



GOVERNMENT RESOURCE ACCOUNTABILITY DURING THE COVID-19 PANDEMIC



A REPORT FROM THE

UNITED STATES

Prepared as Part of a Global and Country-Level Analysis in 18 Countries

This is the 13th “Missing the Target” report produced by ITPC since 2005 and the first MTT report to engage with government resource accountability during the COVID-19 pandemic. As with previous MTT reports, this report highlights the experience and perspectives of advocates in multiple countries to document progress toward global commitments for health, development, and human rights.

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ABOUT

ABOUT ITPC

The International Treatment Preparedness Coalition (ITPC) is a global network of people living with HIV and community activists working to achieve universal access to optimal HIV treatment for those in need. Formed in 2003, ITPC actively advocates for treatment access across the globe through the focus of three strategic pillars:

- Make Medicines Affordable
- Watch What Matters
- Build Resilient Communities

To learn more about ITPC, visit itpcglobal.org

ABOUT WATCH WHAT MATTERS

Watch What Matters is a community monitoring and research initiative that gathers data on access to and quality of HIV treatment globally. It fulfills one of ITPC's core strategic objectives: to ensure that those in power remain accountable to the communities they serve. Watch What Matters aims to streamline and standardize treatment access data collected by communities—helping ensure that data is no longer collected in a fragmented way and that it reflects the issues and questions that are most important to people living with and affected by HIV. It relies on a unique model that empowers communities to systematically, routinely collect and analyze qualitative and quantitative data on access barriers and use it to guide advocacy efforts and promote accountability.

To learn more about Watch What Matters and ITPC's community-led monitoring work, visit WatchWhatMatters.org.

ABOUT MTT

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PrEP4All

PrEP4All is an organization of community members, healthcare professionals, lawyers, and academics all dedicated to increasing access to life-saving HIV medication.

Lead writer: Emily Bass

Lead contributors: Emily Bass, James Krellenstein, Christian Urrutia

Coordination: Sam Avrett, Helen Etya'ale, Pragashnee Murugan, Nadia Raffif

Copy-edit: Janette Bennett

Design: Gerard Best, Sarah Sills

Thank you to all the people living with HIV who shared their experiences and thoughts to inform the report.



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SUMMARY

Health activists and advocates seeking a more equitable distribution of treatments, tests, and vaccines—often collectively called “medical countermeasures”—have, for many years, focused on intellectual property-related obstacles to access. These include global and national accords, regulations, and approaches to manufacturing, importing, and licensing patented countermeasures, particularly when there are no generic equivalents. Another arena of activism, described in this report (and in the [Brazilian report](#) prepared as part of this “Missing the Target” report), focuses on urging governments that hold patents on medical countermeasures marketed and sold by pharmaceutical companies to use their status as co-inventors or patent holders as leverage to make these countermeasures more affordable.

US government financial accountability to its taxpayers (and the global community) for its investments in research is sorely lacking. True financial accountability would include conditions, applied to pharmaceutical company funding, that ensure affordable, accessible products for domestic and international communities; it would also include government-initiated and government-funded actions to manufacture, secure, and share intellectual property rights to, and influence affordable prices for, essential medical countermeasures. Instead, the US government prioritizes the profits and interests of pharmaceutical companies, even when it has intellectual property claims, influence, and leverage in the form of legislative regulations enabling pro-access actions. This is an unacceptable and untenable position for a government seeking to minimize the risk of future pandemics and mitigate the ongoing effects of

the current simultaneous epidemics and outbreaks, including COVID-19, HIV, and mpox.

This report describes activist interventions focused on the United States government (USG) that used USG intellectual property (patents) as the basis for demands on the government to adopt pro-access approaches to research and development, pricing, and manufacturing. It is important to note that this work has been undertaken, and in many instances led, by a range of groups, including Public Citizen, Knowledge Equity International, and Partners in Health. A critical factor in PrEP4All’s successes in these endeavors has been the invaluable assistance and leadership provided by the organization’s lawyers, Amy Kapczynski (Yale Law School) and Christopher Morten (Columbia Law School). PrEP4All works in coalition and solidarity with these and other allies and has taken pains throughout the chapter to identify the key organizations involved in specific examples.

