the ncbio biosciences organization | connections newsletter

**April 2023 Update**

**Serving the NC Life Sciences Industry**

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## NCBIO This Month

- Emerging Companies Forum
- Medicaid expansion passes, tied to budget
- Biden looks to boost FDA funding, expand authority
- NIH declines to march in
- ARPA-H to have three hubs, one's in D.C.
- $25 million Build Back Better grant outlined for BMF


### Panelists offer advice on funding options for emerging companies

Panelists at the NCBIO Emerging Companies Luncheon and Forum held Wednesday, March 22, at the NC Biotechnology Center offering insight into the way their organizations choose investments, when to seek SBIR funding, engaging with a funding agency for the first time and more.Â

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The forum was sponsored by Clancy & Theys Construction Company, JBK Associates International, Nikon and SAS.

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Mike Carnes, senior director of investments, NC Biotechnology Center, said a company must be able to clearly communicate its strategy and progress, including where it has been, where it is currently, and where it needs to go. It is important to be prepared to discuss these basic elements of the company and to polish the company's story before approaching funding resources such as SBIR, SBA or investors, he said.

More at NCBIO

## NCBIO Sustaining Members

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## NCBIO Supporting Members

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# STATE UPDATES

## Legislature ties Medicaid expansion to budget deal

On March 23, the General Assembly passed bipartisan compromise legislation that could expand Medicaid to as many as 600,000 additional North Carolina residents. Gov. Roy Cooper signed the bill into law March 27.
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However, expansion is far from being a done deal as its start is tied to the passage of a state budget, which has long been a source of contention between the Republican legislature and Gov. Roy Cooper. Cooper vetoed all of the budgets passed by the legislature during his first term, and the state once went three years without a budget, in part because lawmakers failed to include Medicaid expansion.
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The legislation includes changes to the state's certificate of need law, which requires health care providers to receive state approval before acquiring, replacing or adding facilities and equipment.
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To receive the maximum payment from the Centers for Medicare & Medicaid Services, a budget would have to be passed and signed by June 30.
Â
If expansion is implemented, North Carolina will become the 40th state to expand Medicaid.Â

## House unveils state budget proposal

On March 29, the NC House of Representatives released its nearly $30 billion budget. The budget would spend $29.7 billion in the coming fiscal year, which begins in July. It would increase state spending by 6.5% over the current year.
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The spending plan would give most state employees raises of 4.25% this year and 3.25% next year. Teachers would get about 10% over two years. There are additional 2% raises over two years for some employees in jobs that are harder to recruit and retain. UNC and community college employees would get 7.5% raises over two years, with additional money to be used for recruitment. The current state employee vacancy rate statewide is 23.4%, which is nearly double what it was before the pandemic.Â
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The One NC Small Business Program, which provides matching dollars to companies who win SBIR and STTR grants, would receive an additional recurring funds under the proposed budget. An additional $2 million in recurring funds would be added this year to the $2 million appropriated for the 22-23 fiscal year, bringing the total recurring appropriation to $4 million for this budget biennium. Unlike in previous years, there are no nonrecurring dollars yet appropriated in addition to the recurring monies for the One NC Small Business program. NCBIo will be working with our partners in the General Assembly to direct additional monies to the fund.
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The NC Biotechnology Center is slated to receive $18.1 million in the first year of the budget and $16.1 million in the second. Compared to the support included in the last budget, this is a $1 million increase in the center's recurring appropriation plus $2 million in nonrecurring funds in the first year of the budget.
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The budget would also cut taxes. The individual income tax rate would be reduced to 4.5% in 2024, which is a year earlier than planned. The child tax credit would be increased by 20%.
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The budget would also invest in infrastructure and workforce development. It

would fund the construction of new schools and the expansion of broadband access. It would also provide funding for training and education programs.
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The budget is still in the early stages of development. More at WUNC

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# NATIONAL UPDATES

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## Biden budget boosts FDA funding, expands regulatory authority

