



September 2024 Update
Serving the NC Life Sciences Industry

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Annual Meeting sold out, waiting list
available



We are very much looking forward to seeing everyone at the the NCLifeSci Annual Meeting and 30th anniversary celebration on Wednesday, Sept. 18, at the NC Biotechnology Center. The 2024 Annual Meeting is **sold out**, but you can still [add your name to a waiting list](#).

The meeting will feature a keynote presentation and three panel sessions.

- **The Future of Pharma Manufacturing is Now: The Role of Strategic Partnerships:** keynote by Edgardo Hernandez, executive vice president and president, manufacturing operations, Eli Lilly and Company
- **Working with Patient Advocates:** Arthritis Foundation, the Biotechnology Innovation Organization, Edwards Lifesciences, Merck and the National Organization for Rare Disorders
- **Best Practices and Lessons Learned from AI:** PPD, SAS, UNC School of Data Science and Society and Womble Bond Dickinson
- **Future Technology and the Patient Experience:** Biogen, Brightseed, the Chordoma Foundation, the Foundation Fighting Blindness and Jurata Thin Film

Thank you to our Annual Meeting sponsors for making this event possible.

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**NCLifeSci
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Members**



**NCLifeSci Supporting
Members**





STATE UPDATES

UNC Chapel Hill names permanent chancellor

The University of North Carolina at Chapel Hill announced that Interim Chancellor Lee Roberts will assume the role permanently. Roberts will serve as the 13th chancellor of UNC.

Roberts had previously served on the UNC System Board of Governors before resigning from the board in January to serve as UNC's interim chancellor.

Roberts officially started his new role on August 12 and is responsible for leading 30,000 students and approximately 14,000 faculty and staff. [More at News & Observer](#)



NATIONAL UPDATES

If there are any topics or issues that are affecting your business or you want to know more about, please contact [Laura Gunter](#).

IRA negotiations slash Medicare list prices for Big Pharma blockbusters by up to 79%

The White House has revealed significantly reduced prices for 10 prescription drugs affected by the first wave of Medicare negotiations mandated by the Inflation Reduction Act, the Biden administration initiative that includes several measures designed to lower the cost of health care in the U.S.

The reductions were sharp, with list prices for all but one of the 10 medicines sliced by at least 50%. However, many of these first 10 drugs are already sold well below list price, and at this point, it's unclear what savings Medicare beneficiaries will see.

The products taking the biggest pricing hits were diabetes treatments: Merck's Januvia was hit with a price reduction of 79%, from a monthly price of \$527 to \$113, while Novo Nordisk's Fiasp for Type 1 diabetes sustained a 76% price drop, from \$495 a month to \$119.

Taking the smallest cut of the 10 is the lone cancer treatment, Johnson & Johnson's Imbruvica, whose price was reduced by 38%, from \$14,934 for a monthly regimen to \$9,139. J&J was the only company with more than one drug on the list. Its autoimmune blockbuster Stelara took a 66% drop while blood thinner Xarelto sustained a 62% price reduction. Novartis, for its part, has seen its top-selling heart failure drug Entresto take a 53% price cut.

New prices go into effect in 2026. Starting in 2027, the negotiation process will expand to another 15 drugs, with more to come in subsequent years. [More at Fierce Pharma](#)

Biden admin to spend billions to blunt spike in Medicare drug premiums

One of President Joe Biden's signature domestic achievements is set to cause a significant spike in Medicare premiums for millions of Americans just ahead of the November election. Now, his administration is preparing to dole out billions of dollars to private insurance companies to blunt the impact of the increase.

The jump in premiums is a consequence of efforts to reduce what older Americans pay for prescription drugs, part of the 2022 Inflation Reduction Act. Insurance companies are on the hook for what patients used to pay and are raising drug plan premiums to make up the difference.

The new premiums will be released in mid-to-late September. Under the administration plan, the Centers for Medicare and Medicaid Services would give participating Medicare prescription drug plans the \$15 subsidy and restrict how much insurers can raise premium rates year over year. The deadline for insurance plans to say whether they will participate has passed and CMS said it is assessing the responses.

