



NIMBL

® The National Institute for
Innovation in Manufacturing
Biopharmaceuticals

2021

ANNUAL REPORT

2022



This Annual Report covers NIIMBL's accomplishments from
MARCH 1, 2021 to FEBRUARY 28, 2022.

The NIIMBL mission is to accelerate biopharmaceutical manufacturing innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing U.S. competitiveness in this industry.

NIIMBL will lead and transform the development and adoption of next-generation biopharmaceutical manufacturing technologies that contribute to patient well-being. As a public-private partnership, NIIMBL will forge and catalyze advancements that are vital to the acceleration of innovative technologies and a skilled workforce, and these strategic efforts and investments will be undertaken to secure U.S. biopharmaceutical manufacturing leadership.

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ACCOMPLISHMENTS



A LETTER TO THE COMMUNITY

Dear Colleagues,

The last two years have tested the resilience of our organization and industry, yet the past year has given us reason to be optimistic for the future. In our 2021–2022 Annual Report, you will see how NIIMBL has contributed to this forward movement, reaching key milestones and accomplishing goals through the year.

In 2021, we celebrated our five-year anniversary, a significant milestone that was accompanied by the news of an additional \$70 million in support from the National Institute of Standards and Technology (NIST) to continue federal funding of NIIMBL for an additional five years. This funding positions NIIMBL to continue its aggressive support of innovation in biopharmaceutical manufacturing and represents a promising future for the community.

We also crossed the 200-member mark, growing our membership with organizations that contribute new technologies, ideas, and opportunities for our entire community. We awarded more than \$14.5 million to new projects through our Project Calls and an additional \$83 million across 32 projects through the American Rescue Plan (ARP) Award. NIIMBL also received \$4.8 million from the Bill and Melinda Gates Foundation to support additional work in vaccine manufacturing and further accelerate our NIIMBL-led Vaccine Manufacturing Program.

These and several other accomplishments throughout the year were made possible through the hard work, dedication, and innovation of our community. From projects that accelerate technology to those that improve the diversity and skills of our workforce, from funding from our federal stakeholders to investments in open access technology, we look forward to building on our progress and continuing our mission to advance U.S. competitiveness in the biopharmaceutical industry.

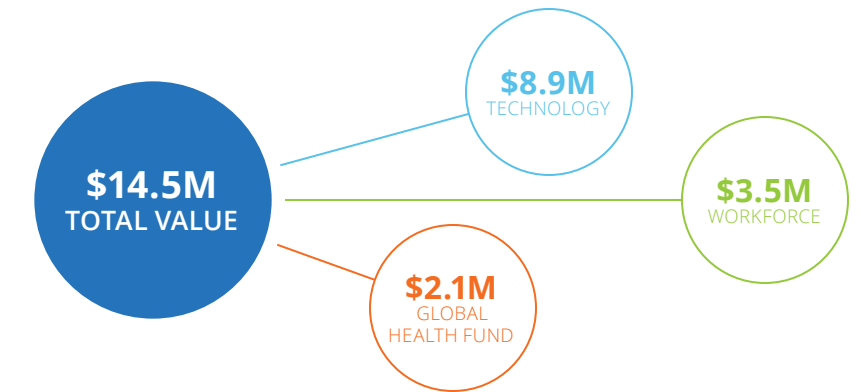
Sincerely,
The NIIMBL Team

PROJECT INVESTMENTS

108 Collaborating Organizations

2021–2022

16 Authorized Projects



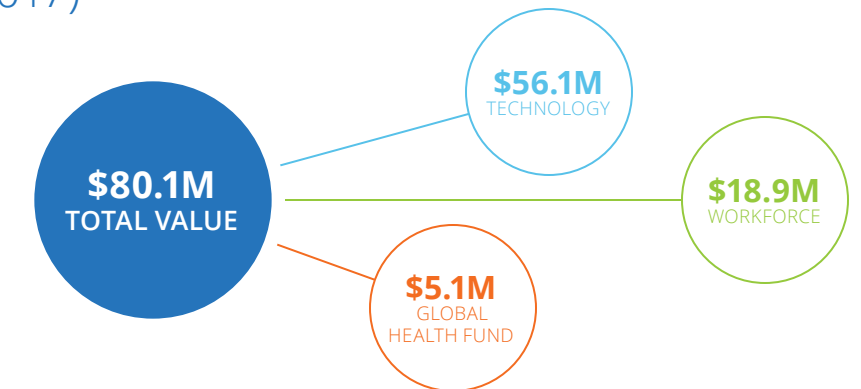
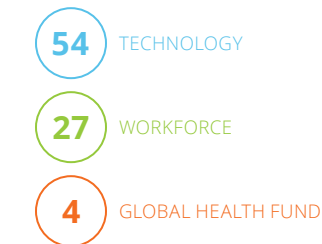
AMERICAN RESCUE PLAN

32 Projects



SINCE LAUNCH (2017)

85 Authorized Projects



The background features a large, abstract, colorful streak effect on the left side, transitioning from dark blue and green to bright yellow and orange. This effect converges towards a central point on the right. The right side of the image is framed by a dark blue border. The text 'INSTITUTE HIGHLIGHTS' is centered in the white space on the right. A small green menu icon is located in the bottom right corner of the frame.

INSTITUTE HIGHLIGHTS



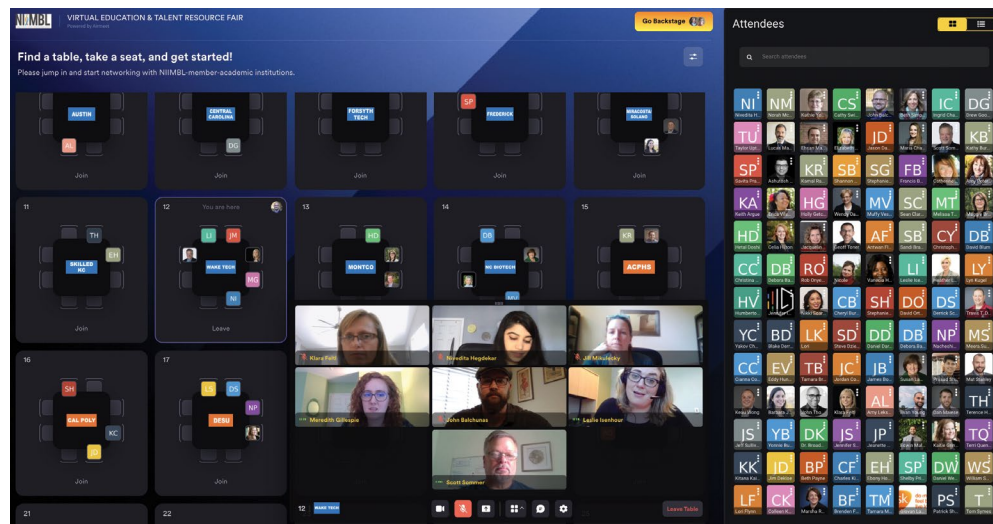
WORKFORCE DEVELOPMENT

Creating New Connections to Strengthen the Biopharmaceutical Workforce

Our workforce development initiatives are designed to foster stronger connections between the biopharmaceutical industry and academic institutions and increase opportunities and resources to help fill critical biopharmaceutical manufacturing jobs now and in the future. These initiatives also help talented students develop into experienced professionals with the skills needed to pursue careers in biopharma. Despite the challenges of the COVID-19 pandemic, NIIMBL leveraged digital platforms to continue to provide the industry with opportunities to cultivate a stronger workforce.

VIRTUAL EDUCATION AND TALENT RESOURCE FAIR

As hiring needs continue to grow, it is vital that the biopharmaceutical industry finds new sources of talent. Our Education and Talent Resource Fair helped to do just that. In April 2021, more than 230 individuals from 32 academic institutions and 28 companies attended the first NIIMBL Virtual Education and Talent Resource Fair. The event gave academic institutions an opportunity to highlight their education and training programs and interact directly with biopharmaceutical company representatives. Each academic institution hosted a virtual table where industry representatives could drop in to chat and ask questions about their programs. The event received a positive response, and the community found it beneficial for both academic and industry members.

