February 2022 Update

Serving the NC Life Sciences Industry

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Applications are now open for companies to receive SBIR/ STTR matching funds from the One NC Small Business Program. For the first time in a long while, the state budget includes incentive funds to reimburse companies in preparing and applying for matching funds in addition to matching funds for companies who receive awards. This is also the first time the General Assembly has appropriated recurring funding for the One NC Small Business program that will be available year after year.

An NCBiotech-led group is pursuing up to $75 million as part of an EDA Build Back Better Regional Challenge grant to bolster the life science workforce in the state and bring opportunity to economically distressed communities. NC Biotech is looking for corporate partners to support this effort by providing guidance, writing letters of support, hiring from the targeted work forces, making in-kind contributions and providing matching funds. If you would like to be involved in this transformative effort, please let me know.

NCBIO continues to work with BIO and other partners in opposition to government price controls on prescription drugs. BIO has shared a couple of new reports in support of our position. One contrasts the massive investment pharma makes in R&D with what the NIH is able to spend. The other breaks down the price of prescription drugs to show how much goes to manufacturers and how much goes to other entities, such as PBMs. Read more below.

This month, NCBIO members had the chance to talk with Sen. Thom Tillis and his staff about building manufacturing capacity, China, intellectual property protections, workforce development and more. You can read more about that conversation below and on our website.

Finally, NCBIO extends our thanks on behalf of our members to Sen. Richard Burr for joining 13 other senators in signing a letter to their Senate colleagues opposing government price controls on prescription medicines in the Build Back Better Act.

Laura Gunter
NCBIO President

NCBIO This Month

- $44 billion > $670 million: Pharma R&D vs. NIH spend
- Best practices in bioscience economic development
- More than half of money spent on brand-name medicines goes to someone other than the maker
- Applications open for One NC Small Business Program SBIR/STTR funds
- NC Biotech & Co. go for $75 million for NC workforce development
- Lock in a $400 discount for BIO 2022

... and more

LEAD STORIES

Who pays to create new medicines?

NCBIO Sustaining Members

Biotechnology Innovation Organization
Biogen
Lilly
Pfizer
WE WORK FOR HEALTH

NCBIO Supporting Members

COOK MEDICAL
GRAIL
MERCK INVENTING FOR LIFE
NOVARTIS
vwr part of avantor

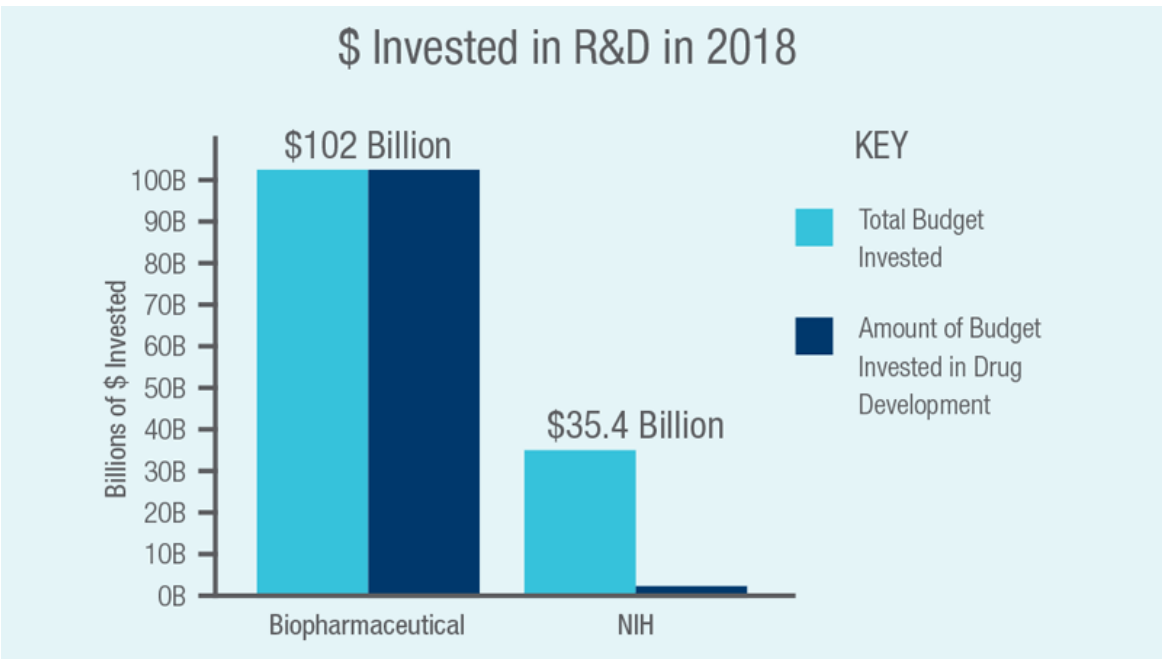
Who pays to create new medicines?

