

GLOBAL ACCELERATOR FOR PAEDIATRIC FORMULATIONS 2022-2024 STRATEGY

Shaping the global innovation and access landscape for better paediatric medicines



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Shaping the global innovation and access landscape for better paediatric medicines: Global Accelerator for Paediatric Formulations 2022–2024 strategy

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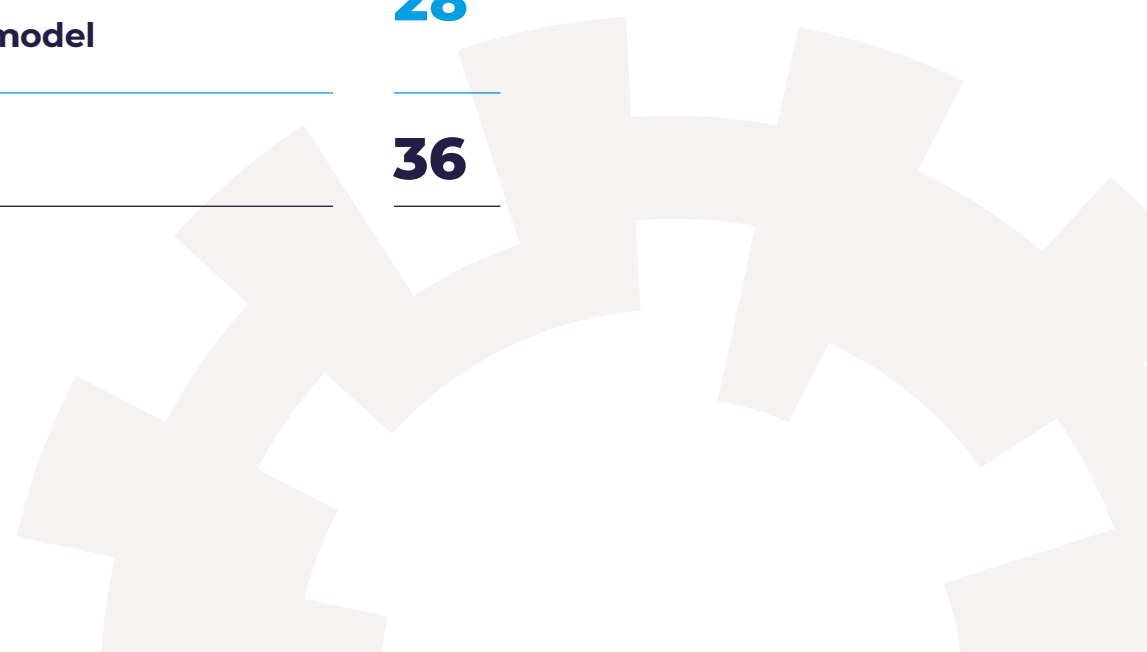
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Why GAP-f?

**Children do not have
equitable access to
medicines adapted
to their needs**

The lack of appropriate paediatric medicines and formulations is hindering the achievement of the Sustainable Development Goals and universal health coverage and is putting children's lives at risk.

'Equitable access to innovation means leaving no one behind; it means leaving no infant, no child behind from the scientific advances and opportunities we have today to accelerate research and development of novel therapeutics.'

Dr Soumya Swaminathan,
WHO Chief Scientist

Children are not small adults, and infants are distinct from children. They cannot swallow tablets or capsules, often cannot bear the taste of liquid medicines and metabolize drugs differently as they develop and grow (1,2). For them, medicines need to be palatable, scored, crushable, dispersible, chewable, sprinkled on food or mixed with breast-milk. When multiple drugs need to be taken together for one purpose, they must be administered with the correct dose of each active agent. For this reason, fixed-dose combinations can make a huge difference, both for ease of administering them and for ensuring that the right dose is taken.

Reality, however, often looks quite different, particularly for disadvantaged or at-risk children, who face barriers in accessing medications (3,4). Appropriate medicines to save and improve the lives of infants and children to address the world's most pressing health priorities often do not exist, are unavailable or are not quality assured, especially in low-resource settings.





Problem #1

Siloed approaches lead to efforts falling through the cracks, especially in a void of global priority-setting of needs, and a lack of coordinated and sustainable funding for paediatric health priorities.

