



November 2022 Update

Serving the NC Life Sciences Industry

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NCBIO This Month

- Sen. Richard Burr speaks at Annual Dinner
- Full crowd for NCBIO Annual Meeting
- New Congress imminent
- Working to protect IP
- BIO names interim CEO
- BIO report documents NC life sciences growth
- Get the [NCBIO 21-22 Year in Review](#)
- Register now for the Nov. 29 CRO Forum

... and more



Burr shares insights from 28-year Congressional career at Annual Dinner

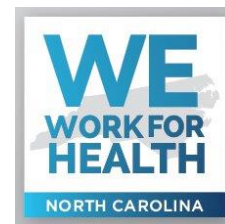
Sen. Richard Burr reflected on his 28-year career in Congress and discussed FDA reform, the nation's response to future pandemics and the pitfalls of the nation's regulatory system at the 2022 NCBIO Annual Dinner held Monday, Oct. 10, at the NC Biotechnology Center.

The dinner was sponsored by Avantor, delivered by VWR; Frankel Staffing Partners; Hatteras Venture Partners; and Marsh McLennan Agency.

Burr is retiring in January after 10 years in the House of Representatives and 18 years in the Senate. He chaired the Senate Intelligence Committee from 2015 to 2020. He is the ranking member of the Senate Committee on Health, Education, Labor, and Pensions and is also a member of the Committees on Finance and on Aging. In the House, Burr authored the FDA Modernization Act of 1997. He also helped create the National Institute for Biomedical Imaging and Bioengineering.

[More >>](#)

NCBIO Sustaining Members



NCBIO Supporting Members



2022 Annual Meeting discusses workforce, health equity, investment, locating in NC

The 2022 NCBIO Annual Meeting held Oct. 12 at the NC Biotechnology Center featured expert panels on locating in North Carolina, talent recruitment, financial trends and health equity and disparities. The meeting returned to being fully in person this year after several years of being virtual or offering an online option due to the COVID pandemic.

The meeting featured multiple networking opportunities and four panel discussions.

- **Success Stories: Talent Recruitment and Retention** with FUJIFILM Diosynth, Lilly, Novozymes and StrideBio
- **Financial Trends and Outlook** with GSK, Incubate Coalition, JPMorgan, Pappas Capital and Solas Bioventures
- **Health Equity and Disparity** features BIO, Biogen, ECU's Center for Health Disparities, the Global Liver Institute and mdgroup
- **Decisions to Locate and Expand in NC** with Amgen, Economic Development Partnership of NC, FUJIFILM and Lilly

Thank you to all of our sponsors who made this event possible.

- Platinum: [Avantor delivered by VWR](#); [Bioventus](#), [Cook Medical](#), [Kymanox](#)
- Gold: [American Laboratory Trading](#), [Azzur Group](#), [FUJIFILM Diosynth Biotechnologies](#), [Grifols](#), [Novo Nordisk](#), [PSC Biotech](#)
- Silver: [AdvaMed](#), [Alexandria Real Estate Equities](#), [The Conafay Group](#), [Frontier Scientific Solutions](#), [Marsh McLennan Agency](#), [Mispro Biotech Services](#), [Smith Anderson](#), [Unifirst](#)
- Bronze: [Amgen](#), [BioCryst](#), [Nikon](#), [Novozymes](#), [PHC Corporation](#), [UCB](#), [UMotif](#)

Save the Date: Next year's meeting is Oct. 4.

Â [More >>](#)



STATE UPDATES

Cooper signs order to support market-driven transition to zero-emission trucks and buses

On Oct. 25, Gov. Roy Cooper issued an executive order requiring state rules to be created that would increase the sale of electric trucks and buses in North Carolina.

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Executive Order 271 directs the North Carolina Department of Environmental Quality to work with stakeholders to propose to the Environmental Management Commission an Advanced Clean Trucks program that would ensure zero-emission trucks and buses are available for purchase in the state. The ACT program would require manufacturers to sell an increasing percentage of zero-emission vehicles over time while providing flexibility, through credits, trading and other features, as segments of the market grow at different speeds.

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The proposed rules would need to be approved by the state Environmental Management Commission. North Carolina would be the seventh state and first in the Southeast to adopt such rules. Â

[More at NC.gov >>](#)



NATIONAL UPDATES

Congress returns to work after elections

When Congress returns on Nov. 14, members will need to develop an omnibus appropriations bill, as well as a compromise ARPA-H authorization bill, Cures 2.0 and the National Defense Authorization Act, among others.

