



August 2021 Update
Serving the NC Life Sciences Industry

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NCBIO This Month

- Sam Taylor scholarship fund passes \$100,000
- State budget and economic plan
- From DC: HR3, TRIPS and cancer screening
- Wisdom from our Lab Space Forum
- Ag training at Durham Tech
- Member news

... and more



Sam Taylor scholarship fund reaches \$100,000 in gifts and pledges

Early pledges and gifts to the [Samuel M. Taylor Memorial Life Sciences Scholarship](#) in the North Carolina Community Colleges Foundation have topped \$100,000 toward our goal of a \$250,000 endowment. The scholarships will support students pursuing training and careers in the life sciences in North Carolina.

Our goal is to cover the tuition of two students in the fall of 2021 and then create an endowed fund that will support up to four students a year in 2022 and beyond. The scholarships are for students enrolled in agricultural biotechnology, biopharmaceutical technology, biotechnology, bioprocess technology, clinical trials research associate, facility maintenance technology and medical laboratory technology programs.

To contribute, make checks payable to the North Carolina Community Colleges Foundation and **write Samuel M. Taylor Memorial Life Sciences Scholarship Fund in the memo field.** Mail them to

**North Carolina Community Colleges System
ATTN Bryan W. Jenkins
200 West Jones Street
Raleigh, NC 27603-1379**

NCBIO Sustaining Members



NCBIO Supporting Members



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STATE UPDATES

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

General Assembly seeks to finalize budget by August's end

North Carolina does not yet have a state budget, a spending plan that would normally have gone into effect July 1.

The NC Senate voted in June to approve its proposed state budget (SB 105) with four Democrats joining the Republicans.

The bill incorporates the tax provisions passed by the Senate in HB 334, with one modification. The package phases out corporate income tax over the next five taxable years, beginning in 2024. It also simplifies the franchise tax base calculation, and for some taxpayers, reduces the amount of franchise tax due by eliminating the two tax bases calculated using property values. Senate lawmakers have allocated a nonrecurring \$2 million in the state budget for the One North Carolina Small Business Program to increase state grants to businesses that win federal SBIR/STTR grants. NCBIO is hopeful that the full \$2 million recurring and \$7 million nonrecurring appropriation that passed the House by an overwhelming margin will remain in the House version of the budget. This will keep it in play during the conference period.

The NC House has not yet passed its budget proposal. Speaker Tim Moore and chief budget writer Rep. Jason Saine, chair of the Appropriations Committee, have said they plan to get their budget out in early August and then spend a couple weeks hashing out the differences with the Senate in a conference budget. That means a budget could be on the governor's desk by the end of the month.

Both chambers agree on the amount they want to spend on ongoing state government operations, but the House is likely to ask for more generous spending overall, including more generous raises for state employees and teachers. The Senate budget includes 3% raises for state employees and an average of 3% raises for teachers in addition to bonuses. Tax cuts are also likely to be a sticking point between the House and Senate.

New strategic plan for economic development highlights workforce development

The North Carolina Department of Commerce released the Economic Development Strategic Plan for the State of North Carolina. The plan, titled First in Talent, recognizes that investing in North Carolina's workforce is the key to building a more prosperous and resilient economy for all North Carolinians.

The comprehensive economic development plan is a four-year plan that identifies three key goals critical to the state's economic development strategy:

- Prepare North Carolina's workforce for career and entrepreneurial success.
- Prepare North Carolina's businesses for success by growing and attracting a talented workforce.
- Prepare communities across North Carolina to be more competitive in growing and attracting a talented workforce and businesses.

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NCBIO members inform state legislators at July Life Science Caucus meeting

Caucus meeting



Representatives from G1 Therapeutics, United Therapeutics and Thermo Fisher Scientific shared insights from their companies with members of the North Carolina General Assembly's Life Science Caucus on during its meeting held Wednesday, July 21.