With a fragmented landscape of paediatric drug innovation and access stakeholders – research groups, product developers, pharmaceutical companies, regulators, policy-makers, implementers, healthcare workers, civil society and funders – efforts often focus on tackling just one part of the product life cycle, with insufficient attention paid to activities upstream or downstream. This is exacerbated by the lack of a global priority-setting mechanism across many areas of paediatric health product development. Further, the current lack of a regular and consistent tracking and mapping of needs, gaps, actors and funding flows reduces the possibility to align actors and efforts, target interventions, benefit from potentially cross-cutting technologies (such as for the administration and taste of products) and achieve more coherent and seamless funding streams that allow translation across phases from early research and development to access.



Problem # 2

Too much time is lost in translation.

A child born today could wait up to 10 years before a newly available drug for adults is tailored for their needs. Drugs are generally first developed for adults, and only when that process nears or achieves completion does the paediatric formulation development process begin (5). In addition, clinical research in paediatric populations is particularly challenging without adequate capacity on the ground and without enabling norms and standards. Indeed, the lack of harmonized regulatory guidance for the development and introduction of paediatric medicines disincentivizes innovation. Further, innovative ways of delivering medications to children often remain untapped because of a lack of collaboration and effective partnerships. Finally, supply cannot meet demand when demand is neither forecast nor pooled: often representing too small a market with sometimes no epidemiological data for children (6), traditional incentives for innovation and manufacturing are insufficient on their own.



Problem #3

In the fragile product development landscape, one gap unfilled can halt an entire life-saving solution.

Paediatric drug research, development and delivery do not have a dedicated funding mechanism and targeted intervention programme. When funding is not aligned across the full product development life cycle, a single gap that stalls or prevents transitioning from one phase to another can bring progress to a halt. Visibility and coordination of funding are desperately needed.

‘For too long children in low-resource settings have been neglected by biomedical research and development, resulting in a lack of appropriate formulations for kids affected by neglected tropical diseases and viral diseases like HIV. GAP-f brings together the global health community behind our common goal: accelerating appropriate and accessible treatments for kids.’

Dr Bernard Pécoul, Executive Director,
Drugs for Neglected Diseases initiative (DNDi)

The impact of COVID-19 on access to paediatric medicines and services demonstrates the fundamental problems and fragility of the landscape. For example, the global supply chain disruptions have caused and are still causing stock-outs of existing life-saving paediatric medicines. Further, the disruption to maternal and child health services exacerbates the systemic barriers to children's equitable access to medicines. Building back better will require even more focus, coordination and funding for paediatric medicines. Across several disease areas, major challenges remain and must be addressed even more purposefully to overcome the negative global repercussions of this global pandemic.



ANTIMICROBIAL RESISTANCE

Infectious diseases and related complications, such as pneumonia and sepsis, are the world's number one cause of morbidity and mortality among children younger than five years of age. More than 3 million deaths result from such diseases and complications each year, with drug resistance a major exacerbating factor (7). Globally, more than 214 000 infants (under one year of age) die because of antimicrobial resistance annually, with up to 40% of all bacterial infections among babies showing drug resistance. Neonates (up to four weeks old) and infants are especially vulnerable because their immune systems are not fully developed, their behaviours naturally expose them to more and different microbes than adults, and children living in poverty are especially susceptible to drug-resistant bacteria because of water, sanitation and hygiene problems (8). Few paediatric-focused formulations are under development today.

CANCER

Each year, about 400 000 children and adolescents (0–19 years old) are diagnosed with cancer (9). Evaluating the life cycle of childhood cancer medicines reveals multiple existing failures, resulting in significant delays in bringing relevant childhood anti-cancer drugs compared to adult cancer therapies (10). Access to childhood cancer medicines remains grossly inequitable for children in low- and middle-income countries. The market for such therapies in low- and middle-income countries is still extremely small in both the private and public sectors because the availability of diagnostic and treatment services is limited. Further, adequate national budgets for cancer are lacking, with few government or other reimbursement systems including these life-saving products among their priorities (11). The recent launch of the Global Platform for Access to Childhood Cancer Medicines (12) led by St. Jude Children's Research Hospital and WHO offers a renewed momentum to tackle these needs globally.

