



2022–2027 Strategic Plan Institute of Human Virology

Solving Medical Problems that Impact People

Discover, Translate, & Implement



UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE

Discover, Translate, & Implement

Vision

To transform global healthcare of human viral diseases through discovery, education, and therapeutic translation and implementation.

Mission

To support innovative basic, translational, and implementation research that advances the management of human chronic viral diseases, we focus on (1) discovering novel mechanisms of pathogenesis to develop therapeutics and vaccines, (2) translating rapidly innovative, life-altering therapies and vaccines, and (3) influencing public health policies through implementation research.

Director's Message

Greetings,

We are pleased to present the 2022-2027 Strategic Plan: Institute of Human Virology (IHV) at the University of Maryland School of Medicine in Baltimore, Maryland. This strategy provides a glimpse into our thinking today and in the near future. I am grateful to my colleagues at the Institute for helping to prepare this document. Our Institute is celebrating its silver anniversary, and I believe it has achieved its highest potential regarding discovery, productivity, equity, and diversity. The past two years of the pandemic have taught us how vulnerable we are to global viral threats and highlighted the major responsibility of the IHV and leadership. There has never been a time more appropriate to define our path to grow and succeed as the most prominent virology institution in the world. In this regard, we have defined a clear path of the components necessary for success: namely, the people, the science, and the environment. This strategic plan defines the avenue forward for our Institute to seek new horizons and designate our role by ***“solving medical problems that impact people.”***



Robert C. Gallo, MD

Robert C. Gallo, MD

The Homer & Martha Gudelsky Distinguished Professor in Medicine;
Co-founder & Director, Institute of Human Virology
at the University of Maryland School of Medicine;
Co-Founder & Chair of the Scientific Leadership Board, Global Virus Network

Executive Summary

The strategic plan will propel and guide the growth of the Institute of Human Virology from 2022 through 2027 and spearhead the Institute's development over the next decade. The plan is designed to cultivate the best environment for all the Institute's faculty and staff to grow personally and professionally, advancing virology research with pioneering breakthroughs in a conducive environment.

This document is the culmination of the commitment from the IHV community in developing a tactical organizational blueprint in accordance with the Institute's desire to maintain its eminence as one of the leading virology institutes in the world and forge ahead to newer heights in global virology research. This blueprint results from a cumulative process implemented by the IHV strategic plan team from the summer of 2021 to the spring of 2022. During this process, the team sought out and interviewed Division directors, key IHV leadership, and critical faculty and staff members through interviews and questionnaires with feedback. There was consensus among the IHV community to accomplish our mission under the umbrella of this new strategic plan designed under the auspices of the University of Maryland, Baltimore's 2022–2026 strategic plan.

This strategic plan aims to accomplish the following anticipated outcomes:

- Develop as the most revered virology institution in advancing our research to reach the global population
- Sustain our creativity and enhance our productivity in developing preventive and curative therapeutics to overcome viral diseases
- Constitute a novel hybrid translational research model within the Institute to command rapid transition of ideas to reality through clinical and implementation research
- Provide leadership and training for the next generation of medical virologists worldwide in a microenvironment conducive to diversity, equity, and inclusion
- Relentlessly practice values and themes of the University of Maryland School of Medicine across all functional aspects of the Institute



Central Themes

Our strategic plan is built around three important themes.



Discovery (inventions advancing science) theme focuses on advancing our understanding of the pathogenesis of viral diseases to alleviate the disease burden. We will invest in our intellectual, technical, and human resources to continue enhancing our discovery platform through a blended organization that constitutes a goal-oriented approach to developing vaccines and therapeutics.



Translation (clinical transformation of discoveries) theme emphasizes the development of prevention and novel mechanism-based therapeutic measures for viral diseases and their complications. We will enhance the Institute's ability to transform discoveries to clinical benefit for scores with high-throughput clinical trials, ensuring scientific advances that reach and benefit all those afflicted despite social, economic, and behavioral challenges.



