



The Global Health
Technologies Coalition:
**A case study in successful
R&D advocacy**

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Contents

Introduction	1
History of GHTC	2
GHTC today	7
Keys to success	8
Looking ahead	11

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Introduction

The Global Health Technologies Coalition (GHTC) is a group of nonprofit organizations focused on increasing investment and advancing policies to accelerate the research and development (R&D) of new health technologies that address critical global health challenges, such as HIV/AIDS, malaria, tuberculosis (TB), maternal and child health, and other neglected diseases. GHTC has more than 25 active members representing the breadth of the R&D ecosystem—including think tanks and academic institutions, product development partnerships (PDPs), and advocacy groups—who work together to advance global health R&D across health and technology areas. Supported largely by independent grant funding and a small full-time staff, the coalition analyzes policies, builds strategic alliances, and engages with US policymakers to champion investments and policies that accelerate the development of global health technologies.

Since its founding nearly a decade ago, GHTC has established itself as an important and influential voice in the broader global health field and a trusted source of information and analysis for policymakers and other stakeholders. GHTC's successes demonstrate the power of a coalition to effect change, and its growth and sustained influence in the field of global health R&D speak to its value as a model for building an effective coalition. Reflecting on GHTC's history and past progress and assessing lessons learned from its successes and challenges can help inform similar efforts in the global health field.

The information included in this case study draws from a series of interviews with leaders from PDPs, advocacy groups, and government agencies who were involved in GHTC's growth or are currently engaged in its operations. In addition, these interview results are supplemented by coalition documents and online resources.

History of GHTC

Origin

The spark for GHTC's creation lies in the Vaccines for the New Millennium Act (VNMA). This legislation—which aimed to use incentive mechanisms, including patent extensions and tax credits, to increase funding for the development of vaccines for neglected diseases such as HIV/AIDS, TB, and malaria—failed to pass the US Senate in 2001, in

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Rachel Wilson, founder and principal of Catalysts for Change, former senior director of Advocacy and Public Policy at PATH, and key player in the development of GHTC

part because of concern about the high consumer cost burden associated with patent extensions.

To identify other steps that could be taken to increase funding for global health R&D beyond VNMA, the Bill & Melinda Gates Foundation sponsored a meeting of the PDPs it funded. During this initial meeting in 2002, many of the PDPs decided to form a working group—called the Incentives Working Group (IWG)—to develop and advance policy solutions to support global health R&D. This group collaborated in an ad hoc capacity and ultimately grew into what is now known as GHTC.

When this initial group of organizations began working together, there was no other collaborative effort focused on increasing US investment in global health R&D broadly across multiple health and technology areas. Advocacy activities were dispersed across different product development and advocacy organizations, with each organization advocating for increased funding for its own organization, health area, or technology area. This left systemic challenges across the R&D process that affected all stakeholders, such as innovative financing mechanisms and regulatory issues, largely unaddressed.

“Before GHTC, there was no platform for organizations to work together toward common R&D advocacy goals,” said Rachel Wilson, founder and principal of Catalysts for Change, former senior director of Advocacy and Public Policy at PATH, and a key player in the development of GHTC. “There wasn't a place for people to come together to understand and discuss the barriers that they all faced...there was no voice for advocacy for R&D.”

From its inception, GHTC was the global health community's first attempt to build collective platforms for R&D advocacy across disease and technology areas. Its ability to

push for impactful policy change throughout its history as one voice for global health R&D has helped build it into the successful coalition it is today.

Early history

One of the first pieces of legislation that IWG (early-stage GHTC) worked on was introduced in the aftermath of the 2001 anthrax attacks. Named the Project BioShield Act, it offered incentives to manufacturers for developing treatments for possible bioterror threats. Recognizing the potential of this bill to generate new financing for global health R&D, IWG advocated for the act to be expanded to include other neglected diseases, such as HIV/AIDS. The bill's sponsors agreed to the expansion in exchange for the coalition's endorsement of the bill, which Congress signed into law in 2004.

