



JULY 2020 UPDATE

Serving the NC Life Sciences Industry

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NCBIO This Month

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General Assembly Working on Mini Budgets

NCBIO - Media

Find the latest news from NCBIO on the website ncbioscience.net, on LinkedIn and on Twitter at

NCBIO Links

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NCBIO Sustaining Members

Biogen



Lawmakers are pushing to leave Raleigh later this week. Following 2019's historic budget stand-off between the Assembly and Governor Roy Cooper, work in this year's legislative session has focused on "mini-budget" bills rather than comprehensive budget legislation. So far in 2020, lawmakers have appropriated \$85M for research, testing and other COVID-related activities at North Carolina universities (H1043) and \$2M for the State's participation in the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) (H472).

Pending proposals include legislation that will:

- Provide \$500,000 to the North Carolina Biotechnology Center to connect COVIDdisplaced workers to jobs in the State's biopharmaceutical industry (H1023);
- Fund North Carolina Central University bioscience programs (H1221);
- Fund a program to promote growth in the State's AgTech cluster (<u>H1099</u>);
- Require pharmaceutical benefit managers to recognize manufacturer rebates as creditable against patient deductibles (<u>\$432</u>); and
- Establish guardrails for insurers' pharmaceutical step therapy requirements (S361)

Legislation has also been approved to reduce the cost of nitrogen-offset credits in the Neuse River Basin (S315). The legislation is important to biomanufacturing companies seeking to locate or expand in this area.

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°Life Science Caucus Hears about COVID Research and Company −Expansion

The Legislative Life Science Caucus got another virtual update in June concerning new developments in the State's life science sector. Dr. Timothy Sheahan of the UNC-CH Gillings School of Public Health briefed legislators on the School's ongoing program of coronavirus research.







Pfizer



We Work For Health



NCBIO Supporting Members

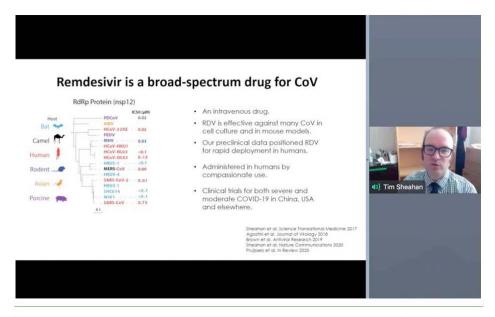
Cook Medical



Merck



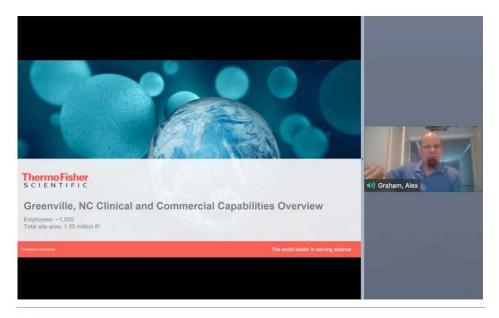




Sheahan said a team led by Dr. Ralph Barric has had a long-term program with Gilead Sciences to develop a broad-spectrum antiviral capable of treating coronaviruses. Gilead's Remdesivir, developed in collaboration with Barric's group, was the first drug approved for treating COVID-19. Sheahan said the group is now working on other drugs that may be useful against the SARS-CoV-2 virus and in addressing future coronavirus outbreaks.

Despite continuing work on coronavirus treatments, Sheahan noted that vaccines will be the best way to protect people from the SARS-CoV2 virus and future coronavirus outbreaks.

Alex Graham, Vice President, Global Sales & Marketing Operations, with ThermoFisher Scientific, said the contract manufacturing company is working on 200 projects related to COVID-19. He reviewed the company's various operations across the State, including operations in Weaverville, High Point, Research Triangle Park, and Greenville.



Graham told the Caucus that the company's Greenville facility has more than 1.5 million square-feet under roof and some 1,500 employees. He said that ThermoFisher is currently amid a \$74M upgrade of the Greenville campus. Graham also noted that recruitment and retention of qualified manufacturing employees is a priority for the company's operations in Greenville.

NCBIO President Sam Taylor agreed about the need for trained workers. He also told lawmakers that the State's large biopharmaceutical manufacturing workforce will make it a prime location for supply-chain re-shoring projects. Taylor called for funding to support marketing of the State as a biopharmaceutical manufacturing location, and to expand and equip North Carolina's already impressive network of biopharmaceutical training capabilities.

