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How could Drugs for Neglected Diseases initiative (DNDi), as a Product Development Partnership, Demonstrate the Impact of its Work, Given its Unique Structure, Mission and Activities?

Submitted by AMRUTHA NAIR, CAROLYN WU, SEUL LEE, XIAOXIAO LIU

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Glossary of Acronyms

CEPA	Cambridge Economic Policy Associates
DAC	Development Assistance Committee
DALY	disability-adjusted life year
DNDi	Drugs for Neglected Diseases initiative
Gavi	Global Alliance for Vaccines and Immunization
GDP	gross domestic product
GPEI	Global Polio Eradication Initiative
HICs	high-income countries
HIV	human immunodeficiency virus
IVI	International Vaccine Institute
KPI	key performance indicator
LMICs	low- and middle-income countries
MMV	Medicines for Malaria Venture
M&E	monitoring and evaluation
NTD	neglected tropical disease
NGO	non-governmental organisation
OECD	Organization for Economic Cooperation and Development
PPC	preferred product characteristic
PDP	product development partnership
R&D	research and development
ROI	return of investment
TPP	target product profile
TDR	tropical disease research
UNICEF	United Nations Children's Fund
USD	United States Dollar
WHO	World Health Organization

I. Project Description

A. Background

Neglected tropical diseases (NTDs), a diverse group of diseases affecting neglected populations, are often excluded from global health agendas. Prevalent mainly in tropical areas, NTDs affect more than one billion people living in impoverished communities. Upholding the Universal Health Agenda, the World Health Organization (WHO) is committed to making strategic goals of controlling, eliminating, or eradicating many of these diseases by 2030.¹ Even though NTDs contribute 12% of global disease burden, a mere 1.1% of the 1393 new drugs brought to market between 1975 and 1999 were for NTDs, reflecting the sheer disregard of addressing them. The NTD Road Map 2021-2030 underscores the disproportional burden of NTDs in the 16 countries that bear 80% of the global burden of NTDs and outlines the strategies for collaborations to address treatment gaps.²

To overcome global health challenges, product development partnerships (PDPs) have emerged as successful public-private partnerships in providing access to new health products, such as medicines and diagnostics, for poverty-related neglected diseases.³ The PDP model is not-for-profit and often funded by governments and philanthropic organisations. Since its inception in the 1990s, various PDP models have contributed to improved access to crucial medicines and life-saving vaccines. The WHO observes PDP as a successful model for carrying out research and development (R&D) in neglected disease areas that lack commercial interest. The potential of PDP to leverage research and innovation to ensure equitable access to health technologies in vulnerable communities, especially in low- and middle-income countries (LMICs), is widely accepted. To date, 2.4 million people have benefited from over 60 new health technologies introduced by PDPs, contributing significantly to global health efforts to alleviate poverty and health inequity.⁴

Founded in 2003, Drugs for Neglected Diseases initiative (DNDi) is one of several PDPs as non-profit entities to conduct and facilitate R&D for new medicines and diagnostics to address the pressing health needs of the most neglected in resource-limited settings. The approach of DNDi is centred on three key pillars. First, bolstering innovation by coordinating and collaborating with public, private, and not-for-profit partners worldwide, DNDi engages in activities spanning from drug discovery, pre-clinical research, and clinical trials to access new treatments. Secondly, DNDi focuses on fostering needs-driven research and sustainable solutions by sharing knowledge and expertise, strengthening capacities, and increasing national and regional collaboration. Finally, DNDi is committed to driving political will and strategic commitments needed to boost the R&D system to ensure equitable access to innovations.⁵ Since its inception, DNDi's needs-driven innovation through R&D partnerships has delivered 13 context-specific and affordable treatments for six neglected diseases.⁶ Evaluating DNDi's impact on global health R&D involves diverse dimensions, demanding a unique approach to measure success. The broad spectrum of diseases, patient demographics, activities, and partners within DNDi's portfolio poses challenges in choosing the most suitable performance framework, which is essential in ensuring the efficacy of the programmes.

B. Objectives

The primary objective of this research project is to assist DNDi in demonstrating the impacts of its efforts within all aspects of its mission, by refining its performance framework and contributing to the mid-term review of the organisation's Strategic Plan for 2021-2028. The specific objectives include:

 Investigating ways how other PDPs and global health collaborators measure and demonstrate their impact.

- Assessing suitability of key performance indicators (KPIs) by other organisations to DNDi's mission, activities, and feasibility of their implementation given DNDi's portfolio.
- Formulating recommendations of a suitable performance framework and KPIs for DNDi as well as a plan for their implementation.

C. Research Questions

The main research question is: "How could DNDi, as a PDP, demonstrate the impact of its work, given its unique structure, mission and activities?" Other relevant research questions include:

- 1. What are the impact frameworks and KPIs utilised by other global health actors?
- 2. What are some potential areas of improvement in DNDi's existing performance framework?
- 3. How can DNDi further develop its performance framework in line with its model and portfolio?

II. Literature Review

In this section, we provide a brief overview on various considerations when developing a performance framework, including the challenges of developing performance frameworks for PDPs given their unique roles, and incorporating evaluation frameworks by the WHO and evaluation criteria by donors in assessing PDP performance.

A. Challenges of Developing Evaluation Frameworks for PDPs

PDPs play a pivotal role in facilitating access to new healthcare products within developing countries. An important concern is the integration of these innovations into

existing healthcare systems of developing countries. To address the challenges, the article by Brooks et al. delineates a comprehensive set of activities and strategies for PDPs.⁸ These encompass close collaboration with developing countries, active support for local production, and involvement in innovative regulatory and financing mechanisms. Furthermore, the document accentuates the importance of acquiring a nuanced understanding of local healthcare systems and market structures, advocating for strategic partnerships as instrumental tools for facilitating access and adopting new health products. The proposed framework posits a focal point on guaranteeing the availability, affordability, acceptability, and seamless adoption of these products within the intricacies of healthcare systems in developing countries. To effectively gauge the impact of PDPs in realising equitable health outcomes and enhancing access to healthcare innovations in these regions, the framework advocates for the incorporation of indicators specifically designed to measure the effectiveness of the partnerships in achieving these objectives.

B. Monitoring and Evaluation Frameworks by the WHO

The WHO has been the main player in developing cross-cutting monitoring and evaluation (M&E) frameworks for programmes and health systems. They call for a common M&E framework in their report "Monitoring the Building Blocks of Health Systems: A Handbook of Indicators and Their Measurement Strategies".⁶ The results chain of the M&E framework can be conceptualised as "inputs and processes \rightarrow outputs \rightarrow outcomes \rightarrow impact". The input and process indicator domains involve health workforce and infrastructure. The output domain involves interventions and services. The outcome domain involves coverage of interventions. The impact domain involves health outcomes, equity, and efficacy. The WHO created the "Building Block" framework with 6 M&E components in health system performance: 1) service delivery, 2) health workforce, 3) health information

systems, 4) access to essential medicines, 5) financing, and 6) leadership/governance. With each building block, they further developed recommended core indicators and proposed data collection methods and sources.

For programme specific frameworks, the WHO developed 3 pillars for target activities in their "Global Report on Neglected Tropical Diseases 2023": 1) accelerate programmatic actions, 2) intensify cross-cutting approaches, and 3) change operating models and culture to facilitate country ownership.¹ Under each pillar, different activities are undertaken to support the pillars. Within the M&E framework, the WHO calls for integrated M&E as an important cross-cutting priority that can boost cohesiveness and coordination throughout all programmatic stages. Specifically, the WHO developed a compendium of 72 NTD indicators, providing a comprehensive and standardised list of the most widely used indicators relevant to countries, with the aim of allowing comparisons over time and across programmes.