The share of private money invested in developing new medicines approved by the FDA in 2020 exceeded the entire budget of the National Institutes of Health by about 6,500%, according to a new study by Vital Transformation.

In fact, total private investment for the 18 approved medicines exceeded NIH funding by orders of magnitude: $44.2 billion in private investment compared to $670 million in NIH. As industry's share of total investment increased, so did the likelihood of approval.

These findings are consistent with scholarship describing the complementary roles of public and private R&D funding, and the significant long-term investments shouldered by industry with no guarantee of approval. In fact, just 12% of medicines in clinical development are ultimately approved by the FDA.

Read More at NCBIO



Pharmaceutical industry spending on research and development is three times greater than the entire NIH budget.

New BIO report outlines best practices in bioscience economic development

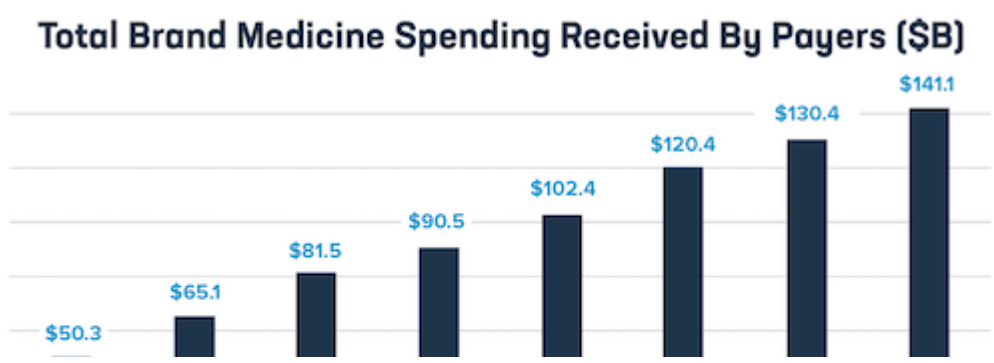
The Biotechnology Innovation Organization, in partnership with the Council of State Bioscience Associations, released a new report on bioscience economic development best practices, "Driving the Bioscience Economy Forward During the COVID-19 Pandemic: Best Practices in State and Regional Economic Development Initiatives."

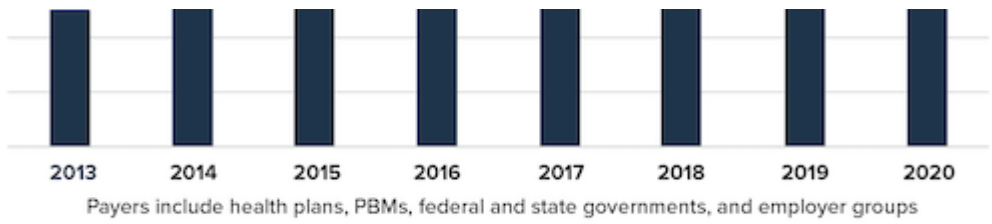
The report, which reviewed public policy strategies and programs in all 50 states, highlights new and innovative initiatives that enhance the future of the bioscience industry. In addition to several evaluations of specific state and policy examples, the report identified seven national trends for state bioscience growth in 2021:

- States are building career pathways for future biosciences talent.
- States and regions are implementing an overall supportive regulatory climate to ensure predictable and stable regulatory treatment of biosciences firms.
- States and regions are focusing on developing their agricultural, industrial, and environmental bioscience sectors in addition to their biomedical and health sectors.
- Physical infrastructure and facilities remain a priority.
- Universities and other research centers' technology transfer efforts are better understood by public agencies.
- Proximity to academic innovation is a driving influence.
- Increased focus on biomanufacturing is the future.

More at NCBIO

Who gets the money spent on brand-name drugs?





More than half of total spending on brand-name medicines in 2020 went to “nonmanufacturer stakeholders — including PBMs, health plans, hospitals, the government, pharmacies, and others,” says a new report from Berkeley Research Group, the latest evidence that drug price controls aren’t the solution for controlling health care costs.

The numbers: “Brand manufacturers retain just 37% of total spending on all prescription medicines (brand and generic medicines),” and 49.5% on brand medicines, says the study, which was funded by the Pharmaceutical Research and Manufacturers of America.

So, who got the largest portion of new spending on brand medicines? “Payers—including insurers/plan sponsors, the government, and PBMs,” receiving more than $140 billion, or 35%.

Read More at PhRMA

STATE UPDATES

Applications open for One NC Small Business Program

The NC Department of Commerce announced that companies applying for or receiving federal SBIR and STTR awards can now apply for incentive and matching awards from the One NC Small Business Program.

The fiscal year 2022 budget includes $5 million for the One NC Small Business Program. Of that funding, $1 million is allocated for the incentive funds program, and $4 million is allocated for matching funds.

Under the incentive funds program, qualified applicants can be reimbursed up to $12,000 for a portion of the costs incurred in preparing an SBIR/STTR Program Phase I proposal. The maximum percentage for reimbursement is 100% for an eligible business located in a Development Tier 1 or 2 county and 50% for any other eligible business.

Under the matching program, companies can receive matching funds equal to 50% of the SBIR/STTR Program award not to exceed $75,000. Eligible applicants are Phase I SBIR/ STTR awardees that are located in a Tier 1 or 2 county **or** have previously received no more than one matching award under the match program.

Companies are eligible to receive one incentive grant and one matching grant during the FY 2021-2022 solicitation period. Applications to the One North Carolina Small Business Program will be accepted until June 30.

LEARN MORE

NATIONAL UPDATES

Supreme Court blocks employer vaccine mandate

The U.S. Supreme Court blocked the Biden administration's vaccine-or-testing mandate for large businesses (those with 100 or more employees). This is a final ruling. The Supreme Court found that the U.S. Department of Labor did not have the statutory authority to enforce the mandate on employers.

However, in a separate ruling, the Supreme Court said that vaccinations can be required for the estimated 10 million health care workers who work in facilities that receive Medicare and Medicaid funds. The court found that Congress had given federal agencies the authority to impose a vaccine requirement on health-care facilities receiving federal funds but not on businesses in general.

In response, OSHA withdrew its mandate-or-testing emergency temporary standard rule for large employers effective Jan. 26. While the ETS has been withdrawn, OSHA is still developing a permanent rule to create a COVID-19 health care standard. Experts have said that OSHA will likely need to create a narrower rule that targets the types of workplaces where it can show Covid-19 is an occupational hazard to survive another court challenge.

The ruling dissolves the larger-employer mandate in its entirety and all employer requirements previously associated with it. However, employers may still decide on their own to require their employees be vaccinated or tested. President Biden called on business leaders to do so after the ruling.

More at Good Day BIO

FDA misses MDUFA V deadline after months of contentious talks

FDA has failed to send the final Medical Device User Fee Amendments V agreement to Congress by the Jan. 15 deadline. The missed deadline follows months of talks that showed the FDA and industry were at odds over critical elements of the MDUFA program.