Caucus co-chairs Sen. Mike Woodard, Sen. Paul Newton, Rep. Donna White and Rep. Robert Reives attended, along with about a dozen other legislators and company representatives.

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NATIONAL UPDATES

Price-fixing bill H.R. 3 unlikely to proceed but ideas still a threat

There has been no movement on H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, since it was referred to a subcommittee at the end of April. While it is very unlikely that H.R. 3 will be signed into law in its entirety, some provisions of the bill are starting to show up in other proposals. NCBIO has been speaking regularly with members of the state's congressional delegation and encouraging them to oppose the bill.

In summary, the bill requires the Department of Health and Human Services to negotiate prices for certain drugs (current law prohibits DHHS from doing so). Specifically, DHHS must negotiate maximum prices for single-source, brand-name drugs that lack certain generics and that are among either the 125 drugs that account for the greatest national spending or the 125 drugs that account for the greatest Medicare spending. DHHS must negotiate the prices of at least 25 such drugs for 2024 and of at least 50 such drugs thereafter and must also negotiate prices for certain newly approved drugs and for insulin products. The negotiated prices must be offered under Medicare and may also be offered under private health insurance unless the insurer opts out.

In general, the negotiated maximum price may not exceed 120% of the average price in Australia, Canada, France, Germany, Japan and the United Kingdom. Drug manufacturers that fail to comply with the bill's negotiation requirements are subject to substantial civil and tax penalties.

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Keeping a wary eye on TRIPS waiver

The Biden administration has proposed a waiver on IP protections for COVID-19 vaccines. India, South Africa, and some U.S. partners claim a portion of the WTO Trade-Related

India, South Africa, and some U.S. senators claim a waiver of the WTO Trade-Related Aspects of Intellectual Property Rights agreement would facilitate COVID-19 vaccine development and production by other countries.

NCBIO has strongly opposed this TRIPS waiver proposal and has discussed it extensively with the state's representatives in Congress. So far, the government has taken no action to implement the waiver since voicing support for it in early May. Instead, the U.S. has taken the more sensible step of supplying U.S. vaccines directly to countries that need it rather than handing over the technology used to make it.

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NCBIO supports Medicare Multi-Cancer Early Detection Screening Coverage Act

NCBIO has been giving strong support to H.R. 1946, the [Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021](#), that was introduced in the House of Representatives in March. This bill provides for Medicare coverage and payment for multicancer early detection screening tests that are approved by the FDA and that are used to screen for cancer across many cancer types. North Carolina Representatives G. K. Butterfield, Richard Hudson and Greg Murphy are co-sponsors of the bill.

A similar bill, the [Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021](#) (S.1873), has been introduced in the Senate.

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Working to abolish outdated paper labeling for clinicians

Providing reams of outdated and wasteful paper prescribing information to pharmacists and prescribers when they can and do obtain the most up-to-date prescribing information online is a wasteful and obsolete practice that's being sustained by the paper industry lobby.

The FDA requires prescribing information to be provided on or within each package of prescription medication from which the drug is to be dispensed. The prescribing information is, of course, different than information given to individual patients.

Congress, at the behest of the paper industry and companies that specialize in printing these materials, has perennially blocked the FDA from following through with a proposed 2014 rule to eliminate the paper requirement and require electronic distribution of prescribing information.

It is time for Congress to step aside and let the FDA take the actions necessary to best serve practitioners, patients, and the environment. NCBIO is working with industry partners as part of the Alliance for Modernizing Prescribing Information and has raised the question with members of the NC congressional delegation in an effort to bring more attention to the issue.

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BIO voices testify in Congress

It was a big week for us on Capitol Hill as Michelle McMurray-Heath, M.D., Ph.D.; Phyllis Arthur, BIO's VP of infectious diseases and emerging science; and Chief Scientific Officer Cartier Esham, Ph.D., exemplified "BIO as a voice of science for science" in a trio of Congressional hearings.