President Biden's proposed fiscal 2024 budget includes proposals to expand Medicare drug price negotiation, increase funding for federal family planning, and provide $150 billion over a decade for Medicaid home- and community-based services. It also provides insight into his health care policy concerns and differences with Republicans.
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The lack of significant spending to fight COVID-19 suggests the president plans to end the public health emergency in May. The budget also highlights areas for bipartisan action, such as mental health care, cybersecurity, and cancer research.
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Biden's budget proposes an overall HHS budget increase of 11.5 percent, authority for CMS to negotiate prices for 40 drugs (up from 20 under current law) and a 79 percent increase to $512 million for Title X.
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Republicans opposed the drug price negotiation provisions in the Inflation Reduction Act and may seek to roll those back. They also see Medicaid as ripe for cuts and are considering proposals to add work requirements, cap spending and repeal Obamacare's Medicaid expansion.
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Biden's budget calls for more money for mental health care, including the rollout of certified community behavioral health clinics, funding for the HHS Substance Abuse and Mental Health Services Administration and the 988 crisis line, along with an extra $200 million for the National Institute of Mental Health. It also boosts funding for the National Institutes of Health to facilitate more spending on research into the opioid and mental health crises.
Â
There's bipartisan concern about the vulnerability of health care organizations to hackers, and the Biden plan seeks a significant funding bump for the HHS Office for Civil Rights, which regulates health data security. The proposed budget is $78 million in fiscal 2024, up from $40 million. Republicans may be receptive to spending aimed at protecting health care organizations.

## Biden budget boosts FDA funding, expands regulatory authority

The Food and Drug Administration would receive a $521 million boost in funding under President Joe Biden’s fiscal 2024 budget proposal, which would boost the agency’s funding to $7.2 billion from tax dollars and industry user fees.
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The White House budget request includes plans to strengthen the FDA’s regulatory authority, some of which directly affect the pharmaceutical industry:

- **Adjusting drug expiration dates to avoid shortages**: The FDA wants to

require drug manufacturers to submit data on the longest shelf-life possible for drugs in the event of a shortage and penalize companies that don't comply.
- **Expanding its mandatory recall reach**: The FDA wants to be able to mandate recalls for all human and animal drugs; currently, the agency can issue mandatory recalls for controlled substances, biologics and cosmetics.Â

In a divided Congress, it's unlikely the White House's budget will come to fruition without significant changes, though the FDA is usually insulated from the partisan battles fought over other budget priorities.

## NIH declines to march in on Xtandi; triggers HHS, Commerce review

On March 21, the NIH rejected a petition to use so-called march-in rights to take ownership of patents tied to the prostate cancer drug Xtandi.
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HHS and the Department of Commerce will launch an interagency review of the government's authorities under the Bayh-Dole Act, which grants the march-in rights.
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The rejection, which affirms a similar 2016 determination, wasn't well received by some Democrats in Congress. It's also a blow to advocacy groups, including Public Citizen and Families USA, who argue that taking such a step would rapidly lower the price of Pfizer and Astellas Pharma's prostate cancer drug.

## Bipartisan bill seeks four years of Medicare funding for breakthrough devices

A bipartisan bill reintroduced March 22 would guarantee four years of Medicare coverage for "breakthrough" medical devices greenlit by the FDA, codifying a Trump-era policy that the Biden administration repealed in January 2021 over concerns about the applicability of certain devices to the Medicare population.
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While the bill has not had much luck in previous sessions, there's added pressure this year because CMS is working on a replacement policy to create an accelerated coverage pathway for medical devices, which means the lawmaker's effort could pressure the agency into proposing a policy friendlier to industry.
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The Ensuring Patient Access to Critical Breakthrough Products Act ? introduced by Rep. Suzan DelBene (D-Wash.) and Rep. Brad Wenstrup (R-Ohio) and notably cosponsored by House Energy and Commerce Health Subcommittee ranking member Anna Eshoo (D-Calif.) and chair Brett Guthrie (R-Ky.) ? would direct CMS to cover such devices for four years.

