

# The Financial Sustainability of Access to Medicines and Intellectual Property Work



make  
medicines  
affordable  
END UNFAIR MONOPOLIES

 **ITPC**  
INTERNATIONAL TREATMENT  
PREPAREDNESS COALITION

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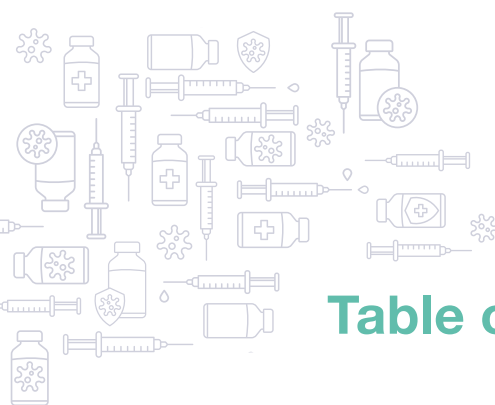
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**About**

[Make Medicines Affordable](#) (MMA) consortium works to bring down the prices of HIV, TB, Hepatitis C, and COVID-19 medicines by removing intellectual property and other access barriers. The MMA consortium is led by civil society organizations from over 20 countries. They include patients, lawyers, health experts and activists, all choosing, instead, to challenge the IP measures that benefit profit but not people.

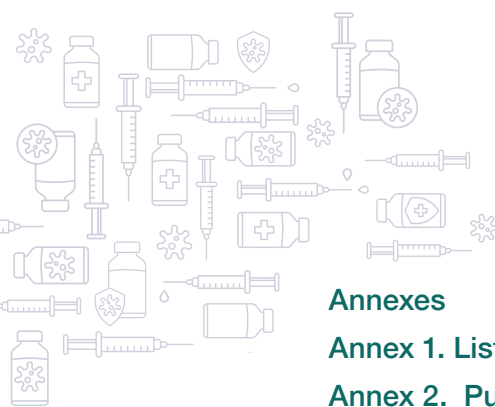
The [International Treatment Preparedness Coalition](#) (ITPC) is a global coalition of PLHIV and community activists working to achieve universal access to optimal HIV, HCV and TB treatment of those in need. Formed in 2003 by a group of 125 HIV activists from 65 countries at a meeting in Cape Town, ITPC actively advocates for treatment access in eight regions across the globe. ITPC believes that the fight for treatment remains one of the most significant global social justice issues. ITPC is an issue-based coalition. ITPC actively advocates for treatment access through three strategic focus areas:

- [#MakeMedicinesAffordable](#)
- [#WatchWhatMatters](#)
- [#BuildResilientCommunities](#)



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## The Financial Sustainability of Access to Medicines and Intellectual Property Work

### Introduction

This report arises from a request of ITPC Global to explore financial sustainability for the Intellectual Property related to Access to Medicines (IPA2M) activities beyond the Unitaïd grant support. This review has hence searched and investigated the landscape of existing and potential donors funding IPA2M activities of non-governmental organisations (NGOs), civil society Organisations (CSOs), and patient networks at global, regional and country level and expanded also the review to selected United Nation (UN) agencies.

### Objective of the working paper

The present document attempts to map the funding landscape on Intellectual Property related to Access to Medicines (IPA2M) work. The report, framed as “working paper”, provides an initial baseline for discussion with donors and organisations working on IPA2M. The intent is to scope the level of funding made available in the last two decades by the main players that financed the work of organisations actively involved on IPA2M. The mapping looked into the recipient perspective and lessons learned in relation to financial sustainability of their IPA2M work. The mapping also interviewed a number of donors directly or indirectly financing IPA2M activities, or having the potential for funding such activities.

The initial objective of the report indicated a 5 years framework for the mapping exercise but data was available for over two decades and informative for the purposes of investigating and describing the trends and lessons learned on financial sustainability of IPA2M work.

Part 1 and 2 of the report present an analysis respectively of the donor landscape and an analysis of the feedback provided by the recipient civil society organisations participating in the enquiry. The enquiry also included UN agencies and organisations (NGOs/CSOs) from high-income countries to provide a larger base to inform this think piece.

Although the original objectives of the study requested an outline of key opportunities to overcome funding shortages to support IPA2M, this analysis has no simple answer to a systemic problem. The appreciation of the policy and financial space outlined and analysed in this report may serve to a constructive and coordinated response to a systemic problem. The report highlights opportunities for reflecting: on financial models (institutional and project base) adapted to the nature of the IPA2M work at global, regional and country level; on the sphere of influence for the missing donors to enter in the picture; on ensuring a more strategic and collaborative approach with the different actors that are needed to ensure impact.

Some recommendations from more operational to more strategic level can be inferred from the analysis, but are meant to be an initial guidance for discussion and formulation.

## Methodology

The mapping of the donor landscape was performed starting from available information on known donors' websites. The websites of the main global, regional and country organisations working on IPA2M were also searched for sourcing information on funding. Donors considered in the study are governments and their development agencies, multilateral donors and philanthropic foundations. Interviews with key organisations and donors were organised to enquire on their experience related to financial sustainability of IPA2M work. The enquiry was not formatted with a standard questionnaire, the organisations interviewed were asked to share information about their experience in the funding IPA2M work, their main lessons learned and their perspective. The enquiry did not ask the organisations to share information about the actual amount of funding received by donors.

Information on amounts and grantees was sourced by donors and organisations' websites when available.

The list of interviewed organisations is reported in Annex 1. The descriptive text and feedback provided by each organisation was cleared by each organisation referent before inclusion in the report. The feedback was analysed, organised and presented by type of organisation (donor, UN agencies and grouped for NGOs/CSOs/networks and other type of organisations).