C. Donor Evaluation of PDPs' Performance Frameworks

Donors of PDPs are often interested in seeing evidence of impact and fiscal responsibility. The 2007 Foundation Strategy Group (FSG) Social Impact Advisors report underscores the importance of including both donor and internal perspectives, as well as incorporating the needs of funders and implementing organisations in developing evaluation frameworks.⁷ Within an evaluation framework, various donors generally have different priorities in assessing PDP performance. Importantly, the report stresses the importance of defining the dimensions of the measurement, that is, what performance means to each PDP model in order to create comprehensive and PDP-specific frameworks.

Boulton et al. conducted a detailed evaluation of the funding activities of PDPs under the purview of the UK Department for International Development (DFID) and the German Ministry for Education and Research (BMBF).⁹ The proposed evaluation framework encapsulates three pivotal elements: 1) economy, particularly highlighting cost-effective resource utilisation; 2) efficiency, evaluating the effective use of resources to yield outputs; and 3) effectiveness, assessing the extent to which PDP outputs achieve intended outcomes in health advancements and poverty alleviation. Notably, the authors recognised the complexity in measuring health impact, referring to challenges such as limited quality in global data, poor diagnostic capabilities, and deficient record-keeping. Furthermore, the report analysed the complexity of evaluating effectiveness of interventions, particularly in consideration of challenges related to data deficiencies and integration of diagnostic tools within healthcare systems in endemic countries.

Another evaluation report of PDPs by Grace and Druce provided nuanced insights and recommendations, outlining key areas for evaluation within the PDP landscape. The authors underscored a multifaceted approach, focusing on four of the evaluation criteria defined by the Organization for Economic Cooperation and Development (OECD) Development Assistance Committee (DAC) Network on Development Evaluation (EvalNet): effectiveness, relevance, efficiency, and impact. Effectiveness evaluation encompassed a comprehensive assessment of PDPs regarding their strategic plan and specific grants. It also examined the facilitative role of governance, organisational structure, and administrative systems. The relevance dimension entailed a thorough analysis of PDPs' objectives whether they aligned with the diversity of beneficiary needs, country priorities, global mandates, partner expectations, and donor policies. The evaluation on efficiency revolved around economic transformation of resources, funds, expertise, and time, into tangible outcomes, emphasising the mandate of optimal resource utilisation for effective outcomes. The report spotlighted the significance of evaluating the impact of PDPs on poverty reduction and health advancements in developing countries, highlighting their role in shaping the global landscape for health

product accessibility. A remarkable finding is the acknowledgment that formal evaluations remained limited as both performance indicators and evaluation measures evolve. The report emphasised ongoing collaborative efforts made by donors, coordinated by groups like the PDP Funders Group, to improve the understanding of PDP effectiveness and address evolving challenges.

As demonstrated above, developing a performance framework requires a multifaceted approach, involving the organisation's own vision and mission, alignment with other global health actors such as the WHO, and consideration of donor's perspectives.

III. Methodology

This study employed a qualitative research design, integrating in-depth document review and interviews to explore the research questions. We implemented the research in three phases, incorporating a systematic review and analysis of relevant documents from DNDi and other stakeholders in the PDP landscape, followed by in-depth interviews with the key stakeholders to obtain detailed insights and perspectives.

Phase I

The initial phase focused on reviewing two key areas. First, the team explored various DNDi documents, including the strategic plan, the theory of change, and the indicator list. The review aimed to gain a comprehensive understanding of DNDi's current evaluation processes and frameworks. Next, we examined the literature surrounding impact evaluation frameworks utilised by other relevant global health actors, including the WHO, with a special focus on NTDs.

Phase II

Phase II consisted of two stages—data collection and data analysis. During the data collection stage, we developed open-ended questionnaires for in-depth interviews with various stakeholders. We interviewed DND's internal stakeholders and other global health actors in Geneva, including Global Alliance for Vaccines and Immunization (Gavi), Unitaid, Medicines for Malaria Venture (MMV), the Global Fund, FIND, and the Global Polio Eradication Initiative (GPEI). We analysed the interviews and explored the status of DNDi's performance indicators, existing challenges, and the feasibility of various potential indicators utilised by other organisations.

Phase III

Phase III focused on data synthesis and formulation of our recommendations. After comparing various frameworks and methods, we proposed a performance framework and associated KPIs for DNDi, ensuring that they are robust, effective, and aligned with the organisation's mission as well as global standards and practices. Prior to submitting the final deliverables, we presented the preliminary findings to the partner organisation and incorporated their feedback into the final report.

IV. Key Findings

In this section, we summarise the key findings from the interviews with DNDi and the external organisations as well as providing a brief discussion of relevant indicators proposed by Policy Cures Research. We then discuss potential areas of improvement in DNDi's evaluation framework.

A. Insight from DNDi Leadership and M&E Team

1. Interview with DNDi Leadership

In this section, we summarise the key points from our interview with Thi Hanh Cao, External Relations Director, and Laura Merrill, Senior External Relations Manager, from the Division of External Affairs, at DNDi.¹⁴ They provided a few key points during the interview.

From an impact perspective, there are significant challenges in obtaining data for measuring impact indicators. The leadership understood that donors are generally interested in health impact and economic impact, but so far it has been difficult to measure them due to lack of resources. For example, they discussed the complexity of demonstrating disease elimination. If elimination is happening, the number of treatments administered decreases over time. However, the challenge lies in showcasing such ongoing impact in their current performance framework.

Regarding collecting data for outcome indicators, the interviewers raised a few challenges. One such challenge relates to measuring treatment uptake segregated by diseases given that the same drug could treat multiple diseases within DNDi's portfolio. They found that due to this difficulty, it is challenging to further translate the outcome data into impact level indicators. Another challenge they identified was collecting and analysing disaggregated data on beneficiaries. Collecting data such as gender, age, and ethnicity, is crucial for assessing equity of DNDi's contribution through interventions including treatments, training on clinicians and researchers, and clinical trials. However, collecting disaggregated data poses challenges because there has not been a mechanism set up for such data collection.

From the R&D perspective, one of the biggest challenges lies in measuring the affordability of drugs. DNDi aims to provide affordable drugs at governmental level, yet measuring this indicator remains difficult. Another R&D challenge that relates to equity is

that many of DNDi's phase I studies have been done in the United Kingdom instead of in LMICs. The leadership raised the importance of inclusive partnership and addressing the needs of the populations in the target countries. It is one area they would like to improve on in order to ensure relevance and accessibility of developed treatments for the targeted populations.

From the capacity strengthening perspective, they noted challenges in measuring the quality of training they provided locally. They also have not been able to track the trajectory of the clinicians trained to translate that into future impact.

Lastly, the leadership related several important factors for the research team to consider when making the recommendations. They stressed their values and commitments in gender equity, inclusive partnerships with target countries, shared knowledge and expertise, and advocacy for policy change.

2. Interview with DNDi's M&E Team

We interviewed Kevin Mulama, Senior Monitoring and Evaluation Manager, and Elly Otieno, Monitoring and Evaluation Consultant at DNDi.¹⁵ Recognising that M&E as an important function of the organisation, Mulama acknowledged that the existing M&E mechanism is in its early stage of development. The current M&E function situates under the performance and strategy unit of DNDi with defined roles to operationalise the global M&E framework. However, apart from employing few human resources for the M&E function, DNDi has yet to establish the backend support mechanism, including dashboards, data collection platforms, and standard operating procedures. There remains work to be done in building an M&E department.

Regarding the indicators, DNDi currently has 23 indicators within 9 domains. However, according to Mulama, the quantitative indicators could be improved on to better

showcase DNDi's contribution to the NTD-PDP ecosystem. In addition, he felt that the indicators could be better aligned with DNDi's strategic outcomes. He also pointed out the challenges in the limited scope of some indicators. For example, the indicator regarding phase I studies in LMICs has limited scope for measurement as the numbers are too small. He explained that when the number of conducted studies was limited to one or two, it became challenging to effectively measure the strategic objective. Moreover, he pointed out some other potential areas of improvement in refining the M&E mechanism, including allocation of responsibility and ownership for data collection, data verification, storage, and analysis.