## ARPA-H releases funding opportunities, site selection process and idea competition

The Advanced Research Projects Agency for Health has announced several new initiatives to accelerate health care breakthroughs for all Americans.
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ARPA-H was established in March 2022 and is now fully operational with the hiring of program managers and mission office directors. It has also announced plans to establish three hubs in different locations to support a network of partners that will actively support the dynamic needs of ARPA-H programs. The first hub will be located in the National Capital Region and will focus on stakeholder engagement and operations, while the other two locations will be selected from proposals responding to a draft solicitation and located in unique geographies in the U.S.
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In addition, ARPA-H has posted its first funding opportunity announcement with an agency-wide Open Broad Agency Announcement and unveiled a nationwide prize competition to identify and promote future health breakthroughs. ARPA-H's recent press release contains more information on these announcements, while its website, ARPA-H.gov, provides additional details on each initiative. With the agency now open for business, it hopes to fulfill the bold, bipartisan vision for health care in America. More at ARPA-H

## House panel approves bill to bar agencies from using quality-adjusted life years metric

The House Energy and Commerce Committee has passed a bill March 24 that would prevent federal agencies from using quality-adjusted life years as a metric to evaluate the cost-effectiveness of drugs and treatments.
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The legislation was introduced by Republican representatives and received no support from Democrats, which suggests that it will face difficulties being passed even if approved by the House.
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QALYs is a method used to assess the value of health care interventions that has been adopted in the UK and other countries. Republicans argue that it discounts the benefits of drugs and treatments for seniors and people with disabilities. Democrats, however, are concerned that the bill may hinder Medicare drug price negotiations by prohibiting other measures of cost effectiveness.
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An amendment to address the Democrats' concerns failed to pass on party lines.

## FDA seeks input on proposed one-trial model for accelerated, full approval of oncology drugs

The FDA is seeking public input on proposed changes to its process for accelerating approval of oncology drugs.
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According to draft guidance, the agency intends to shift away from relying on single-arm studies and instead prioritize randomized controlled trials that could serve as a basis for both accelerated and full approval. Single-arm studies are typically conducted by drug sponsors to measure tumor response. These studies have come under scrutiny for their limited ability to identify rare adverse events, provide comprehensive insights into disease progression and survival rates, predict clinical benefits and facilitate cross-trial comparisons.
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The FDA believes that these limitations can create uncertainties in assessing drug safety and efficacy and may not justify accelerated approval based solely on single-arm studies. In contrast, randomized controlled trials are considered the preferred approach for supporting applications for accelerated approval, even though they are more time-consuming and expensive than single-arm studies. This shift in guidance marks a departure from the current approach, which favors single-arm studies for their speed and cost-effectiveness.
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The FDA is accepting feedback on the draft guidance until May 26. More at FierceBiotech

## White House outlines new drug manufacturing goals

President Joe Biden's administration has set a range of biomanufacturing goals to address issues such as climate change and cell therapy production, according to a recent report titled "Bold Goals for U.S. Biotechnology and Biomanufacturing." (Read the fact sheet.)
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One of the key objectives is to improve supply chains for critical drugs and predict future disruptions. Within the next five years, the administration aims to produce 25% of active pharmaceutical ingredients for small molecule drugs in the U.S.Â
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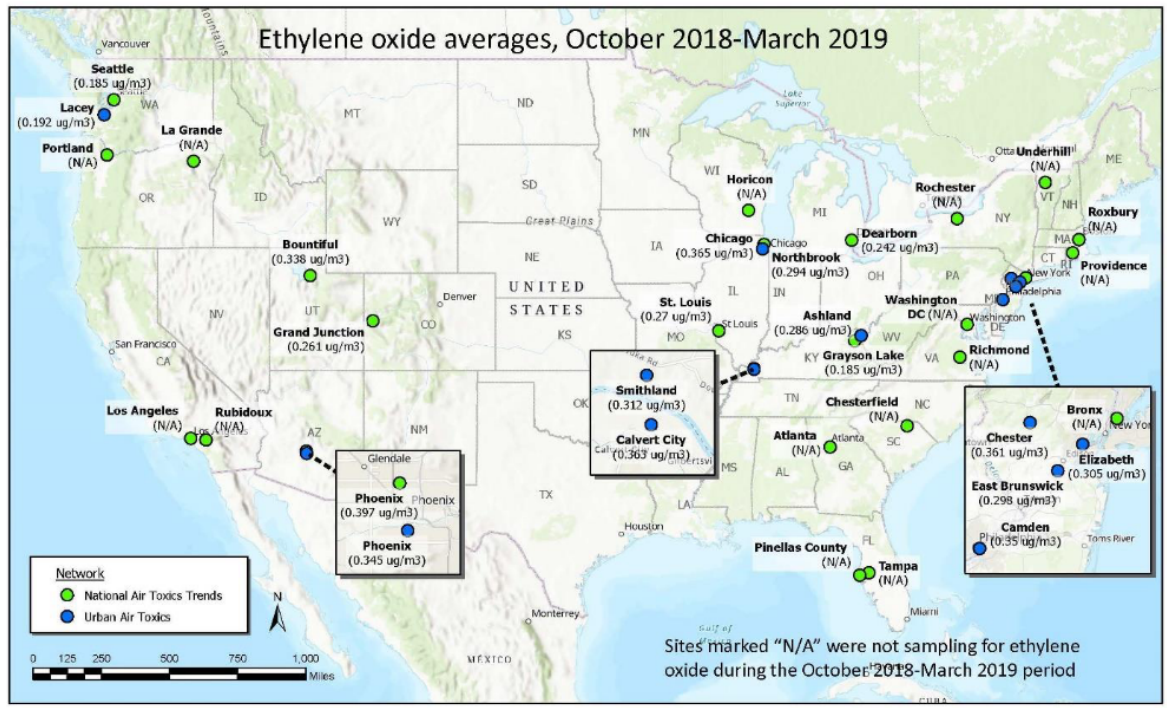
The report also states that the government wants to predict at least 50% of supply chain weaknesses and use biomanufacturing "adjustments" to address bottlenecks. The plan is to roll out real-time biomanufacturing process adjustments within the next 5 years and be able tackle bottlenecks within a week of identification over the next 20 years. The administration also wants more companies to use artificial intelligence to power bioproduction of medicines to improve speed, diversity and assist with the design of new therapies.
Â
To achieve these goals, the Biden administration plans to invest in genetic engineering, AI and domestic biomanufacturing production capacity. The report sheds light on an initiative President Biden announced in September when he issued an executive order calling for investment in these areas and the removal of commercialization obstacles. More at FiercePharma