Taylor also reviewed NCBIO's life science priorities for the 2020 and 2021 legislative sessions.

For more information, contact Sam Taylor or Laura Gunter.

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Proposition Input Needed on Rule Making for Newborn Screening

In 2018, the North Carolina General Assembly provided that the State should automatically follow the federal government's list of health conditions for newborn screening (<u>SL 2018-5</u>, Sec. 11E.1). Now the Department of Health and Human Services is in the final stages of adopting rules to implement the automatic updates.

The first new condition to be added under the rule will be Spinal Muscular Atrophy.

NCBIO members are encouraged to file comments supporting the proposed rule. To do so, see instructions in the North Carolina Register starting at page 2176. The North Carolina Public Health Commission will hold a virtual public hearing on the proposed rule on June 26 and written public comments will be accepted until July 31.

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PONC Life Science Industry Continues to Grow

North Carolina's bioscience industry is one of the nation's largest life science clusters and enjoys diverse strengths and specialized employment concentration. The findings were featured in a new report by TEConomy in a national report commissioned by the Biotechnology Innovation Organization (BIO).

According to the report, employment in North Carolina's life science sector increased by 10 percent between 2016 and 2018, to reach more than 83,000 jobs across 4,210 business establishments. All life science subsectors identified in the report contributed to the employment growth. For more information, see TEConomy's NC Report, or view the Full Report.

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Companies Announce New Facilities, Expansions

A California life science firm has selected North Carolina for its next location. GRAIL, Inc., an innovative healthcare company pioneering a test that detects more than 50 cancers with a single blood draw, will invest \$100 million and create 398 new jobs in Durham. The project will include a new state-of-the-art laboratory facility, as well as office and warehouse space. More

Also in June, international human blood products company Grifols announced plans to invest \$351.6M to expand its Clayton manufacturing facilities. The expansion will also bring 300 new jobs. The project responds to growing global demand for Grifols' medicines. More

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Study Shows Strong Life Science Venture Investment

A new study released by the Council for Entrepreneurial Development (CED) reports that 63 early stage life science companies raised \$634,570,173 in venture capital in 2019. The life science investments were a major contributor to overall venture investment in the State, which totaled \$1,493,787,033 raised by 184 companies. Other sectors tracked in the CED report include technology, cleantech, makers, and advanced manufacturing and materials. More

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№ North Carolina Extends JDIG Grantees Optional COVID-19 Extension

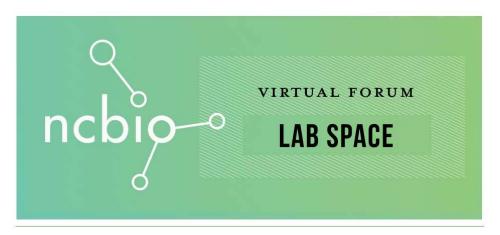
The Economic Development Investment Committee has advised recipients of North Carolina Jobs Development Investment Grants (JDIG) that companies affected by COVID-19 can apply for up to one additional year to meet future grant milestones. Grantees will nonetheless be required to file an abbreviated annual report for 2020 and must pay the annual filing fee.

JDIG grantees have until January 31, 2021 to notify the Department of Commerce that they will elect to take advantage of this compliance relief.

The Department of Commerce will provide detailed guidance on this policy option from JDIG staff in the coming weeks. In the meantime, should you have any questions or comments about this new measure, please contact the JDIG team at: cfc@nccommerce.com.

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PRegister for NCBIO Virtual Forum on Lab Space July 16th



Join NCBIO and members online July 16 for our Lab Space Forum. Bring your lunch and learn how COVID-19 is going to affect lab space design and the functionality of office and shared spaces. How are people working in their existing spaces? How are spaces being retrofitted for new tenants? Panelists include:

- Laura Rowley, Moderator; Director, Life Science Economic Development, NCBiotech
- Doug Cook, Senior Director, Cushman and Wakefield
- Merrill Flood, Director of Planning and Community Engagement, East Carolina University Millennial Campus
- Jason Kaplan, Associate Vice President, Academic & Innovation Quarter Resources, Wake Forest School of Medicine
- Chuck Mummert, Principal, Raleigh Office, Flad Architects
- Marlene Spritzer, Senior Director, Lee and Associates

Thank you to <u>Humboldt</u> and <u>Lee and Associates</u> for sponsoring this Forum. If you are interested in sponsorship, please contact <u>Laura Gunter</u>. If you have any questions regarding registration, contact <u>Amber Niebauer</u>.