## Limitations of the study

The level of transparency or completeness of information provided both on donors and IPA2M organisations' websites is very variable. The enquiry has comprised selected NGOs, CSOs, UN agencies known to have been working on IPA2M. The study is not inclusive of all organisations working on this field and this is the main limitation of the study. The study nevertheless attempted to have a balance between geographical representation and type of work (global, regional, country level). Reference is made to Annex 1 (List of interviewed organisations). It is noted that it would be possible to expand the scope of this enquiry. Not all the contacted organisations accepted to participate in the study. The enquiry has been opportunistic in nature. As a number of contacted organisations were reticent to participate and share information, the study included organisations that were referred to by contributors and that were eager to participate.

The study did not look into the academic organisations working on IPA2M, although several receive funding along with CSOs, NGOs and networks.

While the study attempted to cover the widest set of known donors that are or have been funding IPA2M work, not all donors answered to the request for information. This study does not include the perspective of the Global Fund, although the interviewed organisations and donors have provided feedback on the Global Fund policies, operations and funding in relation to IPA2M.

The enquiry took place between November 2020 and February 2021.

Funding provided by the generic industry and other private sector industry is excluded from this mapping exercise. ITPC Global has commissioned a separate consultancy to investigate feasibility and ethical issues related to funding of IPA2M's work by the generic industry.

## Context

The context under which this mapping exercise was undertaken was very much documented by the organisations that participated and contributed in the study. Much of the feedback described in the narrative of the report relates to the context under which organisations are operating to increase access to medicines.

As documented in the report, the COVID19 pandemic is opening new venues to regain a policy space for re-launching the debate and initiatives on governance systems IPA2M. The COVID19 pandemic has brought to a different scale the debate on access to medicines, vaccines, diagnostics and other new health technologies. The economic crisis spurring from the COVID19 pandemic will likely increase the need to explore financial sustainability of health expenditure. Solidarity mechanisms are under discussion, although parallel modalities of market competition to secure volumes of new vaccines are also visible. However much of the capacity to respond to such an opportunity seems very much linked to the capacity of civil society as a whole to sustain and expand where possible their engagement in the policy space at global, regional and country level.

This study occurs in a phase whereby, Middle Income Countries (MIC) are transitioning out donor supported treatment programmes for HIV and TB. Several Upper Middle Income countries (UMIC) have already transition out from Global Fund support and are faced with very high prices for HIV and TB medicines. Global Fund finances still a considerable budget for third line ARVs, DR-TB treatments and molecular diagnostics in MIC. Considerations on the lessons learned and the current challenges on the ground suggest that transition policies shall be coadiuvated by more organic and programmatic approach at country level to ensure that countries have systems and tools in place to ensure access to affordable quality assured health products.

The MPP negotiated voluntary licenses, their potential and limitations are also pondered in the report, in light also of more recent analysis on voluntary licences as an additional tool rather than a solution for access to medicines. , The key role that NGOs/CSOs/networks have in making an effective use of this tool was highlighted.

In absence of a donor institutionally supporting MoH as the Global Fund does for HIV and TB, governments supported by civil society in MIC have been more active in ensuring access to affordable generic new medicines for the hepatitis C cure. Many MIC presents in-country manufacturers of HCV medicines. This shows that investments for IPA2M for a disease, which have a considerable epidemiology in the country may a catalytic effect on long-term availability and accessibility of medicines and, for HCV, on the elimination of the disease. However, the current approach based on vertical programmes leave patients with unequal access to treatment within countries. The work in silos by disease leaves patients with morbidities neglected by donors, agencies and governments without access to diagnosis and optimal treatment. Within the same country, patients with different diseases face unequal access to treatment.

The Universal Health Coverage concept directly brings into question the nature of financial sustainability and viability of access to treatment in the current IP system.

Further, several efforts have been made to develop FDCs and paediatric formulations to increase adherence to treatment in the last two decades. Public Private Partnerships, donors, and WHO invested financial and technical resources to define Target Product Profiles, use viable technology to develop FDCs, optimize formulation acceptance, and to phase-in of these improved formulations in developing countries. However, these improved formulations are often not accessible to MICs and HICs due to IP barriers, thus reducing the return on public global investment for new health product development.



## Main outcomes of the analysis

- The level of transparency about IPA2M financing is very variable across the websites of donors and recipient organisations, with a few exceptions.
- The level of participation in the enquiry has also been very variable, with some organisations eager to participate and inform the study, and others not interested or reticent to share information.
- The level of funding provided in the last two decades cannot be established using the donors' websites, with one exception (Unitaid).
- The landscape of donors financing IPA2M work is very limited, not coordinated, fragmented and with diverse functioning modalities.
- The financial sustainability of IPA2M work has been reported to be a major concern by all interviewed parties. CSOs/NGOs/networks but also UN agencies with a mandate to provide technical support to UN Member States reported shrinking funding.
- Two main US-based philanthropic foundations providing small-medium size grants stopped their funding on IPA2M in the year 2010-2011, causing a major negative impact on the financed organizations and their IPA2M work stream.
- Open Society Foundation (OSF) has been a flexible and reliable source of countless small-medium grants to several organisations at global, regional and country level since 2007 on IPA2M.
- One major donor has appeared in the landscape for IPA2M funding: Unitaid in 2015, with the first specific call for proposals to support countries to take advantage of provisions under global intellectual property rules that allow increased access to affordable medicines in order to safeguard public health. Aidsfonds started financing IPA2M work since 2015 on with dedicated small medium size grants.
- Despite the Global Fund has supportive policies on the use of TRIPS flexibilities and is compelled to support MIC in view of their transition, the enquiry could only identify one MIC where the Global Fund has financed IPA2M activities.
- Institutional funding to NGOs/CSOs/networks are also reported as shrinking overall, adding an additional challenge to financial sustainability.
- Only a few organisations based in HIC were found as able to fundraise outside the established IPA2M donor landscape: MSF, Public Eyes, Public citizen, Aidsfonds and medico international
- No country government in LMICs finance IPA2M work by NGOs/CSOs. Only two MIC NGOs reported applying for RFP from their country Ministry of Health or Ministry of Science, but in both cases theses were not viable sustainable options for financial sustainability.
- US based philanthropic foundations provide considerable amounts of funds but only for US-focused A2M and drug expenditure work.
- Challenges are reported in relation to the usual short-term funding cycles for IPA2M work, making it nearly impossible to have a programmatic approach.
- In the IPA2M donor landscape, there shall be a more strategic and congruous approach to finance global, regional and country-led work, without neglecting the country-level organisations and the built expertise.