**This EPA map shows some of the communities the agency says are adversely affected by ethylene oxide emissions. Sites in Puerto Rico are not shown.**

## EPA releases draft rules on ethylene oxide

The EPA is poised to propose new restrictions on ethylene oxide, a gas used to sterilize medical equipment and make other chemicals. Leaky facilities have created cancer concerns in some communities around the country.Â

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The EPA's Office of Air and Radiation released new draft rules March 23 on emissions for public comment. The White House recently finished reviewing the updated rules for commercial sterilizers and chemical manufacturers. The final rule is expected in October.

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In a letter the the Biden Administration, AdvaMed welcomed the regulations, sought consideration of the potential threat to patient care if any facilities shut down, asked the EPA to embrace technology-neutral solutions to meet emissions targets and asked the EPA to consider background EtO levels in ambient air and the tiny proportion of EtO used in medical device sterilization compared to other uses and sources.

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In August, the EPA found that ethylene oxide ? used on roughly half of the more than 20 billion medical devices sold in the U.S. annually that require sterilization ? is contributing to elevated cancer risks in 23 communities close to sterilizing facilities.

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For some devices, EtO is the only safe and effective sterilization method currently available. The EPA is working to reduce EtO emissions, and the FDA is looking to identify alternatives to EtO. Â

## Bill introduced to repeal 2017 R&D amortization rule

A bill introduced in the U.S. Senate March 16 would repeal the recently implemented requirement to amortize R&D expenditures over five years.

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The 2017 Tax Cuts and Jobs Act modified Section 174 of the tax code so that businesses could no longer deduct "research and experimentation" expenses in the same taxable year as they occurred. This change went into effect in 2022. Businesses must now amortize domestic R&D expenses over five years and foreign expenses over fifteen.Â

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Sen. Maggie Hassan (D-NH) and Sen. Todd Young (R-IN) introduced the American Innovation & Jobs Acts of 2023 (S. 866) that would restore the immediate expensing of R&D expenditures and remove this tax on innovation.

**NCBIO President Laura Gunter, Biogen's Renae Dill, Tillis, NCBIO Board Chairman Neal Fowler, IQVIA's Andrew Barnhill and Gilead's Bill Bode**

## March sees three DC fly-ins for NCBIO

It was a busy month in Washington, D.C. with NCBIO attending multiple fly-ins hosted by our partner organizations.
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NCBIO President Laura Gunter was in Washington, D.C. for the 2023 CSBA Hill Day March 28-29 to meet with Sen. Thom Tillis and Sen. Ted Budd and the state's House members. The group focused on workforce and threats to innovation, along with the tax amortization issue described above.
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Gunter traveled with the NC Biotechnology Center, Novozymes and some other companies to D.C. for a roundtable with the NC delegation on how North Carolina is currently participating in the bioeconomy and how it is poised to be on the forefront of further development. She also traveled to the capital for the March 7-8 Advamed fly-in concentrating on the value of medtech to the state.

