

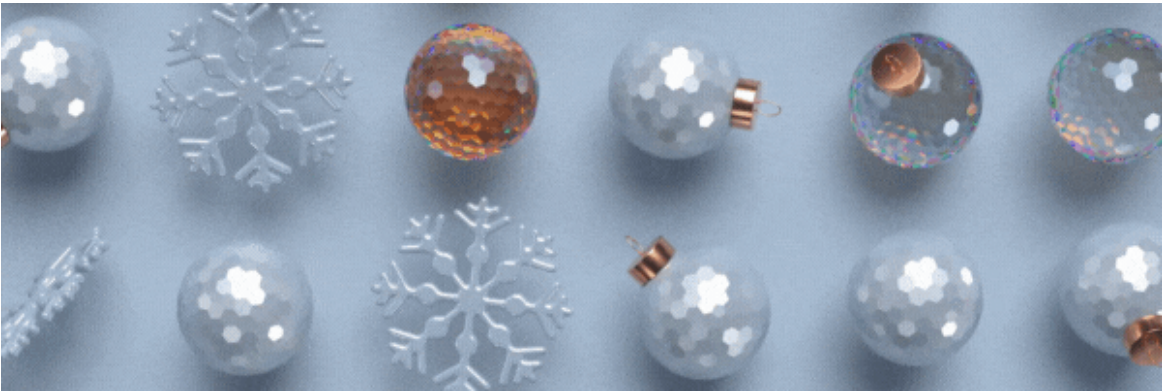


December 2022 Update

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NCBIO This Month

- Removing barriers, achieving diversity in clinical trails
- [NCBIO 21-22 Year in Review](#) is online
- Midterm election roundup
- New Dems question TRIPS waiver expansion
- Welcome to new members
- Request your BIO International discount code NOW!

... and more



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.

NCBIO Sustaining Members



NCBIO Supporting Members





STATE UPDATES

Caucus co-chairs re-elected, GOP nears two-thirds majority

North Carolina Republicans came within one seat in the House of gaining a supermajority in the state General Assembly. The GOP did gain a supermajority in the North Carolina Senate, holding 30 of 50 seats. A supermajority is when a party holds two-thirds of the seats in the legislature, which gives it enough votes within the party to override a veto from the governor.

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Life Science Caucus co-chairs Sen. Paul Newton (R-Cabarrus, Union), Sen. Mike Woodard (D-Durham, Granville, Person), Rep. Robert Reives (D-Chatham, Durham) and Rep. Donna McDowell White (I-Johnston) were all reelected.

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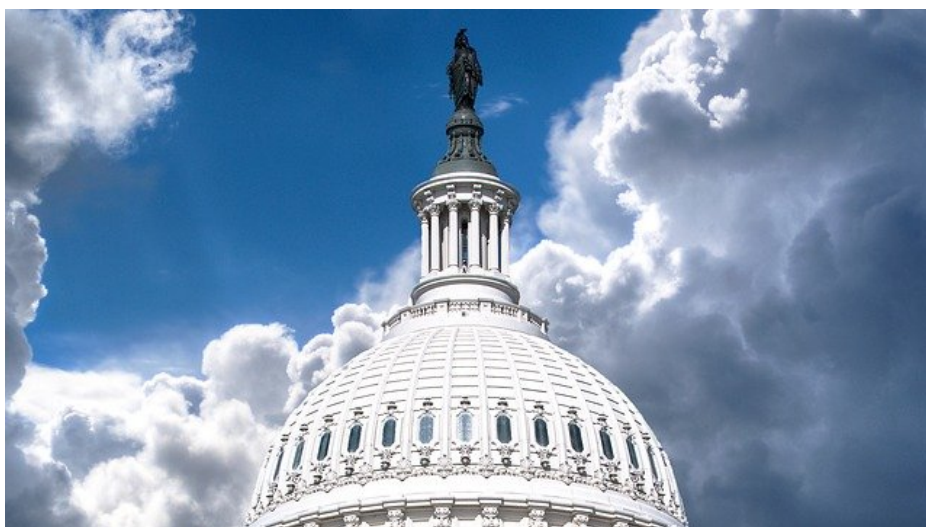
The Senate Republican Caucus chose Newton to be Senate majority leader. Reives has said he will see another term as House minority leader. House Democrats will meet to select their leaders on Dec. 5.