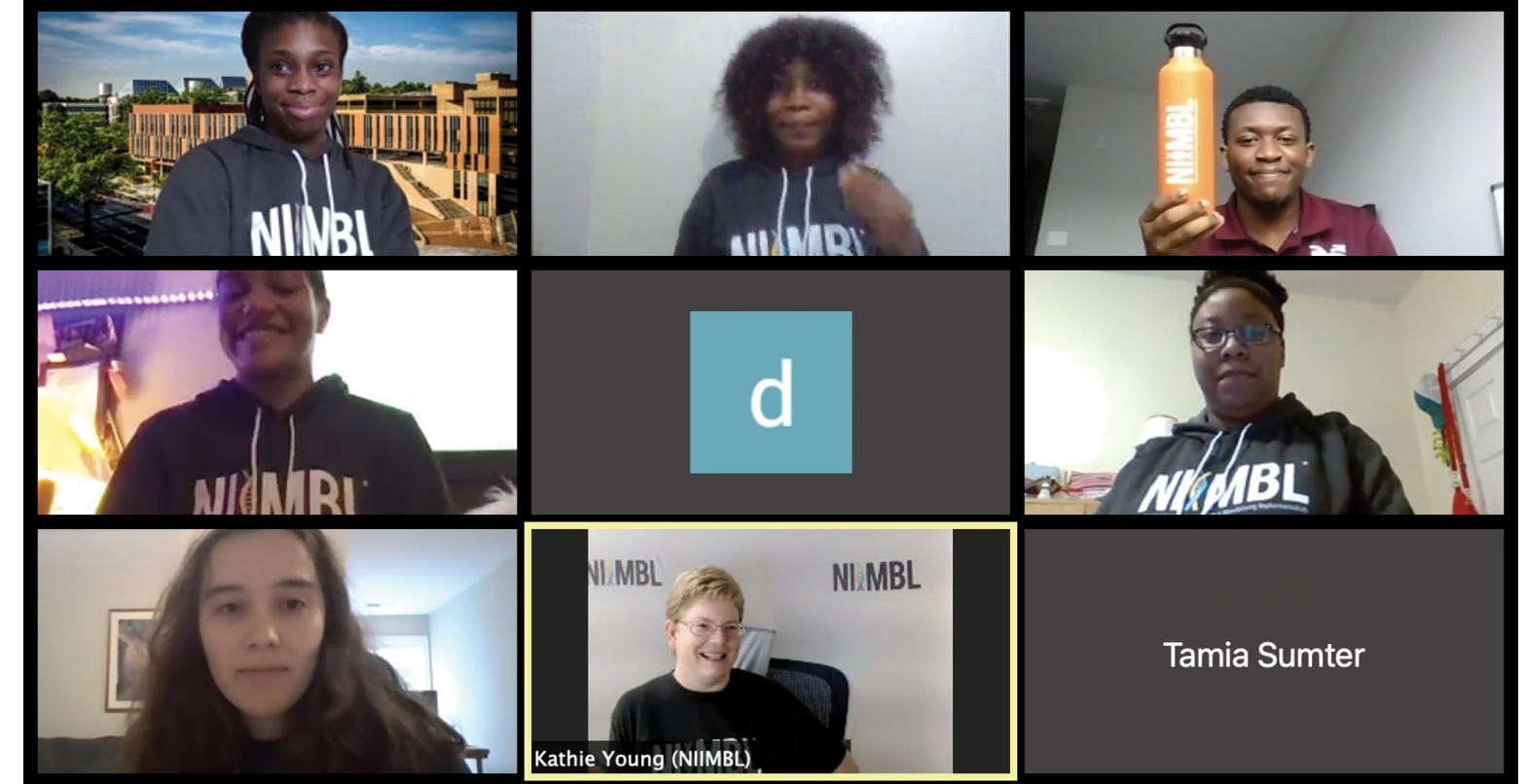


"By networking with academic institutions, I was able to build new relations and find out about resources I did not know existed to help draw in more talent to our company."

Industry member

"We met people from a range of companies and are excited to follow up with them — and I do not know how we would have connected with them so easily otherwise."

Academic member



2021 NIIMBL eXperience

Our third NIIMBL eXperience took place virtually in June 2021 with a talented cohort of college freshmen and sophomores from Historically Black Colleges and Universities and NIIMBL member institutions. The 2021 eXperience cohort included 14 students from 13 colleges and universities across the country including Mississippi Valley State University, the University of the District of Columbia, and the University of Georgia. Ten member companies served as virtual hosts and gave students a glimpse into biopharmaceutical careers through presentations, discussions, and personal career stories.

As a key part of NIIMBL's efforts to help expand diversity and inclusion within the biopharmaceutical industry, the NIIMBL eXperience gives African American/Black, Latinx, and Native American students a chance to discover biopharmaceutical career options through direct interactions with industry professionals. In addition to giving students the chance to learn about a potential new career path, the NIIMBL eXperience helps industry partners meet talented students who could fill internships or even future positions within their organizations.

Since the program's launch in 2019, the NIIMBL eXperience has helped students find internships at leading companies such as Merck & Co., Inc., Genentech, MilliporeSigma, and Eli Lilly and Company.



"I secured an internship with Eli Lilly and Company for the Summer 2022. I will be a Drug Discovery and Development Intern in Indianapolis. This opportunity wouldn't be a reality for me without the NIIMBL eXperience."

TAMIA SUMTER
Clemson University,
2021 NIIMBL eXperience Fellow

VIRTUAL INTERNSHIP, CAREER & JOB FAIR

Our Virtual Internship, Career & Job Fair helped biopharmaceutical companies speak directly to qualified candidates who could fill open internships and positions. Held in February 2022, the three-day event featured two days dedicated to internship and early-career job opportunities. The third day was reserved for opportunities for more experienced professionals. Internship and job seekers could book one-on-one meetings or take part in group sessions with 258 participating recruiters from 35 prospective employers. Over the three-day event, 600 candidates booked 1,940 meetings with recruiters. The Virtual Internship, Career & Job Fair provided a new avenue for the industry to forge connections with top talent from across the U.S.



NIIMBL-LED PROGRAMS AND PROJECTS

NIIMBL-led programs were developed to bring together thought leaders from our community and beyond to tackle key biopharmaceutical manufacturing challenges and to optimize processes for the future. NIIMBL is committed to leading these programs and finding solutions that will push the limits of what is currently possible and accelerate the speed at which we manufacture therapies.

In addition to partner-led projects, NIIMBL has launched six institute-led programs to date. In 2021, NIIMBL completed the NIIMBL-BioPhorum Buffer Stock Blending System project and made progress in Process Intensification, Big Data Analytics, and N-mAb. Programs launched in 2021 include Vaccine Manufacturing, and the Vector Manufacturing Program is scheduled for launch in 2022.

PROCESS INTENSIFICATION

An ambitious 10-year initiative, the Process Intensification Program will transform biopharmaceutical manufacturing in the short, medium, and long term. Thought leaders from within the NIIMBL community are collaborating on an integrated approach to make dramatic improvements in flexibility of manufacturing facilities, process robustness and control, quality, sustainability, and cost. A testbed is being built at the NIIMBL headquarters to enable integrated development and testing of the innovations that will realize the goals of the program.

BIG DATA ANALYTICS

The Big Data (BD) Analytics Program is a collaboration within NIIMBL consisting of five workstreams focused on data contextualization, automated control, multivariate sensor data analytics, data creation and collection, and advanced modeling, which collectively demonstrate how innovative uses of data can be transformative for the manufacturing of biopharmaceuticals. Several BD projects have been launched within the established workstreams including process ontology for data contextualization; hybrid process models for performance predictions; privacy-preserving machine learning for data collection; and a cell line, media, process, and testbed for BD demonstrations.