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# NCBIO Updates

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**Sara Imhof of NCBiotech**

## BMF meeting explores $25 million Build Back Better grant projects

At the March 15 meeting the NCBIO Biomanufacturers Forum, attendees received updates on the $25 million Build Back Better Regional Challenge grant awarded in the fall.
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In September, a statewide coalition of public and private partner organizations and institutions led by NC Biotech and including NCBIO received the award from the U.S. Economic Development Administration’s Build Back Better Regional Challenge. The grant will support a number of life sciences workforce initiatives collectively called Accelerate NC:

- Workforce diversification led by NCCU’s Biomanufacturing Research Institute and Technology Enterprise.
- Expanding training access and faculty recruitment led by the North Carolina Community College System.
- Community engagement efforts led by NCBiotech.

Key industry partners provided 20% in matching funds for these projects. More at NCBIO

## Fintech ranks NC No. 5 best state for small business

Lendio, a financial technology company, has ranked North Carolina as the fifth-best state for small businesses in its 2023 rankings.
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The ranking is based on factors such as the state's population growth, above-average small business survival rate and low corporate tax rate.
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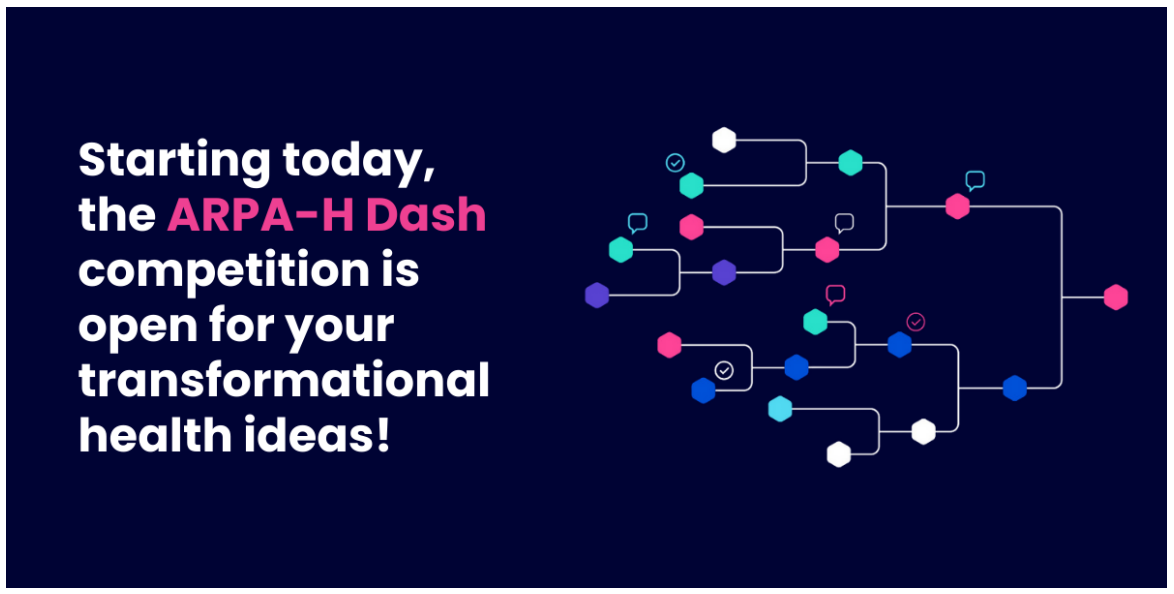
Texas topped the list due to its high volume of small business loans, high survival rate of small businesses, and lack of state income tax, while Florida, Ohio, and Massachusetts followed in the rankings. More at WRAL TechWire




## ARPA-H Dash submissions open

Submissions opened March 29 for the ARPA-H Dash to Accelerate Health Outcomes where everyone can share ideas for the most urgent health transformations, vote and compete to have the best ideas win.
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ARPA-H Dash launched on March 15 to identify revolutionary ideas to transform health. The collaborative, online competition uses a bracket format and online discussion, debate and voting to narrow short submissions to a champion idea with top winners earning a cash prize. Submissions are open through April 7.
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The rules are simple: Register on Polyplexus.com, and submit an evidence-backed idea before April 7. Then, when the voting opens on April 17, participants are encouraged to contribute to the online debate and vote for the most exciting and promising ideas.