Disruption caused by the COVID-19 pandemic meant negotiations over MDUFA V got off to a late start. Yet, negotiations between FDA and other parts of the life science industry wrapped up months ago — the agency published its commitment letter to the pharmaceutical sector in August — and meeting minutes reveal points of major disagreement over a deal that could be worth $1.2 billion.

The FDA has not given a reason for the delay.

More at MedTech Dive

PREVENT Pandemics Act draft released

The Senate Health, Education, Labor and Pensions committee chair, Sen. Patty Murray (D-WA), and ranking member Sen. Richard Burr (R-NC) released a discussion draft of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act.

The PREVENT Pandemics Act is bipartisan legislation focused on strengthening the nation's public health and medical preparedness and response systems in the wake of the COVID-19 pandemic. The senators are also continuing to work with their colleagues on additional provisions to include in the final bill, including consideration of the Advanced Research Projects Agency for Health, which they plan to mark up in committee in the coming weeks.

Feedback on the discussion draft may be submitted to HELPPandemicbill@help.senate.gov until Feb. 4.

FTC, Justice seek to strengthen enforcement against illegal mergers

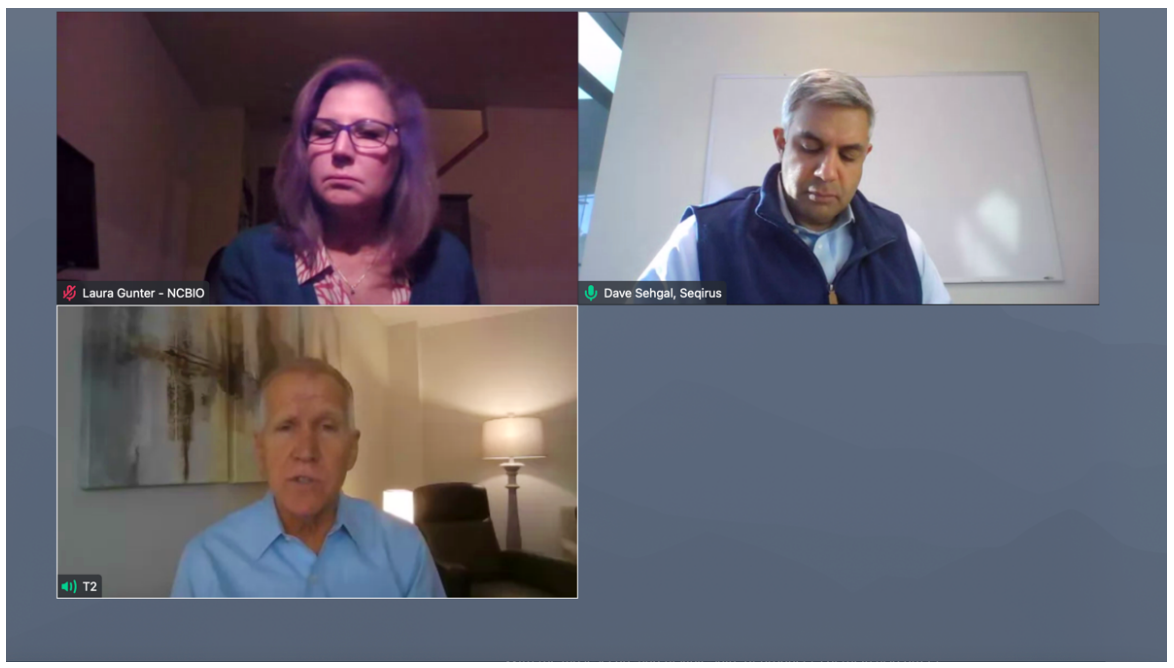
The Federal Trade Commission and the Justice Department's Antitrust Division launched a joint public inquiry aimed at strengthening enforcement against illegal mergers.