VECTOR MANUFACTURING PROGRAM

NIIMBL is committed to addressing the development and adoption of technologies related to vector manufacturing, specifically addressing the production of the two most important vector platforms in use in the industry today: lentiviral vectors (LV) and adeno-associated virus (AAV) vectors. NIIMBL is leveraging the resources and expertise of its partners to build out this program to accelerate development of core manufacturing process platforms and essential analytical capabilities for viral vector product and process characterization. Advances in both areas are critical for broad and rapid expansion of the emerging industry of gene-based therapeutics and ultimately improving access to these novel therapies by the many patients and families who stand to benefit from them. The program is on track to formally launch in Fall 2022.

N-mAb

N-mAb brings together more than 60 industry and government stakeholders from over 20 organizations to develop a case study document with shared expectations and vocabulary around a control strategy for an integrated continuous bioprocess for a hypothetical monoclonal antibody. The N-mAb Team successfully completed the first draft of the case study and has made it available to the biopharmaceutical community for public comment. The final draft is expected by the end of 2022, and will provide a state-of-the-art continuous bioprocess example that will facilitate adoption of principles to practice, invigorate discussion, and promote continued innovation toward the next generation of bioprocessing.

FEATURED PROGRAM: Vaccines Manufacturing

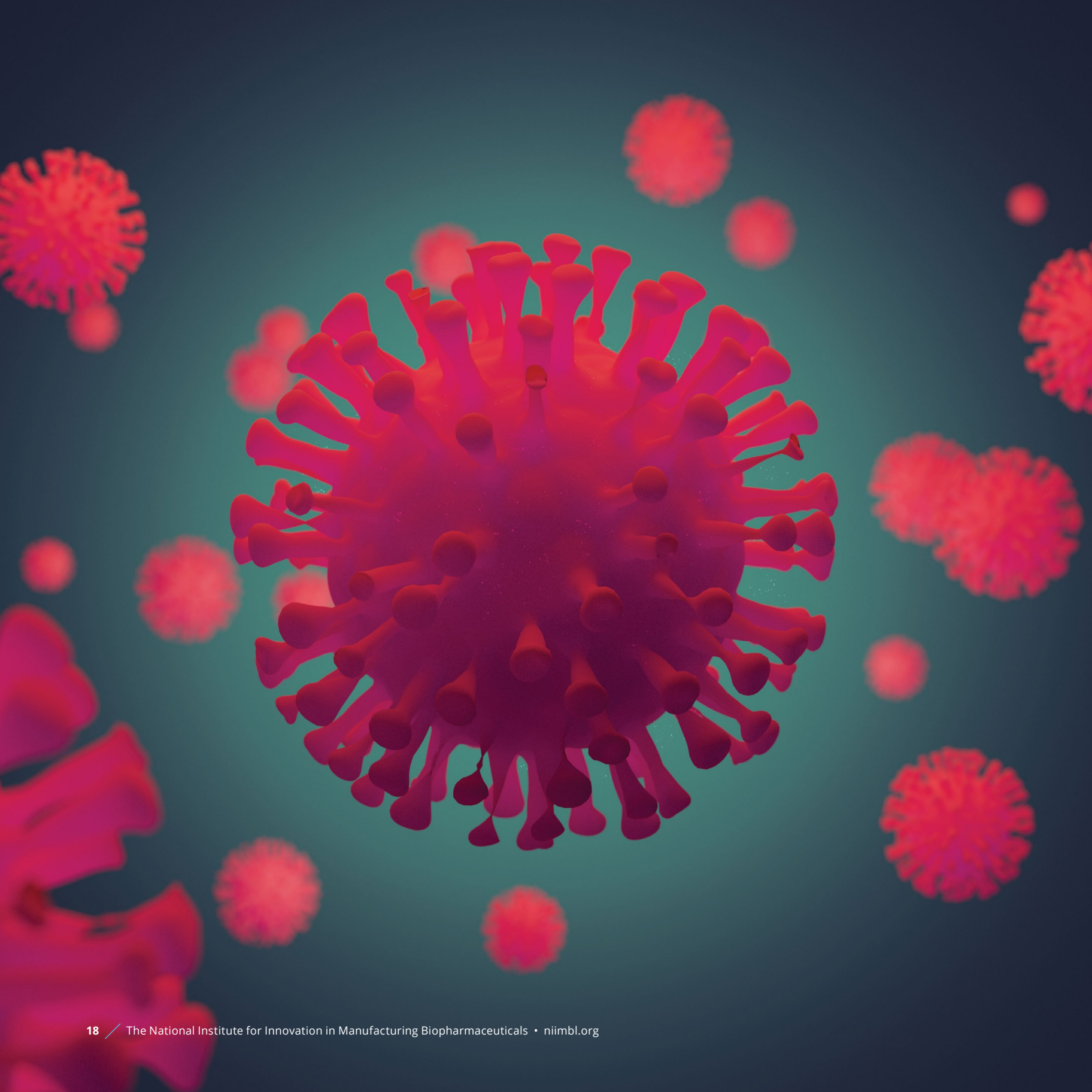
NIIMBL investments in technologies to advance vaccine manufacturing help to accelerate the implementation of new manufacturing and characterization technologies across a variety of platform processes. This effort brings together stakeholders and resources to collaboratively identify opportunities to advance manufacturing-related issues relevant to the development and distribution of vaccines. In 2021, a NIIMBL proposal to establish a Vaccine Analytics and Assays Center of Excellence was funded as part of the 2021 American Rescue Plan to support manufacturing and product characterization of vaccines. NIIMBL Headquarters within the University of Delaware's Ammon Pinizzotto Biopharmaceutical Innovation Center will be home to a state-of-the-art facility for conducting key analytical characterizations for vaccines. The facility will be designed to support expanded access, adoption, and continued evolution of vaccine manufacturing and product characterization innovations. This funding for improved analytical characterization will enable manufacturers to make changes in processes and scale of operation by demonstrating analytical comparability.

GLOBAL HEALTH FUND

NIIMBL investments also address the technology and workforce needs of major vaccine companies and suppliers in the U.S. while also serving the interests of the global community through additional support from the Bill & Melinda Gates Foundation.

With the support and leadership of the FDA, progress is being made to modernize adventitious agent testing using next-generation sequencing, which will not only play a key role in the replacement of animal testing, but also accelerate the release of cell lines being developed for new product candidates for vaccines and therapeutic proteins such as new antibodies and cell-based therapies.

In continued support for this program, NIIMBL received ~\$5M in additional funding from the Bill & Melinda Gates Foundation for the purpose of improving Vaccine Potency Assays, supply chains, and workforce development. This investment supplements current funding that is being applied towards improving vaccine stability and replacing animal-based testing for lot release.



AMERICAN RESCUE PLAN

Building National Capacity to Prepare for Public Health Emergencies

The COVID-19 pandemic showed us that the speed with which our industry responds when faced with a global crisis is critical. Through an extensive portfolio of projects funded through American Rescue Plan (ARP), our community continues to strengthen the nation's capacity to quickly respond to future health emergencies.

At our National Meeting in July 2021, U.S. Secretary of Commerce Gina Raimondo announced an \$83 million award for NIIMBL under the ARP to “prevent, prepare for, and respond to coronavirus public health threats.”