As the report describes, the work to date has yet to lead to USG action aligned with activist demands. Historically, the US government has failed to actively enforce its patent rights to medical countermeasures as a means of ensuring affordable, equitable access domestically and globally. PrEP4All and other groups doing this work have, instead, encountered:

- ❁ Lack of transparency on the part of pharmaceutical companies
- ❁ Apparent disinclination, on the part of the USG, to pursue acknowledgement of co-inventor status
- ❁ Resistance to leverage the USG role as a research funder and co-inventor, as well as



other provisions, notably Section 1498 (a legal mechanism that allows US government use of patented technologies at the cost of government-paid compensation to the patent holder) to scale up government-controlled manufacturing

At present, the USG is missing the target when it comes to accountable use of COVID-19-related intellectual property resources and its considerable leverage. Instead of leading by example, the United States is protecting pharmaceutical interests and relying on a market that has, time and again, failed to deliver equal access to life-saving tools around the world. The United States can and must utilize its legislatively protected abilities to:

- Enable generic production and/or establish government-owned, contractor-operated manufacturing capacity to produce affordable versions of key medical countermeasures.

- Compel pharmaceutical companies to share technologies.
- Waive and/or advocate for the waiver of trade-related intellectual property provisions and ensure that the pharmaceutical industry collaborates with urgency and transparency in addressing outbreaks and pandemics.

Given its outsized role in financing research, the USG must continue to be a target for the types of interventions described here. We share the strategies and outcomes, along with details of ongoing efforts, to build awareness, prompt discussion, and continue the fight to hold governments accountable for using all available resources to reduce suffering and save lives.

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KEY FINDINGS AND RECOMMENDATIONS

Key Findings

- ❁ The US government, as a patent holder and/or co-inventor of life-saving medications and vaccines, does not demonstrate financial accountability for its investments of taxpayer dollars into research. Instead of acting as a responsible steward of public funding, the US government prioritizes the profits and priorities of the pharmaceutical industry over the public interest. Advocacy and activism are crucial to impel the US government to greater financial accountability.
- ❁ Activists with specialized expertise (chemical compound structure and patent law) and access to databases can identify claims for government (and other public sector) patent co-ownership of compounds manufactured and owned by the pharmaceutical industry. These claims, when made public, generate media attention and impel and/or provide additional justification for investigative action on the part of the government, resulting in shifts in practices related to licensing of federally funded inventions to commercial companies and government commitments to more transparency with the public regarding current licenses of government-owned intellectual property.
- ❁ Ongoing advocacy has led to shifts in governmental approaches. For example, in 2022, Representative Pramila Jayapal co-led, with Representative Jan Schakowsky, to secure an amendment to the National Defense Authorization Act (NDAA) to require a report on pricing and equitable access provisions of any publicly developed COVID-19 vaccines or medications via the Department of Defense.

Recommendations

- ❁ Financial accountability with regard to government-funded intellectual property should be a crucial component of pandemic preparedness and response strategies at national and global level, with requirements and expectations that government funding for private sector research, development, and manufacturing is conditional on pricing and intellectual property conditions that ensure affordability and access for all.
- ❁ Government officials' interest (or lack thereof) in asserting ownership and investigators' queries can result in findings that do not resolve key questions about co-ownership. In other words, USG reluctance to assert co-ownership can be an obstacle even when the government itself is seeking clarification. Nevertheless, this avenue of evidence-based activism can be used to raise issues, expand transparency, and set precedents for future action.
- ❁ US government commitments to technology transfer, open licensing, and public manufacturing commitments should become standard components of the grants, contracts, and mechanisms related to next-generation pandemic prevention countermeasures.
- ❁ Activists and community members can and should continually monitor the generation of government-funded and government-owned intellectual property—and ensure that it is being used in the interest of the public.