Regarding qualitative impact measurement options, DNDi has explored case studies. However, leveraging case studies effectively for impact measurement seemed to be challenging for them. Bringing various stakeholders together and getting the case study validated by the country governments require a considerable amount of time and effort.

On data collection, Mulama noted a few challenges. When asked about collecting disaggregated data, Mulama acknowledged that there had been difficulties in developing a mechanism to collect gender-disaggregated data. In addition, data collection on the training of clinicians and field staff seemed basic, needing potential improvements in including important metrics such as the quality of the training and other tracking mechanisms to demonstrate sustainability. One of the major challenge is DNDi's dependency on target countries' government and other entities for data collection. Hence, the organisation has limited control over the data, and data verification remains challenging. Lastly, another area of improvement is to develop a platform for data collection, storage and analysis to ensure the safety and the quality of data.

B. Performance Frameworks and Major KPIs from External Organisations

Next, we interviewed several organisations and PDPs involved in global health, including Unitaid, MMV, FIND, the Global Fund, Gavi, and the GPEI, regarding their organisational impact framework and indicators. Each interview is summarised and analysed. Then, we highlighted a few relevant indicators proposed by the organisation Policy Cures Research.

1. Unitaid

We interviewed Ross Leach, Team Lead of Corporate Performance and Impact at Unitaid.¹⁷ Unitaid is a multilateral partnership hosted by the WHO with its own independent board. They have mainly 3 roles in their organisational framework: 1) pathfinder, by identifying areas of investment; 2) investor, by funding clinical research, trials, and drug development, and aiding the acceleration of drug availability to market; and 3) influencer, by connecting different organisations for collaboration. Currently, they manage a portfolio of 1.5 billion USD.

They started building their "result team" in 2015. They now have 11 members within their "result team", divided into two divisions. One division manages the KPIs and grants. The other division focuses on M&E across different portfolios and works with external consulting evaluation teams.

While their prior framework focused on accountability, their current framework focuses on performance. Overall they have a project-level result framework, which includes their theory of change, impact assessment, and the "performance framework". Within their performance framework, they have 3 main categories of goals containing their KPIs—vision/mission, strategic objectives, and operational/organisational areas (Figure 1). In total, they have 25 KPIs, including 4 impact-level KPIs related to their vision/mission, 9 KPIs

related to strategic objectives (Figure 2), and 12 internal KPIs related to operation/organisation (Figure 3) with clear definitions of each KPI.

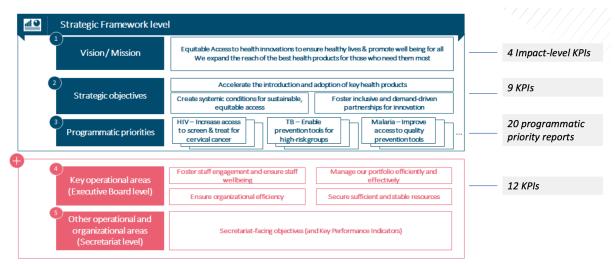


Figure 1. Unitaid's performance framework.



Figure 2. Unitaid's mission strategic objective KPIs.

Key areas	KPI	Description, definition	Target	Results 2022	
Ensure organizational efficiency	A-Secretariat efficiency*	Secretariat costs / Value of Unitaid's portfolio (on 31/12 in a given year)	2%	1.77%	
	B-Secretariat carbon footprint	% reduction of the Unitaid Secretariat carbon footprint compared to 2019 baseline	40% reduction by 2025, on track to meet 50% by 2030	Efforts to be strengthened	
Secure sufficient and stable resources	C- Resource Mobilization	KPI C.1 - Total cumulated US\$ resources committed over strategic period KPI C.2 - % funds secured against multi-year agreements (in value) KPI C.3 - No. of new donors over the strategic period (cumulative)	KPI C.1: USD 1.5 bn KPI C.2: 70% KPI C.3: 3 new donors	 USD 313 m 52% 1 new donor 	
Manage our portfolio efficiently and effectively	D- Speed of grant development	KPI D.1 - Average time taken from GAD kick-off to GAD submission to the Executive Board KPI D.2 - median time from GAD kick-off to submission	KPI D.1: 6 months KPI D.2: no target	8.3 months8.2 months	
	E- Implementers satisfaction	Level of implementers satisfaction reported in the implementers' survey, through 1 question "How would you rate your overall experience with Unitaid?"	75%	90%	
	F- Implementers diversity	% of grants with a lead implementer that is from the Global South (LICs & MICs)	40% by end of the strategy	16%	
Foster staff engagement and ensure staff wellbeing	G- Secretariat gender equality	Percentage of women in management positions (P5 and above)	45-55%	45%	
	H- Staff satisfaction & wellbeing	KPIH.1 - Level of staff satisfaction, as reported in the staff survey, through 5 questions KPIH.2 - Ability for staff to manage their work-life balance, as reported in the staff survey, through 1 question "I am generally able to balance my work and my personal responsibilities while maintaining a healthy lifestyle."	KPI H.1: 75% KPI H.2: 75%	74% 69%	

Figure 3. Unitaid's organisational KPIs.

Importantly, they have impact-level indicators that align with their vision and mission: health and economic impact indicators, return on investment, and accelerating health service delivery. Under the strategic objectives, the 9 indicators also align with their 3 major objectives: 1) accelerate the introduction and adoption of key health products, 2) create systemic conditions for sustainable and equitable access, and 3) foster inclusive and demand-driven partnerships for innovation. Lastly, for their operational and organisational KPIs, they cover key areas such as organisational efficiency, resource mobilisation, portfolio management, and staff satisfaction. Using its existing performance framework, Unitaid is able to demonstrate the direct impact of its grant activities, as well as the indirect impact of scale-up of the grant activities.

Regarding the methodology for their KPIs, they obtain most of their data from projects and clinical trials that receive grants from the organisation. One of their KPIs focuses on building relationships with other organisations for data sharing. As part of their M&E framework, they involve external evaluators to do some primary data collection. The evaluations are guided by Unitaid's evaluation framework, which is based on the OECD DAC evaluation principles and evaluation criteria (Figure 4).¹⁸

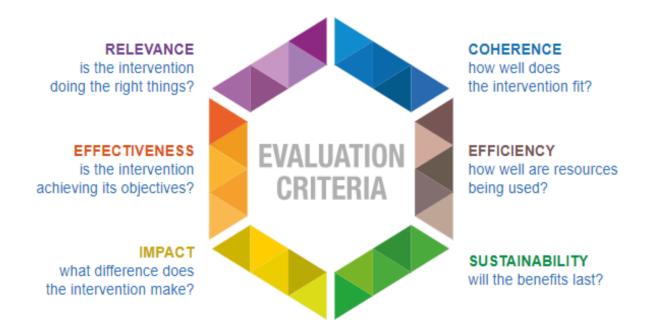


Figure 4. OECD DAC evaluation criteria.

In addition to using their performance framework to demonstrate their impact, they also utilise case studies to showcase their results, relying on reports and data from the WHO and the Global Fund. For example, they conducted a case study on promoting the HIV drug dolutegravir. Through their work, they were able to demonstrate their impact on accelerating equitable access to this drug for the treatment of HIV. Another example is their case study on the next generation bed nets, Intercept® G2, which demonstrated significant impact including nearly reducing cases of malaria by half compared to standard nets.

In summary, Unitaid has a clearly defined theory of change, result framework, and performance framework. They have a succinct list of 25 goal-oriented KPIs that align with their organisational vision and mission. Their case studies further showcase their impact in the global health sector.

2. Medicines for Malaria Venture

We interviewed Dr. Céline Audibert, Director, Market research, access and product management at Medicines for Malaria Venture.¹⁹ MMV is a leading PDP working to deliver a global portfolio of accessible and affordable medicines with the power to treat, prevent, and eliminate malaria. Their four strategic objectives are curing patients (developing new and simplified therapies), preventing infections (preventive drugs and campaigns), eliminating malaria (solutions to reduce parasite loads) and beyond malaria (supporting other disease areas).