Implementation (expansion of evidence-based medicine) theme underscores evidence-based prevention and control of emerging and re-emerging infectious diseases with the expansion of innovative high-yield protocol designs. We will continue to accelerate the implementation of diagnostic, linkage, preventive, and therapeutic strategies to assuage the global burden associated with viral diseases.

The Institute will dynamically recruit, retain, realign, and remodel the organization to accomplish the goals of the central themes. Over the next five years, the Institute will enhance its footprint as a global leader in virology research while increasing diversity, inclusivity, integration, and collaboration, while empowering its members with the best career opportunities to bridge the gaps in our fight against diseases caused by viruses. The Institute will utilize a multi-disciplinary approach, partnering with colleagues on campus when appropriate and as promoted by the University. This plan will critically define our Institute on who we are, what we do, and why we matter in the present and future.

Historic Milestones

- The IHV established in 1996, was initially affiliated with the University of Maryland Biotechnology Institute, and, in 2007, joined the University of Maryland School of Medicine as its first Institute.
- The IHV has received more than \$1 billion from the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) program. The IHV has treated more than 2 million patients with antiretroviral medications and has facilitated the receipt of prevention interventions and HIV testing for close to 4 million people worldwide.
- In 2007, the IHV received the first of three major Bill & Melinda Gates grants for its HIV preventive vaccine candidate, with total funding of more than \$40 million.
- The IHV has received over 100 NIH grant awards in excess of \$400 million, including ones focusing on significant cancer due to infectious agents.
- The IHV spun off five new companies to advance the Institute’s technologies as part of IHV’s discovery platform. The IHV has received over 100 total patents.
- The IHV’s outreach program for people living with HIV and/or those at high-risk for HIV-acquisition, The JACQUES Initiative, opened a center offering a wide range of free services to the marginalized Baltimore community.
- The Global Virus Network (GVN), an international authority and resource for the identification, investigation, and control of viral diseases posing threats to humankind, is incubated in the IHV and was officially established in 2011. As of March 2022, GVN has evolved into 69 Centers of Excellence and 11 Affiliates in 37 countries.
- The IHV established its Annual Greenebaum Lecture series featuring world-renowned biomedical scientists.
- The IHV established the Robert C. Gallo Endowed Professorship for Translational Medicine (2016) and the Charles Gordon Smith Endowed Professorship for HIV Research (2020).
- In 2016, IHV moved several of its outpatient practices forming the University of Maryland Center for Infectious Diseases, at Midtown Campus. The HIV arm of the Center was renamed the THRIVE Program (Together, Healing, Reaching, Inspiring to achieve Victory over illness and Embrace life). In 2021, the THRIVE program moved into the newly opened Midtown Outpatient Tower. THRIVE provides medical and mental health care, and addresses social needs for people living with HIV.
- The Maeve Kennedy McKean Global Public Health Fellowship was established in honor of the public health activist to supplement the Institute’s efforts to end the HIV epidemic in Africa within its Center for International Health, Education, and Biosecurity (Ciheb) and Division of Clinical Care and Research.





Introduction

The **Institute of Human Virology (IHV)** is a premier institution that combines the disciplines of basic science, epidemiology, and clinical translational research in a concerted effort to discover, educate, and speed the development of novel diagnostics and therapeutics for a wide variety of existing and emerging viral diseases.

Formed in 1996 as a partnership between the State of Maryland, the City of Baltimore, the University System of Maryland, and the University of Maryland Medical System, the IHV is an institute of the University of Maryland School of Medicine and is home to some of the most globally recognized and world-renowned experts in the field of human virology.

The IHV was co-founded by Robert Gallo, MD, Director of the IHV; William Blattner, MD, who retired in 2016 and was formerly Associate Director of the IHV and Director of IHV's Division of Epidemiology and Prevention; and Robert Redfield, MD, who resigned in March 2018 to become Director of the U.S. Centers for Disease Control and Prevention (CDC) and was formerly Associate Director of the IHV and Director of the IHV's Division of Clinical Care and Research. In addition to the two Divisions aforementioned, the IHV is also composed of the following: Division of Vaccine Research; Division of Virology, Pathogenesis, and Cancer; Division of Immunotherapy; Center for International Health, Education, & Biosecurity; and Scientific Core Facilities.