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The FY2023 appropriations process stopped once the new fiscal year began on Oct. 1. Now the plan is to craft an omnibus package after the November elections that is likely to include more than the 12 annual appropriations bills but also authorizations for COVID funding, ARPA-H, Cures 2.0, the VALID Act regulating diagnostics, pandemic response, and other key statutes. Also, the NDAA is expected to pass the Senate in November as a separate bill since it already passed the House, then move quickly to conference committee to pass a final bill in both chambers and send it onto President Biden in December.

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The continuing resolution currently funding the government includes reauthorization of FDA's prescription and generic drug, biosimilar and medical device user fee programs for another five years, which means the agency will not have to lay off user-fee funded staff. It does not include the VALID Act, cyber security guidance and other measures that many lawmakers are working to add into the omnibus.

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Key states to watch in the Nov. 8 election that will determine control of the Senate include Arizona, Florida, Georgia, Nevada, North Carolina, Ohio, Pennsylvania and Wisconsin. Most predict the House to flip to Republican control but differ on how many seats will flip.

Expanding COVID IP waiver would harm small, medium enterprises, CSBA says

Every member of the Council of State Bioscience Associations, including NCBIO, [signed a letter](#) to President Joe Biden expressing serious concerns with the proposed expansion of IP protections for COVID technology.

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In June, the World Trade Organization agreed to waive IP protections for COVID-19 vaccines, a decision supported by the Biden administration. The WTO is now considering expanding the waiver to include COVID-19 therapeutics and diagnostics.

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Of the over 350 therapeutics being developed in the United States, 86% ? totaling 307 therapeutics ? originated from SME biotech firms spanning over 28 states, the letter states. For SME biotech firms, the expansion of a TRIPS waiver to therapeutics creates significant market risk for the commercialization of their products for indications unrelated to COVID-19.

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And there's just no justification. Manufacturers are supplying therapeutics at a rate that outpaces demand. Biotech antiviral manufacturers have entered into dozens of voluntary licensing agreements with companies in South America, Africa and Asia to manufacture generic antivirals and distribute these products to countries throughout the developing world.

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What's the alternative? Strengthening health systems infrastructure, addressing vaccine hesitancy, and supporting more robust COVID-19 testing and therapeutic procurement initiatives are examples of some initiatives that can have a meaningful impact.

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[In this podcast](#), Hans Sauer, BIO's deputy general counsel for intellectual property and a professor at Georgetown Law School, talks about about the enormous potential negative consequences of the Biden Administration allowing the WTO to waive IP rights of mRNA technology, potentially creating huge negative consequences for U.S. innovation.

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[More at BIO >>](#)

FTC reports on pharmaceutical product hopping

Congress directed the Federal Trade Commission to report to the Committees on Appropriations of the House and Senate regarding the FTC's efforts to address pharmaceutical product hopping.

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The FTC defines product hopping as a strategy where a pharmaceutical company seeks to shift demand from a brand-name drug that faces generic competition to newly patented or exclusivity-protected drugs that do not face generic competition.

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The outlines the actions the FTC has taken in the past 15 years to address these issues and other issues related to generic competition, and the principles it uses to assess whether a pharmaceutical industry practice is unlawful under the antitrust statutes.Â

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Specifically, the report details the Commission's actions against Warner Chilcott's alleged actions to prevent generic competition to its Ovcon birth control pill and the FTC's settlements with Reckitt Benckise Group and its drug Suboxone, which treats opioid addiction.

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[Get the report >>](#)

From Tillie sign on to letter questioning possible expansion of

Burr, Tillis sign on to letter questioning possible expansion of WTO TRIPS waiver