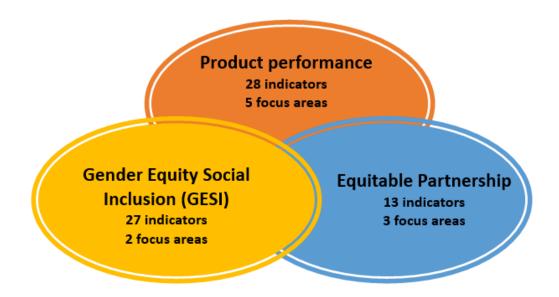


Figure 5. MMV's impact framework pillars.

MMV has an existing impact framework which revolves around three pillars of product performance, gender equity social inclusion, and equitable partnership. The pillar on product performance is the most advanced and frequently used framework by MMV. The pillar on gender equality and social inclusion was most recently added in June 2023. While MMV has a total of over 60 indicators across these 3 pillars, they have identified 28 priority

indicators to focus on. MMV has developed the indicators after a detailed consultation process with the MMV team, partners, and donors. They have also hired a technical agency CEPA to develop indicators and a modelling framework for them to measure the indicators. Even though MMV does not have a big M&E team, they keep an organisational repository called PINK, where the MMV staff can access the developed modelling framework which can be updated by the MMV team.

The methodology they adopted is to start from the volume of products sold such as information obtained from the manufacturers supported by MMV, triangulated with other data sources like President's Malaria Initiatives (PMI), the Global Fund, and IQVIA, then apply the transformation factor that translates the volumes into the number of lives saved. Applying the transformation factors allows MMV to estimate the number of saved and keep the benchmarking with reports from other organisations like Unitaid and the WHO. This enables them to calculate the number of people receiving products based on the modelling framework, which then can be translated into impact. For example, to measure impact, they examine the efficacy of clinical trials and utilise that to estimate the number of lives saved and DALYs.



Figure 6. MMV's modelling framework.

MMV is also keen on understanding their impact on R&D by measuring their contribution to the scientific literature. They measure the volume of publications and the impact factor of the journals. There is no primary data collection involved in institutionalising and operationalising MMV's impact framework. Instead, a well-designed model based on existing literature and rational assumptions helps MMV to measure its impact across 28 indicators. Another interesting aspect of MMV's impact framework is that it calculates both

absolute and relative impact. Measuring absolute impact involves comparing to an assumption if nothing existed, while measuring relative impact involves comparing how MMV's product is better and what added benefit the product brings to existing landscape. In 2023, it was estimated that 109 million people have received an MMV-supported product, averting 1.8 million deaths in absolute terms and 215,000 averted in relative terms.

Impact Measurement Landscaping

MMV performed an impact measurement landscaping in 2019 as the first step in developing its impact framework. The exercise critically analysed how MMV's impact had been measured until 2019 and how others in the PDP space measure their impact. They selected an external technical partner, CEPA, to develop models and indicators. CEPA conducted extensive interviews with MMV stakeholders and organised a consultation workshop to review the long list of draft indicators to provide a rough ranking of priorities.

MMV's Indicator Assessment Framework

After repeated iterations and discussions using a table of indicator evaluation (Figure 7), MMV finalised their indicators and institutionalised them.

	Volume sales		Manufacturing		Supply security		Policy	Community access		Prices	
	# of volumes sales / treatments by product	% of cases that received treatment	# or % of producers of malaria products in MECs	% of products produced in MECs	# of / % of suppliers supported by MMV	# and range of activities to boost supply security	Product registrations and guideline updates	% of health facility with no stock out of malaria commodities	Improved access to IPTp	# Healthcare workers trained	Price trends of MMV- supported drugs
Suggested Inclusion	Yes	No	Yes	No	Yes	No	Yes	No	?	Yes	Yes
Suggested Priority	н	-	м	-	м	-	м	-	?	н	L
Ease of understanding	н	н	н	н	н	м	м	н	м	н	н
Level of effort	м	н	L	м	L	L	L	н	L	L	м
(Expected) magnitude	н	L	L	L	L.	L	м	м	м	м	м
Level of MMV control	м	L	н	м	н	н	м	L	L	н	L.
Robustness/ Uncertainty	м	L	н	н	н	м	н	L	м	н	м
Integrated / used by others	н	ι	м	L	м	L	н	ι	м	н	м

Legend: H=High, M=Medium, L=Low; The traffic light system interprets the assessment in terms of taking an indicator forward: red indicating argument against indicator, green argument for and orange neither

Figure 7. MMV's indicator assessment framework.

In summary, MMV has a robust strategy framework, clearly defined theory of change, and an impact framework with 28 priority indicators across three pillars that align with their organisational strategy.

3. FIND

FIND is a renowned organisation in the global health sector, specialising in the development of diagnostic products. Our team interviewed Dr. Brooke Nichols, the Senior Director of the Impact Department at FIND, who specialises in mathematical modelling and health economics.²⁰

One notable aspect of FIND's Impact Department is its uniqueness among global non-governmental organisations (NGOs). Typically, impact assessment is managed by a single person, but FIND's Impact Department not only conducts impact measurement but also helps the organisation decide which projects to focus on to maximise impact. This internal setup allows them to more effectively assess and optimise the diagnostic tools. Having a dedicated impact assessment modeller or team can significantly enhance the impact of various investments.

FIND's impact assessment framework is built around three main pillars: "Design It", "Build It", and "Use It". In the "Design It" phase, FIND emphasises creating a diagnostic R&D agenda that meets the needs of LMICs. They conduct annual multi-level surveys to directly gather feedback from these countries and communities, rather than focusing solely on the interests of international donors. This approach ensures that the R&D agenda aligns with actual needs of the users, thereby making the R&D process more relevant and effective.

In the "Build It" phase, FIND focuses on innovation, not just seeking minor improvements to existing molecular diagnostics but aiming for significant breakthroughs. They define what innovation means in their context, including the use of artificial intelligence and digital tools. Their goal is to create diagnostic products that represent substantial changes rather than repetitive iterations of existing technologies.

The "Use It" phase ensures that developed diagnostic products effectively meet the real-world needs of the communities they are intended to serve. FIND is actively refining their access strategy and determining appropriate assessment indicators. By considering creating TPPs based on solid evidence, such as models, they aim to ensure these TPPs reflect actual diagnostic needs.

To assess the impact of their diagnostic products, FIND uses various KPIs, primarily focusing on health and economic indicators. For health indicators, FIND uses DALYs to assess the effectiveness of their diagnostic products in improving public health. In terms of economic indicators, they have started calculating ROI for certain projects, such as the impact report for South Africa. But it has not been fully implemented across all projects yet.

During the impact assessment process, FIND faces several challenges and has proposed corresponding solutions. The primary challenge in data collection comes from obtaining sales data from manufacturers. Manufacturers usually know how many drugs or diagnostic tools they have produced but are not always willing to share this data. To ensure sustainable data acquisition, FIND includes clauses in contracts requiring manufacturers to provide distribution numbers for several years. Another challenge is the complexity and uncertainty in evaluations. Because they cannot control the clinical environments where diagnostic tools are used, they must make numerous assumptions when assessing the actual impact of these tools, increasing the complexity of their evaluations. FIND's economic impact assessment relies on product usage data from manufacturers and disease burden data from the WHO. When manufacturers do not provide specific country distribution data, assumptions are made based on the distribution of the disease burden. Although this method is not perfect, it offers a feasible solution when detailed data is lacking.

As FIND transitions from being a primary PDP to a more comprehensive PDP-plus organisation, this involves not just developing products but also focusing on broader impact assessment and optimisation. They recognise that measuring success solely by the number of products developed is insufficient; they must evaluate the actual health outcomes of their products. Based on the interview, DNDi could start by defining the intended use and objectives of the impact assessment framework, then back-calculate the necessary indicators and data to ensure that the framework effectively measures and demonstrates the project's impact. FIND acknowledges the challenge of comprehensive systematic data collection but suggests simplifying this process by using key data points.