Later in 2021, NIIMBL selected and announced funding for 32 projects from multiple organizations across the U.S. through the ARP award. This expansive slate of projects focuses on key technology and workforce development capabilities to help address pandemic needs. Specifically, these projects will:

- Provide testbeds for process development, next-generation manufacturing approaches, and drug product manufacturing approaches that provide access to industrially relevant equipment and facilities for pre-competitive manufacturing innovation
- Support the development of significantly improved methods for vaccine production, quality, and distribution, including mRNA and other vaccine platforms
- Demonstrate rapid scaling for production of coronavirus antigens and medical countermeasures for variants of concern
- Train a diverse biopharmaceutical manufacturing workforce
- Demonstrate the concept of mobile Good Manufacturing Practices capabilities to support mRNA vaccine and gene therapy production

The collaborative efforts of the NIIMBL community will lay the foundation for a rapid response when faced with future public health emergencies. These technologies and training programs will enable the U.S. to meet public health challenges head-on and save lives. For more information about our ARP project portfolio, visit niimbl.org/ARP.



“This is an important investment for America. I am so pleased that NIIMBL will continue to bring together organizations of all types to deliver impacts on our federal investments, strengthen our nation through better pandemic preparedness, and build a more agile manufacturing industry for future economic strength and more cost-effective manufacturing, and less reliance on foreign supply chains for our national needs for life-saving biopharmaceuticals.”

GINA M. RAIMONDO
U.S. Secretary of Commerce
2021 NIIMBL National Meeting



PROJECT
HIGHLIGHTS



Building Models to Optimize COVID-19 Testing Strategies

Designing a Test Kit Supply Chain in Response to COVID-19

NORTH CAROLINA STATE UNIVERSITY

Raleigh, NC

TYPE:

Academic Research Institution

INDUSTRY NEED

When COVID-19 gripped the world in 2020, the U.S. faced three critical issues in its ability to test individuals for the disease. The first was identifying bottlenecks in the supply chain for polymerase chain reaction (PCR), antigen, and antibody test kits. The second was developing an appropriate test kit allocation strategy that would meet the demand for testing and optimize the limited availability of test kits and resources. The third was determining the right combination of PCR and antigen testing in congregate settings such as schools and nursing homes that would allow for continued activity and maintain health and safety. These deficiencies were contributing factors to early pandemic testing issues, such as lack of test kits and long wait times for results.

SOLUTION

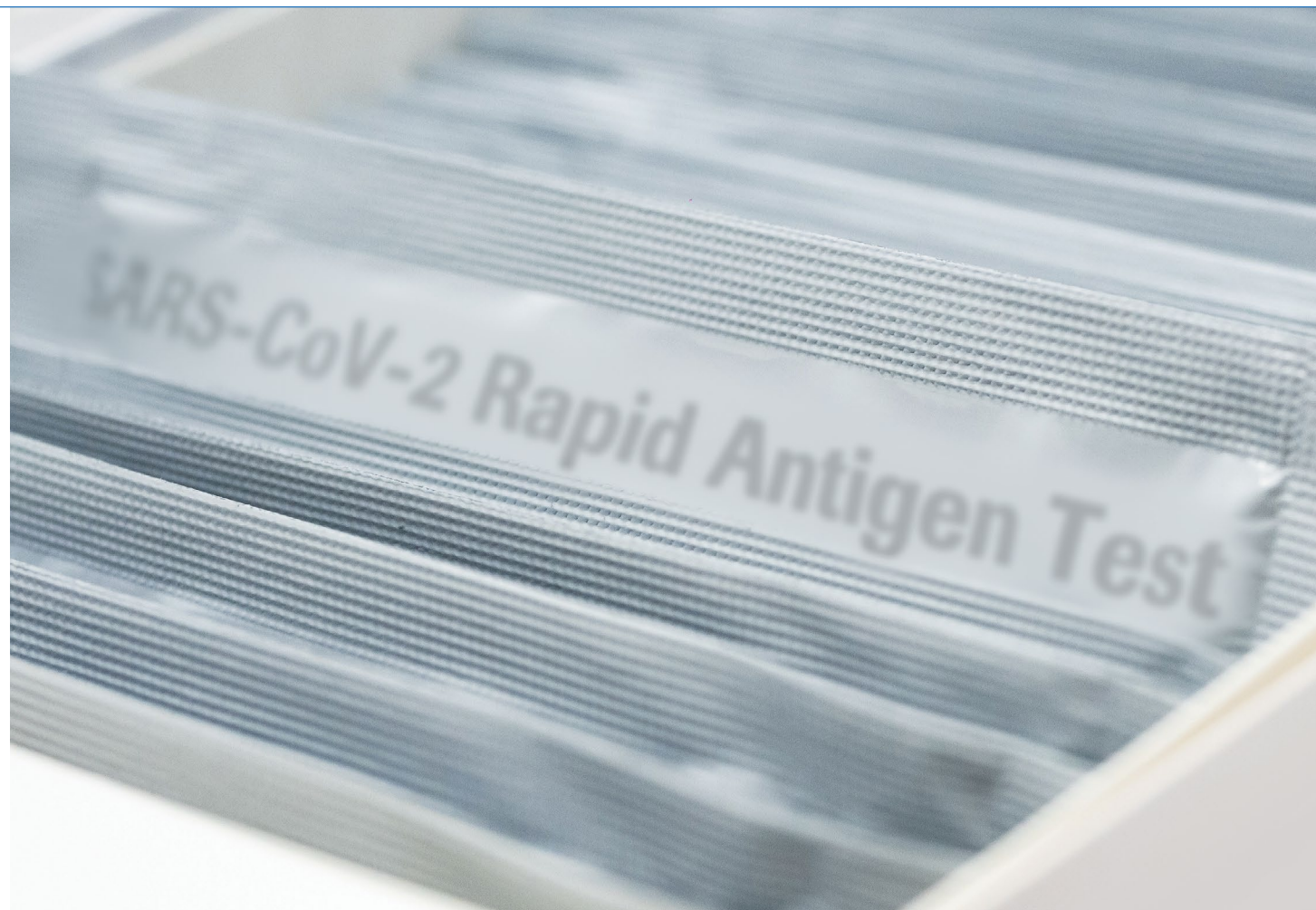
Led by the North Carolina State University Poole College of Management, this project aimed to apply mathematical modeling, social listening, and interviews to develop tools that would help public officials predict test kit supply shortages before they became a problem, allocate a more accurate number of test kits to better meet demand within communities, and combine antigen and PCR testing methods in congregate settings to enhance screening protocols, identify infected individuals, and allow for activities to continue in a safer environment.



"The NIIMBL project allowed us to assemble a team with diverse expertise in mathematical modeling, supply management, and biopharmaceutical manufacturing to collectively address a complex problem."

ROB HANDFIELD

North Carolina State University



OUTCOME

The team uncovered insights that could help policymakers and community leaders predict and manage test kit supply shortages and develop testing protocols. For example, the team determined that widespread screening of individuals without symptoms using rapid antigen tests could help communities more accurately plan for test kit demand and alleviate test kit supply uncertainties while protecting public health. Antigen tests cost as little as \$5, whereas PCR tests cost approximately \$100. This lower cost would allow for more frequent antigen testing to overcome false negatives and potential inaccuracies. The team developed a comprehensive web dashboard to help school, state, and community leaders evaluate the cost and performance of antigen test-based screening protocols based on specific needs and population size. The model lets users define the testing timeline, frequency, and population size. It even lets users account for "exogenous shocks," which are infections introduced through contact outside of the test setting. To gain more insight into supply shortages, the team used machine learning to monitor Tweets and Google searches and found the data could accurately predict future supply shortages. In one example focused on pipettes, Twitter mentions and Google searches could predict large-scale shortages three to four weeks in the future. The models improved the ability to understand and forecast shortages of testing supplies.

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Providing Virus Proteins to Improve Testing Capabilities

Development of a SARS-CoV-2 Polyvalent Microbead Immunoassay (MIA)

NEW YORK STATE DEPARTMENT OF HEALTH (WADSWORTH CENTER)

Albany, NY

TYPE:

Non-profit Research Organization

PARTICIPATING ORGANIZATION:

MassBiologics of UMass Chan Medical School

INDUSTRY NEED

The healthcare industry needed high-throughput and accurate diagnostic tests to screen for SARS-CoV-2 virus-neutralizing antibodies in human blood. When the COVID-19 pandemic began in March 2020, healthcare workers used live virus to measure antibodies, increasing their risk of exposure. Developing a safer and faster method of antibody testing could help to screen quarantined workers before returning to work, identify convalescent patients for potential antibody therapy research, and serve as a benchmark to test the efficacy of future vaccines.