The FTC says recent evidence indicates that many industries across the economy are becoming more concentrated and less competitive, imperiling choice and economic gains for consumers, workers, entrepreneurs, and small businesses. The agency went on to say that these problems are likely to persist or worsen due to an ongoing merger surge that has more than doubled merger filings from 2020 to 2021.

To address mounting concerns, the agencies are soliciting public input on ways to modernize federal merger guidelines to better detect and prevent illegal, anticompetitive deals in today's modern markets.

More at FTC

NCBIO Updates



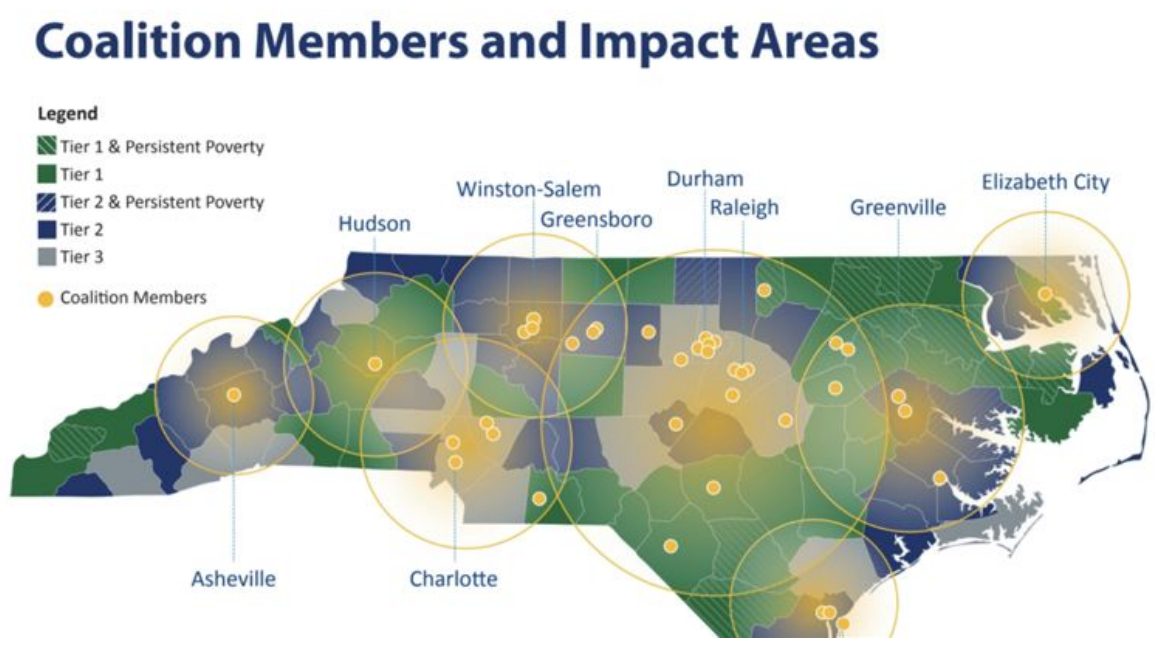
Sen. Tillis joins NCBIO members for Q&A

Sen. Thom Tillis addressed manufacturing capacity, China, intellectual property protections, workforce development and more with NCBIO members during a legislative forum held online Friday, Jan. 14. He emphasized that he and his staff were eager to hear the concerns, issues and ideas of North Carolina's life sciences industry.

NCBIO members had the opportunity ask Tillis about a number of topics, including the following:

- Tillis said that he didn't believe the Build Back Better Act could be passed in its current form.
- In addressing the life sciences industry's need for skilled workers, Tillis said the U.S. should make legal immigration easier for foreign citizens who have the advanced training our industries need.
- The U.S. needs to counter Chinese investment in South and Central America and help create manufacturing capacity in areas like southern Mexico, he said.

Read More at NCBIO



BBB proposal could pull in $75 million to build NC biotech workforce, transform communities

The NC Biotechnology Center and a statewide coalition of public and private partner

organizations including NCBIO are preparing a Phase 2 application to the U.S. Economic Development Administration's $1 billion Build Back Better Regional Challenge after receiving a $500,000 Phase 1 award to develop a Phase 2 proposal.