10 N.C. community colleges to receive \$15 million for biosciences

During the second-to-last State Board of Community Colleges meeting of 2022, board members allocated more than \$16 million to support the bioscience industry.

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The board approved the allocation of nearly \$16.5 million to 10 community colleges and the system office to support the bioscience industry sector. The funds came from the Build Back Better Regional Challenge Grant from the U.S. Department of Commerce Economic Development Administration. \$15 million will go to the 10 colleges, and \$1.4 million will be retained by the system office to administer the grant. [More at EdNC](#)



NATIONAL UPDATES

Democrats control the Senate and Republicans the House after midterm elections

After the Nov. 8 midterm elections, the U.S. House of Representatives will be controlled by Republicans by a slim majority. Republicans currently hold 220 seats to the Democrats' 213 with 218 seats needed to form a majority. Vote counting continues in some states, and the last two seats are expected to go to Republicans.

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Republican U.S. Rep. Ted Budd won North Carolina's open Senate seat. The three-term House member defeated Democrat Cheri Beasley and will succeed retiring GOP Sen. Richard Burr.

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In House races, Democrat Wiley Nickel defeated Republican Bo Hines in North Carolina's 13th Congressional District. The newly redrawn 13th District was considered one of the most competitive in the state. The district includes the southern half of Wake County, all of Johnston County and parts of Harnett and Wayne counties. Nickel's win creates a 7-7 split in the state's delegation, marking the best showing for state Democrats after a decade of trailing the GOP in an otherwise closely divided state.

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In another key area, Democrat Don Davis, who served six terms in the N.C. Senate, has become the new representative for North Carolina's 1st Congressional District. Davis replaces retiring Rep. G.K. Butterfield, who served as a congressman for almost 20 years. District 1 runs from Rocky Mount to Elizabeth City and borders Virginia. Democrat Valeria Foushee, who has served in both the NC House and Senate, succeeds long-time Rep. David Price in the 4th Congressional District.

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Democrats have retained Senate control for the next two years with 50 seats and the tie-breaking vote of Vice President Kamala Harris. Overall, the political parties each held their current seats, except for one Democratic pickup in Pennsylvania with John Fetterman's defeat of Mehmet Oz. A runoff in Georgia for the final Senate seat between incumbent Sen. Raphael Warnock (D) and Herschel Walker (R) is pending, leaving one seat still undecided.

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Congress is back in session as it needs to finalize the appropriations process (likely in an omnibus package that will have lots of legislative measures tacked on) and the National Defense Authorization Act, among other issues.

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The 118th Congress will be sworn in on Jan. 3, 2023.

Ross, New Dems warn against expanding TRIPS waiver

A group of 14 House New Democrats, including NC Rep. Deborah Ross, told U.S. Trade Representative Katherine Tai that a World Trade Organization decision on intellectual property rights for COVID-19 vaccines could have "unintended adverse consequences" if extended to tests and treatment.

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In a Nov. 10 letter to Tai, the lawmakers said they were "concerned that an extension of the TRIPS waiver for COVID-related therapeutics and diagnostics will have unintended adverse consequences, such as hampering American manufacturing and shifting jobs to foreign countries." The signatories include House Ways & Means Committee members Bradley Schneider (IL), Ron Kind (WI), Stephanie Murphy (FL), Stacey Plaskett (VI) and Terri Sewell (AL).

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"The expansion of a TRIPS waiver risks the transfer of innovative technologies and jobs to foreign countries. As you formulate the U.S. position on extending the TRIPS waiver to COVID-related therapeutics and diagnostics, please consider these possible consequences of your decision," the authors wrote. They asked Tai to respond to seven questions asking about the effect of the TRIPS waiver on vaccine supply and on American businesses along with possible alternatives for meeting the administration's goals.