Dr. Nichols believes that establishing a professional impact assessment team is feasible, though it is not an immediate process and requires time and experience. It took FIND two years to reach their current level of assessment capacity. Through collaboration

with professionals, DNDi can conduct more effective impact assessments, ensuring their projects maximise public health impact.

4. The Global Fund

We interviewed Richard Grahn, Senior Policy Analyst of Programmatic Results and Impact, Programmatic Monitoring and Risk Department at the Global Fund.²¹ The Global Fund is an innovative financing and partnership model that supports country-led programs, promotes accountability, and champions equity and rights in the fight against HIV, tuberculosis, and malaria.

The Global Fund employs performance frameworks as a key part of its M&E approach. Each country develops a performance framework as part of their grant agreement with the Global Fund. These frameworks include standardised indicators chosen from a predefined list approved by the Global Fund, covering inputs, outputs, and some outcomes related to service delivery, intervention coverage, and health system performance. Countries set annual targets for these indicators, which are then monitored to track grant performance. The use of standardised indicators across countries allows the Global Fund to aggregate data from the country performance frameworks and report overall results and progress at the global level.

The Global Fund employs a comprehensive results reporting framework to demonstrate the impact of its investments across countries and disease areas. The core of this reporting is based on the performance frameworks developed for each country grant. Countries report data on these indicators to the Global Fund, reflecting the overall national results achieved in areas where the Global Fund invests, rather than solely the outputs of Global Fund-specific projects. This data is then aggregated and published annually in the Global Fund's Results Report, showcasing indicators across its entire portfolio. The Global Fund is careful to frame these results as "programmatic results achieved by countries and regions where the Global Fund invests", acknowledging that the progress is a combined outcome of the Global Fund investments along with domestic funding and other sources.

The Global Fund employs disease transmission modelling to complement the result reporting. In collaboration with academic partners, the Global Fund utilises models to estimate the potential impact of its investments in HIV, tuberculosis, and malaria interventions across supported countries. These models aim to quantify counterfactual scenarios, such as the number of deaths or infections averted due to the scale-up of interventions like antiretroviral therapy or bed net distribution, compared to a hypothetical scenario without these interventions. The modelling exercises help translate raw impact data into tangible outcomes like lives saved, which can be powerful for advocacy purposes and demonstrating the need for continued or increased funding from global donors.

Furthermore, the Global Fund has an independent Evaluation and Learning Office that conducts in-depth impact evaluations at the country level, separate from the routine programmatic monitoring done through the performance frameworks. The evaluation topics are chosen based on strategic priorities, evidence gaps, or requests from the Global Fund Board. These independent evaluations go beyond routine monitoring data to offer an in-depth understanding that can feed into learning and course corrections for the Global Fund's future strategies and policies. The evaluation reports are published on the Global Fund's website for transparency and accountability. While the country performance frameworks track real-time program execution, the independent Evaluation Office takes a step back to comprehensively evaluate impact, outcomes, and lessons that can strengthen the Global Fund's overall model and approach in different contexts. This two-pronged M&E system provides both continuous tracking as well as periodic in-depth assessments.

5. Gavi, the Vaccine Alliance

We interviewed Binay Kumar, Senior Program Manager of Grant Performance Monitoring at Gavi, the Vaccine Alliance.²² Gavi is a global health organisation dedicated to increasing immunisation rates in low-income countries. Gavi collaborates with partners such as the WHO, UNICEF, and the World Bank, using standardised global data collection and reporting to ensure the implementation and monitoring of its vaccination programs.

The selection of indicators reflects the organisation's mission, vision, and theory of change. As an alliance, Gavi's strategic goals and corresponding indicators are developed in collaboration with core partners such as WHO and UNICEF. These indicators align closely with Gavi's theory of change, and they are detailed in their strategic documents available publicly. Gavi's indicator framework includes Mission Indicators, Vaccine Goal Strategy Indicators, Equity Goal Strategy Indicators, Sustainability goal strategy indicators, and Healthy Markets Goal Strategy Indicators (Figure 8).



Figure 8. Gavi Strategy 2023-2025.

Gavi's Monitoring, Evaluation, and Learning Team is an independent team based at the Geneva Secretariat. While Gavi relies on existing global data, this team designs data pipelines to collect and analyse data from various global sources to support strategic goal evaluation. M&E functions are spread across different "vertical" business units, which each have their own M&E functions during project implementation. Gavi does not have specific M&E personnel in each country; instead, it relies on partners to carry out these functions.

Gavi primarily relies on existing global data rather than collecting primary data. It uses established global data reporting mechanisms such as mortality data, vaccine coverage data, and administrative data from joint reporting forms. The quality of information received from countries is a major challenge, as data quality determines which indicators can be used for reporting. Data verification is closely linked to data quality; higher data quality reduces the need for verification. Another challenge is that interventions may vary by country, making it necessary to rely on additional country-level measurements to understand if interventions are successful. This brings challenges related to resources, methodology, timing, and data collection cycles. Additionally, investing in health system strengthening presents significant challenges, particularly in establishing a clear chain of results. For instance, while a country may prioritise investment in improving its information systems and see certain outcomes, it is challenging to precisely measure the specific changes resulting from this investment.

With regard to gender and climate indicators, Gavi focuses on identifying and understanding gender barriers and implementing measures to address these barriers rather than directly measuring improvements in gender equality. Moreover, Gavi's strategic framework does not explicitly include climate-related indicators because this is not part of its primary mission. However, climate considerations are factored in, especially when working

with service providers where environmental and climate impacts are criteria for partner selection.

Gavi employs both quantitative and qualitative methods in their M&E framework. Although quantitative indicators are excellent for showing trends and the scale of interventions, they do not detail the specific processes and reasons behind changes. Qualitative methods can provide these in-depth insights, illustrating how changes occur and what factors contribute to these changes. Gavi uses qualitative methods such as case studies, audio, and video recordings to fill gaps where systematic data is insufficient. These methods help demonstrate project successes and challenges through specific stories and examples, covering areas that quantitative data cannot. While some donors focus more on quantitative data and ROI, qualitative data also holds unique value. By using case studies and videos to show project impacts, Gavi supplements quantitative data, providing a more comprehensive project evaluation.

6. The Global Polio Eradication Initiative

We interviewed Dr. Andrew Kennedy, Head of the Executive Management Unit of the Global Polio Eradication Initiative to gain insights into their impact evaluation framework.²³ The GPEI's primary goal is the eradication of polio, tracked through the number of polio cases and environmental samples indicating the presence of the virus. This straightforward measurement approach focuses on reducing these indicators to zero. Additionally, the impact of their vaccination efforts is assessed through health and economic benefits, such as DALYs and healthy life years gained. These metrics help illustrate the broader benefits of the vaccination program beyond just reducing polio cases. Data collection in the Polio program is robust, with a surveillance system that quickly reports cases from the district level to the global level. This system includes both primary data collection and modelling to assess

economic impact. Unlike other health programs where data collection can be delayed, the Polio program's surveillance system ensures timely reporting and action.

KPIs are used extensively in the Polio program for various purposes, including donor reporting and internal management. However, he noted that many KPIs are being reassessed for their relevance, with a shift towards a risk and performance framework that offers more actionable insights. They emphasised the importance of aligning KPIs with the organisation's operating model and decision-making processes to ensure they are useful and relevant. Also, the meeting highlighted the value of case studies in demonstrating the program's impact, complementing quantitative data. These case studies provide detailed insights into specific challenges and successes, making them valuable for engaging donors and illustrating the program's real-world effects.

Environmental and sustainability considerations are increasingly important in the Polio program. Efforts are underway to develop an environmental framework to address issues like vaccine disposal and campaign logistics. Additionally, the program focuses on transitioning responsibilities to national health systems, aiming for sustainability as the program plans to close by 2029. Training and local involvement are critical to the success of the Polio program. Training is often conducted on-the-job, and the effectiveness of vaccination campaigns is a testament to the quality of training. Local personnel play a crucial role, offering trusted and respected connections within communities, which enhances the program's effectiveness.