The Institute, with its various laboratory and patient care facilities, is housed in a 250,000 square-foot building located in West Baltimore, Maryland. The IHV creates an environment where multi-disciplinary research, education, and clinical programs work closely together to expedite the scientific understanding of viral pathogenesis and develop diagnostic, preventive, and therapeutic interventions to curtail global viral diseases.

The IHV has more than 240 employees, including more than 80 faculty whose research efforts are focused on chronic human viral diseases. From its inception, the Institute's clinical and basic research efforts targeted HIV infection and included hepatitis B/C virus, human T-cell leukemia viruses 1 and 2, human papillomavirus, herpes viruses, and recently SARS-CoV-2. A unique aspect of the IHV and its investigators is its ability to translate ideas rapidly from bench to bedside. In this regard, the IHV is constantly expanding its portfolio to respond to global challenges posed by existing and emerging/re-emerging viruses, including SARS-CoV-2.

The IHV serves over 5,000 patients in Baltimore and Washington, D.C., and more than 2 million individuals in African nations. The IHV is internationally renowned for its mission highlighted by funding from the CDC, the National Institutes of Health, and the Bill & Melinda Gates Foundation.

The IHV has a unique history of successful public-private partnership in the discovery of novel agents, generation of intellectual properties, successful incubator opportunities, accelerated commercialization of novel promising pharmaceutical products, and reaching the most needful assisted by philanthropic support.

Strategic Planning Process

In the fall of 2021, the IHV director and Division directors agreed on the importance of developing a strategic plan for the Institute which is easily understood and remembered. At that same time, the University of Maryland, Baltimore (UMB) released its updated strategic plan for 2022-2026, allowing the IHV to use UMB's strategic themes to guide its strategic planning process.

A small strategic planning group was created out of the IHV Director's Office to facilitate the strategic planning process and ensure all stakeholders were approached for input and feedback within the Institute. The first round of meetings was held with the Division directors to gain their overall input on the framework from which the strategic plan is grounded. Once there was consensus, individual

interviews were conducted with each Division director and two or three key faculty/staff from that Division to articulate their Division’s goals and plans for the next five years within the framework. After the strategic plan was drafted, additional IHV stakeholders were invited to review the draft plan and provide input.

Through this process, the IHV developed a strategic plan to be a world-leading hub of discovery, education, and therapeutic translation and implementation for human viral diseases.

Who We Are

The IHV functions as five well-integrated Divisions, one Center, and Core Facilities under the leadership of preeminent scientists to realize the strategic plan core values exemplified by its goals and objectives. The Division leaders collaborate to achieve the goals and objectives to sustain the core values necessary to accomplish the mission of the IHV. While the research of each Division and Center continues to be distinct, the strategic plan envisions leadership working in tandem to achieve the goals as delineated. Functional integration of the IHV transpires, as displayed in **Figure 1**. This functional thesis endorses a blended approach of the existing and future Divisions and Centers to incorporate functionally and continue to grow with a focused strategy that fulfills the goals and objectives of the core values of our strategic plan. The IHV will incorporate innovative collaborations with industry, non-profit organizations, and philanthropic institutions in achieving the goals of the strategic plan.

Figure 1: Functional integration of the IHV Divisions and Centers to achieve the goals and objectives of the strategic plan



Division of Epidemiology and Prevention

Supports the identification, reduction, and eradication efforts for HIV, other emerging infectious diseases, and cancers in populations in Baltimore and around the world.

Division of Vaccine Research

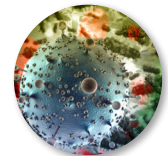
Fosters clinical development of the IHV-O1 vaccine for HIV prevention while expanding our understanding of humoral immunology to improve the efficacy of preventive vaccines for human viral diseases. Carries out basic research on the mechanisms of antibody-mediated protection against HIV-1.