## Part 1. Analysis of the IPA2M donor landscape

### 1.1 Donor landscape for IPA2M in the last two decades

Public available data sourced from donors website allows to draw some conclusions in the donor landscape for financial sustainability of IPA2M work in the last two decades (Annex 2/Table1.1). This study interviewed and complemented data with the donors currently funding IPA2M work. While some donors such as OSF, Unitaid, Aidsfonds have access to treatment inscribed in their strategy, constitution, policies, others such as the RCF happen to fund IPA2M work indirectly as a result of the institutional funds provided to civil society and community networks active in this field. Since its establishment, the Global Fund had very clear and supportive policies on transparent and competitive procurement processes including the use of TRIPS flexibilities as interpreted in the Doha declaration on Public health. Nevertheless, its role seems to remain marginal with nearly no funds reported to sustain IPA2M work in its recipient countries. This study has intrinsic limitations provided by the samples of organisations interviewed. It appears that GF has provided funds for IPA2M work only in Ukraine. The need for investing in this area to ensure sustainable access to antiretroviral medicine in Global Fund recipient countries, with an emphasis in MIC and transitioning countries was underlined by several organisations. L'Initiative, created by France to strengthen the impact of Global Fund (GF) grants, reported it has not provided funds to support IPA2M work, as no project proposals and no major requests for technical assistance in the area of IP and A2M have been submitted. In principle, L'Initiative/Expertise France can finance IPA2M.

It is also worth noting that in the past, other donors and foundations were financing IPA2M work such as MacArthur Foundation, Ford Foundation, and DFID. Their exit from funding landscape has important repercussions on several organisations/NGOs in LMICs and HICs that were entirely or largely funded by these donors. These organisations reported they were on the edge of dismantle and close.

Other multilateral donors such as GAVI or important philanthropic donors with a global mandate in public health and access to new health technologies are not included in the IPA2M donor landscape, as their funding mechanism and philosophy does not seem to “acknowledge” IP as a potential barrier to access even indirectly. Their statute, constitution or policies do not refer to the Doha Declaration on the TRIPS Agreement and Public Health, and do not foresee funding and investment for IPA2M in countries or at regional global level to increase access to affordable health products.  
(<https://pubmed.ncbi.nlm.nih.gov/26368398/>)

It is also worth noting that the USA present several other donors and philanthropic foundations which are funding work on governance and systems to reduce medicines prices, however their focus remain limited to the USA health system and health insurance context. None of the interviewed organisations that are based in the USA managed to fundraise from these new potential donors for their IPA2M work.

**Table 1.1**

List of publicly available information on IPA2M funding over the last two decades (Annex 3)

Donor	Year	Allocated Amount	Organisations	Donor Identification	Main policy statement on IPA2M
Unitaid	2010 - 2020	\$122 437 733,00	Over 95 millions USD are invested for pooling of voluntary licenses and patent transparency, 27 millions for CSOs, NGOs, and governmental organisations working on IPA2M	cross-cutting	Unitaid's approach to intellectual property, adapted from content developed for presentation to the Unitaid executive board for its 26th meeting (December 2016)
Global Fund	2002 - present	No available disaggregated data on IPA2M.	There seems to be no monitoring or tracking system of funds to GF grant recipient countries related to technical assistance, or activities on IPA2M	GF grant agreements GF technical assistance on health product management	The Global Fund, Guide to Global Fund Policies on Procurement and Supply Management of Health Products, 2019
Open Society Foundation	2016 - 2018	\$3 480 132,00	Small to medium-size grants to several organisations (civil society groups, academic groups, or networks). Data for previous years and for the years 2019-2020 is not available on the OSF grant database as disclosed by the donor. To be verified if affiliate offices (OSISA, OSIWE, OSIEA, etc.) provide separate grants which are not recorded in the central database.		
Robert Carr Civil Society Networks Fund (RCNF)	2012 - 2018	\$5 698 779,00	Medium to large size grants to two main consortiums of organisations working on IPA2M.		
Aidsfonds (Dutch non-profit organisation)	2015 - 2020	1 755 079,00 €	Medium size grants to CSO, networks, coalitions on IPA2M.		
Shuttleworth foundation	2016 - 2019	\$1 034 438,62	Expanded fellowships system on IPA2M (Achal Prabhala Advancing innovation and access to medicines)		
MacArthur Foundation	2002 - 2011	\$3 175 000,00	The website did not report grants on IPA2M after 2011		
Ford Foundation	2006 - 2011	\$2 708 392,00	The website did not report grants on IPA2M after 2011		
Commonwealth Foundation grant	2017 - 2020	£180 000,00	Two small size grants have been identified for the period 2017-2020 on IPA2M*		
DFID	2016 - 2021	£4 905 000,00	One large size grant provided to the "Access to medicines Index"		
Arnold Ventures (Laura and John Arnold Foundation)	2016 - 2022	\$20 086 147,00	Over 40 millions USD have been allocated to US-based organisations working on drug prices (including IPA2M)		

\* Commonwealth Foundation (small size) grants are accessible only to Commonwealth-based organisations for work in Commonwealth countries

There is also a plethora of other small foundations, which have provided small grants continuously or ad hoc on IP and health to different NGOs/CSOs, especially in the US. However, these do not seem a sustainable option for extended fundraising. Their websites often do not acknowledge funding on the IP and health area.

While the scoping of the donor landscape was limited to the IPA2M field, a few interviewees highlighted that there has been an important decrease in institutional funding provided to NGOs/CSOs. There are reports of donors such as Sida (Swedish International Development Cooperation Agency), which changed its funding modalities, phasing out from institutional support to organisations, which had quite a wide mandate and areas of intervention to project-based financial support for narrow areas (e.g. specific thematic areas such as SRHR or disease focused). This indirectly impacts on CSOs/NGOs, which work on IPA2M. Organisations which since its establishment favoured fundraising with donors eager to provide unspecified contributions report to be confronted with donors increasingly project-oriented, reducing the space for « core funding » and the flexibility and capacity to finance portfolio areas according to needs.

