



January 2023 Update

Serving the NC Life Sciences Industry

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NCBIO This Month

- State revenue collection is up
- Congress passes spending bill, many FDA changes
- Removing barriers, achieving diversity in clinical trials
- New TEconomy report charts industry growth in NC
- [NCBIO 21-22 Year in Review](#) is online
- NCBIO Legislative Reception is March 1

... and more

Dear NCBIO members,

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I hope you all had a joyful holiday and were able to spend time in the company of friends and loved ones. A new year brings a new face to NCBIO, **Turquoise Burke**, who joins our team as office manager. Please look for her, and introduce yourself at the next NCBIO event.

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The life sciences industry in North Carolina has continued to thrive and propel the state's economy forward with nearly 800 companies now operating in the state. In 2022, we achieved a number of policy successes, including securing recurring NC budget dollars for the One NC Small Business Program, which will help our small emerging members who successfully compete for SBIR federal grants. We also began developing a strategic plan for NCBIO to better support our members, and we launched an effort to embed diversity, equity and inclusion within our offerings and create DEI resources for our members' benefit.

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The strong growth of the industry is increasing pressure for the state to focus on the issues that limit continued expansion. Some of the most salient are wastewater capacity, workforce development efforts, taxation and access to venture capital in the state. These will be areas of focus for NCBIO in 2023 and in the years that follow.

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At the federal level, we will continue to work closely with our national partners to examine the effect the Inflation Reduction Act has on drug pricing and explore mitigation measures. We will continue to work on full R&D tax credits, IP concerns and other innovation-protecting policies.

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Finally, we have raised nearly \$230,000 in gifts and pledges toward our goal of \$250,000 for the Sam Taylor Memorial Scholarship in the Life Sciences at the NC Community College System. We would like to offer a special thank you to **Frankel Staffing Partners**, who doubled their gift to the fund in honor of their clients and in lieu of the gifts the firm

NCBIO Sustaining Members



NCBIO Supporting Members



in honor of their clients and in lieu of the gifts the firm normally distributes at the end of the year.

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Sincerely,

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Laura Gunter
NCBIO President



STATE UPDATES

North Carolina revenues already \$1.2 billion ahead of schedule

North Carolina government revenues keep exceeding projections, despite broader worries about an economic downturn.

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Gov. Roy Cooper's state budget office and the Legislature's Fiscal Research Division agreed that revenues are \$1.2 billion above the target through Nov. 30, the first five months of the fiscal year, officials said this week. That's about 10% more than expected, state budget Director Kristin Walker said.

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All kinds of tax collections are up, the Office of State Budget and Management said, including individual and corporate income taxes, sales taxes and taxes on investments. This revenue increase arrived before the holiday shopping season, which can affect sales tax levels.

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The executive and legislative branch officials cautioned that the risk to the forecast is backloaded to the second half of the fiscal year, particularly when income tax payments arrive in mid-April. But the \$1.2 billion overage remains large, even when compared to an annualized approved state budget of nearly \$28 billion. [More at Associated Press](#)



NATIONAL UPDATES

Omnibus bill funds government through 2023

Congress approved a \$1.7 trillion Consolidated Appropriations Act, 2023 omnibus bill on Dec. 23 to fund the federal government through September. The bill, which is more than 4,000 pages long, includes \$772.5 billion for non-defense discretionary programs and \$858 billion in defense funding.Â

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The package provides more money for National Institutes of Health, the Centers for Disease Control and Prevention and the Assistant Secretary for Preparedness and Response. The funds are intended to speed the development of new therapies, diagnostics and preventive measures, beef up public health activities and strengthen the nation's biosecurity by accelerating development of medical countermeasures for pandemic threats and fortifying stockpiles and supply chains for drugs, masks and other supplies.Â

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The FDA could require druamakers seeking speedy approvals of new treatments to begin

The bill would require drugmakers seeking speedy approvals of new treatments to begin confirmatory testing before gaining the agency's clearance. The legislation also expedites the process for withdrawing conditionally approved drugs. These are changes some lawmakers wanted to see in the PDUFA reauthorization earlier this year.