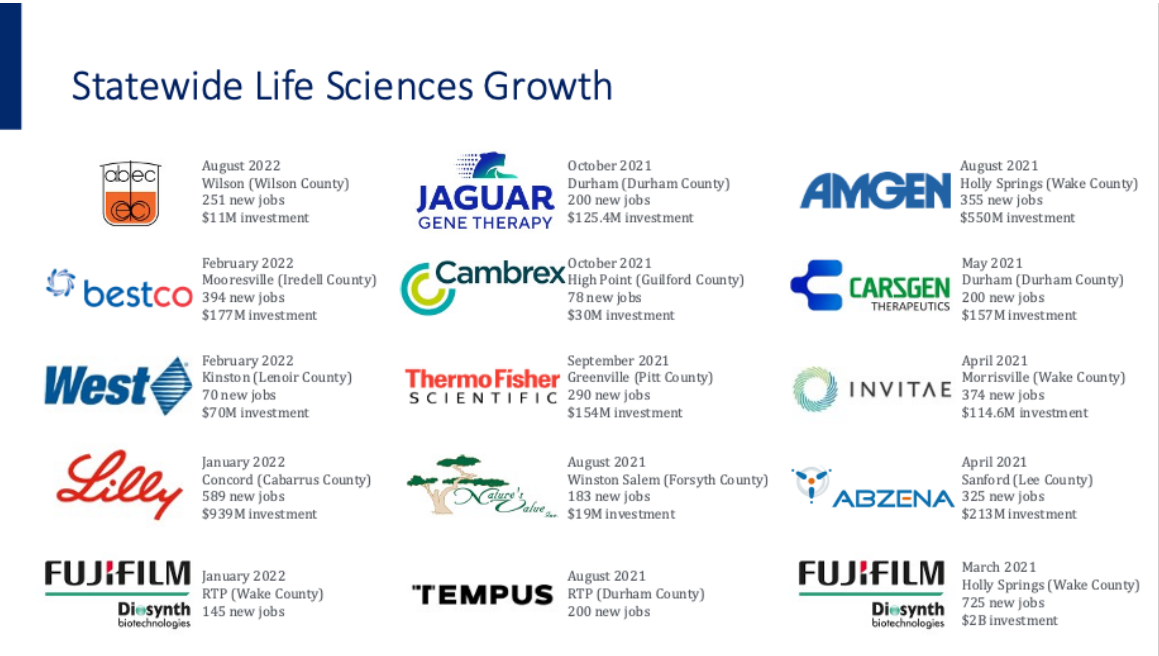
U.S. Senators Tom Carper (D-Del.) and Pat Toomey (R-Pa.) led a bipartisan group of senators that includes North Carolina Senators Richard Burr and Thom Tillis in writing U.S. Trade Representative Katherine Tai to urge the Biden Administration to safeguard American innovation in the World Trade Organization’s negotiations on whether to expand its waiver of IP rights enforcement for COVID-19 vaccines to also include therapeutics and diagnostics.

“The senators are requesting answers to several questions surrounding this waiver, including:

- What economic analysis USTR has conducted regarding the impact of the COVID-19 vaccine waiver on global vaccine supply, and how this information may inform a U.S. position on a possible waiver expansion;
- How the WTO will define a “diagnostic” and a “therapeutic”;
- Whether USTR has produced any analysis on the effect that waiving additional IP protections will have on R&D; and
- How USTR is meeting its legal requirement to consult transparently with Congress prior to December’s decision deadline at the WTO.

[More at Senate.gov >>](#)

NCBIO Updates



The NC Biotechnology Center put together this graphic showing some of the major announcements of growth in the NC life sciences industry over the past two years.

BIO appoints Rachel King as interim CEO

The Biotechnology Innovation Organization announced that Rachel King, co-founder and former CEO of GlycoMimetics, Inc., has agreed to serve as interim president and CEO.

King’s appointment follows Michelle McMurry-Heath, M.D., Ph.D., stepping down as president and CEO to serve as an adviser to the Executive Committee of the BIO Board of Directors. The organization is searching for a full-time successor.

A long-standing member of the BIO leadership, King brings deep expertise across the industry and previously served as chair of the BIO board. King has experience at small and large companies having served as co-founder and former CEO of GlycoMimetics, Inc. and as a senior vice president of Novartis Corporation. Prior to that role she spent more than a decade at Genetic Therapy Inc., including as the company’s CEO. She also served at ALZA Corporation and at Bain & Company. She is an expert in the innovation ecosystem as a former entrepreneur in residence at New Enterprise Associates, one of the nation’s leading venture capital firms.

[More at BIO >>](#)

New BIO report shows strong growth of NC life sciences industry

The Biotechnology Innovation Organization, in partnership with the Council of State Bioscience Associations, released a new report on the state of the bioscience economy that places North Carolina’s life sciences industry among the national leaders in its size, specialized employment concentration and diverse strengths.

The industry in the state has experienced strong growth since 2018, increasing employment by 13 percent to reach more than 92,000 jobs in 2021 across 5,863 business establishments.

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North Carolina has diverse strengths in the biosciences, with specialized employment concentrations in two subsectors: in pharmaceuticals and in research, testing and medical labs. Two other subsectors have high, above-average concentrations in the state: agricultural feedstock and industrial biosciences and bioscience-related distribution.Â

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The state is in the top tier in its bioscience-related university R&D activities with \$2.5 billion in expenditures in 2020. Funding from NIH to North Carolina institutions has been steadily and significantly increasing in recent years and reached \$2.2 billion in 2021, up 60 percent since 2018.