Innovations in R&D are also part of the Polio program's strategy, with efforts to develop new vaccines with fewer side effects. The broader impact of these innovations is assessed through frameworks like Payback Analysis. The meeting also discussed the importance of staff engagement and addressing gender-specific challenges, especially for female frontline workers. The Polio program uses agency-specific surveys and targeted

exercises in countries with known engagement issues to assess staff satisfaction and address challenges.

7. Policy Cures Research

The report "Investing in Global Health R&D: An Impact Assessment Framework" by Policy Cures Research aims to assess the impact of two decades of investment in global health R&D for NTDs.¹⁶ They produced diverse and consensus-driven priority indicators, consisting of the most important and compelling measures of success in global health R&D investment.

They propose 8 domains of impact framework indicators: research activity, research output, knowledge creation and sharing, human and organisational capacity, access enablers, access outcomes, health impact, and economic impact (Figure 9). We highlight some compelling indicators proposed by Policy Cures Research that could be considered in DNDi's performance framework.

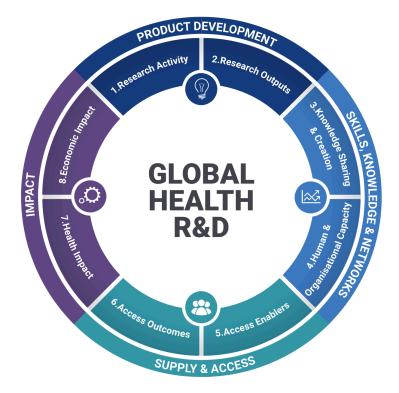


Figure 9. Eight measurement domains proposed by Policy Cures Research.

Within the research activity domain, Policy Cures Research proposes an indicator to evaluate the time between successful trial phases. This is a compelling indicator to consider for DNDi as it would align with their theory of change to accelerate their impact.

For the health impact domain, Policy Cures Research suggests evaluating the effectiveness of interventions using indicators such as DALYs, averted, number of deaths averted, case detection rate, and reduction in major clinical events. Introducing health impact indicators like DALYs averted would not only underscore the effectiveness of their products but also aid in securing further research and development funding.

Economic impact indicators are important for investors since donors in general are interested in economic returns and cost-savings. Policy Cures Research proposes to assess direct and indirect savings to healthcare costs, and return on investment. While comprehensive economic impact assessments can be resource-intensive, they are critical for illustrating the cost-effectiveness and broader societal value of interventions.

C. Potential Areas of Improvement in DNDi's Performance Framework

The document "DNDi Global Indicators Inventory" provides information on indicators used by DNDi to evaluate its activities. When comparing DNDi's indicators with other organisations, we identified a few potential areas of improvement.

The first area of improvement identified is the way the indicators are structured. Currently, the indicators are organised into activity domains without specific goals linked to them. The way the indicators are organised could be improved to make them more purposeful to DNDi's objectives. Secondly, because DNDi is an organisation that focuses on R&D, they focus inputs, outputs, and outcome indicators in its current evaluation framework. There have been challenges for them to obtain necessary data to measure its health and economic impact.

Another area of improvement we identified is an abundance of quantitative indicators over qualitative indicators. The existing indicators appear to be predominantly quantitative. The addition of some qualitative indicators would capture subtler aspects of impact, such as stakeholder satisfaction and quality of partnerships.

V. Recommendations for DNDi

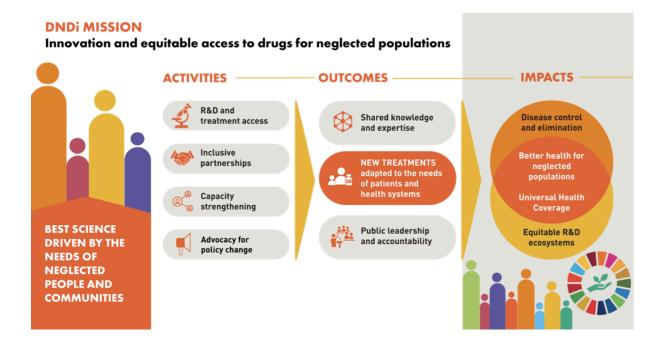
We developed 3 main proposals for DNDi. First, we propose a "performance framework" for the organisation that aligns with their new theory of change and narrative. Next, we propose a list of KPIs under the performance framework, by reorganising and revising their existing KPIs in addition to proposing a few new indicators that we think could be valuable to DNDi. Lastly, we propose a starting point for the organisation to finetune our proposed KPIs and to create a long-term impact or result team.

A. Performance Framework Aligned with DNDi's Theory of Change

Different organisations use different terms for their assessment framework. These include "M&E framework", "evaluation framework", "impact framework", "impact assessment framework", "measurement framework", "performance assessment framework", and "performance framework". We propose to use the term "performance framework" because it encompasses a broader scope of the entire assessment framework, from assessing impact with impact-level KPIs, outcomes and output levels with M&E, to internal organisational KPIs. It is the term used by Unitaid and TDR, the Special Programme for

Research and Training in Tropical Diseases sponsored by the WHO in the most recently updated framework report for 2018-2023.²⁴

Under the performance framework, we identified goal-oriented KPIs that align with the organisation's mission. An important question to consider when deciding what KPIs to include for an organisation is the goal of the indicators. Several interviewees stressed the importance of having a goal for each indicator as the starting point in designing the indicator list. From there, we examined DNDi's most current theory of change and narrative (Figure 10).



THEORY OF CHANGE DNDi LEADING TO THESE IMPACTS TO ACHIEVE THESE OUTCOMES DNDi IMPLEMENTS THE FOLLOWING ACTIVITIES TO DELIVER THESE OUTPUTS artner with patients and o eeds and realities (1, 2, 4) 01. An R&D portfolio of the compounds is managed to meet needs of neglected patients, communities, and health program endemic countries (A, C) A2. Discover and develop drug candidates and drugs with partners using the best science (1, 2, 3, 4) A3. Produce data and evidence through drug R&D and enternic countries (n, c) O2. Researchers, patients, communiauthorities in endemic countries collaborate in active, equitable partnerships that advance the dr development process (A, B, C) mplementation science to support registration, inform ted to the treatment guideline revisions, and guide treatment use (1, 2, 4) es and of patients and co Partner with science, academic, R&D, and industry stakehol in endemic countries, supporting their capacity to conduct end-to-end drug development (2, 3, 4, 5, 7) ed Universal Health Coverage en and children reach the SDGs registered, and used 03. Capabilities and infrastructure to A5. Establish and maintain partnerships and collaborative platforms with science, academic, R&D, industry, governm and civil society actors to drive research and access outco forward (1, 2, 3, 4, 7, 8) rated elimination and control lected and climate-sensitive es aligned with the WHO NTD conduct drug R&D and registration in endemic regions are enhanced (A, B, C) 04. Health system actors, including Roadmap communities, are engaged to pro treatment and diagnostics (A, C) A6. Engage national/regional, finance, and industry stakeholders for sustainable and timely supply of affordable and accessible se are re sustainable, equitable, and O5. Manufacturers have incentives for sustainable supply at affordable prices (A, C) treatments and diagnostics for neglected patients (3, 4, 5, 6) shared foll wing principles of open R&D e cience and transparency, particularly A7. Strengthen clinical trial capacity in countries where we have nic countries activities (1, 2, 3, 4) 06. Funds are allo ated for **purchase of** d diagnostics (A, C) A8. Strengthen regulate activities (1, 2, 3, 4) treatments and diag 07. Increase geographically diverse leadership (governments, researchers, and communities) in global R&D decision A9. Develop a dynamic portfolio of new diseases and new with gover nments to meet evolving public health needs (1, 2) making, priority set allocation (C) tting, and resource Policy makers are mobilized and accountable to enable and sustain equitable and inclusive R&D system for priority public health needs A10. Partner with organizations that strengthen human resource International and national **R&D norms**, standards, laws, and policies are in place to enable needs-driven, open, transparent, collaborative R&D processes, with equitable access embedded end-to-end (C) capabilities and infrastructure for drug R&D and treatment registration in areas where they are lacking (2, 3, 4) A11. Advocate for systemic policy change for sustainable, equitable, and inclusive R&D (2, 3, 4, 5, 6, 7, 8)

Figure 10. DNDi's updated theory of change.