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The bill provides funds to modernize and strengthen the supply chain for vital medical products. The government will back activities to support, maintain and improve domestic manufacturing surge capacity. This includes the use of advanced manufacturing and platform technologies to try to increase the availability of products that can be used to counter a pandemic or epidemic via contracts, grants or cooperative agreements to ensure rapid production.

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The supply chain efforts in the bill include considerations for appropriate manufacturing capacity and capability, as well as a focus on how modifications may affect the availability of products in the health care system and an assessment of the current supply chain, a look at redundancies, domestic manufacturing capacity and current vulnerabilities. Bolstering the strategic national stockpile is another goal outlined in the bill with the government seeking assurances that drugs and other supplies can be manufactured domestically and be rapidly produced and stored.

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A bipartisan package of reforms from the PREVENT Pandemics Act championed by Sen. Richard Burr is included and seeks to improve the country's preparation for the next pandemic. That proposal would set up a mission control in the White House to coordinate the federal response to outbreaks and require Senate confirmation of the Centers for Disease Control and Prevention director. Lawmakers agreed to remove from the package a provision requiring a sweeping nonpartisan analysis of the nation's COVID response.

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The funding package contains a [host of policy changes](#) for the FDA, including the following:

- new cybersecurity requirements for medical devices with an exemption for legacy products
- a waiver of the yearly MDUFA annual establishment fee for medical device companies with less than \$1 million in annual sales
- improvements to the Accelerated Approval pathway that provides flexibility and clarifies requirements
- a provision that clarifies FDA's authority to tentatively approve a subsequent interchangeable biosimilar biological product while a first interchangeable product's period of exclusivity is pending
- a provision to analyze drug development for rare disease that should be helpful for gauging areas of need
- a requirement that the FDA convene a public workshop to discuss best practices for generating scientific data to support the development of cell therapies
- provisions to strengthen the FDA's Emerging Technology Program
- a new designation program allowing the FDA to designate specific "advanced manufacturing" methods a sponsor can use across multiple product lines within the same context-of-use without having to resubmit data to FDA for validation
- requirements for the FDA to update guidance specifying the form and content of diversity action plans, to convene public workshops to enhance clinical study diversity and to annually summarize information related to the diversity action plans
- a requirement for the FDA to issue draft guidance to modernize and provide for decentralized clinical trials
- a requirement for the FDA to issue or revise guidance on the use of real-world data and real-world evidence to support regulatory decision making

Provisions of the proposed VALID Act, which would have created a new category of medical products called in vitro clinical tests and allowed the FDA to oversee tests regardless of whether they came from clinical laboratories or from commercial companies, were not included in the omnibus bill. A push to have the PASTUER Act, which would have helped bolster the antibiotic market to combat an increasingly serious threat of antimicrobial resistance, included in the omnibus bill was also unsuccessful.

North Carolina representatives take leadership roles in Congress

Rep. Richard Hudson, a Republican from Moore County, has been named chairman of the National Republican Congressional Committee. That spot atop the GOP campaign committee makes Hudson fourth in line to be House speaker.

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Rep. Virginia Foxx, a Republican from Watauga County, received a waiver to bypass a term-limit rule in order to retake the top spot as chairwoman of the House Education and Labor Committee. Foxx faces a challenger for the position.

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Deborah Ross, a Democrat from Wake County, has been named one of the party's chief deputy whips by Democratic Whip Katherine Clark.

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[More at News & Observer](#)

NCBIO Updates



Moderator Abby Emanuelson of Care4Carolina, Erin Finot of IQVIA Biotech, Julie Harrell of Ultragenyx and Rose Blackburne of PPD, part of Thermo Fisher Scientific.