SOLUTION

This collaboration between MassBiologics and the Wadsworth Center aimed to produce high-quality proteins to facilitate the development of a Polyvalent Microbead Immunoassay (MIA) that can measure SARS-CoV-2-specific neutralizing antibodies. This polyvalent assay can detect more than one type of antibody by using microbead technology to capture the antibodies for screening. This high-throughput assay would serve as a surrogate to live virus tests, providing flexibility to patients in a safer laboratory environment.



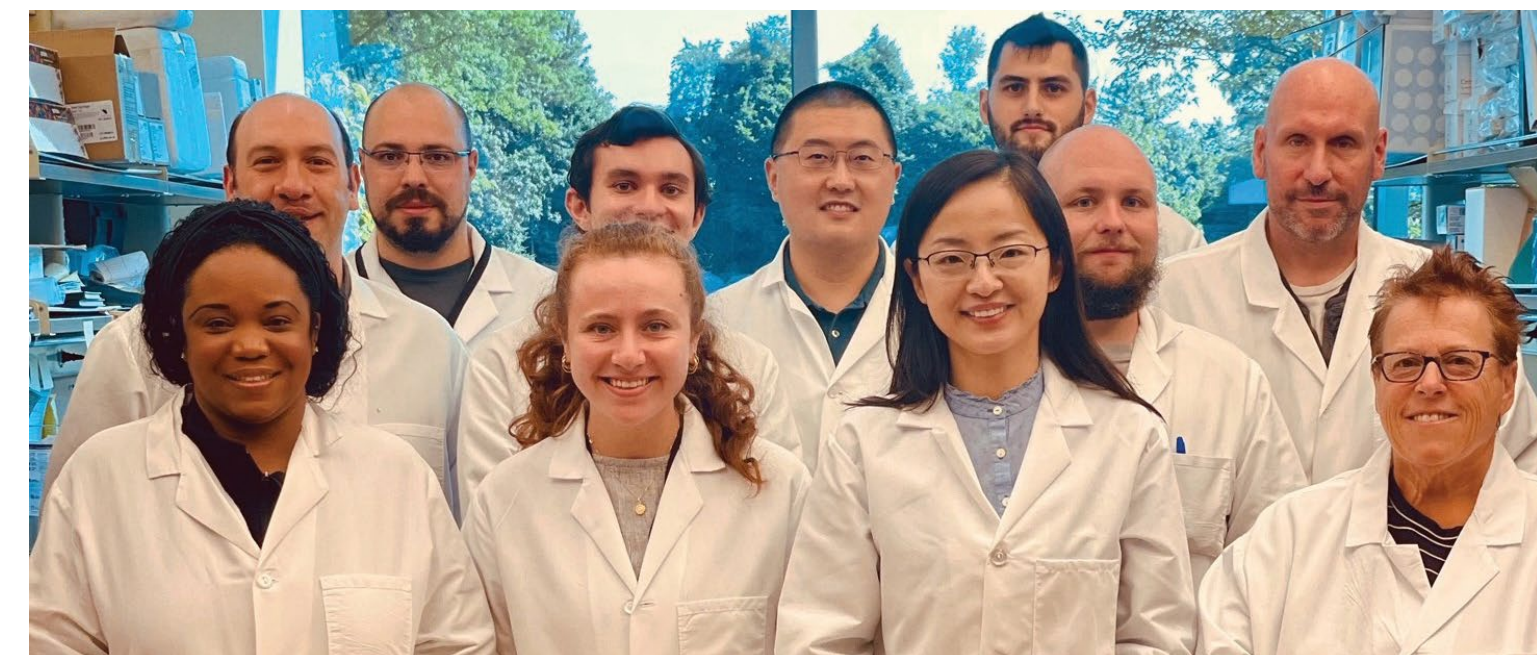
“NIIMBL enabled us to explore multiple different ways to express the protein and qualify the assay to industry standard. Without NIIMBL, a lot of that work is not possible.”

YANG WANG

MassBiologics of UMass Chan Medical School

OUTCOME

The team developed a validated, multiplexed assay for SARS-CoV-2 antibody-based diagnostics. With its high correlation to live virus tests, the assay can serve as a safer, high-throughput surrogate. The assay has the capacity to screen nearly 100 samples within four hours versus the five-day screening time for a live virus assay—a 97% reduction. Furthermore, since the MIA eliminates live virus tests, it reduces the exposure risk for healthcare workers. This MIA can be adapted for new antibodies and viruses in approximately 50% less time than live virus assays, enabling the healthcare industry to meet the challenges of future health emergencies more quickly. The MIA can be adapted for new antibodies in about two weeks and new antigens of virus variants in approximately two months, whereas adaptation of the live virus assay would take nearly a month for new antibodies and up to four months for new viruses and variants.



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Helping Military Personnel Develop New Skills for Careers in Biopharma

Military Service Members in BioPharma Manufacturing (MSMBM)

TEXAS A&M UNIVERSITY

College Station, TX

TYPE:

Academic Research Institution

PARTICIPATING ORGANIZATIONS:

North Carolina Biotechnology Center, Central Carolina Community College, Durham Technology Community College, Merck & Co., Inc., and Pfizer, Inc.

INDUSTRY NEED

According to a December 2020 PhRMA/Techonomy Partners LLC Report, the STEM skills gap will leave 2.4 million positions unfilled in the U.S. between 2018 and 2028.¹ Despite the biopharmaceutical industry's rapid growth, this skills gap has made it difficult to find qualified, skilled workers. In particular, the biopharmaceutical industry values talent with hands-on training so workers can quickly jump into their roles, minimizing training time and expense. To address these challenges, the industry needs to identify additional sources of talent with the right kind of training to quickly fill critical roles in manufacturing and process development.

SOLUTION

Leveraging the extensive military presence in Texas and North Carolina, Texas A&M University and its partners developed the Military Service Members in Biopharma Manufacturing (MSMBM) program. Service members have skills that translate well into careers in the biopharmaceutical industry. MSMBM builds on these transferrable skills and provides targeted technical training for successful careers in the industry. Additionally, the program connects participants to leading biopharmaceutical companies Merck & Co., Inc. and Pfizer, Inc. by facilitating presentations and interviews before and after the training. MSMBM helps industry tap into a significant and underutilized talent source and offers veterans new career possibilities.