HEPATITIS C

An estimated 3.3 million children are living with chronic hepatitis C infection, with 20 countries accounting for 80% of all cases among people 0–18 years of age. For these people, treatment with highly active direct-acting antiviral drug regimens can cure hepatitis C infection with well-tolerated medicines. However, no complete direct-acting antiviral drug regimens have dosage forms suitable for children and are available as generic products, and innovator products remain too expensive for use in low-resource settings.

HIV

About 1.3 million infants are exposed to HIV every year, and they need better antiretrovirals for postnatal prophylaxis to prevent vertical transmission and live a life free of HIV. Just slightly over half of the 1.7 million children living with HIV are receiving life-saving antiretroviral therapy, despite tremendous progress in developing paediatric formulations. Data gaps and lack of appropriate formulation for neonates, infants, and young children remain.

While new technologies are nearly at hand for adults, including long-acting injectable formulations under consideration for preventing and treating HIV, children are at risk of once again being left out of the next generation of innovative medicines.

NEGLECTED TROPICAL DISEASES (NTDs)

Neglected tropical diseases affect poor and marginalized populations, with children especially neglected. For sleeping sickness (human African trypanosomiasis), treatments can either be too toxic for children (such as for the *Trypanosoma brucei rhodesiense* parasite) or problematic to administer (intravenous administration). Although there is currently an effective oral treatment for adults, the dosage of this drug (fexinidazole) does not include children younger than six years of age or weighing less than 20 kg or those with advanced disease. As there is only one oral drug (miltefosine) for the life-threatening kala-azar (black fever or visceral leishmaniasis), combination therapies inevitably include one or more injectable drugs, which are

painful or cumbersome to administer to children. For snail fever (schistosomiasis), no paediatric formulations are currently available. For current treatment of river blindness (onchocerciasis) through mass drug administration, children weighing less than 15 kg are excluded because there is no approved dosing for this category or suitable paediatric formulation. For Chagas disease, a hidden, silent disease, even though two effective paediatric treatments are available, uptake is very low, necessitating greater political will and commitment to change the situation.

TUBERCULOSIS (TB)

About 7.5 million children and young adolescents (0–14 years old) are infected with *Mycobacterium tuberculosis* (13). More than 1 million of them develop TB disease, and a quarter of a million of them die from the disease each year (14). Children diagnosed and treated for TB have very good outcomes, but there remains a significant gap to find, diagnose and treat all children with TB. Despite major recent advances in the

development and availability of child-friendly formulations for first- and second-line treatment, demand has remained stable over the past few years with limited increase in uptake and roll out. There is also a robust pipeline of TB research and development for both preventing TB and treating people with drug-susceptible and drug-resistant TB. This next wave of new TB drugs coming through the pipeline offers an opportunity to do better for kids by closing the gap between when a new drug is approved for adults and when children of all ages can benefit from access to it. Reaching consensus among stakeholders on priority paediatric TB formulations is key to ensuring that researchers, funders and manufacturers focus specifically on the formulations that are most needed. The progress generated to date in identifying and addressing issues that delay or limit access to optimal TB regimens by the TB Procurement and Market-Shaping Action Team partners, under the leadership of STOP-TB and the Global Drug Facility, set a solid ground to expand collaborations and partnerships to tackle remaining gaps and barriers (15).



Who we are: together stronger for kids

The Global Accelerator for Paediatric Formulations (GAP-f) is a network hosted by the WHO providing an umbrella function for partners across the spectrum of innovation of and access to better paediatric medicines, spanning multilateral, public, private and non-profit sectors. GAP-f partners, global champion organizations in their respective fields, are supported by GAP-f in their ongoing work and, where necessary, are enabled through direct intervention by GAP-f.

As a unique interface between WHO and its technical departments and paediatric medicines product developers, implementers, funders and civil society, GAP-f leverages the expertise and resources needed to target and optimize the investment of time, personnel, effort and funding, by:

1

Establishing priorities based on identifying needs and gaps

2

Accelerating time to investigate, develop, and deliver priority products through synchronized action and best practices derived from across technologies and disease areas

3

Directly intervening where needs remain unaddressed

GAP-f's ultimate purpose is to improve the quality of life and reduce illness and death in infants and children with treatable or preventable illnesses.