Recruiting patients the focus of Clinical Research Forum

An expert panel explored the current state of clinical trial participation at the NCBIO Clinical Research Forum held Tuesday, Nov. 29. The panel was moderated by Abby Emanuelson, executive director of Care4Carolina, and comprised

- **Rose Blackburne**, M.D., vice president, global product development, PPD, part of Thermo Fisher Scientific;
- **Erin Finot**, vice president, immuno-oncology and cell and gene therapy, IQVIA Biotech; and
- **Julie Harrell**, director, patient enrollment liaisons, Ultragenyx.

Panelists talked about ways to lower the barriers that stop patients from participating in clinical trials and discussed strategies for achieving diversity. They also explored the role of patient advocates and gave special consideration to efforts focused on rare diseases.

[Sikich](#), [Ultragenyx](#) and [uMotif](#) sponsored the forum.Â

[More at NCBIO](#)

TEconomy report highlights North Carolina's life sciences growth

The global turmoil wrought by the COVID pandemic has produced a positive run for North Carolina's life sciences community, according to a new report commissioned by the North Carolina Biotechnology Center.

- Since 2018, life sciences employment in the state grew by 13%, compared to just 3% in the overall private sector.
- Since 2018 North Carolina has experienced a 38% increase in life sciences-related business establishments, well outpacing national growth at 14%.
- NCBiotech tracked 63 expansion and relocation growth announcements during the last two fiscal years. These efforts have the potential to create 9,115 new jobs in the state.
- North Carolina's life sciences companies provide high quality jobs with average annual wages in 2021 of \$112,000, nearly double the \$60,000 private-sector average.
- The state's life sciences sector generates \$2.4 billion in state and local government revenues.

Every two years for the past fourteen, NCBiotech has published this examination under a contract with TEconomy Partners, the highly respected Columbus, Ohio-based consulting firm. The newly published analysis, "Evidence & Opportunity 2022: Impact of Life Sciences in NC," documents why North Carolina continues to garner global admiration in the field.Â

Â [More at NCBiotech](#)

Gene therapy pioneer Jude Samulski awarded for breakthrough innovations

The European Society of Gene and Cell Therapy, a nonprofit organization supporting scientists and clinicians, recognized gene therapy pioneer and entrepreneur Jude Samulski, Ph.D., with its inaugural Founders Award.

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Samulski is a professor of pharmacology at the University of North Carolina's School of Medicine, as well as the co-founder in 2001 and chief scientific officer of Asklepios

BioPharmaceutical, a gene therapy company based in North Carolina’s Research Triangle Park. He was also the director of UNC’s Gene Therapy Center for 25 years.

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The ESGCT honored Samulski for his work in engineered recombinant adeno-associated virus vectors, which can transport gene therapies into cells to treat various diseases. He began his research in AAV 40 years ago as a graduate student at the University of Florida. There, he cloned and rescued AAV from plasmid in human cells, which laid the groundwork for various innovations in the gene therapy space. Today, he holds nearly 500 AAV-related technology patents and has helped advance therapies for a number of ailments, including hemophilia, Duchenne muscular dystrophy, and congestive heart failure.

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[More at NCBiotech](#)

BioWork added to essential NC credentials

The BioWork certificate has been added as an essential manufacturing credential to list of NC Workforce Credentials.

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The [NC Workforce Credentials](#) list highlights nondegree credentials (e.g., certificates, industry-recognized certifications, licenses) that are below the associate’s degree level, are associated with in-demand occupations and are valued by employers, meaning they give hiring preference to those holding the credential.

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The [BioWork](#) certificate program teaches the foundational skills needed to begin a career as a process technician for a biotechnology, pharmaceutical or chemical manufacturing company. It is currently offered by 11 community colleges around the state.