Around the same time, the United States was facing a severe flu vaccine shortage, prompting constituents to voice their concerns to Senator Richard Lugar (R-IN). To address this problem, Senator Lugar began working with Senator John Kerry (D-MA) to reintroduce the VNMA legislation first proposed in 2001. IWG was heavily involved in this effort, proposing draft language for inclusion in the VNMA around advanced market commitments (AMCs)—a mechanism for incentivizing private-sector investment in R&D by providing an up-front financial commitment to subsidize the future purchase of a vaccine or health product not yet developed and available.

“The AMC was a mechanism that people saw as potentially promising for their own issues, but also realized it would not be achievable if they didn't work together across the different health areas to make the first one possible,” said Wilson.

The IWG published a comprehensive report about the value of AMCs and succeeded in

GHTC's History at a Glance

Key: VNMA/PEPFAR Reauthorization | Coalition Formalization | Project BioShield Act | PRVs | * = Key Policy Win

2000	Vaccines for the New Millennium Act (VNMA) drafted
2001	VNMA introduced by Congress but failed to pass
2002	Incentives Working Group (IWG) formed IWG advocated to expand Project BioShield Act
2003	IWG continued to informally collaborate
2004	IWG language on advanced market commitments (AMCs) included in revised VNMA Expanded Project BioShield Act is passed*
2005	Revised VNMA introduced to Congress but failed to pass
2006	IWG advocated for FDA amendment about priority review vouchers (PRVs)
2007	PRV amendment signed into law* Coalition is named GHTC PATH began servings as secretariat
2008	GHTC-supported AMC language included in PEPFAR Reauthorization* GHTC submitted funding proposal to the Bill & Melinda Gates Foundation
2009	Grant from Gates Foundation awarded

“Without the coalition, these policy achievements really wouldn’t have happened, because you needed a critical mass of groups pushing together saying ‘this is important to all of us.’”

Peg Willingham, head of Global Advocacy & Policy at HarvestPlus, former senior director at Aeras, and longtime GHTC member

getting the language included in the bill. In 2005, the VNMA was reintroduced to Congress, but again failed to pass.

Following this effort, the IWG saw another promising opportunity to come together to advance global health R&D through policy action in 2006, when Duke University published a paper outlining a proposed new incentive mechanism called the priority review voucher (PRV). The idea was to incentivize private-sector investment in product development for neglected diseases by awarding pharmaceutical companies who develop and register products for neglected diseases with a voucher for expedited regulatory review by the US Food and Drug Administration (FDA), which they could then apply to another product. IWG joined other partners and organizations in advocating for legislation that would put PRVs into practice and worked with Senator Sam Brownback (R-KS) and Senator Sherrod Brown (D-OH), who introduced a priority review voucher amendment to the FDA Amendments Act. This

legislation was signed into law in 2007.

By the end of 2007, it had become more than evident that bringing the right organizations together to advocate with one collective voice for policy change was the most effective way to address the systemic challenges hindering the advancement of global health R&D.

“Without this coalition, these policy achievements really wouldn’t have happened, because you needed a critical mass of groups pushing together saying ‘this is important to all of us,’” said Peg Willingham, head of Global Advocacy & Policy at HarvestPlus, former senior director at Aeras, and longtime GHTC member.

While they recognized the value and sustained need for such a coalition, the members of IWG were unable to dedicate the consistent amount of time and resources needed to maximize its effectiveness. The group also lacked a designated leader to help drive consensus and action, and as a result, often had difficulty reaching agreement on a shared agenda to carry forward.

Mitchell Warren, executive director at AVAC and key player in the development of GHTC, said about this period in the coalition’s growth, “There was a significant need for someone to help keep the momentum going, because keeping a handful of people working together on an ad hoc basis is not sustainable.”

Formalizing the coalition

To help increase the group’s effectiveness and address these shortcomings, members began taking steps to establish the coalition in a more formal capacity. This included officially naming it the Global Health Technologies Coalition and designating PATH as its secretariat organization in late 2007 to provide management and operational support.

“PATH worked across all of the areas of R&D,” said Wilson. “It was the only group that already had that kind of crosscutting approach, so it was a clear choice as a convener for these different organizations.”

“Having PATH step up and offer to host as the secretariat, or supervisor/coordinator, for the coalition...was really critical to ensuring projects moved forward,” said Holly Wong, principal deputy assistant secretary for global affairs at HHS and former vice president at IAVI—a GHTC member.