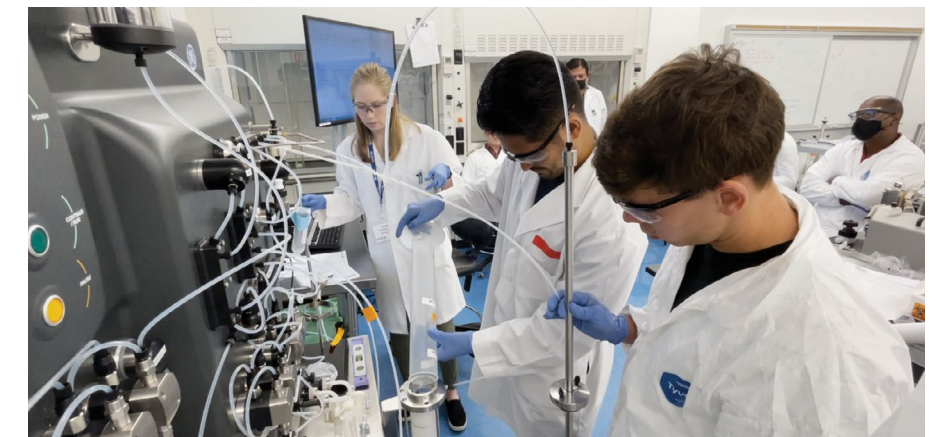
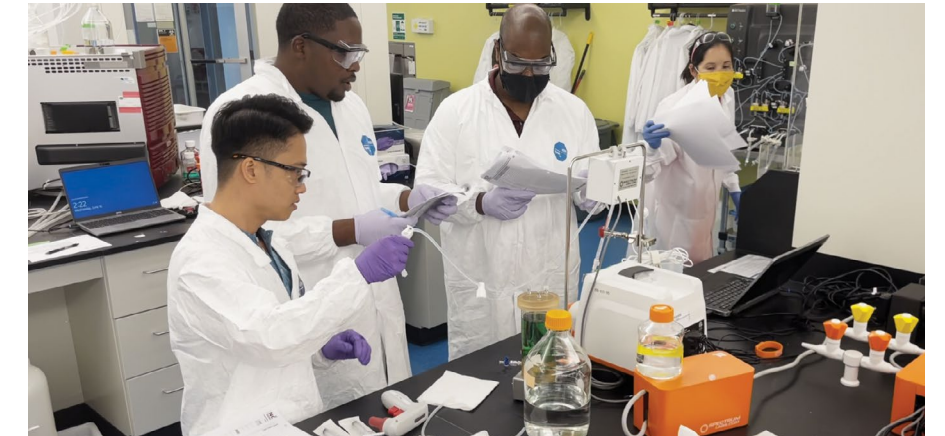
"The military community is an excellent audience to put through a technical training program like this one. These participants can really hit the ground running, add value to pharmaceutical companies, and bring amazing skillsets to the table."

JENNY LIGON

Texas A&M University

OUTCOME

In the summer and winter of 2021, the MSMBM program was delivered to five cohorts in Texas and North Carolina to a total of 41 veterans and military spouses. Courses covered key topics in biopharmaceutical manufacturing: Working Safely and Current Good Manufacturing Practices (cGMP); Measurement, Metrics, Unit Operations, and Documentation; Process Flows, Technology, and Equipment; Analytical Techniques and Maintaining Quality; Aseptic Processing, Fermentation, and Cell Growth; and Harvest, Filtration, and Purification. Students had the opportunity to interview with Merck & Co., Inc. and Pfizer, Inc. upon completion of the program. In addition, participants in North Carolina had the chance to attend BioNetwork's November Career Fair and interview with biotechnology companies. Of the 41 participants across the cohorts, 50% received offers from biopharmaceutical companies within three months of completing the program. One participant from the TX/NC 2021 cohort shared that, "The hands-on experience with instruments, techniques, and technology inspired me to seek employment in biopharma."



¹Sustaining the Growth and Competitiveness of U.S. Biopharmaceutical Manufacturing. PhRMA/Techonomy Partners LLC, December 2020.

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Improving Sensor Design to Reduce Manufacturing Time and Cost

A Multivariate In-Line Optochemical Sensor Platform for Continuous Monitoring of Cross-Category Process Parameters and Product Attributes in Bioreactors

NORTH CAROLINA STATE UNIVERSITY

Raleigh, NC

TYPE:

Academic Research Institution

PARTICIPATING ORGANIZATIONS:

MilliporeSigma / EMD Sorono and Pfizer, Inc.

INDUSTRY NEED

During the cell growth phase, known as the upstream process, attributes such as glucose and carbon dioxide are closely monitored as an indicator of cell health and productivity. The current sensor technologies used in bioreactors to measure these attributes are expensive and most are only capable of measuring one attribute at a time. Because of these limitations, analytical tests may take hours to complete, adding time and expense to the manufacturing process.

SOLUTION

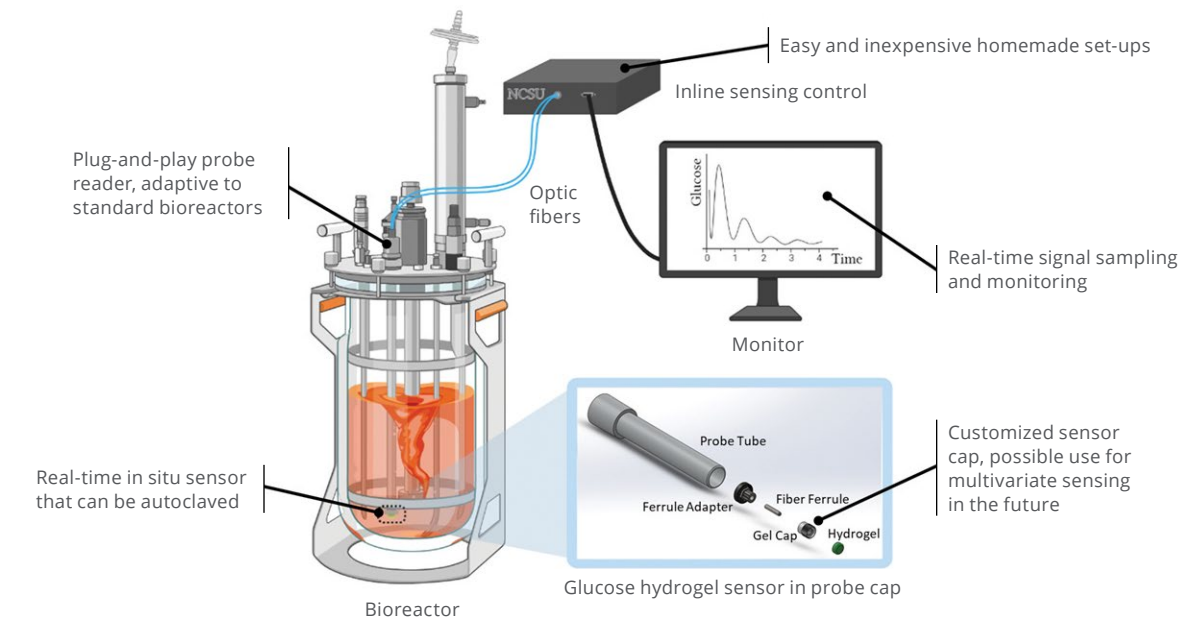
North Carolina State University, with partners Pfizer, Inc. and MilliporeSigma, aimed to develop a multi-attribute inline optochemical sensor platform for continuous monitoring of glucose and carbon dioxide in bioreactors at all scales. The optochemical sensor technology uses fiber optics and fluorescent dyes to measure these two attributes. The inline implementation allows for real-time continuous monitoring of cell culture environments, eliminating the need to pull samples for offline analysis. The new sensor platform lowers costs, reduces analytical time, and helps to transition the manufacturing process from batch to continuous production.



“Through these collaboration opportunities within NIIMBL, we were able to talk to industry partners and really gain an understanding of the issues they need to address.”

QINGSHAN WEI

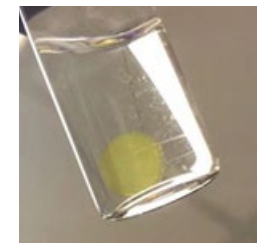
North Carolina State University



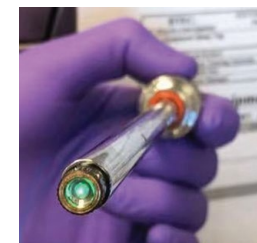
Palm-Size Form Factor



pCO Sensor



Glucose Sensor



Probe Reader

OUTCOME

The team developed a prototype device using a hydrogel-based glucose sensor and fiber optic carbon dioxide sensor that can be used in bioreactors of any size. The device reduces measurement time by more than 95%. The glucose sensor produces readings within 10 minutes, while the carbon dioxide sensor provides readings instantaneously. Each of these measurements takes three hours or more with offline approaches. Also, with an estimated total cost of \$2,500, the multivariant sensor reduces cost by at least 60% compared to other sensor technologies. For example, carbon dioxide probes alone cost approximately \$6,000. This enhanced sensor creates manufacturing efficiency by allowing for continuous real-time monitoring.