## **1.2 Transparency of data on allocated funding**

As noted in the methodology, the level of transparency or completeness of information available on the donor websites is variable. Nevertheless, it has allowed for some analysis of the chronological trends, grant size and type of organisation funded when available. Several donors have searchable grant databases, which allow retrieving data on grants on IPA2M. The information may not be fully accurate or inclusive, nevertheless it allow drawing trends in IPA2M funding in the last two decades jointly with the information provided by the donors (table 1.1). Detailed information is provided in Annex 1.

The Unitaid website allow to search for all grants since Unitaid's establishment. OSF and Aidsfonds have grant databases, but in the case of OSF the available information covers currently a limited time period (2016-2018). MacArthur Foundation and Ford Foundation have grant database which allow seeing the IPA2M work financed until 2011. The Arnold Ventures' grant database reports information on grants related to "drug prices" while the Shuttleworth foundation has a searchable database for grants and fellowships. Information related to the Robert Carr Civil Society Networks Fund (RCNF) was extracted from the annual reports. The Global Fund data explorer does not allow to source information on investment made specifically on IPA2M. There does not seem to be a readable tracking system to assess investments in this area. Also Global Fund publications related to procurement and supply chain management such as Inspector general reports do not disclose or inform if there have been investments in this area within the grant architecture or through other funding streams for technical assistance.

### 1.3 Trends in the funding landscape for IPA2M

In 2011, two main foundations active in providing medium size grants to organisations working on IPA2M suddenly left the funding space. OSF has been providing grants since 2007, while Aidsfonds started in 2015 with a RFP launched in 2014 for project aimed at eliminating intellectual property barriers to access treatment. Unitaid established in 2010 the Medicines Patent Pool (MPP) and since then has financed nearly the totality of its budget. Unitaid started financing IPA2M work of NGOs/CSOs in 2015 with a first grant provided to ITPC, followed by a 2017 RFP to support use of TRIPS flexibilities in order to increase access to affordable medicines. OSF is probably the long-standing donor with institutional and project grants for IPA2M.

The Global Fund seems not to be involved in funding of IPA2M work in the grant recipient countries regardless of their challenges in accessing affordable treatment. This enquiry could identify only one country where grant money were made available for patent law reform use, Ukraine. Country and regional organisations active MICs and also being recipient/subrecipient of GF grants interviewed for this study did not report accessing GF grant money for IPA2M work. In 2018, two regional concept-notes led by civil society ( one in the Middle East and North Africa and one in Eastern Europe) including IPA2M work have been approved by the Global Fund, but few months later the principal recipients were requested to remove the IPA2M related activities from the project.

The US funding landscape on A2M changed in the last 5 years with more funders coming into play following the advent of highly priced HCV direct-acting antiviral agents (DDAs) and new cancer treatment. The USA philanthropic donors such as Arnold Ventures, West Health, Robert Wood Johnson remain until now very much restrained to USA-based organisations working on the USA context. Arnold Venture since 2016 invested an impressive amount (around 40 million USD) on “drug price” grants and health care expenditure. This has had little influence on the financial sustainability of US-based historical NGOs working globally on IPA2M. Arnold Ventures’ perspective is rooted in U.S. healthcare reform and analysis. Except for I-MAK, other US-based NGOs with decades of experience working on IPA2M and probably with a more activist profile attempted but were not successful to fundraise through Arnold Ventures even for US-focused work. Arnold Ventures seems to value more analytical/think tank work than activism.

### 1.4 Geographical distribution of grant funds

OSF has been providing small to medium size grants to organisations in all countries and continents working at global, regional and country level. There may be fluctuations on where funding may go in preference depending from the OSF strategy adopted for IP and public health. Aidsfonds have quite a large base of geographical coverage for its small-medium grants mainly in Africa, Latin America and Asia. RCNF can provide institutional support to civil society and community networks in all continents independently from their income.

Unitaid through its currently 3 active large grants supporting the use of TRIPS flexibilities have a geographical coverage provided by the awarded proposals, which have a variable approach in activities, partnership and geographical coverage. The TWN awarded Unitaid grant covers activities in 10 countries in Asia, Africa and North Africa. Similarly, the South Center administered grant has specific project activities in 12 countries in Latin America, Asia, and Africa although for other interventions the coverage is for all LMICs. <sup>1</sup> The current ITPC Global Unitaid grant covers 17 countries in 4 different continents mainly in Eastern Europe, Latin America, South East Asia and one country in North Africa.

Potentially, Global Fund could have a global coverage in over 100 grant recipient countries including several MICs. While under L'Initiative/Expertise France, 40 countries (principally French speaking countries) are eligible for requesting technical assistance or applying for projects increasing the efficiency of GF grants. The GF policies are indeed clearly supportive of interventions including the use of TRIPS flexibilities for increasing access to affordable quality assured medicines. <sup>2</sup> The Global Fund is the largest multilateral fund on health system strengthening and with the widest country eligibility. As an example, GAVI currently counts only 58 eligible countries of an original 73 eligible countries. GF investment of US\$4 billion a year on health in countries, of which "US\$1 billion a year to strengthen and build diagnostic tools and laboratory facilities; data and surveillance systems; procurement and supply chains; community systems; and training of health workers." <sup>3</sup>

## 1.5 Grant modalities

The document could gather information related to the grant modalities and schemes that are adopted by the interviewed donors, and the feedback provided by the recipient organisations. Detailed information on the donors' modalities and grant models are provided in the donor dedicated sections.

The OSF financed organisations for IPA2M work comprises CSOs, patients groups, NGOs, academic groups. OSF provides funds as a result of targeted relationships, rather than open call for proposals. The majority of the OSF grants on IPA2M are multi-annual « flexible funds», whereby the recipient organisation has freedom to decide how to use funds and will report on an annual bases on their use. Flexible funds can be used for institutional support (staff, indirect running costs). OSF provide funds for project-oriented grants, on average 2 years grants, yet there is still flexibility allowed in this type of grants with no requirements for log-frames or similar tools.