The coalition's Phase 2 proposal is "Accelerating Life Science Manufacturing to Create Economic Resilience and Promote Equity in Distressed NC Communities" and could be worth up to $75 million. The Phase 1 proposal was one of 60 selected from 529 submissions. There will be 20 to 30 Phase 2 awards.

The proposal's seven projects are all centered on expanding job opportunities and training at all levels of life science manufacturing to benefit many North Carolina communities in economic distress, a situation made worse by the COVID-19 pandemic. The various projects proposed are centered in communities across the state that act as hubs with the economic benefits of investment radiating out to citizens in a 50-mile radius.

NCBiotech is asking industry leaders to support the grant application by writing letters of support, engaging with leaders and communities, assisting with aligning projects to industry needs and hiring the targeted workforce. Grant awardees are also required to raise matching funds equal to 20% of the grant amount, and NC Biotech is seeking assistance with that effort. Contact Laura Gunter at NCBIO if you would like to learn more about getting involved.

MORE >>

NCBIO Member News

Member news briefs

To be included in member news, send information about your organization to David Etchison.

Becton Dickinson received 510(k) clearance from the FDA for its BD Kiestra IdentifA system that automates sample preparation for microbiology bacterial identification. More >>

Biogen has entered into an agreement whereby Samsung Biologics will acquire Biogen's equity stake in the Samsung Bioepis joint venture for an aggregate consideration of up to $2.3 billion. More >>

Cambrex celebrated the 40th anniversary of its founding in 1981 and over $100 million in manufacturing investment around the globe, including $30 million at Cambrex's High Point facility focused on clinical-stage drug substance and small-volume commercial manufacturing services. More >>

Chiesi USA has been named a Top Employer in the United States for the seventh year in a row by the Top Employers Institute, a leading authority on identifying and measuring employment best practices worldwide. More >>

FUJIFILM Diosynth Biotechnologies is expanding its BioProcess Innovation Center in Research Triangle Park, adding approximately 145 skilled positions by 2024 and doubling FUJIFILM's capacity to support process characterization programs. More >>

GENIXUS announced the closure of $20 million in financing to support development and commercialization of its portfolio of novel ready-to-administer products for the hospital setting. More >>

Kriya Therapeutics acquired Warden Bio, a company developing novel AAV-mediated gene therapies for glycogen storage disorders. This acquisition serves as the foundation for Kriya's Rare Disease Division. More >>

Kriya Therapeutics announced an exclusive agreement with the Medical University of South Carolina to license next generation complement-targeted gene therapies for the treatment of geographic atrophy and other ocular diseases. More >>

Lilly plans to invest over $1 billion to create a new manufacturing site, along with nearly 600 new jobs in Concord. The brand-new facility will manufacture injectable products and devices and increase the company's manufacturing capacity. More >>

Liquidia Corporation appointed Roger Jeffs, Ph.D., as chief executive officer effective Jan. 3, and he will continue as a director on the board. He succeeds Damian deGoa who will remain a director of the company. More >>

Pfizer and **Beam Therapeutics** announced an exclusive four-year research collaboration focused on in vivo base editing programs for three targets for rare genetic diseases of the liver, muscle and central nervous system. More >>

Precision BioSciences has entered into an agreement with a syndicate of investors led by ACCELR8 to separate its wholly owned Elo Life Systems subsidiary and create an

independent food and agriculture business. More >>

ProKidney has entered into a definitive agreement to become a publicly traded company via a business combination with Social Capital Suvretta Holdings Corp. III, a special purpose acquisition company. More >>

Thermo Fisher Scientific has completed its acquisition of **PPD** for $17.4 billion. With the addition of PPD, Thermo Fisher will offer a comprehensive suite of services across the clinical development spectrum. More >>

Events

NCBIO Roadmap to Diversity in Life Sciences

NCBIO is committed to prioritizing diversity, equity and inclusion and supporting its members on their DEI journeys. In early 2021, NCBIO established a DEI committee and subcommittees to assist with this effort. In August 2021, we held our first DEI Roadmap event with nearly 200 attendees.