NCBIO Member News

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

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Baebies has received FDA 510(k) clearance for its rapid, point-of-care test for glucose-6-phosphate dehydrogenase deficiency. [More >>](#)

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Beam Therapeutics Inc. announced that the FDA has lifted the clinical hold and cleared the Investigational New Drug application for BEAM-201 for the treatment of relapsed/refractory T-cell acute lymphoblastic leukemia/T-cell lymphoblastic lymphoma. [More >>](#)

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Biogen Inc. announced the European Medicines Agency has accepted the Marketing Authorization Application for review of tofersen, an investigational drug for the treatment of superoxide dismutase 1 amyotrophic lateral sclerosis. [More >>](#)

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Biogen Inc. announced that Priya Singhal, M.D., currently head of global safety and regulatory sciences and interim head of research & development, has been promoted to executive vice president, head of development. [More >>](#)

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Biogen Inc. and **Sage Therapeutics** announced the completion of the rolling submission of a New Drug Application to the FDA for zuranolone in the treatment of major depressive disorder and postpartum depression. [More >>](#)

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Chimerix announced the successful launch of the ONC201 Phase 3 ACTION study at the recent Society for Neuro Oncology Conference. [More >>](#)

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G1 Therapeutics, Inc. provided initial results from a 24 patient Phase 2 mechanism of action trial showing favorable alterations in the tumor microenvironment from a single dose of trilaciclib monotherapy in patients with early-stage triple negative breast cancer. [More >>](#)

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Grifols has been included in the Dow Jones Sustainability World Index for the second consecutive year and the Dow Jones Sustainability Europe Index for the third straight year. [More >>](#)

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Novan, Inc. announced that its subsidiary EPI Health, LLC has entered into an exclusive license agreement with Sato Pharmaceutical Co., Ltd. granting Sato the right to develop, manufacture and market RHOFADÉ for rosacea in Japan. [More >>](#)

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PPD, the clinical research business of **Thermo Fisher Scientific Inc.**, has been named Best Vaccine CRO at the Asia Pacific Vaccine Excellence Awards 2022 organized by IMAPAC for the second consecutive year. [More >>](#)

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PPD, the clinical research business of **Thermo Fisher Scientific Inc.**, has earned numerous recognitions, including the highest honor of Clinical Research Company of the Year at the 2022 PharmaTimes Clinical Researcher of the Year-The Americas competition. [More >>](#)

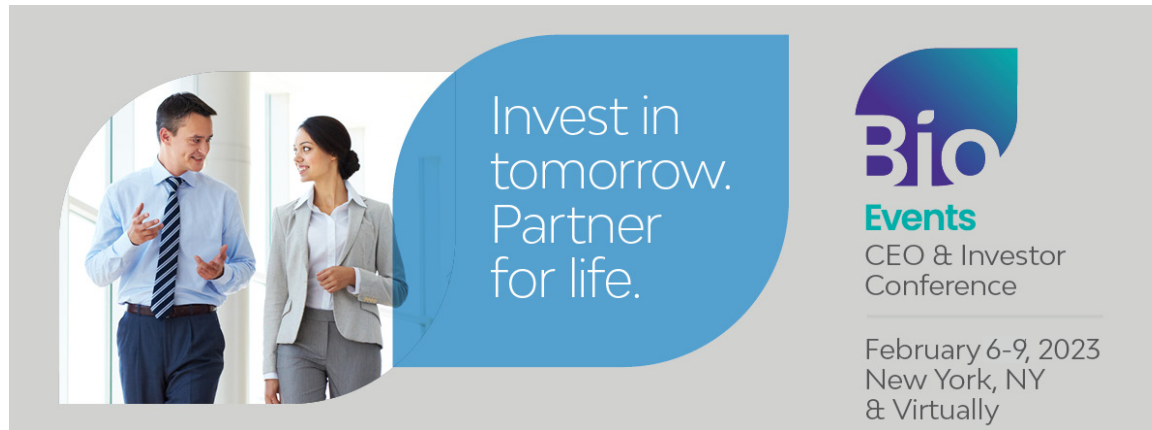
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United Therapeutics has been named on Newsweek’s list of America’s Most Responsible Companies 2023. [More >>](#)

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Xilis added four members to its newly formed Scientific Advisory Board: Mike Varney, Ph.D., chairman; James Allison, Ph.D.; Padmanee Sharma, M.D., Ph.D.; and David Tuveson, M.D., Ph.D. [More >>](#)