The Unitaid grants are provided as a result of calls for proposals. The calls for proposals are usually launched based on an indicative financial envelope approved by the Unitaid board. Several rounds of institutional reviews are performed for the selection of the proposals. The Unitaid IPA2M grants were conceived and developed to fit into the existing Unitaid grant framework on a 3-5 year period, which was developed for the introduction of new health technologies. There isn't currently a differentiation of grant frameworks, which may be more suitable to the nature of IPA2M work and its longer timeframes. The modality for the financing of the MPP is delinked from the usual call for proposals and selection process. The 2019 awarded grants on IPA2M are on a three years basis.

Aidsfonds –Soa Aids Nederland is a Dutch NGO, which operates with several modalities. Internationally, Aidsfonds functions as a donor (involved funder) to sister organisations, mainly PLWHA networks, communities and vulnerable populations' organisations. Grant making is normally done through either participatory grant-making or peer informed grant-making, or through partnership development and co-creation with existing partners. In the IPA2M case, specific calls for proposals for country regional level work were launched and opened to NGOs in 2016 and in 2018. The duration of the IPA2M provided grants lasts from 2 to 4 years. Aidsfonds is currently re-considering its strategy and placement in the IPA2M donor landscape.

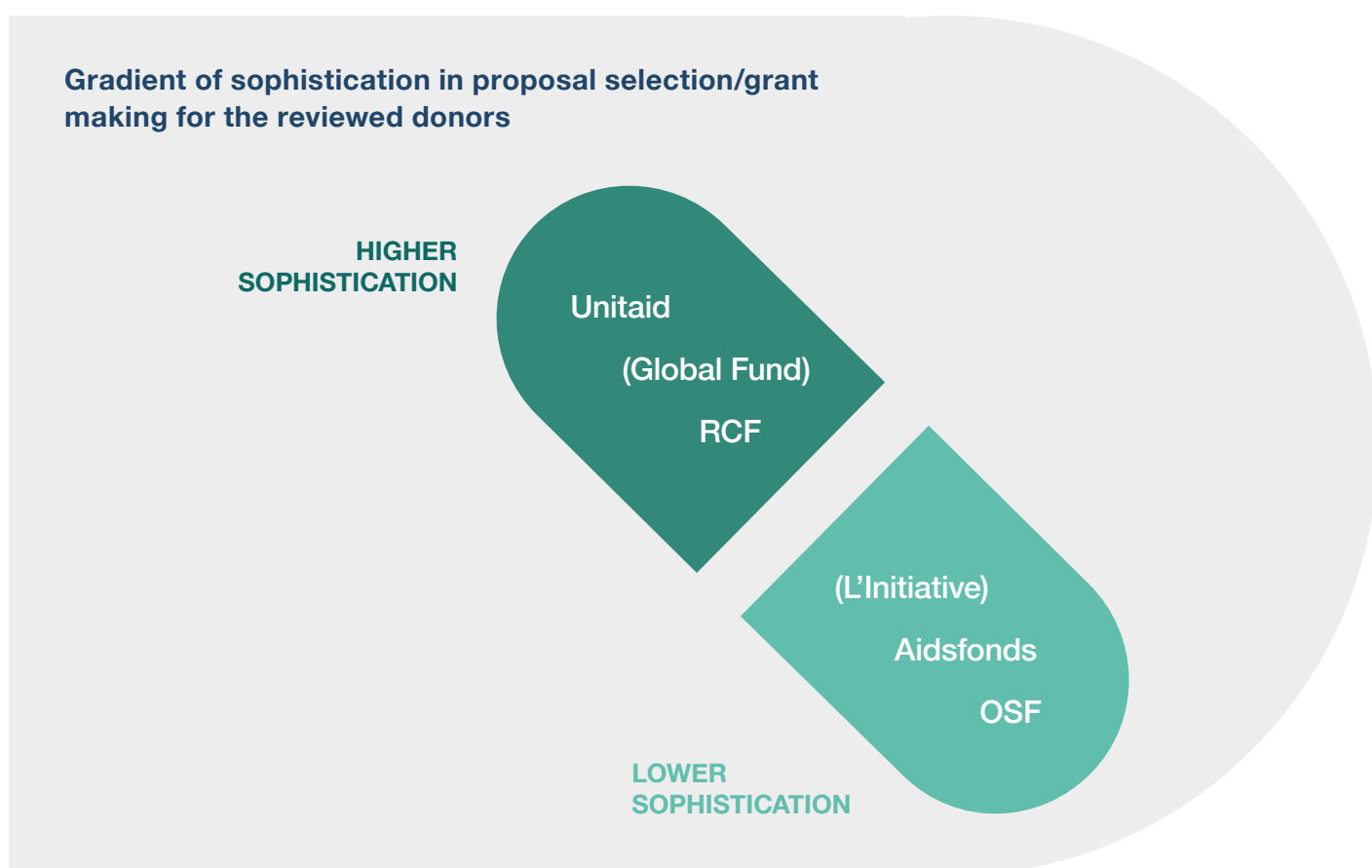
The Robert Carr Fund is a financing mechanism, which channel funds through a governance system to civil society and community networks. The system is based on calls for proposals launched every three years. The RCF works with requirements sets by donors and implement a strong accountability mechanism for its grants. As noted, RCF mandate does not specify an IPA2M mandate, but may fund civil society networks that work on IPA2M. RCF and Aidsfonds may have overlapping grantees, but the two grant funding mechanisms are completely distinct.

The Global Fund works with a very well established system for grants in eligible countries for the three diseases, HIV, TB and Malaria and for Health System Strengthening. Over the years, the GF has established initiatives to perform assessments or mobilize technical assistance outside the grant system and envelopes. The only known exception of a country using funds for IPA2M is Ukraine, where the principal recipient managed to include IPA2M activities within the HIV grant in 2018 (case study).