GHTC was soon put to the test in its official capacity when, in early 2008, the President’s Emergency Plan for AIDS Relief (PEPFAR) bill came up for reauthorization. GHTC members saw the opportunity to expand the bill to focus not only on expanding access to tools to fight HIV/AIDS, but also on developing new tools. As a result, GHTC quickly got to work drafting proposed language for PEPFAR about AMCs, building upon the language the coalition had previously developed for the VNMA. This language also specifically called out the need to develop new vaccines, as well as prevention and diagnostics tools.

Working together, GHTC members leveraged their extensive networks to meet with policymakers and advocate for the inclusion of the global health community’s agreed-upon language in the bill. The coalition met with US Treasury Department officials to win their support for innovative financing and enlisted advocacy support from the Center for Global Development; Gavi, the Vaccine Alliance; and the World Bank. The coalition also held congressional briefings to educate Congress about AMCs.

Thanks to GHTC’s hard work, the PEPFAR Reauthorization Act (H.R. 5501) was signed into law on July 30, 2008, with the R&D-focused language included. It not only authorized up

GHTC’s Major Achievements: 2009 to today

- 2009** GHTC staff hired; operational structure established
- 2010** GHTC testifies at FDA hearing for neglected diseases review group
GHTC launches first annual policy report with recommendations to US policymakers
- 2011** State Department adapts its definition of “research and innovation” to include principles recommended by GHTC
- 2012** GHTC releases landmark analysis on impact of US investment in global health R&D
- 2013** GHTC testifies before House State and Foreign Operations Appropriations Subcommittee on importance of sustaining US investments in global health R&D
- 2014** GHTC releases analysis on US government global health R&D activities with recommendations for enhancing interagency coordination; hosts policymaker dialogues
Appropriations report language for FY 2015 reflects GHTC priorities
- 2015** United Nations Sustainable Development Goals include global health R&D target, following GHTC advocacy
GHTC-supported Global Health Innovation Act passes House of Representatives

“GHTC’s ability and willingness to focus on single issues and not sway in the context of a very dynamic political environment is something that fellow advocates, industry, and government representatives truly value.”

Kaitlin Christenson, PATH strategy advisor and first coalition director of GHTC

to US\$48 billion to combat global HIV/AIDS, TB, and malaria, but also outlined support for the development of new, more cost-effective prevention and treatment tools.

“It was a huge success getting that language into the bill,” said PATH Strategy Advisor and GHTC’s first Coalition Director Kaitlin Christenson. “PEPFAR’s treatment priorities were originally focused on scaling existing treatments. GHTC advocated for additional legislative language for the development of new tools for tomorrow’s needs.”

Building off of this first major policy win as a formal coalition, GHTC ramped up efforts to expand its membership and broaden the coalition beyond PDPs to include think tanks, academic groups, and other advocacy groups interested in accelerating global health R&D. PATH also submitted a proposal to the Gates Foundation at the end of 2008 to secure

independent funding for GHTC, which it received in early 2009.

This was a critical moment for the organization. With this new funding, GHTC was able to hire a director and a small staff to help lead and carry out its day-to-day operations, including organizing meetings, analyzing policies, reporting out to members, and engaging with policymakers on a more regular basis. But as membership ballooned to nearly 50 organizations, GHTC hit another turning point in its development: a paralyzing lack of agreement and tension around what advocacy areas to focus on.

To address this issue, GHTC developed a “terms of reference” to better define the principles that would guide the group’s advocacy activities and a membership application that required members to agree to the terms. It also limited the membership to nonprofit organizations. In addition, the coalition established a steering committee with its own terms of reference to provide strategic vision and guidance to the coalition and elected representatives from IAVI, AVAC, Aeras, and the Drugs for Neglected Diseases *initiative* as the initial members, with PATH holding a permanent seat as secretariat. Although putting these processes and principles in place initially cost GHTC some of its members, it was a critical action that has enabled the coalition to continue presenting a unified platform for R&D across global health areas today.

“Since its formalization, GHTC’s focus has been unwavering; it’s been protected by members and staff in a way that is greatly appreciated by the global health community,” said Christenson. “GHTC’s ability and willingness to focus on single issues and not sway in the context of a very dynamic political environment is something that fellow advocates, industry, and government representatives truly value.”