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"Coming on the heels of the [bipartisan Senate letter](#) on the same subject, it is clear that opposition to the expansion of the TRIPS waiver to therapeutics and diagnostics is bipartisan," says David Lachmann, BIO's senior director of federal government relations. NC Senators Richard Burr and Thom Tillis signed last month's Senate letter.

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The New Democrat Coalition is made up of more than 94 Democrats who consider themselves to be supportive of economic growth, innovation and fiscally responsible policies and seek to bridge the gap between left and right by challenging outmoded partisan approaches to governing.Â

DHHS expected to extend COVID emergency

The U.S. Department of Health and Human Services signaled it will extend the COVID-19 public health emergency beyond Jan. 12.

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Many health care stakeholders recently urged the Biden Administration to maintain the PHE and related policies through the winter to help address a potential COVID surge and to grant states more time prepare for the Medicaid redetermination process slated to restart once the emergency ends. The move also provides the telehealth industry additional time to convince Congress to further extend, or make permanent, regulatory flexibilities that vastly expanded virtual care during the COVID-19 pandemic.

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In the past, HHS has extended the PHE in 90-day increments, so the PHE is now expected to be extended until mid-April. HHS most recently extended the PHE on Oct. 13, which carries the emergency through Jan. 12. Â

Senate passes fast-track patent program for humane inventions

The Senate passed bipartisan legislation Nov. 28 that would codify a U.S. Patent and Trademark Office program to accelerate patent reviews that address global humanitarian needs.

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The measure (H.R. 5796), known as the Patents for Humanity Act, would put into law a pilot program that provides an acceleration certificate to expedite patent reviews and appeals. The annual competition provides awards in five categories: medicine, nutrition, sanitation, household energy, and living standards.

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The Senate passed the bill by unanimous consent as amended; the House passed a similar version earlier this year with broad support. The bill now goes back to the House.

NCBIO Updates

NCBIO board visits Wake Tech, welcomes new members

The NCBIO Board of Directors met Thursday, Nov. 17, at the Wake Tech RTP Campus.

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Members of the Board's Executive Committee were approved. They are Neal Fowler (chairman) of Pathalys Pharma, Tom Adams of Pairwise, Daniel Amburn of UCB, Sinu Bhandaru of Precision Biosciences, Chris Capel of Smith Anderson, Bill Edwards of Merz, Tom Fagley of Hughes Pittman & Gupton, Bennett Love of BioKier, Mike McBrierty of Biogen, Julie Meigs of Womble Bond Dickinson, Scott Sewell of Cook Medical, Susan Thompson of IQVIA and Christine Vannais of FUJIFILM Diosynth.

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The board was updated on the organization's strategic planning process and budget, the value afforded by the BIO Business Solutions program, state and federal policy goals and the status of the Sam Taylor Scholarship Fund, which has received \$225,000 in gifts and pledges.

The board unanimously approved and welcomed the following new members:

- [AES Clean Technology's](#) sole focus for over 35 years has been providing cleanrooms and critically controlled environments.Â
- [Clancy & Theys](#) is headquartered in Raleigh and known nationwide for its excellence in the construction industry and is among the nation?s Top 100 CM at-Risk providers.
- [E4H Architecture's](#) future-focused strategists and visionary health architects create flexible, state-of-the-art facilities designed to enhance the well-being of patients, staff and families.
- [Facility Logix, LLC](#) one of only a few leading facility-related consulting services firms in the country that specializes only in the life sciences industry.
- **GXP Storage, LLC** provides flexible off-site GXP compliant storage in restricted access facilities located in North Carolina to meet the growing needs of our life science clients.
- [IngateyGen, LLC](#) works to deliver innovative, allergen-free peanuts with improved safety and nutritional value that offer enhanced health and wellness benefits for consumers.
- [TeamLogic IT](#) is a national provider of technology services and solutions for businesses of all kinds.Â
- [McGough](#) brings six generations of experience to prominent, distinctive and complex projects from renovations to new construction.
- [NAI Tri Properties](#) is a trusted partner with 29 years of experience and the local insight and industry expertise to professionally manage all your commercial real estate needs.Â
- [Neurocrine Biosciences, Inc.](#) has applied its unique insights into neuroscience to advance medicines for neurological, endocrine, and psychiatric disorders for three decades.Â
- [Oerth Bio, LLC](#) designs targeted protein modulators specifically for plant health applications by harnessing a naturally occurring protein recycling system.Â
- [PHC Corporation of NA](#) is a subsidiary of PHC Holdings Corporation, Tokyo, Japan, a global leader in development and manufacturing of laboratory equipment.
- [Sikich](#) is one of the largest CPA firms in the United States and specializes in technology-enabled professional services.
- [SpiraTec Solutions, Inc.](#) develops comprehensive process control solutions for industries such as (bio)pharmaceuticals, chemicals and petrochemicals.Â
- [TimelyText, Inc.](#) provides instructional designers, technical writers, marketing content writers, corporate communicators, and project managers on a contract basis.
- [uMotif](#) provides the next generation eCOA/ePRO and engagement platform designed to power clinical, post-marketing and real-world research.

Following the meeting, Wake Tech President Scott Ralls spoke briefly to the board and new member guests. Board members were then given a tour of the campus's new Lily Science and Technology Center, which houses the Sam Taylor BioWork lab, RTP Bio, the Fujifilm Diosynth Biotechnologies Early College Suite and the Amaen Co-Laboratory.Â



New NCBIO member representatives



Board members explore the Sam Taylor BioWork Lab

NCBiotech awards \$1.4 million in latest quarter

The North Carolina Biotechnology Center awarded 23 grants and loans totaling over \$1.4 million to bioscience companies, universities and nonprofit organizations in the first quarter of its fiscal year.

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The awards, made in July, August and September, will support life sciences research, technology commercialization and entrepreneurship throughout North Carolina. The funding will also help companies attract follow-on funding from other sources.

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Twenty-five bioscience companies that previously received loans from the Biotech Center raised \$256 million in follow-on funding from other sources in the first quarter, according to research by the Biotech Center's Life Science Intelligence staff.

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Universities received research grants totaling \$863,093 from three programs.

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Three universities and one nonprofit organization received grants totaling \$28,250 to sponsor regional events or national meetings in the life sciences.Â

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NCBiotech awarded the City of Greenville a \$100,000 Partnership Development Grant to expand the Pharma K12 program. It provides local high school graduates the opportunity to train at the NC Pharmaceutical Services Network at Pitt Community College and interview for careers at Thermo Fisher Scientific.Â [More >>](#)



Grail's Galleri named to Time's list of the Best Inventions of 2022

GRAIL's Galleri multicancer early detection test was included in Time Magazine's Best Inventions of 2022 list.

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The magazine reported that Galleri can screen for over 50 types of cancers ? about 10 times as many as can be screened for with current recommended tests. Galleri's machine learning technology looks for circulating tumor DNA from a blood draw and claims a low false positive rate and high positive predictive value. In the recent Pathfinder study, about 50% of the detected cancers were early stage. [More at GRAIL](#)

Mikhail recognized by Fierce Pharma

Sheila Mikhail, CEO and co-founder of the pioneeringÂ gene therapy company AskBio and a member of the NCBIO Board of Directors, was honored as one of 20 ?[Fiercest Women in Life Sciences 2022](#)? by industry publication Fierce Pharma.

