



# connections newsletter



**JUNE 2020  
UPDATE**

**Serving the NC Life  
Sciences Industry**

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## NCBIO This Month

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- New Members

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## NCBIO - Media

Find the latest news from NCBIO on the website [ncbioscience.net](http://ncbioscience.net), on [LinkedIn](#) and on Twitter at [@ncbio](#).

## NCBIO Links

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[North Carolina Pharmaceutical Services Network](#)

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## NCBIO Sustaining Members

[Biogen](#)

## General Assembly Back in Session for Second Time in a Month



The General Assembly has returned for the 2020 session to focus on budget items. In late April, lawmakers were in a brief session to address COVID-19 issues. Lawmakers expect to be in Raleigh for several weeks to make adjustments to the budget as they face declining State revenues because of COVID-19's impact on the economy.

Economists for the legislature and the Administration of Governor Roy Cooper have tentatively estimated that the State will experience a decline of approximately \$4.2 billion from 2019 forecasts of General Fund revenues for the 2019-21 biennium due to COVID-19 economic impacts. In a report to the Joint House and Senate Appropriations Committees on May 25, Barry Boardman, the legislature's chief economist said the forecast did not take into account the possibility of a "second wave" of COVID-19 cases in the summer of this year. Boardman said he and economists in the Governor's budget office hoped to have a more accurate estimate of revenues in early August, after the July 15, 2020 extended filing date for state income and other taxes.

As of March of this year, North Carolina had approximately \$1.1 billion in its savings reserve account and another \$2.2 billion in unappropriated funds from the 2019-20 fiscal year.

Earlier this month, appropriations leaders in the State Senate identified 19 essential appropriations needs, including funding for additional enrollments in public schools, community colleges and universities, that will require funding during the current legislative session. The package did not expressly include funding for economic development programs.

"The extremely challenging revenue situation facing legislators will make it very difficult to secure funding for life science program priorities in the 2020-21 fiscal year," said NCBIO President Sam Taylor. "Indeed, the magnitude of the estimated revenue shortfall suggests that legislators will need to make cuts to existing programs in order to balance the 2020-21 budget."

"Given these fiscal realities, NCBIO's 2021 legislative agenda will focus on protecting existing life science and innovation programs while advancing non-budgetary policy measures important to the life science community," Taylor continued.

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Lilly



Novartis



Pfizer



We Work For Health



**NCBIO Supporting Members**

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## NCBIO Highlights Patient Protection Measures for Life Science Caucus

NCBIO briefed members of the Legislative Joint Life Science Caucus in mid-May on legislation that would curb insurance practices that limit patient access to appropriate pharmaceutical therapies. The presentation highlighted two bills -- one regulating pharmacy benefit managers and a second designed to mitigate insurers' use of step therapy to limit patient access to certain drug therapies.

Measures to address both issues are in legislative conference committees and could see action in the current session.

Legislation regulating pharmaceutical benefit managers was inserted by the State House into an unrelated Senate bill and returned to the Senate concurrence last session. The measure, [Senate Bill 432](#), was rejected by the Senate, sending the legislation to conference committee. As passed by the

House, the bill --

- Requires pharmacy benefit managers operating in North Carolina to be licensed by the Commissioner of Insurance
- Gives doctors, pharmacists and patients more control over how prescriptions are filled
- Requires pharmacy benefit managers to give consumers credit for discount coupons on brand name medicines without a generic equivalent

Step therapy legislation ([Senate Bill 361](#)) has also passed the House but was sent to conference committee after the Senate failed to concur with the House measure. The legislation would establish a consistent and transparent process for patients and their doctors to request exceptions from step therapy.

Step therapy protocols put insurers squarely in the middle of doctor–patient relationships,” said NCBIO President Sam Taylor. “More than 20 states, including Georgia and Virginia, have passed legislation to put guardrails on insurers’ step therapy protocols. North Carolina needs to join its neighboring states in assuring that patients have rapid access to the best therapies available to them.”