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Expanding Diversity in the Biopharmaceutical Workforce

WORDE: A Biopharmaceutical Training Center to Promote Development of the Workforce, Outreach, Research, Diversity, and Education

DELAWARE STATE UNIVERSITY

Dover, DE

TYPE:

Academic Institution

PARTICIPATING ORGANIZATIONS:

Merck & Co., Inc., Montgomery County Community College

INDUSTRY NEED

As the biopharmaceutical industry looks to fill talent gaps, it has emphasized increasing diversity within its workforce as an essential factor. Companies are looking for talented, diverse candidates who can hit the ground running and step into roles without extensive training time. New educational programs that are accessible to underrepresented populations could expand the talent pipeline and offer students a pathway to a successful career in the biopharmaceutical industry.

SOLUTION

Delaware State University (DSU), a Historically Black College and University, set out to establish the WORDE Institute (Workforce, Outreach, Research, Diversity, and Education), offering new opportunities for students in the growing biopharmaceutical industry. The goal of the institute is to prepare the next generation of a diverse and knowledgeable workforce by coupling a competitive educational curriculum with essential hands-on training. Leveraging the expertise and guidance from its partners, Merck & Co, Inc. and Montgomery County Community College, DSU installed equipment and developed curriculum for the new biomanufacturing program. In addition, DSU researchers underwent training to become instructors in the new program during a week-long bootcamp at Merck & Co., Inc., during which they enhanced their knowledge of industry needs to further support program participants.



"When I attended conferences in the past, I noticed there were not a lot of people of color. Dr. LaTia Scott said, 'If you want to see a change, go out and create it.' This program and the support of NIIMBL and our partners are helping us to do that."

DERRICK SCOTT

Delaware State University

OUTCOME

In the fall of 2021, DSU soft launched the WORDE Institute with an initial cohort of four students. The students took part in classroom instruction and hands-on training in upstream processing, downstream processing, and analytics. As part of the program, students spent time at the Jefferson Institute for Bioprocessing (JIB) in Philadelphia, one of the premier bioprocessing training centers in the country. Two students have received internship offers from JIB. After the program's first semester, DSU aims to have 12 students enrolled in the program by 2024. It is well on its way to meeting that goal as more than 10 students to date have expressed interest in entering the biopharmaceutical field.



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MEMBERSHIP



MEMBERS AND PARTNERS 2021–2022

INDUSTRY

4th Phase Water Technologies
 908 Devices, Inc.
 ABL
 Accugenomics Inc.
 Aerosol Therapeutics
 Agilent*
 Akron Biotechnology, LLC
 Amgen Inc.
 Applied Biosensors
 Applied Control Engineering, Inc.
 Applied Materials, Inc.
 Artemis Biosystems Inc.
 Asimov
 AstraZeneca
 Automated Control Concepts Inc.
 Ballydel Technologies, Inc.*
 Batavia Biosciences Inc.*
 Bill & Melinda Gates Foundation
 BioCurie, Inc.*
 Biostealth Inc.*
 Bristol-Myers Squibb
 Calidi Biotherapeutics*
 Catalent Pharma Solutions, LLC
 CellFE, Inc.
 Centivax Inc.
 Century Therapeutics*
 Chromatan Corporation
 Colby Pharmaceutical Company*
 Commissioning Agents Inc.
 CompassRed, Inc.
 CSL Behring, LLC*
 Cygnus Technologies
 Denali Therapeutics
 Dyadic International Inc.
 Eli Lilly and Company
 Emergent BioSolutions, Inc.*
 Extrave Bioscience, LLC
 Fisher Rosemount Systems Inc.
 Genentech
 GlaxoSmithKline, LLC
 Halo Labs (Optofluidics)*
 iBio, Inc.
 ILC Dover LP
 IMA Life North America Inc.

InDevR Inc.
 Intabio
 Intergrated Micro-Chromatography Systems, Inc. (IMCS)*
 IPS-Integrated Project Services, LLC*
 Isolere
 Janis Research Company
 Janssen Research & Development, LLC
 Just - Evotec Biologics
 Landmark Bio*
 LigaTrap Technologies, LLC.
 Lindy Biosciences, Inc.
 LumaCyte, LLC
 M Davis & Sons Inc.
 Mango Inc.
 Matterworks, Inc.*
 Merck & Co., Inc.
 Metalytics
 MilliporeSigma/EMD Serono
 MOBILion Systems Inc.
 MockV Solutions, Inc.
 MTI BioScience, LLC
 National Resilience, Inc.
 Nature's Toolbox Inc. (Ntx)*
 Novilytic LLC*
 OUAT!*
 PAK Biosolutions
 Pall Corporation/Cytiva*
 Pfizer, Inc.
 Physical Sciences Inc.
 PMT (USA) LLC
 Raven Biomaterials LLC*
 Redbud Labs Inc.
 RedShift BioAnalytics
 Repligen Corporation
 Resilience US
 Sanofi
 Sartorius Stedim
 Scientific Bioprocessing
 Sepax Technologies Inc.
 Sepragen Corporation
 Sequence, Inc.*
 SP Industries
 Spark Therapeutics, Inc.
 Sudhin Biopharma Co
 Sutro Biopharma

Takeda Pharmaceuticals
 Univercells Technologies, S.A.
 Unum Therapeutics Inc.
 Uvax Bio LLC
 Vericel Corporation
 Vir Biotechnology, Inc.
 Waters Technologies Corporation*
 Werum IT Solutions America Inc. | Körber Group
 WhirlCell LLC.
 Xcellerate Biotech Inc.
 Yokogawa Corporation Of America*
 Zea Biosciences*
 Ziccum AB*

ACADEMIC INSTITUTIONS AND NON-PROFITS

AABB Center for Cellular Therapies
 AlChE
 Alamance Community College
 Albany College of Pharmacy and
 Alliance for Regenerative Medicine
 Austin Community College
 Automation Anywhere, Inc., Life
 BioBAT, Inc.
 BioKansas
 Bioscience Core Skills Institute (BCSI)*
 Biotility
 Brunswick Community College
 California Polytechnic State University
 Cape Fear Community College
 Caring Cross, Inc.
 Carnegie Mellon University
 Cecil College
 Cedars-Sinai Biomanufacturing Center*
 Center for Entrepreneurial Innovation Maricopa CCCD
 Central Carolina Community College
 Clemson University
 Delaware BioScience Association
 Delaware Prosperity Partnership
 Delaware State University
 Delaware Technical Community College
 Delaware Valley Industrial Resource Center
 Developing Countries Vaccine Manufacturers Network
 Durham Technical Community College
 Forsyth Technical Community College
 Fraunhofer USA
 Frederick Community College

Gaston College
 Georgia Tech Research Corporation
 Gustavus Adolphus College
 Harrisburg University of Science and Technology*
 Health Sciences
 International Academy of Automation Engineering
 Johns Hopkins University
 Johnston Community College*
 Keck Graduate Institute
 Life Science Washington
 Maryland Tech Council*
 Massachusetts Institute of Technology
 Massachusetts Life Sciences Center
 MassBio Education Foundation
 MiraCosta College
 Missouri Biotechnology Association
 Missouri University of Science and Technology
 Montgomery College
 Montgomery County Community College
 Montgomery County Economic Development Corporation*
 National Institute for Pharmaceutical Technology and Education, Inc. (NIPTe)
 New Jersey Economic Development Authority
 New Jersey Innovation Institute
 New Jersey Institute of Technology*
 New York State Department of Health (Wadsworth Center)
 North Carolina Biosciences Organization
 North Carolina Biotechnology Center
 North Carolina Central University
 North Carolina Community Colleges Systems BioNetwork
 North Carolina State University