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™Medical Device Forum Developing and Advancing Products

Medical device product development was the topic of NCBIO's June 2 Medical Device Member Forum. The program took a broad look at North Carolina's medical device development infrastructure. Panelists included representatives from the State's biomedical engineering programs at Duke University, North Carolina State University, and the University of North Carolina at Chapel Hill, as well as leaders from three North Carolina medical technology start-up companies.



The 90-minute event was moderated by Manthan Bhatt, Director, State Government and Regional Affairs, AdvaMed, who kicked off the discussion by noting that "Med tech companies are well-positioned to drive the future of health, but most cannot do it alone. It costs a manufacturer an average of about \$94 million to bring a medical device onto the market through PMA and \$31 million for the 510(k) process."

Paul Dayton, Ph.D., William R. Kenan Jr. Distinguished Professor and Interim Chair, UNC-NC State Joint Department of Biomedical Engineering, outlined an 11-month professional master's degree program for biomedical engineering students that serves as a launch pad for entrepreneurs advancing biomedical technologies. Dayton said the program works to help students interested in acquiring the skills necessary to lead biomedical-related early stage ventures or to drive new product development in healthcare. He also discussed how students and faculty became instant innovators, when the Joint School pivoted this spring to make masks, ventilators, and COVID-19 tests in response to the pandemic.

Sunny Kasoji, Ph.D., Chief Technology Officer, Triangle Biotechnology, discussed how North Carolina also offers a variety of resources to help aspiring biomedical entrepreneurs. Kasoji said his company used several of these local and state level business resources to help pull together his company's business development and commercialization plan.

The forum also showcased CYPREX Biosciences, a company that has developed a novel "bioresorbable" resin that can be used for drug delivery and regenerative medicine applications. Arthur Alfaro, Chief Executive Officer and Director at CYPREX, discussed how the company's first product, Bupivacaine, is an absorbable film that can be used to dispense non-opioid analgesics to reduce pain from biomedical implants.

Joy Parr Drach, Chief Executive Officer, Advanced Animal Diagnostics, discussed how her company's QScout blood test platform -- which was developed to detect disease in cattle -- has been repurposed for use in detecting COVID-19 infections in humans.

Drach's explanation epitomized the challenges and opportunities facing all entrepreneurs in the post-COVID world – as was noted by panelist Barry Myers, M.D., Ph.D., Professor and Director of Innovation, Clinical and Translational Science Institute, Duke University. "We are in interesting times, "said Myers, who also serves as an Executive-in-Residence at Pappas Capital. "It is unclear how capital markets will look in three, six or nine months," Myers continued, reiterating that "It is important that we build bridges not piers."

NCBIO thanks Share Vault and Smith Anderson for sponsoring this Forum.

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P NCBiotech Center Has New Board Chairman

Santo Costa, an attorney and pharmaceutical executive with more than 40 years of senior operating management and board advisory experience in the life sciences, has been elected chairman of the North Carolina Biotechnology Center's Board of Directors. More

At the National Level

Wide Range of Topics at BIO Digital Convention.

The first-ever BIO Digital Convention, June 8-12, welcomed more than 7,000 attendees from 64 countries, for 524 sessions and 27,000 partnering meetings across 28 time zones. BIO created a digital event to replace the annual convention that was scheduled for San Diego. Diversity in the industry, COVID-19 response and future pandemics, understanding patients, innovation, and a variety of other topics were covered during the digital event.

BIO's President and CEO Dr. Michelle McMurry-Heath led a discussion with black CEOs of biotechnology companies and BIO leadership: Dr. Tony Coles, CEO and Chair of the Board of Cerevel Therapeutics LLC; Dr. Ted Love, President and CEO of Global Blood Therapeutics; and Dr. Jeremy Levin, CEO of Ovid Therapeutics Inc. and Chair of the Board of BIO.



The speakers reflected on their own experiences to provide clear steps for how to improve diversity and inclusion in our companies and our clinical trials and ensure that minorities, particularly African Americans, can access the technology we create. <u>View the discussion</u>.

Speaking during a one-on-one chat with BIO President and CEO Dr. Michelle McMurry-Heath, Dr. Anthony Fauci, Director of the NIH National Institute of Allergy and Infectious Diseases, drew viewers from around the globe. Dr. Fauci's chat can be found at www.bio.org/bestofbio.