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## **Lawmakers Fund Research to Fight COVID-19, Provide Protections for Companies**

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Meeting in late April to respond to federal COVID-19 legislation, the North Carolina General Assembly appropriated more than \$85 million for university research into diagnostics, treatments and vaccines for COVID-19. Grants provided in [House Bill 1043](#) included –

- \$15M to Duke Human Vaccine Institute
- \$29M to UNC-CH (antibody countermeasures, vaccine, other uses)
- \$15M to ECU Brody School of Medicine (antibody countermeasures, vaccine, support rural primary care, other uses)
- \$6M to Campbell University (testing, treatment, education)
- \$20M to Wake Forest University Health Services (surveillance testing)

For additional information about the legislative session, contact [Sam Taylor](#).

In addition to the research funding the April COVID-19 [Senate Bill 704](#) provided unemployment insurance tax relief to North Carolina employers and employees. The bill also provides limited immunity for essential businesses, such as pharmaceutical research, development and manufacturing companies, whose employees or customers allege they contract COVID-19 as a result of working for or doing business with the essential business. Employees seeking compensation from injuries arising from work-related COVID-19 infections will still be able to bring workers compensation claims.

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## **Life Science Caucus Meeting Focuses on COVID-19**

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Representatives from Pfizer and Grifols outlined the work their companies are doing to find treatments and vaccines for COVID-19 during the virtual Legislative Life Science Caucus meeting in May.

Three of the Co-Chairs of the Caucus, Sen. Mike Woodard (D-Durham), Rep. Donna McDowell White (R-Johnston) and Rep. Robert Reives (D-Chatham & Durham) opened the meeting recognizing the work of the life science industry during the pandemic.

**Pfizer's Global Response**  
Pfizer is driving for a vaccine and treatment through industry collaboration

**Pfizer's Five-point Plan to Battle COVID-19**

1. Sharing tools and insights.
2. Marshalling our people.
3. Applying our drug development expertise.
4. Offering our manufacturing capabilities.
5. Improving future rapid response.

**Vaccine**

- Tuesday, May 5, Pfizer announced that the first U.S. participants have been dosed in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19 infection (in partnership with BioNTech).
- Pfizer has begun to invest at risk to actively scale up our manufacturing capacity and distribution infrastructure.

**Anti-viral**

- Pfizer continues to make progress with our protease inhibitor and studies demonstrate cellular anti-viral activity.

Breakthroughs that change patients' lives

Morrison, Al

Ramon Frontanes, Vice President of the Pfizer Rocky Mount site, discussed Pfizer's plans for fighting COVID-19, including the start of clinical trials on the BNT162 vaccine program to prevent COVID-19 infection (in partnership with BioNTech). He noted that the Rocky Mount site, which makes 20% of the sterile injectables used by the US hospital system, makes over a dozen products used by hospitals in COVID-19 related treatment protocols. Frontanes also reviewed the steps the Pfizer facilities are taking to ensure employees are safe as they work.

**Grifols Response to COVID-19 Pandemic**

**March 25:** Grifols announces formal collaboration with Food and Drug Administration (FDA) and the Biomedical Advanced Research Development Authority (BARDA) to collect convalescent plasma and produce hyperimmune globulin for COVID-19.

**April 13:** Grifols begins work to expand multi-purpose facility (MPF) in Clayton, where hyperimmune will be produced. The expansion will specifically deploy viral inactivation technology (methylene blue) to inactivate convalescent plasma.

**April 19:** Grifols announces its plasma donation centers to begin collecting convalescent plasma from recovered COVID-19 patients.

**May 5:** Grifols completes development of high sensitivity molecular test to detect SARS-CoV-2 virus in plasma, blood, and respiratory samples.

The News & Observer  
A facility in Clayton will play key role in a potential therapy for COVID-19

WRVA TechWire  
NEWS  
Grifols begins accepting plasma from recovered COVID-19 patients

Doug Burns

Doug Burns, President of Grifols Therapeutics in Clayton, talked about the company collaboration with FDA and BARDA to collect plasma from individuals who have recovered from the virus and then produce hyperimmune globulin for COVID-19. Grifols is expanding the Clayton facility where the hyperimmune will be produced. Burns said, recovered COVID-19 patients have SARS-CoV-2 antibodies, which may have therapeutic value for current COVID-19 patients who have no immunity. He also noted the limiting factor in moving forward is the ability to collect convalescent plasma, and he encouraged meeting participants to encourage recovered individuals to donate plasma.