We identified that DNDi's mission is to deliver equitable access to drugs for neglected populations starting from the people and community needs. They aim to have an impact on patients and their communities by delivering affordable treatments and enabling them to develop their full potential. They also aim to have an impact on national health systems that can provide Universal Health Coverage to its population by delivering access to the product at primary healthcare level, which in turn contributes to the elimination of diseases as defined by the WHO NTD roadmap. To demonstrate the impact of the mission, we designated a mission level list of impact indicators under the performance framework (Figure 11). Then we examined DNDi's proposed narrative including their principles, pillars, and goals. We felt that the best way to organise KPIs is to structure them according to their strategic objectives, in other words, by linking the KPIs to their goals instead of domains. Using the updated DNDi narrative, we streamlined their principles and pillars into 3 overarching strategic objectives: **1) R&D and access to needs-driven treatment, 2) inclusive partnerships and**

capacity strengthening, and **3) shared knowledge, expertise, and policy change**. Below the strategic objective level is the organisational and operational level of KPIs. We then reorganised DNDi's existing KPIs into those 3 strategic objectives and organisational/internal operations category with suggested modifications for certain KPIs.



Figure 11. Proposed performance framework for DNDi.

B. Proposed KPIs Aligning with the Performance Framework

In this section, we discuss the KPIs selected for each level of the performance framework in detail, from the rationale to the methodology. First we discuss the 7 impact-level KPIs selected to align with DNDi's mission of innovation and equitable access to drugs for neglected populations, followed by discussion of the KPIs within the 3 strategic objectives, and lastly the organisational and internal operational KPIs.

1. Impact-Level KPIs

We have identified 7 impact-level indicators spanning 3 domains: health, economic, and accelerating impacts (Figure 12). Under the health domain, we have chosen 4 indicators, including disability-adjusted life years (DALYs) (indicator 7.1 by Policy Cures Research), number of lives saved or death averted (indicator 7.4 by Policy Cures Research), number of

cases averted (indicator 7.6 by Policy Cures Research), and percentage change in the burden of disease (indicator 7.3 by Policy Cures Research).¹⁶ The indicator DALYs is a very critical standardised unit of measure for assessing portfolio-wide impact across a diverse range of diseases and product areas. The indicator 'number of lives saved' closely aligns with DNDi's strategic objectives—innovate to save lives—hence important to measure. In addition, this indicator highlights the human impact of DNDi's treatments, advocating for public health prioritisation, communicating the effectiveness of the interventions, and creating increased demand for NTD treatments. In summary, all of these newly suggested indicators are closely aligned with DNDi's mission and strategic objectives such as innovating to save lives, advocating for policy change, and promoting equitable access. In addition, these indicators hold significant potential to capture and showcase DNDi's impact in creating public goods in the NTD landscape, thereby strengthening the health systems.



Figure 12. Proposed impact indicators.

The economic impact indicators include savings to healthcare costs from health impact (indicator 8.1 and 8.2 by Policy Cures Research) and return on investment (indicator 8.5 by Policy Cures Research).¹⁶ The former indicator measures the direct or indirect impact

of DNDi's treatments on total healthcare spending on the patient population, including savings from averted admissions and readmissions in healthcare facilities, shorter treatment duration, less expensive treatment options, shorter hospital stays, reduced morbidity, cost in healthcare workforce, while the latter measures the net benefit delivered by DNDi's treatments divided by its initial cost. Both of these indicators are aligned with the DNDi strategic objectives such as advocating for policy changes and promoting equitable and affordable access. These indicators would help the organisation to showcase its impact in economic terms and attract new investments in the NTD-PDP landscape.

Lastly, in alignment with DNDi's impact mission to accelerate elimination and control of neglected diseases, we proposed to include the indicator "accelerating the global health response". This indicator measures the extent to which key products accelerate the delivery of mission objectives. It may be obtained by counterfactual modelling.

2. Strategic Objective KPIs

a. R&D and Access to Needs-Driven Treatment

Below the mission level, we proposed 3 strategic objectives that align with DNDi's narrative (Figure 11). The first strategic objective is "R&D and Access to Needs-Driven Treatment", where DNDi aims to conduct research and development activities to create new health technologies, products, and innovations that adapt to the needs of underserved populations affected by neglected diseases. Under this objective, we recommend 9 KPIs including one revised indicator and one new indicator (Figure 13). We suggest revising the existing indicator measuring innovations around DNDi R&D agenda (indicator ID 4.5) into "Scale and Uptake of Innovations across the R&D Lifecycle", measuring the percentage of new/existing partnerships or projects that have successfully scaled up or enabled widespread uptake of an innovative technology introduced to DNDi's portfolio at any stage of the R&D

lifecycle (from discovery to access), such as a new drug delivery technology, artificial intelligence method, drug modality, or other innovative approach. This revised indicator captures not only the introduction of innovations but also their successful scale-up and uptake, which is crucial for sustainability and impact. It is measured as a percentage to provide a standardised metric across DNDi's diverse portfolio.

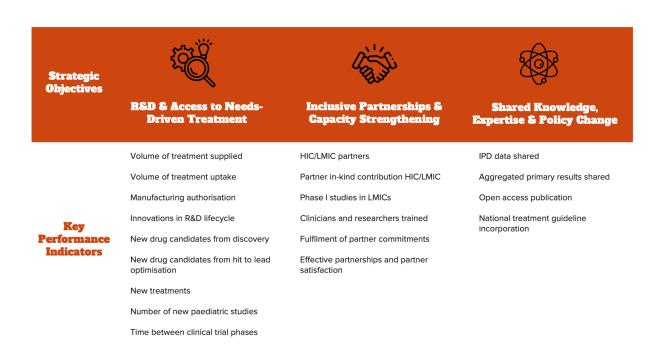


Figure 13. Three strategic objectives with their associated KPIs.

In addition, a new indicator we would like to add under this strategic objective is "time between clinical trial phases", which is indicator 1.12 proposed by Policy Cures Research.¹⁶ This indicator measures the average time between the successful conclusion of a clinical trial and the commencement of a subsequent clinical trial at a progressed clinical trial phase. We are proposing this indicator because it provides insights into the efficiency of the clinical development process and has the potential to show where in the process investment may be more effective in accelerating progress and reducing waiting times. We felt that this indicator is worthwhile to include because it aligns with DNDi's accelerating impact mission.

The other 7 indicators within this objective are not revised from the current DNDi's global indicators inventory besides minor recommended renaming, including:

- Volume of treatment supplied [ID 9.2]
- Volume of treatment uptake [ID 9.2]
- Manufacturing authorisation [ID 9.1]
- New drug candidates from discovery [ID 2.1]
- New drug candidates from hit to lead optimisation [ID 2.2]
- New treatments [ID 4.4]
- Number of new paediatric studies [ID 4.1b]

These KPIs aim to quantify the output and outcome of DNDi's R&D activities, such as the volume of treatments delivered, accessibility in target countries, innovations introduced, and new drug candidates and treatments developed. The indicator on the number of new paediatric studies in particular aligns with DNDi's goal to address the needs of the affected populations.

b. Inclusive Partnerships and Capacity Strengthening

Our second proposed strategic objective is "Inclusive Partnerships and Capacity Strengthening". This objective focuses on fostering inclusive partnerships and strengthening capacity to achieve global health equity and sustainability. Under this goal, we recommend 6 KPIs, including a revised indicator and a new indicator.