L'Initiative/ Expertise France provides two main types of support to its 40 eligible countries: technical assistance and funding of catalytic projects complementary to the Global Fund grants. IPA2M may be considered in both channels. More information on the modalities to access funds of L'Initiative is provided in section 3.2.

The current donor landscape for IPA2M financial sustainability shows different approaches and variable grant modalities. Some such as Unitaid and Aidsfonds opened specific call for proposals for IPA2M grants, RCF runs calls for proposals for support to civil society organisations and networks. Others such as OSF identify organisations that are aligned to their mandate and values and provide both project-based grants, but also institutional grants. The length of the provided IPA2M grants currently varies between two to four years maximum. OSF seem to be a donor which can engage for long term continuous support in the IPA2M field as noted by several interviewed OSF grant recipients. Nevertheless, OSF works on strategies that are reviewed every 4-5 years and strategic changes come at the cost of shifting funds at global, regional, country level and across subareas of work within A2M, IP and Innovation. Further, grants are provided by the OSF New York office but also by its several regional and country affiliate offices, which have full decentralized decision making processes in relation to budget and grant making.

The requirements for proposal description and grant making also varies greatly among the donors. Unitaid requests elaborated proposals according to very detailed formats and project management tools, which are further refined during grant making. It also demands a strong M&E system and financial management system to its grantees. Other donors such as OSF and Aidsfonds are more flexible in the grant making and much less demanding towards their grantees. The sophistication and complexity of the proposal selection and grant-making seem to have an impact on the type of organisations able access the donor funds, as analysed in section 2.3.



OSF has noted better results, in terms of outcomes, when it provides flexible funds. These types of grants allow the grantee to pivot and take advantage of opportunities without having to constantly check with the funder.



## 1.6 Donor coordination and information sharing

There is no formal platform for coordination or information sharing among donors funding project or organisations working in the IPA2M. The interviewed donors mentioned that there hasn't been formal information discussions or meeting with other donors also at bilateral level aimed at sharing information or discussing IPA2M financial sustainability. There seems to be a need for a space for donors to share their expertise, lessons learned and approaches on IPA2M funding streams. Informal discussions for information sharing may exist but it could be beneficial to understand each donor's mandate, way of operating, lessons learned, and to be informed of strategic changes that may impact the geographical and thematic scope of the donors' investments on IPA2M. The possibility for donors to better consider their complementarity in the IPA2M field, may also support the definition of better-informed strategies for investments in this area. All donors reported to have strategies that are reviewed on a regular bases and that determine also if/how they will invest on IPA2M. This may also be beneficial to call for a more coordinated approach with donors that have a mandate on IPA2M provided by their constitution or policies, but are currently not investing in this area.

## 1.7 IPA2M financial sustainability: Feedback provided by the interviewed donors

Transfer and continuity of Unitaid IPA2M funded work in MIC are considered important, and financial sustainability has been highlighted as a point of attention to the Unitaid grantees. Set aside the financial support to the MPP, Unitaid with the three grants awarded in 2018 is the donor providing the largest grants on IPA2M. The risk is that by injecting considerable amount of funds in the grantees/sub-implementers for a limited period of time, these organisations may suffer from a major drawback when funds will end. The acknowledged complexity for proposal submission and grant making, along with the Unitaid requests for strong M&E system and financial management system, may serve the recipient organisations to apply for funding to other major donors with similar standards and requirements. Nevertheless, this would only help recipient organizations if there are other donors.

Financial sustainability of CSO networks is also one of the core areas of the RCF strategy. The RCF notes in its 2019 annual report that "for some grantees, long term financial sustainability is uncertain. RCF continues to encourage grantees to prioritize activities to ensure sustainability for individual organizations as well as the sector as a whole." Other donors also expressed concerns on the financial sustainability of CSOs/NGOs they support also in relation to the shirking financial opportunities and the changes that may occur following their own strategy review.

Two donors working on calls for proposals for IPA2M or for institutional support acknowledged that they received many more proposals than those it is able to fund. As an example, in the last call for proposals to RCF, only 1/3 of the received proposal got funded. Similarly, Unitaid reported to have received many more proposals on IPA2M for the available budget.

As analysed in section 2.7, financial sustainability of high income country based NGOs which do use contributions from private citizens donation is an area which require a considerable set up, reputation and that would not be an option for organizations working exclusively on IPA2M. If HIC government funds may be strategically applied for and used by some HIC-based NGOs, this is not an option for LMIC-based organisations. Only two MIC-based organisation have reported to have applied and received government funds, but that did not represent a viable sustainable source of funds, but rather an add-on ad hoc opportunity. Similarly, Aidsfonds reported that advocacy work is very difficult to use for fundraising with private citizens. There is need to have a balance between advocacy and concrete results that can be used for fundraising. This influence also the donors balance in providing grants. Aidsfonds undertook a survey regarding private citizens fundraising feedback on IP and treatment access work. The feedback highlighted the private citizens appreciation for the work, but generally private citizens wants to fund concrete projects for women, children, eventually also for LGBT/MSM. IPA2M work is appreciated as a second line in the NGOs work, but it is not a “marketing subject for fundraising”. Private citizens financial contributions are not used by Aidsfonds for A2M and IP work and for providing grants to CSOs/NGOs in LMICs.

LMIC governments do not finance IPA2M work by NGOs/CSOs, technical organisations or UN agencies. UN agencies are often requested to provide technical assistance to LMICs along with the related budget. It is worth noting that none of the interviewed donors provide funds to the UN agencies having a mandate on IPA2M.

Western Europe governments may have conflicting internal view on IP and A2M, with Ministries of Foreign Affairs (MoFA) inclined to support this type of work in LMICs and Ministries of Trade with a conservative and protective approach in favour of the pharmaceutical multinational industry. Aidsfonds was able to source funds for its IPA2M grants through Dutch MoFA. RCF channels funds to CSOs/networks also on behalf of Western European cooperation agencies (e.g. DFID, NORAD-Norwegian agency for development cooperation, Dutch MoFA). The RCF may be considered an indirect donor on IPA2M, as its main focus is support to CSOs/networks working for inadequately served populations (ISPs) on protection and promotion of human rights and on access to HIV services-among others. Further, being very vocal on IPA2M does not impede German NGOs to receive funding from German government for emergency aid, development and human rights projects.