Legislators asked questions about supply chains and the availability of securing masks, PPEs and other essential medical products.

NCBIO President Sam Taylor reviewed some of the activities under way by life science companies such as:

- Developing COVID-19 treatments, vaccines and diagnostics
- Producing materials to support COVID-19 products
- Shifting to contract manufacture of traditional products to make room for COVID-19 products

- Repatriating manufacturing of products and supply chain
- Seeing increased demand for traditional products as patients react to perceived potential for supply disruptions

“NCBIO will keep updating lawmakers on these issues and others of concern to the industry as we all navigate our way through the pandemic,” stated Taylor.

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## NCBIO Assisting Members on COVID-19 Issues

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NCBIO has been hosting bi-weekly calls for members to discuss best practices, stay-at-home orders and other issues related to the COVID-19 pandemic. NCBIO has provided members a Best Practices White Paper for operation in the workplace as companies develop plans to bring employees back to work sites, and also conducted a survey of practices being used by members. Please let us know if there are issues of concern to your company or if you have best practices you would like to share with other members.

“We want to make sure our members have the information needed to make plans for ensuring the health of employees and for ensuring ongoing operations,” said NCBIO President Sam Taylor.

If you to share information or need best practice material, send an email to [ncbioadmin@ncbioscience.net](mailto:ncbioadmin@ncbioscience.net), and Casey Nelson will share with others on the NCBIO staff. [Click here](#) for NCBIO information and COVID-19 resources online.

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## Medical Device Forum June 2

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Join us online June 2 from noon to 1:30 p.m. for a panel discussion focused on [Medical Devices: Product Strategy and Implications](#). The discussion will be moderated by **Manthan Bhatt**, Director, State Government and Regional Affairs, AdvaMed. The panel features speakers from academia and industry highlighting new technologies, convergence, combination products, hurdles, and regulatory issues.

Members will also learn about the technologies and commercialization activities at local biomedical engineering programs and hear from companies commercializing new technologies.

- **Arthur Alfaro**, Chief Executive Officer and Director, CYPREX Biosciences
- **Paul Dayton, Ph.D.**, William R. Kenan Jr. Distinguished Professor and Interim Chair, UNC-NC State Joint Department of Biomedical Engineering
- **Sunny Kasoji, Ph.D.**, Chief Technology Officer, Triangle Biotechnology
- **Barry Myers, MD., Ph.D.**, Professor and Director of Innovation, Clinical and Translational Science Institute, Duke University
- **Joy Parr Drach**, Chief Executive Officer, Advanced Animal Diagnostics

[Online registration](#) closes May 29 at 10 am. If you have registration questions, please contact [Amber Niebauer](#). Thank you to [ShareVault](#) and [Smith Anderson](#) for sponsoring this Forum.

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## North Carolina Biotechnology Center Awards Grants and Loans

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The North Carolina Biotechnology Center awarded 13 grants and loans totaling \$1.8 million to universities and bioscience companies in the third quarter of its current fiscal year. The awards, made from January to March, will support life science research, technology commercialization and entrepreneurship throughout North Carolina. The funding will also help universities and companies attract follow-on funding from other sources. [More](#)

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## Fast-Track Program for COVID-19 Test Development and Distribution

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[The National Institutes of Health](#) (NIH) announced a new initiative aimed at speeding innovation, development and commercialization of COVID-19 testing technologies, a pivotal component needed to return to normal during this unprecedented global pandemic. With a \$1.5 billion investment from federal stimulus funding, the newly launched Rapid Acceleration of Diagnostics (RADx) initiative will infuse funding into early innovative technologies to speed development of rapid and widely accessible COVID-19 testing. At the same time, NIH will seek opportunities to move more advanced diagnostic technologies swiftly through the development pipeline toward commercialization and broad availability.

NIH is now accepting proposals for support on a rolling basis until further notice. Please see the [program webpage](#), [press release](#), and [blog post](#) from NIH Director, Dr. Francis Collins, for details.

Also, the National Center for Advancing Translational Sciences (NCATS) has several targeted and investigator-initiated [funding opportunities](#) available through the Small Business Innovation and Small Business Technology Transfer ([SBIR and STTR](#)) programs for entrepreneurs aiming to commercialize innovations in translational science. View the updated [SBIR/STTR Application Instructions](#) with additional instructions for the newly reinstated SBIR Direct-to-Phase II application preparation and submission is now available. The next NCATS SBIR and STTR program deadline is Sept. 8.