We suggest replacing the existing indicator measuring the number of strategic advocacy partners engaged by DNDi (indicator ID 5.1) by a new proposed indicator, "effective partnerships and partner satisfaction", measuring the quality and effectiveness of the partnerships instead. We find it a more meaningful indicator assessing the actual quality and effectiveness of partnerships rather than measuring the sheer number of partnerships without knowing the nature of the partnerships.

The new indicator is "Fulfilment of Partner Commitments", measures the extent to which DNDi partners meet their funding commitments for specific projects. This indicator is crucial as it reflects DNDi's effectiveness in fundraising and project execution. By ensuring that partners fulfil their commitments, DNDi can maintain financial stability and project continuity. Organisations like Gavi and the Global Fund also use similar indicators.

The other 4 indicators remain unchanged from DNDi's current global indicator inventory besides recommended minor renaming, including:

- HIC/LMIC partners [ID 1.1]
- Partner in-kind contribution HIC/LMIC [ID 1.2]
- Phase I studies in LMICs [ID 3.5]
- Clinicians and researchers trained [ID 3.2b]

By tracking these KPIs, DNDi can effectively monitor progress towards the second proposed strategic goal.

c. Shared Knowledge, Expertise, and Policy Change

Under the third strategic objective of "Shared Knowledge, Expertise, and Policy Change", we kept 4 existing indicators and proposed to remove one. We recommend removing the indicator "key lessons shared" (indicator ID 5.2). This indicator appears to be difficult to measure as policy change usually takes time to achieve. At the present moment, the indicator also remains in the definition stage with challenges to obtain data. Therefore, we propose to remove this indicator.

Otherwise we kept 4 existing indicators listed below by minor edits to their names:

• IPD data shared [ID 6.1a]

- Aggregated primary results shared [ID 6.1b]
- Open access publication [ID 6.1c]
- National treatment guideline incorporation [ID 8.1]

The indicator "open access publication" is critical to measure as it showcases DND's impact in the scientific community and aligns with DNDi's theory of change and strategic objectives. The indicator "IPD data shared" assesses DNDi's efforts in promoting data sharing and contributing to the global research community by making clinical trial data accessible for further analysis and validation. The indicator "aggregated primary results shared" evaluates DNDi's performance in making primary clinical trial results accessible to the public and ensuring timely reporting in alignment with best practices for clinical trial transparency. Lastly, the indicator "national treatment guideline incorporation" measures the extent in which DNDi is able to influence registration of treatments in target countries via policy and advocacy efforts.

3. Organisational and Internal Operational KPIs

Lastly, we reorganised the rest of DNDi's existing indicators that are relevant to organisational and internal operations into the "organisational and internal operations" category with minor renaming. We also proposed to add a new indicator for a total of 6 KPIs within this level (Figure 14).

The 5 existing organisational and internal operation indicators are as follows:

- Leadership equity in country economy [ID 3.1a]
- Leadership equity in gender [ID 3.1b]
- Lead author gender equity [ID 3.4]
- Fundraising [ID 10.1]
- Carbon footprint reduction [ID 11.1]

We agreed with their values and purposes for the organisation. While being internal indicators, they align well with the organisation's narrative and goals. For example, KPIs "leadership equity in country economy", "leadership equity in gender", and "lead author gender equity" all align with the organisation's principle on equity. And "carbon footprint reduction" KPI demonstrates the organisation's commitment to the climate. One additional organisational KPI we thought is important is "staff satisfaction and wellbeing". A successful organisation requires having dedicated staff passionate about their work with good work-life balance. We believe that it is important for DNDi to include this new indicator in their performance framework to foster a collegial working environment that promotes work-life balance.

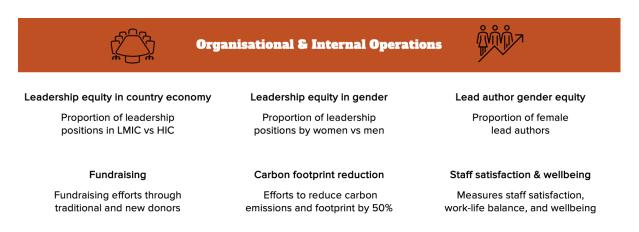


Figure 14. Proposed 6 "organisational and internal operations" KPIs.

C. Consultation Workshop and Creation of an Impact Team

Consultation Workshop

The research team has done an impact measurement landscaping to find how others measure their impact. In our analysis, MMV has turned out to be one of the closest models to DNDi in the PDP landscape. DNDi can adopt MMV's approach in fine-tuning the suggested performance framework and KPIs to make them more closely aligned with the organisational strategy and theory of change. DNDi could organise a consultation workshop with its internal

stakeholders, donors, partners and other relevant stakeholders to review the list of indicators and collect feedback. Based on the feedback, DNDi can develop a ranking of priorities using relevance, feasibility, ease of understanding, level of effort, level of DNDi control, and robustness as criteria. Further, through repeated iterations and brainstorming, DNDi could co-create the final list of impact indicators. Once the performance framework is finalised, the organisation could streamline its processes to create a dashboard or repository for indicators and implement a system for regular updates.

Creation of an Impact Team

DNDi can enhance its impact assessment framework by considering two distinct models: MMV's external consulting firm model and FIND's internal team model. MMV developed its indicators through detailed consultations with its team, partners, and donors, and hired CEPA, a technical agency, to develop indicators and a modelling framework. Despite having a small M&E team, MMV maintains an organisational repository called PINK, where staff can access and update the modelling framework, ensuring flexibility and adaptability. This model's advantages include leveraging external expertise for rapid development of complex frameworks and continuous improvement through diverse inputs. However, it may result in weaker internal capacity building, and external models may not always align perfectly with internal needs.

In contrast, FIND has a unique internal setup with a dedicated Impact Department that not only measures impact but also helps decide which projects to focus on to maximise impact. The advantages of this model include building internal expertise, better alignment between impact measurement and organisational goals, and a more sustainable, integrated approach to continuous improvement. However, establishing such a professional impact assessment team is time-consuming and resource-intensive, as evidenced by FIND's two-year timeline to reach its current capacity.

Dr. Nichols believes that establishing a professional impact assessment team is feasible but requires time and experience. Therefore, DNDi could consider a hybrid approach, combining elements of both models. In the short term, DNDi can collaborate with an external consulting firm to develop a robust impact assessment framework quickly. Over the long term, DNDi can gradually build an internal impact assessment team to ensure sustainability and continuous improvement.

VI. Conclusion

This research project aimed to refine the impact evaluation framework of the DNDi. By analysing current practices and comparing them with other global health organisations, several gaps were identified, and a set of recommendations were proposed. DNDi has significantly contributed to global health through innovation, sustainable solutions, and advocacy. However, gaps in their impact evaluation framework include insufficient long-term assessment, qualitative indicators, and health and economic impact metrics. There are also challenges in data availability and collection.

To address these issues, we recommend developing a performance framework aligned with DNDi's theory of change and strategic goals. This framework should incorporate mission-level, strategic objective, and operational KPIs. Introducing new KPIs for health and economic impacts, such as DALYs and ROI, along with revising existing indicators to better reflect the scale and uptake of innovations, is crucial. Including qualitative indicators to capture aspects like stakeholder satisfaction and collaboration quality is essential. This can be achieved using case studies and in-depth interviews. Establishing robust mechanisms for data collection and verification, including tools for gender-disaggregated data and automated data management processes, will improve data accuracy and reliability. Training clinicians and field staff to enhance data collection and management capabilities is another vital step, as it will improve data quality. Additionally, conducting workshops with stakeholders to refine KPIs and regularly update the performance framework based on feedback and evolving needs will ensure the framework remains relevant and effective.

Implementing these recommendations will enable DNDi to develop a more comprehensive impact evaluation framework. This will better demonstrate the value of its initiatives, enhance its ability to secure funding, and advocate for policy changes. An improved framework will help DNDi measure both immediate outputs and long-term impacts, aligning with global health standards and promoting equitable access to treatments for neglected populations.

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