Events



Stay Ahead and Request Your Meetings

Feb. 6-9 | New York Marriott Marquis and Virtually

Start using BIO One-on-One Partnering today to connect with investors, business development executives, and service providers. At the BIO CEO & Investor Conference, you will have access to two days of in-person meetings in New York, Feb 6-7, followed by two days of virtual partnering to introduce your pipeline or products and seek new investment opportunities. The BIO One-on-One Partnering system makes it easy to arrange meetings during the conference. Explore powerful, easy-to-use features including:

- Efficient User Experience: identify ideal prospects in minutes with advanced search filters
- Automated calendar updates for up-to-date meeting information
- Extended Value: system access continues for a year after the event for follow-up

REGISTER NOW



Join NCBIO members and legislators for an evening reception highlighting the state's life sciences industry. You will have the opportunity to discuss workforce training, life science program funding, innovation and tax policy and other topics of interest with legislators and policy makers.

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If you are interested in sponsoring this event, please contact NCBIO Membership Director [Natacha Janvier](#).

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CED Venture Connect pitch applications open

[Company applications](#) are now open for high growth startups interested in pitching at Venture Connect 2023. If selected, your company will have the opportunity to gain premium exposure as you take the stage in front of investors, corporate partners, ecosystem resources, and potential talent.

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Venture Connect 2023 is a one-of-a-kind capital conference that brings together the tech and biotech communities under one roof in North Carolina. This two-day event aims to highlight innovation across the Southeast and create an environment where powerful connections are made. If you are an early stage or scaling company seeking investment, talent or customers, we encourage you to apply.Â

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Deadline to apply is Jan. 13.

APPLY NOW



The North Carolina Institute of Political Leadership's Fellows Program is a comprehensive, nonpartisan training program for aspiring public leaders interested in understanding how North Carolina politics works.

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The three-month program is offered in the fall and spring of each year and combines five weekends of in-person instruction and six virtual seminars. Each class of 15 to 20 individuals represents the state's demography and partisan disposition. Learn from our expert faculty on subjects including

- Campaign strategy: Planning, Budgeting, Polling, Scheduling
- Communication: Public Speaking, Messaging, Handling the Media
- Fundraising: Growing Your Network, Making the Ask
- Coalition Building: Successful
- Policy-Making: Coalitions, Negotiating
- Fundamentals: Ethics, Voter Demography, Managing Consultants

Applications for the spring 2023 class close on **Jan. 18**.

LEARN MORE

NCBIO calendar

- [21st Annual Economic Forecast Forum hosted by NC Chamber \(1/6/2023\)](#)
- [41st Annual Healthcare Meeting hosted by JPM \(1/9/2023 to 1/12/2023\)](#)
- [The Future of Biomimicry hosted by NC State University \(1/20/2023\)](#)
- [Precision Medicine World Conference \(1/25/2023 to 1/27/2023\)](#)
- [Nagoya University Tech Roundtable \(1/26/2023\)](#)
- [Outlook for Tech hosted by NC TECH \(2/3/2023\)](#)
- [CEO & Investor Conference hosted by BIO \(2/6/2023 to 2/9/2023\)](#)
- [Virtual Internship, Co-op, and Early Talent Career Fair - Employers Must Register by Jan. 10 \(2/7/2023\)](#)

BIO Business Solutions

**Extensive Offering of Late Model
State-of-the-Art Lab Instruments from**



NCBIO members, don?t miss an auction opportunity of late model lab instrumentation. Our BIO Business Solutions partner ALT is hosting an online auction of state-of-the-art equipment from Rubius Therapeutics Cambridge, MA Lab. Bids open January 9.

LEARN MORE



Start the new year off right with BIO Business Solutions

It?s a new year. Are you reviewing your company?s operational and service contracts?Â As you think about renewing or upgrading services, consider the programs already available to you through your NCBIO membership.Â
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From lab and clean room services to insurance and HR solutions, we have you covered. Visit bio.org/save and join the 4,700 life science companies already saving on business-critical services.

LEARN MORE




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