

NORTH CAROLINA *Vaccine Consortium*

North Carolina is a worldwide leader in innovative vaccine research.

Consortium Goals

Assure that our existing world-class biotechnology worker training capabilities keep pace with new vaccine development and manufacturing technologies.

Support further enhancement of North Carolina's vaccine-related research and development infrastructure, including expanded BSL-2 and BSL-3 research and testing facilities.

Assist North Carolina companies seeking to become suppliers of vaccine and medical countermeasure technologies.

Accelerate translation of research discoveries through development, testing and clinical trials.

The North Carolina Vaccine Consortium brings together established state-of-the-art resources for vaccine development and emergency preparedness. The consortium consists of industry, academic and education partners who align their research, product development, manufacturing and workforce training for common goals.



Wake Forest
Duke
UNC-CH
NC State

Partners include:

- North Carolina Biotechnology Center
- North Carolina Biosciences Organization
- Duke University, North Carolina State University, the University of North Carolina at Chapel Hill, and Wake Forest University
- Biotechnology manufacturing companies
- Life science research and development companies



University of North Carolina – Chapel Hill

Carolina Vaccine Institute

The Carolina Vaccine Institute (CVI) fosters interactions among investigators at the University of North Carolina at Chapel Hill who have shared interests in the development of vaccines for the prevention of infectious diseases, or targeting other diseases, such as cancer or addiction, amenable to vaccine prevention or treatment.

CVI research programs focus on fundamental aspects of innate and adaptive immunity relevant to immunization; molecular virology and the pathogenesis of viral or bacterial infections; and the use of systems genetics approaches to identify host genetic determinants that regulate both pathogen susceptibility and vaccine efficacy.

CVI meets its mission by partnering with numerous centers and organizations:

- UNC Center for AIDS Research
- UNC Center for Infectious Diseases
- UNC Lineberger Comprehensive Cancer Center
- UNC Gillings School of Public Health – Office of Global Health
- Global Vaccines, Inc.
- International AIDS Vaccine Initiative
- Universities Allied for Essential Medicines



North Carolina State University

Center for Comparative Medicine and Translational Research, a consortium led by the NCSU College of Veterinary Medicine

The Center for Comparative Medicine and Translational Research (CCMTR) promotes scientific discovery and facilitates its clinical application to achieve the goal of improving the health of animals and humans.

Initiatives at the CCMTR are designed to develop the multidisciplinary teams necessary to bring an idea from the lab to the patient.

Vaccine development is one of the focus areas for the Emerging and Zoonotic Diseases Core, one of eight research cores at the CCMTR. The goal of this core is to integrate basic and clinical research to investigate infectious diseases of companion and production animals and to advance animal models of human disease.



Facilities

North Carolina Vaccine Consortium partners collectively offer approximately 45,000 square feet of space devoted to 10 BSL-3 labs, a BSL-3 aerosol exposure chamber, multiple BSL-2 labs, cold rooms, tissue culture suites, virus rooms and equipment rooms. There is also a 63,000 square-foot, state-of-the-art simulated cGMP facility with bioreactors from 2L to 300L for fermentation and cell culture projects.

Carolina Community College System. NCBioImpact has training programs for a wide range of professions including process technicians, facility engineers, process development scientists and quality assurance associates. Collaboration under this initiative resulted in an internationally recognized, first-of-its-kind training program built around three training partners – BRITE, BioNetwork and BTEC.

Training

NCBioImpact is a public/private partnership combining the resources of the life-science industry, the North Carolina Biosciences Organization and the North Carolina Biotechnology Center with the University of North Carolina System and the North

Biomanufacturing Research Institute and Technology Enterprise (BRITE) at North Carolina Central University, is one of the newest and most innovative biotechnology educational initiatives offering a formal biotech degree program. Both bachelor's and master's degree programs are available, and a doctoral program is currently in development.



Duke University

Duke Human Vaccine Institute

The Duke Human Vaccine Institute (DHVI) develops novel research strategies for drugs, vaccines and diagnostics in the fight against AIDS and other emerging infections such as tuberculosis, plague and pandemic influenza.

The DHVI has established a place of national and international leadership in the fight against major infectious diseases. By focusing on the bottlenecks for the development of HIV, tuberculosis and other vaccines, DHVI investigators are poised to make major new contributions to global health challenges.