The GAP-f 2022–2024 Strategy builds on the work undertaken to date by the network of leading partners, both individually and collectively, through GAP-f. During the start up phase (Phase 1) of GAP-f, the GAP-f strategy focused on HIV, TB and hepatitis C products. This new three-year strategy for Phase 2 of GAP-f builds on the work undertaken in these disease areas, targeting additional therapeutic areas including cancer, antimicrobial resistance and neglected tropical diseases. In addition, GAP-f responds to urgent needs related to emerging pathogens of public health concern such as SARS-CoV-2. It capitalizes on the accelerating potential of cross-cutting work that addresses systemic barriers to innovation and access, transcending product-specific considerations, to benefit all paediatric medicine innovation and access undertakings going forward, including funding and financing. Finally, it paves the way for improving governance and an agile operating model that is fit-for-purpose and best serves the strategy.

GAP-f network partners



GAP-f funding partners



Hosted by:



**GAP-f: a unique and
concerted response
to a fragmented
landscape and
critical gaps**

Since its launch by WHO and founding members in October 2020, GAP-f has catalysed the response to World Health Assembly resolution 69.20 from 2016 on promoting innovation and access to quality, safe, efficacious and affordable medicines for children (16). It addresses specific bottlenecks to achieving Sustainable Development Goal 3, Good Health and Well-being, across several targets, including universal health coverage.

GAP-f is only as strong as its partners and their individual and collective ability to provide unique contributions to accelerating the development of child-appropriate medicines and their availability where they are most needed. GAP-f partners, all global leaders in their respective fields, have joined forces, committing to work collaboratively with a common vision, mission and shared principles to save and improve the lives of children.