Northeastern University
 Open Applications Group, Inc.
 Open Biopharma Research and Training Institute*
 Oregon Bioscience Association
 PATH Center for Vaccines Innovation & Access
 Project Lead The Way*
 Purdue University
 Qulnc.y College
 Regents of the University of Colorado (Boulder)
 Regents of University of Minnesota
 Rensselaer Polytechnic Institute
 Research Corporation Technologies Inc.
 Rutgers, The State University of New Jersey*
 Santa Clara University
 Science Division
 Shoreline Community College
 Skilled KC Technical Institute
 Sloan Kettering Institute for Cancer Research
 Solano College
 Southwest Research Institute
 Standards Coordinating Body
 Texas A&M University System
 The American Society of Mechanical Engineers (ASME)
 The Ohio State University*
 The Pennsylvania State University
 The Research Foundation for the State University of New York, on behalf of State University of New York Polytechnic Institute
 Thomas Jefferson University
 Tulane University
 United States Pharmacopeial Convention
 University City Science Center

University of California, Davis*
 University of California, Los Angeles
 University of Colorado Denver | Anschutz Medical Campus*
 University of Delaware
 University of Georgia Research Foundation
 University of Houston*
 University of Maryland
 University of Maryland, Baltimore County
 University of Massachusetts System
 University of North Carolina, Chapel Hill
 University of Pennsylvania
 Vance-Granville Community College
 Villanova University
 Wake Technical Community College
 Washington State University
 Worcester Polytechnic Institute
 Xavier University of Louisiana

MANUFACTURING EXTENSION PARTNERSHIPS (MEP)

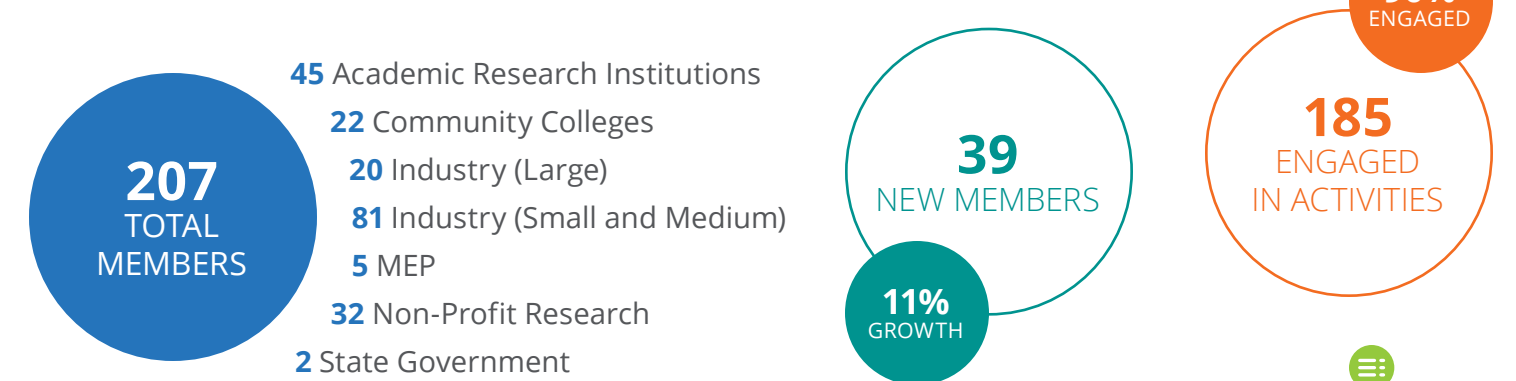
New Jersey Manufacturing Extension Partnership
 North Carolina Manufacturing Extension Partnership
 Delaware Manufacturing Extension Partnership

OTHER PARTNERS

National Institute of Standards and Technology
 Food and Drug Administration
 National Institutes of Health
 NIIMBL interacts with several other federal agencies and institutes.

*New members

MEMBERSHIP ENGAGEMENT





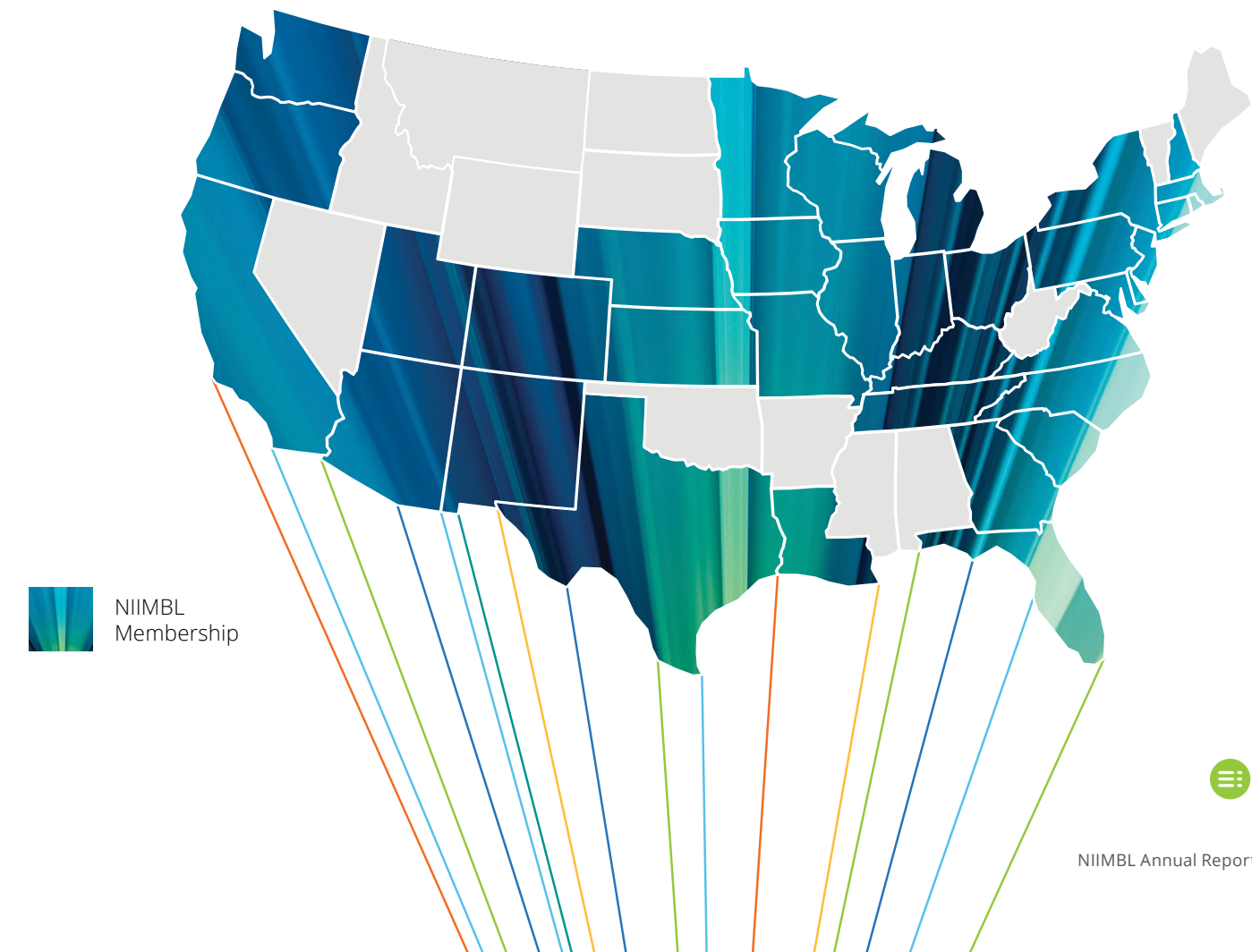


ABOUT NIIMBL

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is a public-private partnership whose mission is to accelerate biopharmaceutical innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing U.S. competitiveness in this industry. NIIMBL is part of Manufacturing USA®, a diverse network of federally sponsored manufacturing innovation institutes, and is funded through a cooperative agreement with the National Institute of Standards and Technology (NIST) in the U.S. Department of Commerce with significant additional support from its members.

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