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## **PhRMA Collaborative Actions to Reach Equity (PhRMA CAREs) Grant**

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PhRMA CAREs will award grants for practical ideas that can be cultivated or implemented to address immediate challenges related to COVID-19 faced by communities of color and that may also demonstrate promise for long-term progress toward health equity solutions. Specifically, this initiative asks respondents to offer ideas to address the following challenge question: *What are practical solutions to address disparities in treatment of chronic conditions among communities of color that may be exacerbated by COVID-19?* [More](#)

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## **New Members**

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Seven new members have joined NCBIO. Companies approved by the NCBIO Board of Directors at the May meeting are:

- [Bürkert Fluid Control Systems](#) is one of the world's leading manufacturers of measurement and control systems for liquids and gases.
- [Danis Construction Company](#) offers expertise in construction management, general construction, design/build and build-to-suit lease-back, as well as experience in the corporate, healthcare, senior living, education, retail, hospitality/entertainment and industrial markets.
- [EternaTear, Inc.](#) is developing a product that is closest to natural tears for the treatment of dry eye.
- [JPMorgan Chase](#) is a leader in investment banking, financial services for consumers and small businesses, commercial banking, financial transaction processing, and asset management.
- [Maku Technologies](#) focuses on producing rare cannabinoids that are available for commercial products and scientific research.
- [SAS Institute](#) provides innovative software and services for healthcare, lifesciences, manufacturing, retail and government agencies. SAS is currently providing a free Coronavirus Dashboard report.
- [Vikor Scientific](#) is a molecular diagnostics company focused on antibiotic stewardship and tangible solutions for the practice of value-based medicine in the treatment of infectious disease. The company has introduced a molecular diagnostic test for Covid-19, which is authorized for use by CLIA certified labs.

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## New Leader for BIO



BIO announced that [Michelle McMurry-Heath, MD, PhD](#), will become the organization's next President and CEO on June 1, succeeding former Rep. Jim Greenwood, who has led the organization since 2005.

McMurry-Heath has served in numerous senior leadership roles at Johnson & Johnson (J&J) since 2014. Most recently, as Vice President of External Innovation and Global Leader for Regulatory Science, she led a team of 900 employees charting the evidence generation and regulatory strategy across J&J's medical device companies, specializing in using cutting-edge tools and innovative methods to bring new breakthroughs to patients. [More](#)

## Modernized Biotech Regulation Will Unleash Greater Innovation

The U.S. Department of Agriculture (USDA) released a modernized, science-based regulatory system for plant biotechnology aimed at maintaining oversight while driving innovation. Now government and industry must do more to build an informed and trust-based dialogue about biotechnology innovation in food and agriculture and its potential to achieve greater outcomes for the planet, our food system and human well-being, says the Biotechnology Innovation Organization (BIO). [More](#)

## Register Now for BIO Digital June 8-12



BIO Partnering momentum is strong and it's not too late to **register for [BIO Digital!](#)** Get your full access pass today to join thousands of peers in the biotech and pharma industry from around the world.

[FDA Commissioner Dr. Stephen M. Hahn](#) will participate in a Fireside Chat on Monday, June 8, 10:00 am - 10:55 am. The session will be moderated by Cartier Esham, PhD, Executive Vice

President, Emerging Companies, Biotechnology Innovation Organization.

More than [5,000 attendees registered](#) for BIO Digital! Plus **42% of the attendees are new!** Attendees will be joining from **55 countries!** Explore where BIO Digital participants are from in this [new, interactive map](#).

**Partnering activity is up with over 70,000 meetings requested.** You can meet more than **2,500 companies** already active in the system and hundreds of new companies added every week. Explore the [Partnering Company list](#) to see who you can meet. [Register Now](#).

### The MedTech October 5-7 in Toronto

NCBIO encourages members of the medtech community to attend [The MedTech Conference](#) this October 5-7, 2020, in Toronto, ON. Over 3,300 of the world's top medtech executives and decision makers will come together to learn about the newest developments in medical technology.