A REPORT FROM THE UNITED STATES

Intellectual Property Activism and SARS-CoV-2

Since 1995, the World Trade Organization’s (WTO’s) Agreement on Trade-Related Intellectual Property Rights (TRIPS) has imposed provisions that protect patents, copyrights, and the profits that accrue from them on nations and communities seeking medical countermeasures for illnesses, outbreaks, and pandemics that threaten their lives. More than two decades ago, TRIPS provisions were a singular focus of AIDS activism centered on removing obstacles to global access to antiretroviral therapy. Many subsequent campaigns have centered on the deleterious effects of TRIPS, and in October 2020, India and South Africa requested a temporary waiver to intellectual property

protections that would allow countries to produce medical countermeasures for COVID-19, particularly vaccines, more easily.

There has been widespread support from many countries in the WTO, a global movement demanding this shift, and daily reminders of the costs in human lives and suffering of a global approach to intellectual property that favors profits over people. Nevertheless, the WTO decided in June 2022 that it would not adopt the waiver but would instead offer some clarifications to current “flexibilities” within TRIPS and institute an exception to export restrictions on COVID-19 vaccines for five years. The so-called “Geneva Package” included a commitment to consider within six months (by December 2022) expansion to cover treatments and tests, as well as vaccines.

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The limited scope and practical benefits of the WTO concessions—which the WTO and wealthy nations sought to configure as a success—make it all the more urgent to identify alternative routes to ensure better access in spite of this outcome. These alternative strategies are a supplement to and not a substitute for continued, sustained demand for a comprehensive revision of TRIPS provisions to facilitate equitable access to essential medicines.

US Government as a Patent Holder on Medical Countermeasures

The United States government is the largest public funder of biomedical research in the world, with more than US\$32 billion invested by the National Institutes of Health¹ (NIH) each year, nearly \$2.4 billion invested each year by the Department of Defense (DOD), and \$2.1 billion invested each year by the Department of Veterans Affairs (VA)². The DOD, NIH, and VA make grants and awards to a wide array of scientists and researchers, including those working on the development of novel vaccines, therapeutics, and diagnostics.

US government funding often supports pre-clinical and early clinical phases of research into molecules, techniques, and approaches that are integral to drugs, vaccines, and tests ultimately licensed to and sold by pharmaceutical companies. The intellectual property associated with those products is covered by patents. In drug and vaccine development, inventors often file multiple patent applications to cover different aspects of a single product. An inventor is defined by US patent law as someone who aids in the conception of the invention. Individual inventors in universities, government agencies, and company laboratories often assign their patent rights to the institution they work with.

There are many instances in which the US government holds (or could claim) a patent for a component of a medical countermeasure

controlled by a pharmaceutical company. It is possible to impel the US government to exercise its rights as a patent holder to promote equity. PrEP4All's prior work on US government-owned intellectual property compelled the government to bring a suit against Gilead Science's HIV pre-exposure prophylaxis (PrEP) monopoly.

Activism Based on USG Patent Ownership: The Case of Tenofovir-Based PrEP

By the time SARS-CoV-2 began, PrEP4All, a small US-based activist group, had collaborated with the Global Health Justice Partnership at Yale University, led by Amy Kapczynski and Christopher Morten, to assess and confirm the validity of the US government Centers for Disease Control and Prevention (CDC) patents on emtricitabine and tenofovir (and their chemical derivatives)³. Both of these drugs are used in the oral PrEP strategy and manufactured and marketed by Gilead as Truvada. After the 2019 affirmation of the US government's patent rights to tenofovir-based PrEP and a Congressional hearing on this issue, the US government brought a lawsuit⁴ against Gilead, claiming that the company had infringed on its patent rights and failed to provide royalties from the sales of the medication.

PrEP4All and other activists involved in this campaign called on the US government to use the royalties received as a result of the lawsuit to end “the domestic HIV epidemic” by increasing access to PrEP through funding to “organizations that provide support services to people vulnerable to HIV to connect and maintain them in PrEP care; covering the cost of drugs, lab visits, and associated clinical care for uninsured patients; and/or establishing a federal program aimed at achieving universal PrEP access.”⁵ Two years after the lawsuit was filed, it remained unresolved—although a federal court denied Gilead's motion to dismiss the suit. The United States government did announce its commitment to a national PrEP



program in the FY2023 budget request, but funding and Congressional support for this program, in the form of language in the FY2023 budget reconciliation legislation, had yet to materialize at the time of writing. The resolution of the lawsuit, with payment of royalties by Gilead to the US government, would provide much-needed funding for this crucial program. PrEP4All continues to pursue a national PrEP program and resolution of the US government lawsuit.