DFID seems to have withdrew from work on IP and A2M field, with the exception of one large grant provided to Access to Medicines Index, a foundation measuring the largest pharmaceutical companies’ behaviours in several areas and providing an annual ranking. Data on provided grants is not available from the DFID website. DFID seemed to have a supportive approach to use of TRIPS flexibilities back in the years 2000s.<sup>4</sup> One interviewed organisation reported to have received financial support by DFID from 2009 to 2014 for their entire A2M work including IP, but that the support was withdrawn suddenly. A recent article analyse the investments made by DFID in the last years on access to medicines suggesting that DFID opted to invest largely on PPP such as DNDi, MMV, TB alliance, CEPI.<sup>5</sup>

## 1.8 Missing and potential donors

One of the missing donors in the IPA2M field is the Global Fund despite having clear policies and mandate in this area. As noted above, the GF presents a wide eligibility list of countries also in comparison to GAVI. Several MICs are recipient of GF grants, and they face exorbitant prices for certain categories of medicines such as third line ARVs, which are currently financed by the GF. There is the impression that GF transitioning work for MICs remains quite weak. Reports on the transitioning out of GF in Eastern Europe indicate that countries were left with a reduced capacity to access more affordable prices for the procurement of health products for HIV, TB and Harm reduction programmes. Some of the analysis also point of to the need for bridging funds and IPA2M work among other aspects.<sup>6, 7, 8</sup> Information on GF pooled procurement mechanism (ppm) accessibility for transitioning or non-GF countries is also not readily available The GF ppm price list for ARVs does not include third line medicines and the requested pre-payment modality is not an option in several national procurement procedures/systems in MICs. MICs are paying extremely high prices for third line ARVs fluctuating from around 4.000 USD up to 13.000 USD per person per year EX WORK (Source: GF PQR).<sup>3</sup>



There seems to be a fracture between the investment on IPA2M between Unitaid and Global Fund, with Global Fund being totally absent and ignoring the challenges on IPA2M in the MIC they support financially for HIV treatment.



Add Name, Add Country?



GAVI and CEPI don't acknowledge that IP impact on A2M and rely on private companies willingness on the supply and prices of vaccines. GF appears to act with a « stay-away » attitude.



Name, Country?

Based on preliminary analysis of governance systems in multilateral large donors, there seems to be an influence of donor board composition on the implementation of IPA2M supportive policies and mandates as discussed in the below section 1.9.

While the need for solving urgent access barriers in MICs has been reported by several interviewed organisations across the considered categories (donor, NGOs/CSOs, UN). It has also been highlighted that although there is some visible work and progress achieved on IP in MICs for HIV and Hepatitis C, it would be a mistake to neglect work in Low Income Countries.

Among the missed donors, there could also be the Enhanced Integrated Framework (EIF), hosted in the WTO secretariat and managed by UNOPS. The EIF partnership of 51 countries, 24 donors and eight partner agencies works closely with governments, development organizations and civil society to assist least developed countries (LDCs) use trade as an engine for development and poverty reduction. One organisation reported to have tried fundraising on trade, IP and public health for LDCs but without success. Another LDC-based organisation with extensive expertise in IP did not know about this mechanism.

This review did not manage to establish contacts with the US donors such as Arnold Ventures to explore directly if they could finance USA-based IPA2M work with a global impact. Despite the US-based interviewed NGOs reported that they have not been successful to fundraise with this types of major US based foundations, this may be an area for further investigation.

The online search also identified some international fellowships programmes, which have provided support to researchers and personalities in the IPA2M field (Table X). The amount of these fellowships is not known except for the Shuttleworth foundation (Annex 2). This enquiry did not investigate further the identified fellowship programmes. However, this appears more as an add on opportunity than a sustainable source of funds for institutional activities and programmes of IPA2M organisations.

**Table 1.2**  
 Identified fellowships on IPA2M

Fellowships
Ashoka
Ecoing Green
Shuttleworth foundation

Medico internation (MI) also provided one small grant to ABIA in the past. MI clarified that it provides project-related as well as instittional funds to its partner organizations in countries with a long stand commitment, and currently no funds are available for IPA2M projects. MI has limited resources, hence shifting is difficult in normal circumstances.

## 1.9 Multilateral donor boards and their potential influence on IPA2M funding

In relation to IPA2M, the NGO delegation to the Unitaid board had to advocate to have dedicated grants on IPA2M and succeeded in 2018. Unitaid until then had only invested on the MPP. The composition of the multilateral donor board may influence the opportunities to finance IPA2M activities of NGOS, CSOs and networks. A description of the Unitaid board composition and the role of the Unitaid NGO delegation is reported in 4.7.1. Unitaid board members representing the community delegation and the African countries have been mostly in favor of expanding the IPA2M work in Unitaid. However it was noted that not all board members have the same vision regarding IPA2M investments towards use of TRIPS flexibilities or other public health related safeguards. Thus suggesting that also expanding the level of knowledge and understanding of the importance of IPA2M work could be beneficial to unlock situations in the future.

GAVI does not report any statement in its statute about IP as a barrier to access to vaccines and any policy in relation to IP and access to affordable vaccines. GF has spelled out policies in favor of the use of TRIPS flexibilities for A2M, however any proper investment and engagement in this area seems more problematic due to the composition of the GF board. The USA government and the private sector are indicated as having a major influence on the board decisions and organization interventions.

Although both GAVI and GF boards do present NGO/CSO delegations, private sector representation and other consideration on the board composition seem to affect acknowledgement and/or implementations of IPA2M policies. As an example, Of the 27 voting members in the GAVI board, one seat only is for CSOs.