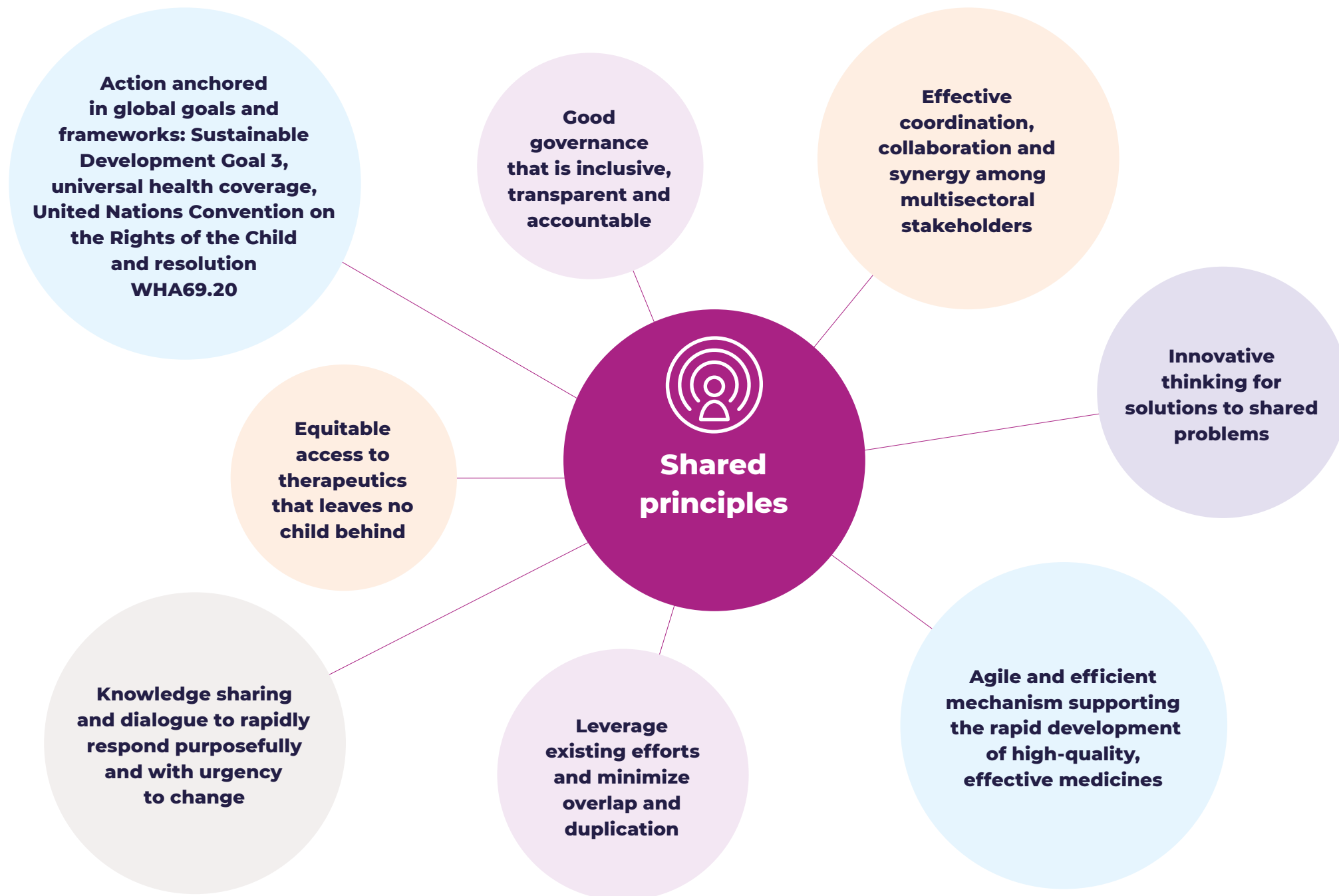
Vision

All children have equitable access to the medicines they need.



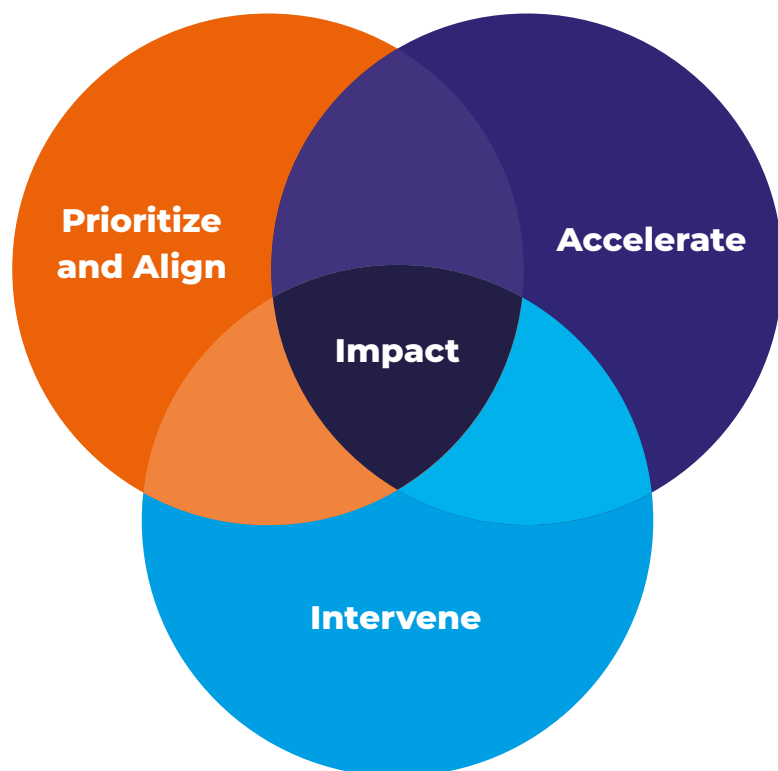
Mission

Remove barriers to developing and delivering appropriate, quality, affordable and accessible medicines for children and contribute to universal health coverage by spurring **collaboration** across stakeholders to identify gaps, **set priorities** for needs and **accelerate** product investigation, development and delivery to improve and **save the lives of children**.



**The GAP-f 2022–2024
Strategy: from
priority setting to
targeted action for
greater impact**

Building on lessons learned, achievements and consultations, this Phase 2 GAP-f 2022–2024 Strategy solidifies the foundations laid in Phase 1, while bringing a more refined and renewed approach that enhances the unique position, added value and partners of GAP-f to date to extend its reach and impact. The strategy paves the way to a more sustainable, resourced and well-coordinated mechanism for years to come. The three-tiered approach – **prioritize and align; accelerate; and intervene** – provides the framework to deliver impact.