Activism Based on USG Patent Ownership and Intellectual Property Provisions in SARS-CoV-2: Three Examples

1 Asserting USG patent ownership of the SARS-CoV-2 antiviral, remdesivir, to bring down costs

In the early months of the SARS-CoV-2 pandemic in 2020, the antiviral, remdesivir, emerged as a potential effective treatment to accelerate recovery in people with severe illness associated with the novel coronavirus. Without conclusive evidence of its benefit, the US Food and Drug Administration granted an emergency use authorization for the medication. In April 2020, Gilead donated all of its stocks of the medication to governments across the world.

PrEP4All and its collaborator at the New York University School of Law were nevertheless concerned about the price that Gilead might set for this antiviral and its willingness (or lack thereof) to issue voluntary licenses that would allow generic production of the medication. As a first step to pre-emptively addressing these concerns, activists sought to determine whether remdesivir was, indeed, “owned by Gilead” via an analysis of the patents related to the molecules in the medication. Pharmaceutical companies and the US government are often highly opaque about the patents held by various investors.

To conduct this research, PrEP4All co-founder and managing director James Krellenstein first determined the molecular structure of the relevant molecules found in remdesivir and then performed a systemic search of patent applications using the World Intellectual Property Organization’s (WIPO’s) PATENTSCOPE search engine for filings that disclosed the chemical structure of GS441524 (a molecule of which remdesivir is a prodrug⁶) and remdesivir. The activist analysis identified two patents claiming and disclosing the precise structure of remdesivir. Both of those patents were held exclusively by Gilead.

However, the language in the patent filing strongly suggested that US government scientists were involved in the discovery of the drug and, therefore, that the US government could be considered a co-inventor and patent holder, even though it was not named as such. In a report published in May 2020,⁷ “The US Government’s Apparent Co-Ownership of Patents Protecting Remdesivir,” PrEP4All and its collaborator at New York University asserted, “If remdesivir proves safe and effective in treating COVID-19, as the world hopes it will, the U.S. government could exercise its patent rights to lower prices and expand access to remdesivir, if need be.” This report was cited in (and may, via media attention, have accelerated and/or contributed to the launch of) a subsequent investigation by the US Government Accountability Office⁸ (GAO) that concluded that “federal contributions did not result in government patent rights because federally-supported research did not generate new inventions,” according to US officials interviewed during the investigation.

The GAO investigation did not, however, clarify whether a CDC scientist had co-invented Gilead’s remdesivir compound patents, as the language in the patent filing implied. If this scientist had been involved as co-inventor, the CDC would, under the default rules of patent law, have a claim to co-ownership. The CDC and US government appeared uninterested in pursuing these legal rights, based on the



information provided to the GAO investigators and in response to public questions about their involvement in drug development.⁹

Lessons learned/implications for activism

Activists with specialized expertise (chemical compound structure and patent law) and access to databases can identify claims for government (and other public sector) patent co-ownership of compounds manufactured and owned by the pharmaceutical industry. These claims, when made public, generate media attention and impel and/or provide additional justification for investigative action on the part of the government. The outcomes of these investigations include extensive documentation of federal funding for, and scientific contributions to, the development of medical countermeasures.

This information is often closely held and difficult to obtain, and publication in the public record expands resources for activists, media, and others to use in access-related advocacy. Government officials' interest (or lack thereof) in asserting ownership and investigators' queries can result in findings that do not resolve key questions about co-ownership. In other words, USG reluctance to assert co-ownership can be an obstacle even when the government itself is seeking clarification. Nevertheless, this avenue of evidence-based activism can be used to raise issues, expand transparency, and set precedents for future action.