GHTC today

GHTC continues to serve as an influential and effective voice in the global health field today, and it remains the only cross-platform and cross-health-area advocacy coalition in the global health R&D space. It currently is composed of more than 25 active members who form working groups to tackle specific topics, such as public financing and regulatory issues, and report back to the coalition to inform the coalition’s policy positions and activities. It also relies on its

transparent steering committee to make strategic decisions about the overall direction and positioning of the organization and is supported by its permanent secretariat, which conducts the day-to-day operations of the coalition, including managing its budget and communications.

GHTC convenes as a full coalition monthly to discuss and provide input to the activities being carried out by the working groups and secretariat staff. Members receive regular communications such as policy analyses and updates about the latest R&D policy

GHTC’s Structure



opportunities, interface with peers on shared opportunities in a collaborative environment, and have access to US policymakers and government officials that they might not otherwise have.

“Some of GHTC’s members by themselves might find it challenging to secure a meeting or receive an email response from congressional staffers,” said Willingham, “But if they get to go to the Hill as part of GHTC, they get a foot in the door and get heard in a way that they just wouldn’t by themselves.”

GHTC has also become a valued source of information and consensus to US policymakers and government officials, as well as donors looking to invest in high-impact R&D areas. From her perspective at HHS, Wong said: “When issues do come up...it’s easier for me to make one call [to GHTC] rather than to call each of its member organizations and perhaps get a different perspective from each one of them... it’s like having a trade association...you have one central point of contact to go to that can give you a consensus view.”

Keys to success

From its experience in building the coalition, GHTC and its members have learned a number of key lessons that have been critical to its success and can be applied for use in building other coalitions in the global health field.

Establish a core set of shared principles

At the beginning of its formalization, GHTC learned firsthand how critical establishing a core set of shared principles was to its functionality. “Having terms of reference and a clear vision for members is key,” said Christenson. “It helps members understand

what they can expect from the secretariat of [the] coalition and agree on issues of focus—what the coalition’s purpose is and is not and what it will and will not pursue.” Taking the time to develop clear guiding principles ensured that GHTC’s work could move forward in areas of agreement, rather than stagnating around sources of dissention.

Pursue membership diversity

While it is important to agree to a set of common principles, it is equally as critical to ensure that a wide range of perspectives is represented in a coalition’s membership. GHTC has benefitted from a broad membership base of health R&D actors and stakeholders who have experience in different health and technology areas and across the continuum of product development from early research, to product development, to regulatory approval and expanding patient access. Not only does this range of members ensure that GHTC truly represents the voice of the global health R&D community, but it expands the coalition’s understanding of complex policy issues, enabling GHTC to knowledgeably speak to and support policies that will make significant strides for global health R&D. “Because GHTC links advocates with technical experts,” said Wilson, “the coalition has been able to engage in the actual technical content of policy issues as well as the funding side.”

Identify the right convening organization

As a nonprofit that conducts R&D across a number of technology platforms as well as diseases and health areas, PATH has served as the ideal convener and secretariat for GHTC. PATH has helped protect the coalition from fracturing along the lines of disease or

health area and has ensured that its activities do not promote the importance of one member's perspective or area of R&D over another. PATH's actions have engendered the critical trust between the secretariat staff and coalition members that has helped GHTC maintain its role as a collective, unified voice for the global health R&D community.

Elect a representative steering committee

In addition to identifying the right convener, establishing a representative steering committee has been critical to GHTC's focus and ability to make informed decisions. GHTC developed an elections process outlined in the terms of reference that all members must agree to. The elected committee represents the breadth of the coalition's membership, providing a forum and mechanism for strategy development and guidance without depending on consensus from every coalition member for every decision. "Active direction on key issues is critical," said Christenson. "Establishing a steering committee enables the coalition to have more transparency around decision-making and leadership when guidance is needed."

Remain transparent and member driven

Decision-making within GHTC's organizational structure is an intentionally transparent process—every GHTC member has the opportunity to offer an opinion on a decision or policy position through surveys, calls for feedback, or open discussion, even if it means that GHTC avoids taking a stance in an issue area in response to member disagreements. As a result, members have remained engaged and invested in GHTC's work, preserving the strength of the coalition's collective voice.