Cartier Esham, EVP of Emerging Companies at BIO, talked with FDA Commissioner Dr. Stephen M. Hahn about collaboration and COVID-19 response efforts.

During a morning town hall, Dr. Peter Marks, Director of FDA's Centers for Biologics Evaluation and Research (CBER), talked about the agency's COVID-19 priorities and how the pandemic will shape the new normal. "At the end of the day, we better be putting things down in our pandemic playbook," said Dr. Marks.

<u>Click</u> to see Dr. Hahn, Dr. Marks and other presentations from BIO Digital.

RALI Webinar: Strategies to Prevent Opioid Misuse During the COVID-19 Pandemic

Rx Abuse Leadership Initiative (RALI) hosted a webinar with Code 3 Association, the Community Anti-Drug Coalitions of America (CADCA), the National Association of Social Workers – North Carolina (NASW-NC), and special guest U.S. Senator Thom Tillis, to discuss how the COVID-19 pandemic is impacting those struggling with substance use disorder and those in recovery and how to keep loved ones safe.

"As difficult as this time is for all of us, it's especially important to recognize the impact of the COVID-19 pandemic on our friends and neighbors battling substance use disorders," said Senator Tillis during his welcoming remarks. "For those in recovery or receiving treatment for addiction, social distancing measures may severely impact their normal means of support - recovery requires connection, and we all can help provide support for our loved ones. Understanding how to spot the warning signs of substance misuse is particularly important during this time of increased anxiety."



The MedTech Conference Going Virtual

The <u>Virtual MedTech Conference</u> will feature a mix of live and on-demand content, available to all registrants right from their homes or offices. On-demand sessions will be available in early September, with live sessions streaming from October 5-7. In addition, the MedTech Connect partnering platform will open in August and allow all participants to schedule virtual meetings. More updates and a program schedule will be available on the website in the coming weeks!

President and CEO of AdvaMed Scott Whitaker stated in announcing the change, "We know how important our annual conference is and that it can play a very special role for our industry this year, but we also recognize the importance of gathering safely and responsibly. Therefore, AdvaMed is excited to introduce an all-virtual conference experience for 2020 – The Virtual MedTech Conference." See more.

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

To be included in Member News, send information about your organization to Brenda Summers.

<u>AgBiome</u> has had a busy spring with several team members being interviewed on air or featured in articles in agriculture publications. <u>More</u>

Asklepios BioPharmaceutical, Inc. (AskBio), announced that Jude Samulski, PhD, President, Chief Scientific Officer and Co-founder, has been awarded an international patent application from the World Intellectual Property Organization (WO/2020/076892) for his regulated gene editing system. This system applies the advantages of gene editing while limiting genome-wide off-target effects, immunogenicity and repeat dosing challenges that can potentially occur when using CRISPR. More

Baebies 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

<u>BioCryst Pharmaceuticals, Inc.</u> announced new data published in Science Translational Medicine show, in a primate model, that galidesivir was safe, provided post-exposure prevention of Zika viral replication across a range of doses, and rapidly reduced viral loads to undetectable levels when dosed up to 72 hours after infection with Zika virus. <u>More</u>

<u>Biogen Inc.</u> announced new results from NURTURE, the longest study of pre-symptomatic patients with spinal muscular atrophy (SMA) that is transforming expectations of early treatment with SPINRAZA (nusinersen). In infants genetically diagnosed with SMA, new data demonstrate that early and sustained treatment with SPINRAZA for up to 4.8 years enabled unprecedented survival.

Patients continued to maintain and make progressive gains in motor function compared to the natural course of the disease. <u>More</u>

<u>Chimerix</u>, a biopharmaceutical company focused on accelerating the development of medicines to treat cancer and other serious diseases, announced the appointment of Allen Melemed, M.D., M.B.A., as Chief Medical Officer. More

<u>CureDuchenne Ventures</u> launched its 2020 Pitch Contest through July 13, seeking applications from innovators who are focused on new therapeutics or therapeutic targets, or technology platforms related to Duchenne muscular dystrophy. <u>More</u>

<u>G1 Therapeutics, Inc.</u>, a clinical-stage oncology company, and Genor Biopharma Co. Inc., a precommercial stage biopharmaceutical company focused on developing and commercializing immune-oncology therapeutics, announced an exclusive license agreement for the development and commercialization of lerociclib in the Asia-Pacific region (excluding Japan). <u>More</u>