Division of Virology, Pathogenesis, and Cancer

Focuses on pathogenesis and mechanism-based prevention and therapeutic approach for human viral diseases and pathogen-associated cancers, including HIV, HTLV-I, hepatitis viruses, coronaviruses, and other emerging viral pathogens.

Division of Immunotherapy

Develops immune-based therapeutic approaches for chronic viral infections such as hepatitis, HIV infections, and cancer, whether as a direct approach or as adjuvant therapy.



Division of Clinical Care and Research

Comprised of an extensive clinical cohort including the THRIVE clinic for HIV patients, an outreach program (The JACQUES Initiative), a clinical care program, and a clinical trials unit housed at the IHV. Division goals include providing state-of-the-art care for HIV and marginalized patients, enhancing retention and reducing attrition rates of marginalized patients, providing state-of-the-art training for tomorrow's medical virologists and infectious diseases specialists, and conducting avant-garde translational and implementation research to eliminate human viral infections and improve lives of people infected with viruses.



Center for International Health Education and Biosecurity (Ciheb)

The Center is comprised of a network of international experts who work with local stakeholders to combat infectious and non-communicable diseases in resource-limited regions of the world.



Scientific Core Facilities

Provides ancillary support to the Divisions by developing, maintaining, and conducting preclinical and discovery research on viral infections.



Core Values—This strategic plan strengthens our existing core values as a premier virology institute **for over 25 years**. This plan focuses on defining specific objectives anchored to these core values that will accomplish IHV's mission.

Discovery through Research

Laboratories at the IHV that work exclusively on advancing our understanding of the basic pathogenesis of viral diseases will constitute the Institute's knowledge-based advancement (Discovery). This approach will be predicated on developing and maintaining various unique patient cohorts in Washington, D.C.-Baltimore metropolitan areas and global sites. This approach will also utilize animal care facilities at the IHV to develop novel animal models for studying viral infection and animal models for preclinical development of discovery assets. A major focus of knowledge-based advancement includes strategies to develop preventive medicine, such as vaccines which constitute the Institute's prevention-focused theme.

Goal: Advance our understanding of the pathogenesis of viral diseases to alleviate the disease burden

Objectives:

- Enhance our understanding of viral diseases through bench research and utilization of novel animal models, including pathogenesis of microbial infections and comorbidities
- Develop methods and agents for prevention and management of human viral diseases through the role of broadly neutralizing antibodies in viral infections
- Elaborate mechanism-based therapeutics for diseases and disorders caused by viruses

Anticipated Outcome:

- Generate a pipeline of valuable discovery products for viral diseases while accelerating intellectual property rights and business incubator programs

Integration with UMB's Strategic Plan Themes

The IHV's Discovery through Research core value directly aligns with UMB's theme of Innovation and Reimagination which calls for new discoveries and collaborations across UMB's schools, partners, and community and an environment of research and discovery.

Translation through Experimentation

All scientific approaches of the Institute will focus on mechanism-based translational research that advances preventive and therapeutic strategies for human viral diseases (Translation). The IHV will utilize its state-of-the-art, vibrant Clinical Research Unit (CRU) to conduct mechanism-based clinical trials to advance preventive and therapeutic approaches for human viral infections and comorbidities. The IHV has multiple patient cohorts that provide these study populations access to novel therapeutic approaches, including the THRIVE cohort for people living with HIV, patients with chronic hepatitis B and C infections, and specifically marginalized patient cohorts at risk for acquiring HIV infection.