What GHTC members think

"This is the most effective coalition I've ever been a part of because it's focused, it's got super smart people leading it, it's organized, and it gets things done."

-Karen Goralesski, executive director of the American Society of Tropical Medicine & Hygiene (ASTMH)

"[The coalition] is about creating opportunities for people with information to be able to share it in a safe space, in a collaborative fashion. That is critically important and I think incredibly effective."

-Mitchell Warren, executive director at AVAC

"GHTC is a force multiplier; it amplifies and really helps the greater cause in a way the individual groups simply couldn't do by themselves."

-Peg Willingham, head of Global Advocacy & Policy at HarvestPlus and former senior director at Aeras

“GHTC is very good at giving its members a chance to provide input,” said Jodie Curtis, executive vice president at District Policy Group and a consultant who works closely with GHTC. “There are no hidden agendas, no sense that GHTC [secretariat staff] wants to hold all the power; it is a very transparent organization.” To remain member driven, GHTC staff prioritize regular communication with members through regular meetings and more informal interactions that help make sure the coalition’s work always aligns with member priorities.

Secure a dedicated staff and source of funding

GHTC’s full-time staff manage a range of the coalition’s day-to-day activities, including member communications, outreach, and the logistics of their advocacy efforts. “A lot of coalitions don’t have staff or infrastructure, and they suffer tremendously because of that,” said Curtis. Having this dedicated staff allows GHTC’s members to focus on contributing to the coalition’s overall strategy and advocacy content and amplifying its work and ensures all members have the capacity to remain up to date on and involved in the coalition’s activities. To support this staff, GHTC has obtained independent grant funding to finance most of its work and collects modest member dues—a commitment members are willing to make to ensure GHTC’s continued efficacy.

Conduct active education and relationship-building efforts

Building relationships with policymakers and breaking down the issues for them is critical

to making desired policy changes a reality. GHTC’s staff prioritizes relationship building with key decision-makers and their staff, meeting regularly with them, providing them with targeted communications materials that accurately reflect the coalition’s positions, and organizing meetings and events where they can interface with GHTC members. As a result, “GHTC has become so credible that it is recognized by the US government,” said Willingham. Members also appreciate the direct access these relationship-building efforts offer them. “As a member, it certainly helped to have others who were strolling the halls of Congress more frequently than we were and who knew how to get a lot of things done in D.C.,” said Wong. “The coalition itself was really useful in getting meetings organized on the Hill, or at NIH [National Institutes of Health], or USAID [US Agency for International Development]. It was like having an extra staffer to run those advocacy activities for us.”

Stay connected to the broader global health community

While GHTC maintains its focus on R&D advocacy, its staff and members are constantly working to understand the broader global health landscape, including development aid infrastructure and systemic issues, and to make sure the coalition has a seat at the right tables it needs to exercise influence. GHTC attends external functions and joins other coalitions and working groups as a member, not only to ensure that the voice of global health R&D is heard in these forums, but also to learn more about what is happening in other areas of the field and how it can shape its priorities to better support the changing environment. “To be effective, a coalition needs to make an effort to be an

active member of the broader global health sector,” said Christenson.

now has a strong foundation of success to build upon as we continue to advance innovation to save lives.”