## New EU regulations mean possible import delays, Biocair warns

Biocair is alerting NCBIO members that on March 1, the European Union rolled out Release 2 of its new large-scale advance cargo information system, the Import Control System 2. This information system supports the implementation of a new customs prearrival security and safety program in the EU, as well as in Northern Ireland, Norway and Switzerland.
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There are 12 EU Member States which have not yet connected to ICS2: Austria, Belgium, Croatia, Denmark, Estonia, France, Greece, Luxemburg, the Netherlands, Poland, Romania and Sweden. These 12 EU member states will have until June 30Â to transition to ICS2 Release 2.
Â
With some of Europe’s largest air cargo hub airports being located in these states, the International Air Transport Association warns that this may cause customs clearance delays. More at Biocare


**On March 30, NCBIO members Alexandria Real Estate Partners, Epigenos Biosciences, Jericho Sciences and Lindy Biosciences pitched at CED Venture Connect. The event, which was held at the GSK campus in RTP, was attended by over 1,000 investors, entrepreneurs and corporate partners.**

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**Aqui Tu is a Durham based, minority owned, water company established in 2021, with ties to both NCCU BRITE and NC A&T. Aqui Tu is offering NCBIO members a discount on 5 gallon jugs (use code NCBIOSCIENCE and 24 packs of bottled alkaline or mineral water (use code NCBIOTTLES). Contact Kayla Walker for more information.**

**ORDER NOW**

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## NCBIO Member News

*To be included in member news, send information about your organization to David Etchison.*
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**Acadia Pharmaceuticals** announced that the FDA has approved DAYBUE (trofinetide) for the treatment of Rett syndrome in adult and pediatric patients two years of age and older. DAYBUE is the first and only drug approved for the treatment of Rett syndrome. More >>
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**AgBiome's** Laura Potter, chief science officer, was named a recipient of a 2023 Women in Business Award (leader in STEM) by the Triangle Business Journal. More >>
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**Biogen** announced that its Board of Directors has elected Caroline Dorsa as chair of the Board of Directors effective immediately following the company's 2023 annual meeting scheduled to take place on June 14. More >>
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**Chiesi USA** contributed more than $830,000 in 2022 through its Chiesi in the Community corporate social responsibility program. Close to 200 Chiesi employees supported 65 unique charitable organizations with 769 hours of time or donations in 2022. More >>
Â
**Eli Lilly and Company** announced price reductions of 70% for its most commonly prescribed insulins and an expansion of its Insulin Value Program that caps patient out-of-pocket costs at $35 or less per month. More >>
Â
**Gilead Sciences'** Shelly Smith, associate director, was named a recipient of a 2023 Women in Business Award (leader in STEM) by the Triangle Business Journal. More >>
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**Kymanox** has acquired Agilis Consulting Group, a human factors partner for the global medical market specializing in helping new and established companies achieve successful HF submissions while navigating the complex global regulatory landscape. More >>

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**Nexsen Pruet** has completed its merger with Maynard Cooper & Gale and will be moving forward as Maynard Nexsen. More >>

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**Novan** announced the sale of approximately $6 million in common stock, which it says it intends to use the proceeds to fund its berdazimer gel, 10.3% (SB206) development program activities, along with sales, marketing and operating expenses. More >>

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**Novo Nordisk** announced it is lowering the U.S. list prices of several insulin products by up to 75% for people living with type 1 and type 2 diabetes. More >>

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**RTI International's** Stephanie Hawkins, vice president, transformative unity for equity, was named a recipient of a 2023 Women in Business Award (nonprofit leadership) by the Triangle Business Journal. More >>

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**Smith Anderson's** Sharita Whitaker, partner, was named a recipient of a 2023 Women in Business Award (inspiration) by the Triangle Business Journal. More >>

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**Thermo Fisher Scientific's PPD** clinical research business was awarded a five-year contract to provide regulatory affairs support and related services for the NIH's Blueprint MedTech program. More >>

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# Events

## Let's Talk DEI networking event April 25

Members have been asking for more in-person events where they can share their DEI experiences. Join us for an afternoon of networking with others working on the DEI journey hosted by The Diversity Movement at their offices in Raleigh. For those who might want more guided conversations, we will have some tabletop talks around mentoring, leadership, employee resource groups, DEI training and more.