2 Asserting USG patent ownership of the prefusion conformation of coronavirus spike protein as an avenue for cost reduction and government-owned manufacturing

Early in the SARS-CoV-2 pandemic, Public Citizen, a nonprofit, US-based consumer advocacy group, reviewed the disclosures (which include patent applications and ownership) in peer-reviewed literature relevant to the development of mRNA vaccines. Based on this information, the group searched for and identified two disclosed applications by US government scientists that appeared relevant to COVID-19 vaccines.¹⁰ Public Citizen first published its findings in mid-2020, updating them as evidence of vaccine efficacy emerged. In the following year, it was established that US government scientists developed, and the US national government holds the patent¹¹ on, an approach to “freezing” coronavirus spike protein in its pre-fusion conformation (shape).¹² This approach, also known as “2P,” was used in most of the first-generation SARS-CoV-2 vaccines, including those developed by Pfizer/BioNTech, Johnson & Johnson, Novavax CureVac, and Moderna¹³. As Public Citizen, stated, “The Biden Administration should require reasonable pricing. It should also require corporations to share technology and know-how to scale up supply around the world. That is the only way to bring a rapid end to the pandemic.”¹⁴

In addition to the acknowledged US government patent on the prefusion spike protein, there is an ongoing dispute between the NIH and Moderna regarding the pharmaceutical company's exclusion of NIH scientists from the principal patent application for its vaccine.¹⁵



Activists' work to establish and publicize US government patents on mRNA vaccines was paired with calls to the US government to exercise its influence and status as a patent holder to ensure that the vaccines that used the "2P" approach were affordable and accessible, that the technology to manufacture these vaccines was transferred, and that the intellectual property was shared without restriction to ensure global vaccine equity.

Additionally, PrEP4All and collaborators argued that the US government should pursue government-owned, contractor-operated manufacturing (GOCO) of mRNA vaccines. This proposal, which PrEP4All calculated could lead to vaccines being produced for \$2 per dose in a facility that would cost roughly \$4 billion to establish, was based in part on the United States government's substantial role in and claim to co-invention of the Moderna mRNA vaccine. In a report that detailed the rationale, specifications, and urgency of scaling up mRNA supply and vaccination programs, PrEP4All wrote, "[T]he NIAID/Moderna vaccine was funded almost exclusively by the US government (\$2.5 billion invested so far) and relies heavily on intellectual property invented and owned by the United States. Thus the United States has unique leverage with Moderna."¹⁶

The outcomes of this line of advocacy have been mixed. On the one hand, the United States government, including under the Biden Administration, has steadfastly refused to take steps to compel pharmaceutical companies, including Pfizer and Moderna, to license, transfer technology for, and ensure access to their vaccines. President Biden's early endorsement of the TRIPS waiver notwithstanding, the US government actively opposed an expansive, pro-equity shift in the TRIPS language during the WTO negotiations that led to the limited and insufficient outcome described at the beginning of this chapter.

On the other hand, Congressional leaders are independently taking up the GOCO approach, which PrEP4All popularized with its coalition partners, on different legislative vehicles. Representative Pramila Jayapal co-led, with Representative Jan Schakowsky, to secure an amendment to the National Defense Authorization Act (NDAA) to require a report on pricing and equitable access provisions of any publicly developed COVID-19 vaccines or medications via the Department of Defense. This reporting requirement asks whether technologies will be licensed exclusively or non-exclusively to private manufacturers or manufacturers contracted to operate publicly owned facilities (such as the GOCO approach). The effort initially started as a requirement for non-exclusive licensing and public manufacturing of next-gen COVID vaccines and treatments. However, Jayapal's colleagues insisted that such a requirement would slow the R&D pipeline down because, they argued, exclusive agreements with pharmaceutical companies were needed to accelerate R&D. This, of course, is the entire point of the GOCO approach. But Jayapal lost this battle and had to settle for a reporting requirement.

Lessons learned/implications for activism

Once a government intellectual property "resource" is identified, advocates can use that information to advance a range of demands and recommendations for actions that could be taken based on this patent ownership or investment. In the case of the US government's role in development of the Moderna vaccine, PrEP4All and collaborators advanced an argument for a new approach to US government-financed manufacturing that secured support in Congress and within the broader coalition of groups working on the issue. Support was not unanimous insofar as a GOCO approach, as advocated by PrEP4All, centered manufacturing within the United States and did not address the need for distributed manufacturing globally.



Balancing the needs for globally redistributed intellectual property rights and manufacturing capacity with the potential actions that the US government could take domestically, within the US, is a strategic challenge and imperative for US-based, equity-focused activists and coalitions working on access to medicines and other medical countermeasures.

