinical Supervision Workshop Series hosted by UNC-Wilmington \(1/8/2022\)](#)
- [Annual Healthcare Conference with BIO Partnering hosted by J.P. Morgan \(1/10/2022 to 1/14/2022\)](#)



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](#).

AON

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BIO's partner, Aon, provides members with human capital services spanning employee rewards, sales force compensation and effectiveness, talent assessment, total rewards strategy and optimization and workforce analytics.

We understand the world — and workplace — have changed. This partnership allows our members to make better workforce decisions with data, analytics and advice from Aon.

Members receive the following discounts on Aon products and services:

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- Employee rewards
- Sales force effectiveness consulting
- Talent assessment
- Workforce analytics

Additional Benefits (7.5% discount):

- Compensation survey participation, including McLagan and Radford products.
- Access to select Aon articles and research, including proprietary insights from the Radford Global Compensation Database.

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Open enrollment season is here!

Here's what you need to know about employer-based health plans

We've partnered with Mercer to assist you with health care options that will benefit you and your loved ones.

During open enrollment season, many businesses are reviewing their employee benefits and health plans. In addition to cost, here are some important things to consider when selecting a health plan:



Does your health plan include popular coverage options like telehealth and mental health?

Providing employees with these and other special features will help keep them safe and happy.

Are you able to offer plans that meet the needs of everyone?

If your employees consist of multiple generations, and they probably do, consider offering multiple plan types so employees can choose the plan that works best for them.

Is your health plan competitive with other organizations like yours?

It's imperative to your company's turnover and recruitment efforts to make sure that your health plans are as good as or better than your competition.



Need help adjusting your benefits package and health care offering to your employees?

Our new and improved BIO Health Small Group Health Plans may be a great fit for your business. Even if you have gotten a quote from Mercer before, you'll want to see their nation-wide expanded offering from multiple carriers.

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