Early bird pricing ends July 24. Don't miss out on this opportunity to save! [Register](#) now through the partnership registration. NCBIO members get a 10% discount. Contact [Amber Niebauer](#) to get the code.

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## Member News

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

[AskBio](#) announced the appointment of Tim Trost as Chief Financial Officer. Mr. Trost is a highly accomplished CFO with more than 25 years of experience building, managing and financing emerging life sciences companies. [More](#)

[Baebies](#), a growth-stage company developing diagnostic products to provide a healthy start for children everywhere, announced the submission of FINDER G6PD to the U.S. Food and Drug Administration (FDA). [FINDER™, a near-patient testing platform](#), includes a toaster-sized instrument and a disposable cartridge, which tests for Glucose-6-Phosphate Dehydrogenase (G6PD) from low blood volume (50 µL) with a turn-around time of approximately 15 minutes after sample introduction. [More](#)

[Biogen Inc.](#) announced additional data from the SPINRAZA (nusinersen) clinical development program that further demonstrate the sustained efficacy and longer-term safety of SPINRAZA in a broad range of patients with spinal muscular atrophy (SMA). [More](#). Biogen is bringing its well-recognized Community Lab science learning program together with the Lemelson-MIT Program (LMIT) at the Massachusetts Institute of Technology to launch the new online Biogen-MIT Biotech in Action: Virtual Summer Lab. This virtual lab will offer 400 Massachusetts and North Carolina high school students a first-hand experience in biotechnology and provide the opportunity to learn directly from, and be mentored by, leading scientists at Biogen and MIT. [More](#)

[Cambrex](#) will host a webinar June 17, 10am ET on "Rapid and Data-Rich Chromatographic Method Development – how to efficiently deliver powerful methods that enable well-characterized impurity profiles for new drug candidates." [Register](#)

[Chimerix](#) announced the company's initiation of a Phase 2/3 study of dociparstat sodium (DSTAT) in COVID-19 patients with acute lung injury (ALI). [More](#) Chimerix has received clearance from the U.S. Food and Drug Administration (FDA) for a rolling submission of its New Drug Application (NDA) for the approval of brincidofovir (BCV) as a medical countermeasure for smallpox. [More](#)

[CSL Behring](#) and [Takeda Pharmaceuticals](#) are part of the [CoVlg-19 Plasma Alliance](#), which also includes Biotest, BPL Group, LFB, and Octapharma, to develop a potential plasma-derived therapy for treating COVID-19. In addition to those announced at its inception - Biotest, BPL, CSL Behring, LFB, Octapharma and Takeda - the Alliance welcomes new industry members ADMA Biologics, BioPharma Plasma, GC Pharma, and Sanquin. Together, these organizations will contribute specialist advisory expertise, technical guidance and/or in-kind support to contribute to the Alliance goal of accelerating development and distribution of a potential treatment option for COVID-19 [More](#)

[First Flight Venture Center](#) has space available. Become part of a scientific entrepreneurial community. Amenities include: Short term leases, access to business advisors, attendance to all First Flight educational and social programs, use of conference rooms, Wi-Fi. [Contact](#) for more information.

[Flad Architects](#) has developed a guide, [Scientific Workplace Strategy Document](#), for research



companies seeking to re-occupying labs on a phased basis. The firm notes that as new information is becoming available almost daily, we are focused on updating our material to keep in step with changes and new ideas.

[IQVIA™](#) announced that the Walter and Eliza Hall Institute of Medical Research, a leading biomedical research organization in Australia, has selected IQVIA to manage COVID SHIELD, a Phase II/III randomized, double-blinded clinical study of preventive care for frontline healthcare workers fighting the COVID-19 pandemic. [More](#)

[Merck](#) announced three significant scientific initiatives to combat COVID-19: two agreements to develop potential vaccines against SARS-CoV-2, and a research collaboration to advance the development of a novel antiviral candidate. [More](#)

[Pfizer Inc.](#) and BioNTech SE announced that the first participants have been dosed in the U.S. in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19. The trial is part of a global development program, and the dosing of the first cohort in Germany was completed in late April. [More](#)

[PPD, Inc.](#) has extended its digital clinical trial solutions to support biopharma companies' research continuity initiatives and to help ensure patient safety as part of its integrated response to the COVID-19 pandemic. [More](#)

[SAS](#) is bringing a powerful resource to scientists who are fighting with [COVID-19 Scientific Literature Search and Text Analysis](#), a free visual text analysis environment that uses artificial intelligence (AI) and machine learning to quickly search tens of thousands of research articles on COVID-19 and deliver potentially lifesaving answers to these scientists. [More](#)

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## Bio Business Solutions

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In 2019, BIO saved 4,300 companies nearly \$430 million through BIO Business Solutions with volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more.