CMS has the authority to test changes to Medicare payments and reimbursements and has done similar projects in the past, but Republicans argue that this latest effort has no clear statutory basis or credible research goals. They have asked the General Accountability Office to investigate.

The Inflation Reduction Act placed a \$2,000 cap on out-of-pocket drug costs for older Americans, allowed beneficiaries to spread their annual drug costs over monthly installments and shifted responsibility to insurers to cover more drug costs after a beneficiary spends a large amount.

Judge dismisses U.S. Chamber challenge to Medicare price talks

The U.S. Chamber of Commerce's challenge to Medicare drug price negotiations was dismissed by a federal judge.

The judge found that the lawsuit was filed in the wrong venue and that the other plaintiffs lacked standing. The U.S. Chamber, along with state and local chambers, had challenged the program, but only the Chamber had a "plausible" but "questionable" claim, the judge said as he accused the groups of forum shopping and said that the two companies the Chamber aimed to help could have brought their own challenges.

The judge rejected the idea of allowing any individual or company to bypass venue rules by becoming a member of an association related to a challenged law. The Chamber is now considering its next steps, including potentially appealing the decision.

Value-based payment agreements could boost patient access

Innovative payment agreements can increase patient access to transformative new treatments while helping states control their Medicaid costs, according to BIO.

Transformative therapies, including cell and gene therapies, offer new treatment options for patients, often for conditions with limited or no treatment options available, but payment is a challenge.

"Innovation needs to not just happen on the research and development side, it needs to happen throughout all drug delivery aspects, and that includes reimbursement and payment," said Jack Geisser, BIO's senior director, health care policy, Medicaid and state initiatives.

Creative payment arrangements include:

- Funding single-course curative treatments, such as revolutionary cell and gene therapies, which can have a high up-front cost but save money over time.
- Value-based payment arrangements, in which Medicaid programs only pay for treatments that prove effective.

The Medicaid VBPs for Patients, or MVP, Act and creative state-level legislation could meet a vast medical need among Medicaid patients, and the limits in state budgets make state Medicaid programs a natural place to launch innovative payment arrangements. [More at BIO](#)





NCLifeSci President Laura Gunter and Rep. Greg Murphy were hosted by Novartis Gene Therapies Aug. 23 for a tour of the company's facility in Durham.

NCLifeSci Updates

Womble Bond Dickinson alert: FTC noncompete ban struck down

In a blog post, Womble Bond Dickinson explains the significance of a federal court blocking the Federal Trade Commission's rule that sought to ban most employment noncompetes in the United States. While an appeal by the FTC seems likely, WBD wrote, for now the rule will not go into effect in September and businesses may continue to use noncompete agreements with employees consistent with current laws in their jurisdiction.

WBD writes that the judge held that the FTC lacked authority to promulgate substantive rules on this issue; that the FTC exceeded its statutory authority in issuing the noncompete rule and that the Rule was arbitrary and capricious. The court rejected the FTC's argument that the order should be limited only to the parties in the case, and Judge Brown instead ruled that the order had nationwide effect. Accordingly, the court set aside the Rule in its entirety and ordered that that Rule could not be enforced or take effect. [More at Womble Bond Dickinson](#)



Build Back Better program addresses workforce inequity

To address workforce inequity in biomanufacturing, the North Carolina HBCU/HAIU Coalition was established under the Accelerating Life Science Manufacturing program to create economic resilience and promote equity in distressed communities. This program is composed of a group of strategically aligned partners led by the North Carolina Biotechnology Center for the Build Back Better Regional Challenge grant.

A two-week advanced training program was created to introduce and train participants in the upstream and downstream processes required by industry to develop qualified candidates to move directly into manufacturing opportunities within the biomanufacturing industry.

Six HBCU/HAIU sites were selected and outfitted to host the training: UNC-Pembroke, Winston Salem State University, Fayetteville State University, Livingstone College, Elizabeth City State University and Saint Augustine's College. Each site can train twelve participants per two-week session in the following areas:

- Workplace safety
- Current manufacturing practices
- Measurements, metrics, and math
- Process flows

As of August, 49 participants have completed the two-week training course at four of the sites.