This area may worth additional investigation and thinking, also in light with the changed geopolitical context including the USA leadership and impact of the COVID pandemic.

## Part 2. Recipient organisations: experiences, lessons learned and perspectives on financial sustainability of IPA2M work

### 2.1 Nature of IP work, context and implications on financial sustainability

All respondents provided feedback on how financial sustainability shall be re-considered in relation to the nature of IPA2M work, which is very much distinct from other public health interventions. All respondents highlighted the complexity, technicality and advocacy needs for IPA2M work, which requires dedication in the timeframe of several years if not decades. All respondents presented IPA2M work as a continuous process.



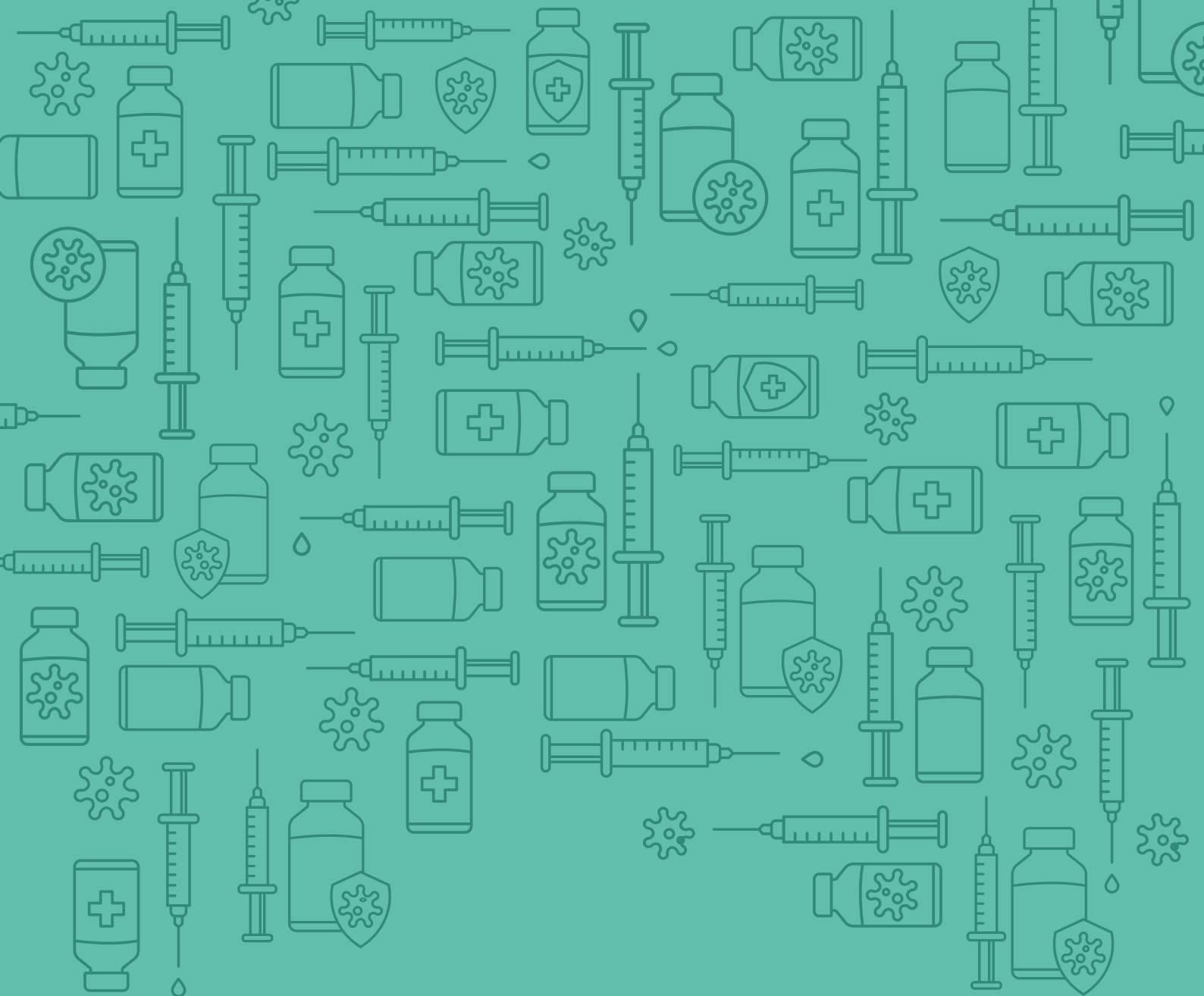
#### Sensitivity.

HIC governments often regard IP either as extremely technical and complex or controversial (e.g. when it comes to CL and PO) and are therefore wary of funding it. IP sensitivity has been highlighted by several respondents from different regions. IP is a sensitive topic also in Africa for several Sub-Saharan MIC governments, not to negatively impact on bilateral agreements and partnerships. In the African region, country governments may be eager to fund treatment, but not A2M advocacy and technical work.

#### Complexity and longer timeframes.

Given that IPA2M work often addresses policy and legal change with longer timeframes, the impact of IPA2M work where it is framed as a project can be limited. It takes time to understand and identify the policy/legislative issues and it is also often subject to the changing geopolitical context. There is often the assumption from some donors that the CSOs/NGOs organization can become sustainable and that the funded IPA2M projects can be considered achieved. The nature of IPA2M work is that of a continuously changing environment with endless work, which require continuous monitoring of the situation, and flexibility to adjust advocacy and technical work to the political, legal and economic changing context at global, regional and country level. When it comes to advocacy work, many events are not under the advocates' control, it is hence difficult to fix a multi-year plan as often requested by donors. Capacity building on IPA2M shall be accounted for as a regular activity considering that turnover of staff/officers in government structures occurs. Similar feedback was provided for what concern in-country CSOs and patient networks.

Non-easily measurable. IPA2M work often require longer timeframes and measuring impact is more challenging than for other areas. Processes such as PO, CL, patent law reforms can take years. Donors want measurable outcomes in the reasonably short term as they are also under pressure to report back to parliaments and public opinion.



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