Wake Forest University

Wake Forest Baptist Medical Center

Wake Forest Baptist Medical Center (WFBMC) has a number of programs in vaccine development. Programs include developmental vaccines against drugs of abuse and allergy, and the flagellin adjuvant platform that has resulted in vaccines against pneumonic plague, poxviruses and *Pseudomonas aeruginosa*.

The WFBMC-generated vaccine against pneumonic plague has entered a National Institute of Allergy and Infectious Diseases/NIH-sponsored Phase I clinical trial. In

DHVI Programs

- Center for HIV/AIDS Vaccine Immunology
- Collaboration for AIDS Vaccine Discovery
- HIV Research and Development
- Regional Biocontainment Laboratory at Duke
- External Quality Assurance Program Oversight Laboratory
- Immunology Quality Assessment Center
- DHVI Training and Mentoring Program

addition, WFBMC has developed two viral-based vaccine vectors that offer substantial opportunities for novel vaccine development. Translational research models include a range of animal models including nonhuman primates.

WFBMC also possesses substantial expertise in a number of immunologic systems and molecules as well as a collaborative group of outstanding immunologists, virologists and bacteriologists.



Impact

BioNetwork supports the mission of the North Carolina Community College System aligning world class workforce training and education to the biotechnology, pharmaceutical and life science industries. Comprised of seven centers, BioNetwork trains workers at all levels from entry level to management.

Biomanufacturing Training and Education Center (BTEC) at North Carolina State University provides educational and training opportunities to develop skilled professionals for the biomanufacturing industry. The center has extensive capabilities for providing process and analytical services. It has the equipment and infrastructure to handle large scale batches and process studies on vaccine manufacturing.

Spotlight on BTEC

BTEC provides training for government agencies and international organizations in vaccine manufacturing.

- During 2011, the fourth cohort of trainees from the U.S. Food and Drug Administration will begin a series of training courses at BTEC including upstream bioprocessing, downstream bioprocessing, quality control/analytical and fill/finish.
- BTEC has a contract with Biomedical Advanced Research and Development Authority (BARDA) and the World Health Organization. BTEC will train three cohorts of students during 2011 for selected vaccine manufacturers from developing countries.





Assets

Several leading vaccine manufacturers call North Carolina home. GlaxoSmithKline has its U.S. headquarters in North Carolina. Other household names from the vaccine industry include:

- Merck & Co. in Durham,
- Merck Biomanufacturing Network in Research Triangle Park,
- Novartis in Holly Springs,
- Pfizer in Sanford, and
- Pfizer Poultry Health in Research Triangle Park and Maxton.

A vibrant community of more than 30 additional companies in the state conducts vaccine-related research, testing and production. Plus, the newest vaccine-production technologies are being launched here:

- The \$1 billion Novartis Vaccines and Diagnostics manufacturing plant in Holly Springs is the first large-scale flu vaccine cell-culture manufacturing facility in North America.

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- Medicago USA is building a \$42 million facility in Research Triangle Park that will use tobacco leaves in the vaccine-production process.

North Carolina scientists secured \$111 million in vaccine-related grants in 2009 alone.

Strong support network

Vaccine development relies heavily on clinical testing. More than 100 contract research organizations (CROs) in North Carolina support clinical trials, from trial design to report submissions, to ensure that products gain U.S. and worldwide approval. Two of the original, and now largest CROs, are headquartered in North Carolina – PPD and Quintiles.

In addition, more than 1,000 companies provide direct support to biotech and life science firms, from specialized construction or legal know-how to the right expertise in IT or staffing.

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For more information

- **North Carolina Biotechnology Center**
ncbiotech.org/vaccines
- **North Carolina Biosciences Organization**
ncbioscience.net
- **Biomanufacturing Research Institute and Technology Enterprise**
brite.nccu.edu
- **Biomanufacturing Training and Education Center at NCSU**
btec.ncsu.edu
- **BioNetwork**
ncbionetwork.org
- **Carolina Vaccine Institute at UNC Chapel Hill**
med.unc.edu/cvi
- **Center for Comparative Medicine and Translational Research at NCSU**
cvm.ncsu.edu/cmtr
- **Duke Human Vaccine Institute at Duke University**
humanvaccine.duke.edu
- **NCBioImpact**
ncbioimpact.com
- **Wake Forest Baptist Medical Center at Wake Forest University**
wakehealth.edu/research



ncbiotech.org/vaccines