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The life sciences industry in North Carolina is among the top 10 states in number of companies, number employed and NIH funding but is in the second quintile for venture capital investments and patents generated.

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Now in its sixth edition, the BIO report serves as a leading analysis of legislative and regulatory initiatives at the state and regional level for economic development in the bioscience ecosystem.

[More at BIO >>](#)

NIIMBL pilots biopharma manufacturing program to NC high school students

The National Institute for Innovation in Manufacturing Biopharmaceuticals is launching NIIMBL bioLOGIC, a pilot program designed to bring awareness to and foster interest in careers in the biopharmaceutical manufacturing industry.

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NIIMBL has partnered with the North Carolina Biotechnology Center and has selected Southern High School of Energy and Sustainability in Durham to pilot the five-week program where students not only will learn and innovate but also will visualize themselves with a career in the industry.Â

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Southern High School was selected for the pilot because the region has experienced robust growth in recent years, and the institution has a 95% minority enrollment rate. By implementing the program at Southern High, Black and Latine high school students will have access to the biopharmaceutical manufacturing industry within their own community.

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NIIMBL bioLOGIC was created in partnership with NextFlex as part of a \$5 million funding grant from the Office of Naval Research. The grant?s purpose is to develop new education programs modeled after NextFlex?s award-winning project-based learning FlexFactor program. Following a successful pilot launch and expansion in North Carolina, NIIMBL looks forward to deploying the program in other regional ecosystems nationwide.

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[More at NIIMBL >>](#)

Look to NCBIO and The Diversity Movement for DEI resources

NCBIO understands that diversity, equity, and inclusion is critical to the continued growth and success of the life science industry in the state.Â

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NCBIO is committed to working with legislators and public policy makers to ensure equity, as well as to continue to embed DEI within our offerings and resources so members, their organizations and the life science industry within the state of North Carolina will continue to thrive and impact the world with breakthrough innovations and technologies.

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For our members, NCBIO and The Diversity Movement curate a variety of web-based DEI resources, including videos, white papers and guides, at www.ncbioscience.net/dei/.

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LEARN MORE

NCBIO Member News

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

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AgBiome's Esendo fungicide is the latest in the company?s lineup of microbial-based solutions and the first of its proprietary Connate portfolio to receive approval from the Environmental Protection Agency. [More >>](#)

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Atsena Therapeutics announced positive results from the Phase I/II clinical trial of ATSN-101, its lead investigational gene therapy product, for the treatment of GUCY2D-associated Leber congenital amaurosis. [More >>](#)

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Biogen Inc. announced that the FDA has extended the review period of the new drug application for tofersen by three months until April 25. Tofersen is an investigational treatment for superoxide dismutase 1 amyotrophic lateral sclerosis. [More >>](#)

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Biogen Inc. dosed the first patient in the global clinical study, AMETHYST, a Phase 2/3 study evaluating the clinical efficacy and safety of litifilimab, a first in-class, humanized IgG1 monoclonal antibody targeting blood dendritic cell antigen 2 in participants with cutaneous lupus erythematosus. [More >>](#)

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Biogen Inc. and Denali Therapeutics Inc. commenced dosing in the global Phase 3 LIGHTHOUSE study to evaluate the efficacy and safety profile of BIIB122 (DNL151) in approximately 400 participants with Parkinson’s disease and a confirmed pathogenic mutation in the leucine-rich repeat kinase 2 gene. [More >>](#)

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Bioventus received a 2022 Leadership in Diversity Award from the Triangle Business Journal. [More >>](#)

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Chiesi USA, Inc. has been ranked No. 15 among Fortune’s 25 Best Small and Medium Workplaces in Biotechnology and Pharmaceuticals. [More >>](#)

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Chiesi USA, Inc. concluded its presenting strikeout partnership with the Durham Bulls minor league baseball team by donating \$5,000 to three Triangle-area nonprofits: Activate Good, Ronald McDonald House of Durham & Wake, and Children’s Flight of Hope. [More >>](#)

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Curie Co., an early stage enzymes company based in New York City, has relocated to Research Triangle Park. [More >>](#)

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G1 Therapeutics, Inc. is supporting a Phase 2 investigator initiated study of trilaciclib and lurbinectedin in patients with extensive stage small-cell lung cancer. [More >>](#)

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G1 Therapeutics, Inc. announced that the last patient has been randomized in PRESERVE 2, G1’s Phase 3 clinical trial of trilaciclib in patients with metastatic triple negative breast cancer receiving chemotherapy. [More >>](#)

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JLL announced the launch of a dedicated life sciences practice in the firm’s Raleigh-Durham office to build upon the firm’s capabilities and demonstrate its continued investment in the sector. [More >>](#)

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Medix has assessed the state of the post-pandemic workforce in [a new report](#) that identifies big-picture insights so you can plan for the road ahead. Get the report [here](#).