NCLifeSci Member News

The Diversity Movement's Susie Silver was named a 2024 Leader in Diversity by the [Triangle Business Journal](#)

Triangle Business Journal. [More >>](#)

Eisai and **Biogen** announced that the humanized amyloid-beta monoclonal antibody Leqembi (lecanemab) has been granted a Marketing Authorization by the Medicines and Healthcare products Regulatory Agency in Great Britain. [More >>](#)

G1 Therapeutics and Pharmacosmos A/S announced that they have entered into a definitive merger agreement under which Pharmacosmos A/S, through its U.S. subsidiary Pharmacosmos Therapeutics Inc., will acquire all outstanding shares of G1 Therapeutics common stock. [More >>](#)

Humacyte announced the successful completion of its business combination with Alpha Healthcare Acquisition Corp. The resulting combined company, Humacyte, will commence trading of its shares of common stock and warrants on the Nasdaq. [More >>](#)

Humacyte announced advancements in its commercial operations with the appointment of B.J. Scheessele as Chief Commercial Officer. [More >>](#)

Lindy Biosciences announced a multi-target exclusive global licensing agreement and strategic collaboration with Novartis Pharma AG to transition select medicines from the Novartis portfolio to self-administered subcutaneous injections using Lindy Biosciences' proprietary microglassification suspension technology. [More >>](#)

Pathalys Pharma, a private biopharmaceutical company in the late stages of developing treatments for kidney disease, has successfully closed a \$105 million Series B financing round. [More >>](#)

Safety Partners announced that Lauren Laidlaw has joined the company as vice president of client engagement and strategic alliances. [More >>](#)

Smith Anderson's Taylor Dewberry was named a 2024 Leader in Diversity by the Triangle Business Journal. [More >>](#)

Events

NCLifeSci calendar

- [U.S. Data Privacy for Health Summit \(9/10/2024\)](#)
- [International Life Science & Biotech Conference \(9/11/2024 to 9/12/2024\)](#)
- [NCLifeSci Annual Meeting 2024 \(9/18/2024\)](#)
- [Life Sciences Economic Development Summit & 40th Anniversary Celebration hosted by NCBiotech \(9/19/2024\)](#)
- [The MedTech Conference powered by AdvaMed \(10/15/2024 to 10/17/2024\)](#)
- [CED's 40th Birthday Party \(10/15/2024\)](#)

NC Manufacturing
COUNCIL

PFAS: Understanding Your Liability

SEPT. 10, 2024 AT 3 P.M.

VIRTUAL

REGISTER TODAY

PFAS and your business webinar Sept. 10

As PFAS and “forever chemicals” dominate headlines, do you know what it means for your business? Join the NC Chamber of Commerce online on Tuesday, Sept. 10, for the next NC Manufacturing Council meeting to gain more insight into PFAS, the environmental and health concerns, current state of PFAS regulation and litigation, and practical steps that manufacturers can take to identify and manage PFAS-related risks.

REGISTER NOW

DATA PRIVACY

FOR HEALTH

Summit

MyData-TRUST

Research Triangle Park

North Carolina Biotechnology Center.

NCLifeSci

TOPICS

AI in Clinical Trials

U.S. Privacy Landscape

Data Breaches

Global DPO

CRO Code of Conduct

Networking

September 10

Durham, North Carolina

iapp

GET 5.5 CPE CREDITS

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MyData-TRUST Data privacy summit Sept. 10 at NCBiotech

After more than five years in organizing Data Privacy for Life Science Summit in Europe, MyData-TRUST is bringing its concept to the U.S. Join them for their first edition of the U.S. Data Privacy for Health 2024, taking place Sept. 10 at the NC Biotechnology Center.

The perfect occasion to meet other data privacy officers, privacy experts, lawyers and clinical professionals ? all with the same goal: Share knowledge, discuss challenges and find solutions for their Global Data Privacy in the Life Sciences Industry.

NCLifeSci members receive a 20% discount on their registration. Contact [Amber Niebauer](#) for the discount code.

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OCTOBER 15-17

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Contact [Amber Niebauer](#) for a discount registration code. (update)

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FACSS PRESENTS

SCIX2024

The Great SCientific eXchange

SCIX Science and Technology Career Fair Oct. 22-23

Job hunting, hiring or just looking to expand your professional development skills? Attend the

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free Science & Technology Expo and Career Fair at SciX in Raleigh, Oct. 22-23. The SciX Conference offers this valuable opportunity for networking and career advancement within the spectroscopy and analytical chemistry community.