- McMurray-Heath [testified](#) before the Senate Finance Committee on the need for the U.S. to strengthen its enforcement of USMCA to ensure Mexico lives up to its biotech trade commitments.
- Arthur [testified](#) before the Senate Health, Education, Labor, and Pensions Committee during a hearing on lessons learned from the COVID-19 pandemic. See what she told the Senate [here](#).
- Esham [testified](#) before the House Energy & Commerce Health Subcommittee on the need for more investment and dialogue to increase development of biopharmaceuticals for neurodegenerative diseases.

NCBIO Updates

Laura Gunter named NCBIO president





Laura Gunter, M.B.A., has been selected as the new president of NCBIO, the N.C. Biosciences Organization, succeeding longtime president Sam Taylor who died in February. Gunter has served as the organization’s executive vice president since 2020 and has filled the executive role since Taylor’s death. Gunter joined NCBIO in 2013 as director of membership development and government affairs.

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NCBIO forum offers guidance on creating new lab space



When it comes to creating lab space for a new or established business, getting your team together early and allowing plenty of time to plan are the keys to success, according to panelists assembled for NCBIO’s Lab Space Forum held online Tuesday, July 13.

The pandemic has caused employers to pause and rethink the office space needed for employees, said NCBIO President Laura Gunter as she opened the forum. Many of these employees will return to work on site, but for others, working remotely may continue. For office space that is no longer needed, employers are repurposing those spaces for expanded lab or flex space.

NCBIO assembled a panel of experts to discuss the opportunities and pitfalls that come from trying to convert office space to lab space. Krista Covey, president of First Flight Venture Center, served as moderator of a panel that included

- Sue Back, life sciences practice group lead, Davis Moore Advisors;
- Crystal Booth, regional manager, PSC Biotech;
- Pat Chisholm, senior vice president, BE&K Building Group; and
- Blake Stevens, Ph.D., vice president, science and technology, Alexandria Real Estate Equities.

The event was sponsored by [Alexandria Real Estate Equities](#), [American Laboratory Trading](#), [BE&K Building Group](#) and [Davis Moore Advisors](#).

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NCBiotech awards \$1.9M in grants, loans in latest quarter

The North Carolina Biotechnology Center awarded 21 grants and loans totaling more than \$1.9 million to universities and bioscience companies and other entities in the fourth quarter of its fiscal year.

The awards, made in April, May and June, will support life science research, technology commercialization and entrepreneurship throughout North Carolina. The funding will also help universities and companies attract follow-on funding from other sources.

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New program at Durham Tech will train students for growing jobs in plant science



A new training program at Durham Technical Community College will prepare students for good-paying entry-level jobs in North Carolina's growing agricultural biotechnology industry beginning this fall.

The program, called the Bio-Agricultural Program Readiness Opportunity, will train about 40 students in plant science over its first two years, beginning with the first 10 students in September. Durham Tech also announced a [Better Skills, Better Jobs](#) marketing campaign that aims to engage adult learners with opportunities for career changes, retraining classes, and financial support opportunities.

BioAg PRO is being developed by a partnership of Global Agricultural Development Corp., Durham Tech and North Carolina State University. It is supported by a \$500,000 grant from the National Institute of Food and Agriculture, an agency of the U.S. Department of Agriculture that provides leadership and funding for programs that advance agriculture-related sciences.

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New NCBI members

The following companies were approved for membership by the NCBI Board of Directors on July 29.