NCBIO and its DEI committee members are planning a second hybrid DEI event on March 9 in Research Triangle Park and hope you will join us in person or virtually. The program features a keynote address by Celeste Warren, vice president, Global Diversity and Inclusion Center of Excellence, Merck, along with two panel sessions:

Success Stories

- **Drew Duncan**, director, human resources and global HR business leader, Biogen (moderator)
- **Sheila Mikhail**, chief executive officer and co-founder, AskBio
- **Erica Paine**, director, value and market access, Chiesi
- **Nicole Thompson**, vice president, inclusion, diversity, equity & engagement, BD

Overcoming Barriers

- **Ronna Dornsife**, instructional technology specialist, North Carolina Central University BRITE (moderator)
- **Joe Ruiz**, president, Enzerna Biosciences
- **Alma Montemayor**, director, project development, Flad Architects
- **Ashley Jefferson**, associate director, early career and talent outreach, Beam Therapeutics

There is no cost to attend for NCBIO members, but you do need to register for the event.

REGISTER NOW

Event Sponors

AskBio Biogen novo nordisk®

MERCK INVENTING FOR LIFE the diversity movement

Act Now! Lock in $400 discount for BIO 2022 by Feb. 1!

As a valued NCBIO member, we are pleased to offer you the opportunity to lock in a $200 discount on your registration for BIO 2022. This discount may be applied to your nonmember premier or general access registration types.

Click below to request your code by Feb. 1. BIO's customer care team will email a custom code to you by Feb. 11. **Combine this discount with early-bird registration by March 17, and you will save $400.**

REQUEST DISCOUNT CODE

Invest in Cures: A Disease Foundation Forum

Feb. 24, 9 a.m. to 1 p.m.

Invest in Cures explores how disease foundations and social venture funds are accelerating the commercialization of early-stage technologies and therapies. LaunchBio and the North Carolina Biotech Center welcome researchers, advocates and investment professionals from leading disease foundations that have successfully partnered with local startups focused on oncology and rare disease.

Session topics include "Advancing Patient Outcomes through Partnership," "Innovation in Rare Disease" and "Impact Investing to Address Health Disparities."

REGISTER NOW

MedTech Conference calls for session proposals

AdvaMed is seeking session proposals for The MedTech Conference 2022 that are relevant, timely and practical to the medical device, diagnostic and digital health industries. Organizing a session at The MedTech Conference allows you to set the agenda for the industry's greatest minds and firmly establish your position as a leading authority in medtech.

Organizations from or affiliated with the medtech industry are welcome to submit session ideas dealing with the latest trends, advancements and critical issues in our field. Session proposals should fall under one of the following tracks:

- Business Strategies
- Digital Technologies
- Diversity, Inclusion and Equity Issues
- In Vitro Diagnostics Tests & Technologies
- International
- Legal and Health Care Compliance Best Practices

- Market Access, Payment and Health Care Delivery Issues
- Regulatory, Quality and Good Manufacturing Practices

The deadline for submissions is Friday, March 4. Incomplete proposals will not be reviewed or considered. In order to be considered, session proposals must be submitted by the deadline. Each submission will be reviewed by an advisory program committee. Acceptance notifications will be sent via email in May.

LEARN MORE

NCBIO is partnering with the Medical Device Manufacturers Association to offer our members a discount on registration for the upcoming FDA Forum being held virtually March 9-10. NCBIO members should use the promotional code "STATE" during registration.

MDMA's 2022 FDA Forum will feature senior officials from FDA and industry and focus on the key regulatory issues impacting the medical device industry.

Designed specifically for medical device regulatory professionals and executive decision makers, MDMA's FDA Forum promises to deliver key regulatory insights and preview trends that will impact your regulatory and business strategies.