Looking ahead

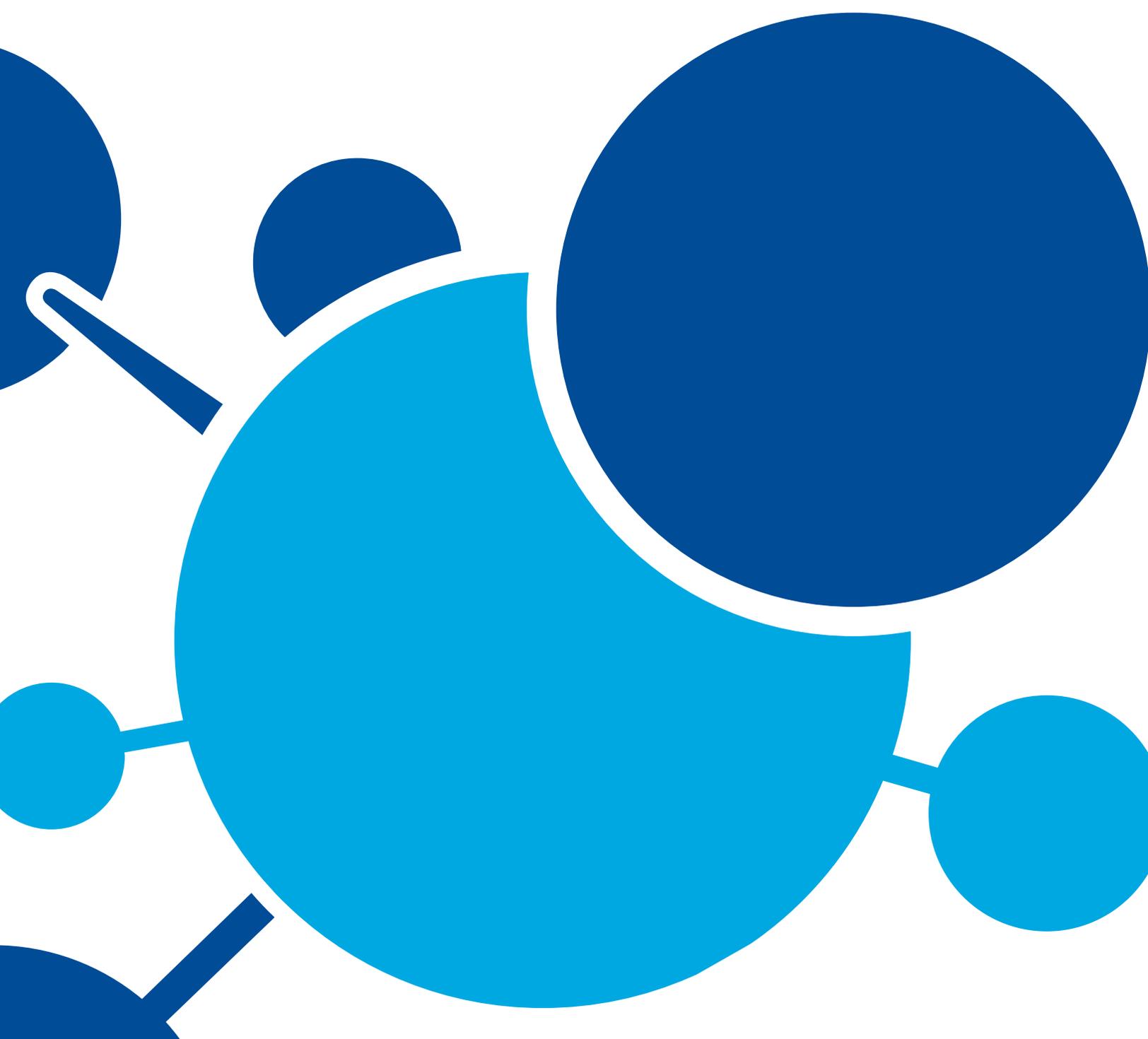
From its early days as an ad hoc working group of loosely connected organizations to the professional and efficient coalition it is today, GHTC has made remarkable inroads catalyzing positive policy change for global health R&D. In doing so, it has laid the groundwork for future progress, proving the power of working together and speaking with one voice.

GHTC’s commitment to its shared values, transparency in its operations, and grounding of its work in member priorities have underpinned the coalition’s success and made it a trusted and valued resource for its members and policymakers alike.

As the coalition’s record of success and reputation continue to grow, GHTC faces both opportunities and challenges in the constantly evolving global health landscape. The coalition must balance member growth and member interest in pursuing new advocacy targets, opportunities, and expanding geographic reach with the need to maintain a clear guiding vision, operational efficiency, and manageable and achievable scope of work. Relying on its core values, the capabilities of its staff, and the expertise of its passionate members, GHTC will address these challenges head-on as it works to accelerate the development of technologies that meet the critical health needs of tomorrow.

“Over the last decade, GHTC has evolved into a powerful and trusted voice in the global health community,” said Erin Will Morton, current director of GHTC. “The organization





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