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RTI International's Kristina Brunelle received a 2022 Leadership in Diversity Award from the Triangle Business Journal. [More >>](#)

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PPD, the clinical research business of **Thermo Fisher Scientific Inc.**, has created the PPD DCT Network to support global investigators and research sites participating in decentralized clinical trials for pharmaceutical and biotech customers. [More >>](#)

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PPD, the clinical research business of **Thermo Fisher Scientific Inc.**, has been awarded the Eagle Award for the second consecutive year for its outstanding leadership, professionalism, integrity and dedication to advancing the clinical research profession through strong partnerships with research sites. [More >>](#)

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Smith Anderson received a 2022 Leadership in Diversity Award from the Triangle Business Journal. [More >>](#)

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Syneos Health received a 2022 Leadership in Diversity Award from the Triangle Business Journal. [More >>](#)

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Events

Johnson & Johnson Networking Reception Nov. 7

Members of the Johnson & Johnson Innovations team will be traveling to North Carolina to meet NC therapeutic companies and ecosystem stakeholders Nov. 7 at NCBiotech. They will introduce the various units within J&J and discuss how they support early-stage therapeutics companies. Â

Panel Discussion with J&J and a Local Entrepreneur: Navigating the Corporate Relationship

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The J&J panelists will discuss:

- Strategies for identifying and approaching potential strategic partners

- Evaluating companies for partnership and investment
- What you can expect from the deal-making process
- How deals are structured
- Recent trends in biopharma partnering

LEARN MORE

Reflecting on DEI in 2022 and Looking Ahead at 2023

Join us virtually on Nov. 9 to hear from The Diversity Movement's Kurt Merriweather, co-founder and vice president of products and innovation.

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Merriweather will look at what progress made and challenges companies faced in 2022 in implementing diversity, equity and inclusion programs. He will also share what he thinks we can expect in 2023 and will be available for questions following the presentation.

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Join us virtually on Wednesday, Nov. 9, at 12 p.m. You can also take advantage of the DEI resources from The Diversity Movement curated [here](#) on the NCBIO website.

REGISTER NOW



Meet UNC student interns at Carolina Startup Connect Nov. 9

Is your startup or small business interested in recruiting talented student interns to your team? Have a fun, fast-paced internship role that would help a student learn and help your company grow?

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Attend Carolina Startup Connect to meet top college students who can help your company or organization complete important projects and meet key goals. This isn't your average college career fair. It's designed specifically as a way for companies like yours to meet with entrepreneurial-minded students from UNC-Chapel Hill and Carolina Central Community College who have high-demand skills and a passion for working at startups.

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You can join us for one -- or both -- of the sessions below. They're conveniently held back-to-back on Wednesday, Nov. 9, from 4 to 6 p.m. at the Carolina Union on the UNC-Chapel Hill campus.Â

- Celebrating Diverse Startup Founders (starting at 4 p.m.). If you are a minority- or female-founded company or organization, join this informative, inspirational panel discussion to share your wisdom and journey with students.Â
- Internship Startup Meet and Greet (starting at 5 p.m.). This session is open to startups in the Piedmont area of North Carolina. As a startup, you'll share a bit about your company or organization and available internships and then network with students.Â

Note: This event is open to paid and unpaid internships. All registered startups will be contacted about an info session in October. Check the Carolina Startup Connect site for the latest details and attendees. If you have questions, please contact Kimi.Yingling@unc.edu.

REGISTER NOW

Register now for NCBIO CRO Forum Nov. 29

Join NCBIO for our Clinical Trials Luncheon and Forum on Tuesday, Nov. 29, from 11:30 a.m. to 1:30 p.m. This luncheon and program will be held at the NC Biotech Center located at 15 TW Alexander Drive, RTP, NC 27709.