**REGISTER NOW**

## Mark you calendar: Medical Device Forum and Luncheon May 16

Save the date for the next NCBIO Medical Device Luncheon and Forum sponsored by Clancy & Theys Construction Company and Hughes Pittman & Gupton to be held Tuesday, May 16, at NC Biotech. The discussion will focus on overcoming regulatory and supply chain challenges today and tomorrow and include

- Bob Balderas, vice president of biological sciences, BD, andÂ
- Edgard Ngaboyamahina, Ph.D., sustainability subject matter expert, RTI International.

Additional speakers have been invited to participate. If you are interested in sponsoring this event, please contact Membership Director Natacha Janvier.

**LEARN MORE**


## Discount code available for MDMA Annual Meeting

Register today for MDMA's flagship event, the 2023 MDMA Annual Meeting, held April 26-28 in Washington, D.C. MDMA is the leading voice for innovative and entrepreneurial medical devices companies, and this year's Annual Meeting will deliver key insights on issues facing the industry.
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Attendees at this year's conference will hear from congressional, federal agency and industry leaders on current and upcoming issues affecting our industry. Attendees also have an opportunity to visit Capitol Hill and meet with our Congressional delegation during MDMA's popular Congressional Fly-In.
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NCBIO members can contact Amber Niebauer for the discount registration code.

- MDMA Members - $895
- State Member - $1,095 (with code)
- Non-Members - $1,195

**REGISTER NOW**


## Innovations in Ag: A Regional Perspective July 19, Danville Va.

NCBIO is excited to announce that we are partnering with Virginia Bio and the Institute for Advanced Learning and Research for an ag biotech event on July 19

in Virginia. This program will look at innovations in ag from a regional perspective. We hope you will join NCBIO members and others in Virginia for this event.
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If you are interested in sponsoring the joint event, please contact NCBIO Events Director Amber Niebauer for more information.

**REGISTER NOW**


## Submit sessions for BIO Raleigh ag, environment event

The BIO Impact Ag & Environment Conference will be held, Sept. 19-20, in Raleigh This premier event brings together biotech innovators, investors, and policy makers focused on strengthening the bioeconomy to meet societal challenges.
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BIO is seeking compelling session submissions in the following focus areas:

- Climate Change & Food Security. How are innovative new products, processes, and partnerships addressing these issues in the short and long-term?
- Market Access & Acceptance. What is being done to build market acceptance and demand for biotech breakthroughs?
- Promoting Innovation. Share best practices and case studies that help ensure regulatory processes keep pace with innovation while improving public trust.

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**APPLY NOW**

## NCBIO calendar

- Modifying Current Indication Prioritization Practices hosted by Syneos Health (4/4/2023)
- How to Prepare for a Media Interview hosted by NCBiotech (4/4/2023)
- Member Showcase Event hosted by NCWTA Triangle Chapter (4/6/2023)
- What to Do and Not Do as Regulatory Enforcement Increases for Life Sciences Communications hosted by BIO (4/13/2023)
- CureDuchenne FUTURES National Conference (4/20/2023 to 4/23/2023)
- High-Impact, Cost-Effective DEI Strategies for Every Business hosted by The Diversity Movement (4/20/2023)
- The Soul of Science: Shaping the Future of Human Genomics hosted by LaunchBio (4/20/2023)
- The Three I's: Research Integrity & Biosecurity Conference hosted by NCABR (4/24/2023 to 4/26/2023)
- Let’s Talk DEI and Networking Event (4/25/2023)
- MDMA Annual Meeting (4/26/2023 to 4/28/2023)
- Upstream Production Process Development for Biopharmaceuticals hosted by BTEC (5/12/2023 to 5/26/2023)
- Biomanufacturing Automation Fundamentals hosted by BTEC (5/16/2023 to 5/17/2023)
- NCBIO Medical Device Luncheon and Forum (5/16/2023)

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## BIO Business Solutions

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