<u>Grifols</u> announced the start of production of its anti-SARS-CoV-2 hyperimmune immunoglobulin with specific antibodies using the plasma of people who have overcome the disease. It is the first specific drug developed to combat COVID-19. <u>More</u>

<u>Heat Biologics, Inc.</u>, a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, including multiple oncology product candidates and a novel COVID-19 vaccine, announced initiation of the first clinical trial site for PTX-35. <u>More</u>

<u>Pairwise</u> hosted a meeting with U.S. Secretary of Agriculture Sonny Perdue who wanted to learn more about how the food tech company is working to solve health challenges through food. Secretary Perdue and company leaders discussed how small business innovation and modern technology are helping find new ways to help make healthier food choices available across the United States. <u>More</u>

<u>Pfizer Inc.</u> announced the establishment of the Pfizer Breakthrough Growth Initiative, through which Pfizer will invest up to \$500 million in biotechnology companies to help provide funding and access to Pfizer's scientific expertise to ensure continuity of the biotechnology companies' most promising clinical development programs. <u>More</u>

Shattuck Labs, Inc., a clinical-stage biotechnology company advancing its proprietary Agonist Redirected Checkpoint (ARC™) platform to develop a novel class of biologic medicines for the treatment of cancer and autoimmune disease, announced the closing of a \$118 million Series B equity financing. More

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POBIO Business Solutions



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 hiobusinesssolutions@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!



Aon and BIO have teamed up to bring comprehensive coverage for Executive Liability and Cyber Insurance programs. Aon has undertaken an extensive request for proposal process to vet and select an elite group of insurers based on their ability to deliver distinctive value to life sciences clients. Through these programs, BIO members can access and benefit from expansive coverage of offerings, and competitive pricing utilizing broad Aon-negotiated policy language, along with a unique array of defined services, all designed to enhance program efficiency and effectiveness through these reputed insurance carriers. More



Brex, the Corporate Credit Card for the Life Sciences, is designed to empower its life sciences customers to spend less time on end of month closes and more time on life changing R&D. The card offers its customers streamlined reporting functions, rewards and unmatched controls including; no personal guarantee requirements, higher limits than traditional credit cards, instant creation of virtual cards, automatic receipt capture and, tailored rewards such as 3x points multipliers on lab equipment. Points can be redeemed as cash back to pay down statement balance, book travel, or transfer miles to select partner airlines. More

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To view full calendar, click.

Resilience & Analytics: What We Can Learn From the Pandemic

Tuesday Jun 30, 2020

... read more

<u>Learning and Adapting during COVID-19 Series I Webinar 3: Can a Planetary Health Lens Inform Pandemic Response?</u>

Tuesday Jun 30, 2020

... read more

LDTI: The Journey Toward Compliance and Beyond

Tuesday Jul 7, 2020

... read more

Making Your Case and Selling Your Ideas: Hear from the Experts (Using Al and Analytics in Government Program Expenditure Management Webinar Series) Tuesday Jul 7, 2020 ... read more Holistic CX Measurement: How to Reflect Loyalty and Business Value Metrics

Triangle COVID-19 Response Through a Global Health Lens

Wednesday Jul 8, 2020

Wednesday Jul 8, 2020

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... read more

Putting Al and Machine Learning to Work in Human Resources

Thursday Jul 9, 2020

... read more

ON Helix

Monday Jul 13, 2020 - Tuesday Jul 14, 2020

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Master Agility and Automation for Lasting CX Advantage

Tuesday Jul 14, 2020

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Marketing in Uncertain Times

Wednesday Jul 15, 2020

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Analytics 101 (Part 2)

Wednesday Jul 15, 2020

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NCBIO Forum: Lab Space in North Carolina

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Ask the Expert: How Do I Get the Most From Al-Enhanced BI with SAS® Visual Analytics for SAS® Viya®?

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BTEC Short Courses: Cell Culture Engineering- A Single-Use Perspective

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BTEC Short Courses: Biopharmaceutical Assay Essentials

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2020 Women's Leadership Conference

Tuesday Jul 21, 2020 - Thursday Jul 23, 2020

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Ag Tech Professional Forum

Wednesday Jul 22, 2020

... read more

BTEC Short Courses: Fermentation Engineering

Tuesday Jul 28, 2020 - Friday Jul 31, 2020

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