Attend the free Science & Technology Expo and Career Fair at SciX in Raleigh Oct. 22-23 and connect with world-class talents who specialize in groundbreaking analytical instrumentation and data science techniques for clinical, biopharmaceutical, nanotech and industrial applications This career fair will take place on Tuesday and Wednesday during the conference in the exhibit hall.

Oct. 22: 9:30 a.m. - 5 p.m.
Oct. 23: 9:30 a.m. - 4 p.m.

The employer package includes

- All access to Expo
- 6' skirted table and chair
- Lunch ticket for each day of Career Fair
- Digital, social media, and print brand recognition

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BioFuture Returns to New York City Oct. 28-30

Demy-Colton's BioFuture conference convenes trailblazers, disruptors, and forward-thinkers who are shaping the future of science and healthcare. BioFuture returns to New York City October 28-30 to explore the convergence of biopharma R&D, artificial intelligence, technology and healthcare delivery. This year's conference will introduce the TechBio Showcase featuring innovators applying tech-first approaches to biopharma innovation in a transformative shift for the industry.

NCLifeSci members can get \$200 off registration. Contact [Amber Niebauer](#) for the discount code.

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First Flight High Flyer Awards Luncheon Nov. 1

First Flight Venture Center's High Flyer Awards Luncheon is designated to celebrate and

honor those companies and individuals who have contributed to the HIGH SCIENCE, DEEP TECH, HIGH IMPACT and the entrepreneurial ecosystem as a whole. This event promises not only a unique platform for world-class networking but also an opportunity to join First Flight Venture Center in celebrating those who are shaping the future with their innovative projects.

Friday, Nov. 1, 11 a.m. - 1 p.m.
Prestonwood Country Club
300 Prestonwood Pkwy, Cary, NC 27513

Tickets for the High Flyer Awards Luncheon are available on a first-come, first-served basis. Don't miss out on this premier event celebrating the best in high science, high impact innovation.

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Join NCLifeSci for kickoff reception at JPM Jan. 12

We're kicking off JPM Healthcare Week 2025 in style on Sunday, Jan. 12, from 4 to 7 p.m. at the [Marker San Francisco](#). Hosted by AZBio, Biocom California, BioNJ, Bio Utah, Colorado Bioscience Association, Georgia Bio, Life Sciences Pennsylvania, MichBio, **NCLifeSci**, New York Bio, Oregon Bio, Virginia Bio and more, the State Bio Friends Reception kicks off the largest annual gathering of health care innovators and investors in the world.

This is a private reception by invitation only, and tickets are limited. If you are interested in attending, please contact [Alex Caruso](#) to be added to the list of possible attendees.

NCLifeSci JPM Kickoff Reception Sponsors



Business Solutions from NCLifeSci

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Success Every Step of the Way.

A collage of four images: a microscopic view of a cell, a woman wearing a medical device on her arm, a laboratory setting with equipment, and a person working on a computer. A central blue hexagon contains the text "Your Life Science Solutions Partner" and "Bio | Pharma | Device | Combo".

Partner with Kymanox

The Kymanox logo, featuring a stylized 'K' and the word "Kymanox®".

NCLifeSci thanks Kymanox for being a platinum sponsor of the 2024 NCLifeSci Annual Meeting.

Kymanox, your life science solutions partner

Kymanox, your life science professional services organization, has been advancing life science innovation since 2004, embodying the journey from design to life. Our seasoned team, enriched with expertise from former FDA professionals, is committed to accelerating the development and delivery of your modern medicines.

With a proven track record of over 4,000 projects and collaboration with 300+ clients, our expertise is unmatched. As your right-sized partner, Kymanox is optimally positioned to meet client needs, offering a tailored experience at every stage of the engagement. Together, we'll make a significant impact on the world of life sciences?because patients deserve better.

Support includes Design, Development, & Testing; Technical Operations & Drug Development; Facilities & Manufacturing; Quality & Compliance; Regulatory Affairs; Executive Strategy & Support.

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