Goal: Development of prevention and novel mechanism-based preventive and therapeutic measures for viral diseases and their complications

Objectives:

- Delineate immune mechanisms involved in protection for human viral infections
- Implement strategies to reduce transmission of viral infections and improve disease-free recovery
- Facilitate clinical development of preventive vaccines and therapeutics to achieve global control of viral diseases by conducting human challenge studies for preventive and therapeutic trials

Anticipated Outcome:

- Emerge as the world leader for high quality, high-throughput clinical and translational development of products for viral diseases

Integration with UMB's Strategic Plan Themes

The IHV's Translation through Experimentation core value advances UMB's theme of Innovation and Reimagination by focusing on solutions to the multifaceted problems that face our local and global communities.

Implementation through Practice

Implementation and interventional research will progress medicine through clinical research at the Institute, local partner sites, and its global sites (Implementation). The IHV leads the world in initiation and maintenance of HIV treatment, prevention of acquisition of HIV in high-risk cohorts and mother-to-child transmission, and prevention and treatment of comorbidities, including hepatitis viruses, opioid use disorder, human papillomavirus infections (HPV), and cancers in the U.S. and globally.

Goal: Implementation of evidence-based prevention and control of emerging and re-emerging infectious diseases.

Objectives:

- Implement strategies to eliminate the global risk of emerging and re-emerging viral infections to avoid another global pandemic like the recent COVID-19 pandemic
- Explore novel approaches to improve health care delivery for viral infections through implementation research by expanding education, task shifting, and colocation models of care, particularly among marginalized populations
- Train early-career scientists in advanced virology, immunology, epidemiology, public health, and clinical virology through the highest standards of graduate and post-graduate instruction to promote a one-health approach that improves outcomes for people with viral diseases

- Disseminate cutting-edge scientific knowledge through various global communication platforms, such as conferences and retreats to enhance global awareness and scholarship through partnerships with philanthropic institutions and individuals

Anticipated outcome:

- Emerge as a global leader in delivering innovative health care for viral diseases and comorbidities

Integration with UMB’s Strategic Plan Themes

The IHV’s Implementation through Practice core value strongly supports UMB’s themes of Innovation and Reimagination, Community Partnership and Collaboration, and Global Engagement and Education through its research to find evidence-based strategies that translate into “meaningful solutions” for our world’s complex health issues. It harnesses existing and new partnerships in Baltimore, the surrounding area, and around the globe with the focus on improving the human condition through engagement, education, and research.

Path Moving Forward—Discovery, Translation, and Implementation

IHV’s core values have guided our Institute and will continue as we grow. The IHV, as a Center of Excellence of the Global Virus Network (GVN), has put forward several task forces for emergency pandemic preparedness and contributed several key scientific advances for SARS-CoV-2. We will continue to accelerate our leadership role for COVID-19 and future pandemic preparedness, pioneer novel discovery paths, and execute care models to alleviate the viral disease burden. The IHV will seek public-private partnerships toward commercialization and philanthropic support for public recognition of high-impact outcome-driven goals. The IHV also commits to continuing our scientific growth while exemplifying diversity and inclusion at every level as we move forward.

The IHV will accomplish the goals laid out by this strategic plan through dedicated recruitment, augmented fundraising strategies, and fostered internal and external collaborations to pioneer our discovery-based research on existing and emerging viral pathogens.

Process Timeline—The IHV strategic plan is projected for 2022–2027.

Financial Growth—The IHV funding sources include federal and non-federal competitive grants, contracts, intellectual property, and philanthropy.

The IHV has received more than \$1 billion of funding from the federal government and the private sector. The IHV’s financial status is disclosed annually as part of the Institute’s annual report. The strategic plan will allow the IHV to augment its overall funding profile with more diversified funding to achieve its goals and objectives. The IHV projects overall three-fold growth of total funding by 2027. The proposed strategic plan envisions significant financial growth of our institution through increased federal grants and industry collaborations over the coming five years. Specifically, a substantial increase in intellectual property and philanthropy to augment key areas of IHV’s development is projected as part of this strategic plan. In this regard, the following areas will be specifically targeted.

- Endowed Distinguished Professorships for Division directors and key scientists
- Program-specific funding for viral oncology, global health, and community outreach
- Educational grants and scholarships for medical virology and public health training



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