NCBIO members, you are eligible for BIO Business Solutions volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more. This is a benefit of your NCBIO membership. Review the cost-savings offered by clicking [here](#) and choose the programs you're interested in. Email [biobusinesssolutions@bio.org](mailto:biobusinesssolutions@bio.org) with your choices and they will get you started. For all the latest news, promos, and event information, follow [BIO Business Solutions on LinkedIn!](#)



In an effort to help businesses as they plan to reopen following Coronavirus shutdowns, **NCBIO and BIO's Partner Clean Harbors** has launched a new program: "[D3 Clean – Disinfection, Decontamination, Disposal](#)." As the top decontamination and hazardous waste disposal company in North America, Clean Harbors is proud to offer their customers a sense of confidence with routine and ongoing deep cleaning services and options that no other service provider can match. [Learn More.](#)



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## Need Help Setting Up Workspaces to Meet Safety and Social Distancing Guidelines?

As employees return back to work, Humboldt is here to help businesses and workplaces operate.

Humboldt's team of professionals follow updated CDC guidelines, prepared with the proper protective gear including masks, gloves and disinfectants. Their equipment and trucks are sanitized after every move. Humboldt will work with you through every step of the process so you can relax and get moving.

NCBBIO members enjoy preferred discounts on all moving needs, including local, long-distance and international solutions, office and employee relocation, as well as climate-controlled specimen relocation for laboratories. [Learn more](#).



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## Cross-Border M&A in the Age of COVID-19

Navigating cross-border M&A transactions has always been fraught with nuances and challenges, but what does it mean when the global economy is affected adversely by a worldwide pandemic? Social distancing and a remote workforce have significant implications for almost every aspect of the cross-border M&A transaction lifecycle, including a shakeup of the order in which that lifecycle traditionally unfolds. Find out more from [ShareVault](#).

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## Calendar

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To view full calendar, [click](#).

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### [COVID-19 Unites Us All: Remote Pulmonary Monitoring](#)

Friday May 29, 2020

... [read more](#)

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### [NIH SBIR/STTR Proposal and Commercialization Strategy](#)

Friday May 29, 2020

... [read more](#)

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### [Monitoring the Impact of COVID-19 on the Pharmaceutical Market](#)

Monday Jun 1, 2020

... [read more](#)

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[NCBIO Forum - Medical Devices: Product Strategy and Implications](#)

Tuesday Jun 2, 2020

... [read more](#)

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[Café con Prospanica \(Moving from Grit to Great\)](#)

Wednesday Jun 3, 2020

... [read more](#)

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[COVID-19 Bending the Curve: The Path to a Vaccine](#)

Thursday Jun 4, 2020

... [read more](#)

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[NIH SBIR/STTR Proposal and Commercialization Strategy](#)

Friday Jun 5, 2020

... [read more](#)

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[VIRTUAL BIO International Conference 2020](#)

Monday Jun 8, 2020 - Thursday Jun 11, 2020

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[Monitoring the Impact of COVID-19 on the Pharmaceutical Market](#)

Monday Jun 8, 2020

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[COVID-19 Bending the Curve: Impact to Health Care Policy](#)

Thursday Jun 11, 2020

... [read more](#)

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[Monitoring the Impact of COVID-19 on the Pharmaceutical Market](#)

Monday Jun 15, 2020

... [read more](#)

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[SAS Global Forum Virtual 2020](#)

Tuesday Jun 16, 2020

... [read more](#)

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[WEBINAR: Rapid and Data-Rich Chromatographic Method Development](#)

Wednesday Jun 17, 2020

... [read more](#)

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[Raising Money: Real World Stories from Entrepreneurial Companies](#)

Thursday Jun 25, 2020

... [read more](#)

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