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Mikhail was named the Overall U.S. Entrepreneur of the Year by Ernst & Young (2021), received the Distinguished Alumni Award ? Entrepreneurial from the Booth School at the University of Chicago (2022), was recognized as one of the 100 Most Intriguing Entrepreneurs by Goldman Sachs (2020), was listed on the Inc. Female Founders 100 (2020) and earned Springboard Enterprise?s Northstar Award (2019). [More at NCBiotech](#)

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. The test is run on the FINDER platform, which features a toaster-sized instrument and a disposable cartridge. [More >>](#)

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Biogen appointed Christopher A. Viehbacher as president and CEO and a member of the Board of Directors, effective Nov. 14. Viehbacher succeeds Michel Vounatsos, who had led the company since 2017. [More >>](#)

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Chiesi USA had an article published describing a health economic model comparing selective early rescue surfactant administration versus standard surfactant administration for infants with respiratory distress syndrome. [More >>](#)

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Chiesi USA is sponsoring the American Society of Health-System Pharmacists Advantage initiative to support pharmacy technician recruitment and retention. [More >>](#)

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G1 Therapeutics, Inc. closed an underwritten public offering of 7,700,000 shares of its common stock at a public offering price of \$6.50 per share, receiving \$50,050,000 in gross proceeds from the offering.Â [More >>](#)

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IQVIA announced a long-term collaboration with Clalit, the largest health services organization in Israel, to launch the first Prime Site in the country. [More >>](#)

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Kriya Therapeutics, Inc., has acquired Redpin Therapeutics, Inc., a privately held biotechnology company developing regulatable gene therapies for intractable diseases of the nervous system. [More >>](#)

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Oerth Bio and Yara International announced a first-of-its-kind collaboration applying Oerth?s novel protein degrader technology to crop efficiency applications to boost plant resilience to combat escalating climate stress impacting crop production and farm economics. [More >>](#)

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Opus Genetics announced that the FDA has cleared its Investigational New Drug application for a Phase 1/2, first-in-human clinical trial of OPGx-001 in patients with Leber congenital amaurosis resulting from biallelic mutations in the LCA5 gene. [More >>](#)

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SAS and the Regenerative Medicine Development Organization SAS are collaborating on the ReMDO RegeneratOR Test Bed, a novel regenerative medicine endeavor in North Carolina. [More >>](#)

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Smith Anderson was recognized by LMG Life Sciences in the Licensing and Collaboration category in its 2022 rankings, the only law firm headquartered in North Carolina to be included. Additionally, two Smith Anderson attorneys were recognized as Life Sciences Stars. [More >>](#)

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Events



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January 9-12, 2023

Register now and expand your business development opportunities during JPM Week Jan. 9-12

Registration for BIO Partnering @ JPM 2023 is now open. During JPM week, maximize your potential and schedule meetings with BIO One-on-One Partnering. BIO?s system allows you to use

- BIO's in-person meeting space at the San Francisco Marriott Marquis,
- your own in-person meeting space in San Francisco,
- BIO-provided Zoom links, and
- your own video call link.

Don't miss this opportunity to directly connect with partners, industry leaders and supporters. Want some prep so you can get the most out of JPM Week 2023? Check out this [Navigating Network Events webinar](#) Dec. 13 from 1-2 p.m.

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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Get your discount code before it's too late!

As an active member of NCBIO, you are eligible for a \$200 discount on premier or general registration rates for BIO International 2023. And if you redeem your code during early bird registration, your total savings may exceed \$400. Contact NCBIO Membership Director [Natacha Janvier](#) for the link to request your discount code.Â

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Codes must be requested by Dec. 19. **There are no exceptions.** Codes will be distributed to individual requesters on Jan. 13.

NCBIO calendar

- [TAXparency - Understanding Tax Credits and Incentives for Biotech Startups](#) hosted by LaunchBio (12/1/2022)
- [Expanding Reach and Impact: Using Tech to Innovate Decentralized Clinical Trials](#) hosted by LaunchBio (12/8/2022)
- [Navigate Networking Events at JPM Week](#) (12/14/2022)
- [41st Annual Healthcare Meeting](#) hosted by JPM (1/9/2023 to 1/12/2023)

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