Topics will include

- FDA's Continued COVID-19 Response
- Navigating 510(k), De Novo, PMA Programs
- Digital Health
- CDRH Update
- Best Practices for Presubmission Meetings
- Emerging Issues (Biocompatibility, supply chain and more)
- MDUFA Update

Registration Fees

- MDMA Members - $395
- State Member - $495 with promotional code "STATE"
- Nonmembers - $595

LEARN MORE

First Flight Venture Center 2022 FAST Boot Camp

First Flight Venture Center's 2021/22 FAST cohort program can help startups and entrepreneurs accelerate the process of preparing a competitive SBIR/STTR grant. Experts from NCBIO member Eva Garland Consulting will be conducting a two-day boot camp this spring that is complementary to companies who are selected to attend, thanks to support from the U.S. Small Business Administration.

- Thirty-five companies will be selected for the 2022 FAST Boot Camp cohort to attend a two-day grant-readiness evaluation boot camp (complimentary);
- receive expert SBIR grant writing assistance;
- receive business mentoring and coaching from investors, serial entrepreneurs and innovation stakeholders;
- be considered for additional one-on-one SBIR grant assistance after Boot Camp is completed; and
- be considered as one of six companies selected to join the LiftOff program that provides a complimentary strategic plan and Phase I grant written and submitted.

The FAST Boot Camp will take place from April 20-21. The location in Research Triangle Park is to be determined.

APPLY NOW

NCBIO calendar

- eQMS Basics and ACE EssentialsÂ® Demo hosted by PSCSoftware (2/1/2022)
- Don?t Let G6PD Off the Hook! sponsored by Baebies (2/2/2022)
- Spring Internship, Career & Job Fair hosted by NIIMBL (2/8/2022 to 2/10/2022)
- Clinical Supervision Workshop Series hosted by UNC-Wilmington (2/12/2022)
- CEO & Investor Conference hosted by BIO (2/14/2022 to 2/17/2022)
- BPD's BioGrow "Training and Education Across NC" Symposium (2/17/2022)
- The Bid for Talent: Recruitment and Retention in a Competitive Job Market hosted by LaunchBio (2/17/2022)
- Champions for a Cure Tournament (2/20/2022 to 2/21/2022)
- 6th Microbiome Movement: AgBioTech Summit (2/22/2022 to 2/24/2022)
- Ag Tech Professional Forum: Nematodes, What A Pest hosted by NCBiotech (2/23/2022)
- Invest in Cures hosted by LaunchBio (2/24/2022)
- Outlook for Tech hosted by NC TECH (3/4/2022)
- FDA Forum hosted by MDMA (3/9/2022 to 3/10/2022)
- NCBIO Roadmap to Diversity in Life Sciences (3/9/2022)

Ready to kick off your year with cost saving benefits?

A new year brings new opportunities. BIO Business Solutions Program provides the opportunity to access new cost-savings benefits.

Here's how it works.

BIO Business Solutions make it their mission to vet the most qualified businesses who are supporters of the life sciences industries to ensure they have a wide variety of products and services that will benefit you.

The BBS team works continuously to ensure competitive pricing and favorable terms for products and services such as lab supplies, insurance, shipping, office supplies and more. Their diligence enables you to have more time to focus on your organization’s core mission.

For all the latest news, promos and event information, follow BIO Business Solutions on LinkedIn.

NCBIO members can participate and save with some of our top vendors such as:

AVANTOR, DELIVERED BY VWR

75% off Lab Supplies

CLEAN HARBORS

40% off Lab Waste Removal

NIKON INSTRUMENTS

15% off Microscope Systems

UNIFIRST

Up to 50% off Workwear/Cleanroom

Ready to dive into our outstanding cost-saving benefits?

Step 1: Give the BIO Business Solutions team a call (Bob Dearth 781-716-7555)
Step 2: Let them know how you’d like to save money.
Step 3: BIO Business Solutions handles the rest.

START SAVING

REGISTER NOW

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