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Connect with NCBIO members for lunch and a panel on diversity in clinical trials featuring

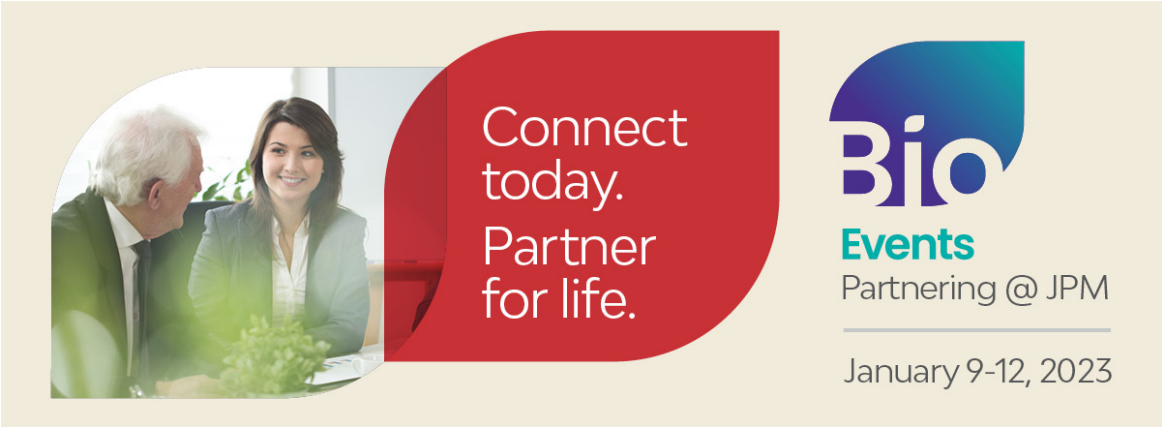
- Rodrigo Garcia, M.D., vice president, Sites & Patients Center of Excellence, PPD, part of Thermo Fisher Scientific;
- Julie Harrell, patient enrollment liaison, Ultragenyx; and
- Josh Sommer, executive director, Chordoma Foundation (moderator).Â

Panelists will address some of the barriers and challenges to diversity in clinical trial enrollment, rare disease considerations in clinical trial enrollment and solutions to these challenges. Decentralized clinical trials will also be a topic of discussion.

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Please share this invitation with others in your organization who might be interested in joining us on Tuesday, Nov. 29. All representatives from member companies are welcome. To register, contact Events Director Amber Niebauer.Â

REGISTER NOW



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.

REGISTER NOW

NCBIO calendar

- Upstream Production Process Development for Biopharmaceuticals hosted by BTEC (10/24/2022 to 11/4/2022)
- Let's Talk About: Core Values hosted by LaunchBio (11/3/2022)
- NC Life Sciences Career Fair hosted by NCBiotech (11/4/2022)
- Navigating the Corporate Relationship hosted by J&J (11/7/2022)
- Bioanalytical strategies for oncolytic virus therapeutics hosted by BioAgilytix (11/8/2022)
- Reimbursement and Health Policy Conference hosted by MDMA (11/9/2022 to 11/10/2022)
- Reflecting on DEI in 2022 and Looking Ahead at 2023 hosted by NCBIO (11/9/2022)
- High-Resolution Accurate Mass (HRAM) Mass Spectrometry: A Vital Tool for the Development of Modern and Future Medicines hosted by BioAgilytix (11/9/2022)
- Carolina Startup Connect hosted by UNC (11/9/2022)
- Joint Networking Event hosted by RTP Chapters of WIB and HBA (11/9/2022)
- cGMP Boot Camp hosted by Azzur Group (11/15/2022)
- Virtual Career Fair hosted by BioNetwork (11/15/2022)
- Aseptic cGMP Boot Camp hosted by Azzur Group (11/16/2022)
- Investigation Boot Camp hosted by Azzur Group (11/17/2022)
- Practical Advice for How to Measure DEI Success hosted by The Diversity Movement (11/17/2022)
- NCBIO Clinical Trials Luncheon and Forum (11/29/2022)

BIO Business Solutions

Ransomware isn't just about data: The rising risk of cyber business interruption



With increasing ransomware attacks, businesses need to stay ahead of digital disruptions and cyber risks. "Cyber criminals' new goal is to disrupt businesses rather than just extract data. Now is the time to tighten up your understanding of your business interruption risk," said Bianca McKenzie, head of claims preparation, advocacy and valuations, UK at Aon. "Does your company have a cyber risk strategy? Professionals at Aon, BIO's Preferred Partner for cyber liability coverage, highlights new digital disruptions and cyber risks."

AON

[LEARN MORE](#)




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