- [ABL](#) is Advanced Bioscience Laboratories, a biotech corporation with headquarters located in Rockville, MD, providing contract manufacturing and laboratory research services to advance leading vaccines and therapies from clinical development to the commercial market
- [Aktis Oncology](#) is a biotechnology company pioneering the discovery and development of a new class of targeted radiopharmaceuticals to treat a broad range of solid tumor cancers.
- [Atsena Therapeutics](#) is a clinical-stage gene therapy company focused on bringing the life-changing power of genetic medicine to reverse or prevent blindness.
- [Azzur Group](#) partners with leading pharmaceutical, biotechnology, and medical device manufacturers to provide efficient and innovative solutions that help them start, scale, and sustain their GxP organizations.
- [GENIXUS](#) is creating a platform that brings together the brightest minds and latest innovations to reinvent how acute and critical care medicines are manufactured and delivered.
- [ICQ Consultants](#) partners with the world's largest biopharmaceutical manufacturers and emerging life sciences companies to provide comprehensive commissioning, qualification, and validation services that accelerate the delivery of medications and therapies to patients in need.
- [Life Edit Therapeutics](#) offers a next-generation platform allows it to target any genomic sequence and develop life-changing therapies for the most challenging genetic disorders.
- [Nexsen Pruett](#) is a legal, strategic communications and IT security and solutions company offering a variety of services to clients in multiple industries and areas of practice.

Member news briefs

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

AskBio's CEO Sheila Mikhail was named a winner of an Ernst & Young Entrepreneur of the Year 2021 Southeast award. Jim Datin, president and CEO of **BioAgilytix Labs**, was also chosen as a finalist. [MORE >>](#)

BD acquired Velano Vascular as a step toward providing what BD calls a “one-stick hospital stay” with Velano's PIVO device, which collects blood painlessly after the initial placement of an IV line, eliminating the need for multiple needle sticks. [MORE >>](#)

Biogen Inc. contributed four virtual posters that showcase data from its clinical trials with ADUHELM (aducanumab-avwa) injection 100 mg/mL solution at the Alzheimer's Association

International Conference. [MORE >>](#)

Biogen, Pfizer and AbbVie have collaborated to create the world's largest browsable resource linking rare protein-coding genetic variants to human health and disease. The tool is available at <https://genebass.org>. [MORE >>](#)

Bioventus Inc. will acquire Misonix, a provider of minimally invasive therapeutic ultrasonic technologies and regenerative medicine that enhance clinical outcomes,, in a cash-and-stock transaction. [MORE >>](#)

Eli Lilly and Company expanded its holdings in the Research Triangle Park yet again last month with the purchase of a 102-acre assemblage as work continues on its new campus in the park. [MORE >>](#)

G1 Therapeutics, Inc. received an FDA Fast Track designation for COSELA (trilaciclib) for use in combination with chemotherapy for the treatment of locally advanced or metastatic triple negative breast cancer. [MORE >>](#)

G1 Therapeutics, Inc. appointed of Andrew Perry as its chief commercial officer. Perry brings nearly 25 years of leadership experience in product commercialization and managed markets to G1. He most recently served as Vice President, US Marketing at ViiV Healthcare NA. [MORE >>](#)

Kriya Therapeutics, Inc. closed a \$100 million Series B financing to support its mission of transforming the design, development and manufacturing of gene therapies. [MORE >>](#)

Lucerno Dynamics has entered into a master resellers agreement to add its Lara System to the Siemens Healthineers portfolio of medical imaging products. Siemens is Lucerno's first United States partner reseller. [MORE >>](#)

Mycovia Pharmaceuticals, Inc. had its new drug application for oteseconazole, an oral antifungal product for the treatment of recurrent vulvovaginal candidiasis, accepted for review by the FDA. [MORE >>](#)

Novartis and the Novartis US Foundation will join forces with Thurgood Marshall College Fund, Morehouse School of Medicine, 26 other historically black colleges, universities and medical schools and others to address root causes of disparities in health and education. [MORE >>](#)

Pairwise, its founders, Haven Baker and Tom Adams, and its genetically edited raspberries and other produce are included in a New York Times Magazine story on genetically modified foods. [MORE >>](#)

Seqirus has begun to ship its portfolio of seasonal flu vaccines to health care providers across the United States. It is prepared to supply approximately 60 million doses to meet demand for the 2021-2022 flu season. [MORE >>](#)