3 Public calls to the White House for USG to exercise intellectual property rights of next-generation pan-coronavirus vaccines

In the previous two examples, the advocates identified US government intellectual property ownership on medical countermeasures already and/or soon to be used as part of the public health response. In addition to retrospective analysis and related advocacy, civil society is raising demands now about how the US government should use its intellectual property rights in the event that the pan-coronavirus vaccine, under development by the Walter Reed Army Institute for Research, proves effective. Public Citizen brought together a coalition of groups, including PrEP4All, on a joint letter¹⁷ to President Biden calling on the US government to commit to open licensing, technology transfer, and government manufacturing of the vaccine, which is, as of 2022, in Phase I human trials.

This approach can and should be extended to other government-funded next-generation vaccines. However, tracking US government intellectual property rights, patents, and claims from the earliest stages of product development will be a potentially powerful tool for shaping a more equitable approach to this pipeline of necessary products.

Lessons learned/implications for activism

Efforts to ensure that next-generation candidates, developed with support from the US government, are developed with conditionalities tied to future access and commercialization are crucial and ongoing. Building pressure for access provisions and strategies prior to efficacy—a strategy deployed during Operation Warp Speed with limited success—continues to be essential. As activists take stock of the “wins” and challenges from the COVID-19 pandemic and its research and development pipeline, it is clear that work must continue to focus on identifying, publicizing, and demanding action based on USG patent claims and rights and that upstream work on candidates in clinical trials must aim for equitable access and commercialization plans even before efficacy is determined. The US government has yet to accede to demands about the US Army product; this and other candidates in the pipeline must be tracked from early stages of clinical development. It will also be crucial to evaluate the success of CEPI provisions designed to ensure affordability and access in its current next-generation grant portfolios.



CONCLUSION

Information on US government patents and patent claims is often difficult to source as neither the government nor industry make the details of collaborations and contributions to licensed products readily available. The US government has historically been cautious and/or passive regarding exercising its claims as a patent holder,

though the ongoing dispute between the NIH and Moderna about the mRNA SARS-CoV-2 vaccine is a notable exception. Raising attention to these claims triggers media, Congressional, and government agency action and is a key strategy to continue to deploy for existing candidates and the broader pipeline.





ENDNOTES

- 1 <https://www.nih.gov/grants-funding>
- 2 <https://www.gao.gov/assets/gao-22-105107.pdf>
- 3 <https://law.yale.edu/sites/default/files/area/center/ghjp/documents/ghjpmortenstatement.pdf>
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- 5 <https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/61dc694cba488b1aa94f51fe/1641834828656/U.S.+v.+Gilead+2+year+anniversary+sign+on+-+CLEAN+FINAL.pdf>
- 6 Prodrugs are pharmacologically inactive compounds that can be efficiently absorbed and then converted by the body into the active drug compound. During remdesivir's development, Gilead referred to remdesivir by its code name, "GS-5734."
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- 9 <https://endpts.com/us-government-does-not-own-any-remdesivir-patents-gao-report-finds/>
- 10 <https://www.citizen.org/article/the-nih-vaccine/?eType=EmailBlastContent&eld=4b69c711-13b4-452f-81c9-22b1cff5412d>
- 11 <https://www.techtransfer.nih.gov/bundle/tab-3261>
- 12 Proteins on the surface of viruses fuse with receptors on cell surfaces, causing changes to both the cell and the virus that ultimately allow the virus to enter and infect the cell. These surface proteins have different shapes before, during, and after fusion with the cell. Effective vaccines need to teach the body to make effective immune responses against a specific form of the surface protein. Developing a stable form of the surface protein to use as an antigen (the part of the vaccine derived from the pathogen that the vaccine is fighting) is key step in vaccine development. It is an ongoing challenge for HIV vaccines; it has been solved for SARS-CoV-2 virus and other coronaviruses.
- 13 https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/#_ftn4
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The “Missing the Target” report series is part of *Watch What Matters*, a community-led monitoring and research initiative to gather data on access to, and quality of, HIV treatment globally. To learn more, visit WatchWhatMatters.org.