Xilis, Inc. closed a \$70 million Series A financing. The round was led by Mubadala Capital joined by new investors including GV (formerly Google Ventures), LSP, Catalio Capital Management and Duke Angel Network. Current investors also participated. [MORE >>](#)

Upcoming Events

Keynote speaker announced for Aug. 24 NCBIO Roadmap to Diversity in Life Sciences Event Series

Join NCBIO members in this virtual event to hear about best practices for engaging a diverse workforce in the life science industry. Hear from panelists on recruiting and attracting a diverse workforce and retaining and engaging diverse employees.

The keynote speaker for the event is Pfizer's global diversity, equity & inclusion lead, Mona Babury, who leads DEI strategy for Pfizer's Global Supply, Finance and Global Business Solutions. Babury is responsible for building organizational and leadership capability in DEI. Leveraging her 15-plus years of a career journey in supply chain, taxation, digital and HR organizations, she develops “fit-for-purpose” programs, strategies and interventions that enable Pfizer's DEI aspirations – to be “as diverse as the patients and communities we serve.”

More details about the speakers will be released in the coming weeks.

Event co-chairs are Shaylah Jones, government & public affairs, Novo Nordisk, and Neil Jones, vice president, corporate strategic partnerships, Lindy Biosciences.

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Registration open for NC BIO 27th Annual Meeting Oct. 5

Join us for NC BIO's Annual Meeting on Tuesday, Oct. 5. This year's Annual Meeting is a hybrid event that can be attended virtually or in person and is scheduled from 8:15 a.m. to 3:30 p.m.

Our keynote speaker is Jude Samulski, Ph.D., president, chief scientific officer and co-founder of AskBio.

North Carolina features a critical mass of life science companies. Join us to hear from four homegrown companies from various sectors as they share their stories on navigating the stages of success.

- **Juliana Blum**, Ph.D., co-founder and executive vice president, corporate development, Humacyte
- **Gil Golden**, M.D., Ph.D., executive vice president and chief medical officer, United Therapeutics
- **Ken Reali**, chief executive officer, Bioventus
- Speaker TBD, AgBiome

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Accelerating Health Care Innovation in North Carolina

NCBiotech and FastTraCS at UNC-Chapel Hill are collaborating with health systems across North Carolina to provide a foundation for clinician innovation.

The two-day virtual event will put an emphasis on action and connect attendees with the people, insights, and strategies needed to systematically tackle the clinical innovation process from ideation through execution.

This event is perfect for health care providers including physicians, nurses, nurse practitioners, physician assistants, allied health professionals (e.g., physical therapy, respiratory therapy), EMTs and paramedics.

We highly encourage anyone interested in the event to register. All registrants will be given access to session recordings after the event, even if you are unable to join us on September 23 or 24.

REGISTER NOW

Attend an NC IDEA fall 2021 grants info session

We are officially kicking off our Fall 2021 Grants Cycle with the return of in-person information sessions throughout the state in July and August. The sessions will highlight NC IDEA's two upcoming grant opportunities supporting ambitious, growth-oriented companies:

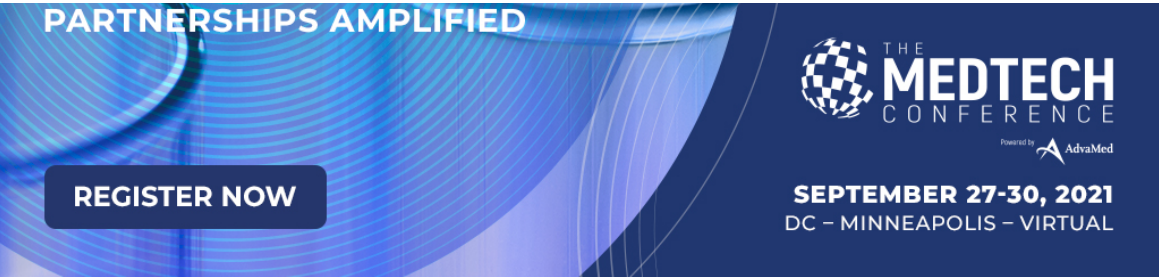
- [NC IDEA MICRO](#) awards small, project-based grants in the amount of \$10K to young companies looking to validate and advance their idea.
- [NC IDEA SEED](#) offers early stage companies the critical funding they need to scale faster. The \$50K grants are awarded to innovative startups with a proven concept – even if they are not yet profitable.

Interested applicants may attend any of the following information sessions to learn more about NC IDEA's grant opportunities and gain insight on how to write a competitive application. Learn more on how to apply, what NC IDEA looks for in an application and which opportunity may be most appropriate and beneficial for you and your company.

- [Wilmington Info Session](#) – Monday, August 2 at 5:30 p.m.
- [Research Triangle Info Session](#) – Tuesday, August 3 at 12:00 p.m.
- [Winston-Salem Info Session](#) – Wednesday, August 4 at 5:30 p.m.

NC IDEA MICRO and NC IDEA SEED grant applications opened Aug. 2 and close Aug. 30 at 5:00 p.m. EST.





Register today for the leading and most comprehensive global event in the medical device and diagnostics industry on Sept. 27-30 and be part of the community that’s defining the path to better health care.

The MedTech Conference will be held virtually with optional in-person opportunities in Washington, DC and Minneapolis, MN. The hybrid structure combines the benefits of in-person and virtual events, with manageable face-to-face gatherings that tap into the unique opportunities presented by two host cities, and a digital component that facilitates global participation. No matter how you participate, you are guaranteed to experience the same quality programming and networking that you’ve come to expect from the MedTech Conference.

NCBIO members can contact [Amber Niebauer](#) for a discount registration code for the Medtech Conference.

NCBIO calendar

- [BTEC Biopharmaceutical Lyophilization and Spray Drying Course \(8/3/2021 to 8/6/2021\)](#)
- [BTEC Hands-On cGMP Biomanufacturing of Vectors for Gene Therapy Course \(8/3/2021 to 8/6/2021\)](#)
- [BTEC Fermentation Engineering Course \(8/10/2021 to 8/13/2021\)](#)
- [Education and Workforce Conference hosted by NC Chamber \(8/11/2021\)](#)
- [Leadership Summit: Adaptability - The New Competitive Advantage hosted by NC TECH \(8/12/2021 to 8/13/2021\)](#)
- [NCBIO "Roadmap to Diversity in Life Sciences" Event Series \(8/24/2021\)](#)
- [Diversity, Equity & Inclusivity Conference hosted by Raleigh Chamber \(8/25/2021\)](#)
- [Diversity, Equity & Inclusivity Conference hosted by Raleigh Chamber \(8/26/2021\)](#)
- [BTEC Introduction to Chemical Modification of Protein Therapeutics \(9/7/2021 to 9/10/2021\)](#)
- [Larger than Life Science: Putting Your Best Foot Forward - Connecting with Pharma Partners and VCs hosted by LaunchBio \(9/9/2021\)](#)

BIO Business Solutions Highlights



Four steps to saving with your NCBIO membership

NCBIO members are eligible for BIO Business Solutions volume-based discounts and favorable contract terms to help you save on products and services you already use. How does it work? Here it is in four simple steps!

- [Browse our cost-savings programs](#) – from lab supplies and equipment, research-grade microscopes, office supplies, shipping, insurance, research services and more.
- [Contact us](#) – Fill out a short inquiry form to let us know which cost-saving options you’re interested in hearing more about.
- Sign up – Depending on the program, you can enroll yourself, talk to the partner for more information, and/or start a free trial.
- Enjoy the benefits – Once your account is set up, your savings will be in place. If you have questions or need support, our team is always here to help!

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

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