Prioritize and Align

- **Set global priorities** for therapeutic areas and missing formulations
- Communicate global gaps and priorities through **targeted advocacy**
- **Align stakeholders' priorities** and action to respond to global needs
- **Monitor and track global research and development** pipelines, gaps, stakeholders and investments



Accelerate

- **Facilitate collaborative efforts and mobilize partners** to minimize barriers that inhibit innovation and access to paediatric formulations and stimulate activities for acceleration
- **Identify and promote best practices** to accelerate clinical research, product development and delivery activities
- **Support innovations** to advance the development of original research methodologies, novel technologies and innovative financing



Intervene

- **Address gaps** by facilitating, leading or fundraising for **product-specific projects** on clinical research, development, regulatory, access and delivery
- Support GAP-f partners and engage public and private stakeholders to **minimize or eliminate product-specific bottlenecks**



Prioritize and Align

The first pillar stems from the paramount importance of a transparent and robust method for setting priorities and identifying needs across paediatric therapeutic areas globally.

Identifying missing paediatric formulations is a first step to mobilization, to be matched by mapping the pipeline of specific projects that each stakeholder conducts at each phase of research, development and delivery: who is doing what at which stage. In this way, bottlenecks in transitioning from one phase to the next can be identified more rapidly and time-saving solutions sought, thus reducing the risk of projects being unnecessarily stalled. Importantly, understanding and tracking the funding sources and the funding available and still required to bring a priority product to fruition will help to leverage a more diversified donor and investor forum to increase overall resourcing. These elements – all of which are powered by global advocacy – form the first core pillar driving the strategy: **Prioritize and Align.**



Accelerate

The second pillar brings cross-cutting and cross-learning approaches to research, development, and delivery efforts for paediatric medicines.

By communicating widely on best practices across products and therapeutic areas, all stakeholders benefit. Applying lessons learned to develop more enabling policies and guidelines and, where needed, developing specific technical tools for interventions, are key to this pillar. Working towards ensuring that regulatory developments from one therapeutic area or drug type can be applied to others addresses one of the most harrowing barriers partners face. GAP-f, by leveraging the work done in HIV and TB, can work with regulators and partners to open new, critical regulatory pathways, applying them to the new priority therapeutic areas. Seeking solutions to common problems is key to saving time and money, and innovations should target such common barriers. Finally, concrete piloting of financing mechanisms can pave the way to moving from a niche area to a sustainably resourced field. While enshrined in all of GAP-f's work, this second pillar has a multifaceted, yet sole goal: **Accelerate.**

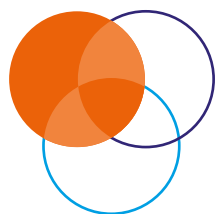


Intervene

The first and second pillars connect the dots at several levels, but product-specific gaps undoubtedly arise that require targeted support, whether by direct engagement through a partner, by stopgap funding or by providing ad hoc support. GAP-f will identify, define and take up projects that are not being addressed by other actors and that pose a threat to acceleration with a clear aim to: **Intervene.**







Prioritize and align

‘To truly realize universal health coverage, access to medicines for the world’s most vulnerable children has to remain a global priority for governments, industry and regulators. GAP-f is here to support alignment of global partners with public health needs.’

Dr Mariângela Simão,
WHO Assistant Director General

Strategic Objectives

1

Develop a global priority-setting approach, informed by global disease burden and anticipated public health needs, that will result in timely engagement across therapeutic areas and a list of prioritized missing formulations and indications

GAP-f will leverage WHO’s expertise, global technical and statistical data, its country presence and convening power to develop an appropriate analysis of the global needs for paediatric medicines, identify gaps and set priorities. This will include estimating the associated global funding needs, gaps and priorities for paediatric medicines.

2

Prioritize products needed within at least three new therapeutic areas

During Phase 1, GAP-f focused on HIV, TB and hepatitis C products. Recently, it has been exploring several other therapeutic areas including cancer, antimicrobial resistance, neglected tropical diseases and COVID-19. GAP-f will continue to follow the priorities to be defined through Paediatric Antiretroviral Drug Optimization (PADO) processes (17) led by WHO technical departments for the exploratory therapeutic areas. It will also continue exploring needs and gaps in paediatric medicines for malaria and additional noncommunicable diseases, such as sickle cell disease and epilepsy.

In addition, GAP-f will complete the ongoing scoping assessment of needs and gaps in appropriate formulations for essential medicines and define a clear framework to set priorities for GAP-f future engagement to address the full range of missing essential paediatric medicines.

3

Facilitate a system to monitor and track global paediatric-focused research and development, including gaps, actors and financing

GAP-f will leverage WHO's Global Observatory on Health Research and Development (18) and bring together the work of WHO technical departments to develop a tracking system capable of providing up-to-date information across several indicators for innovation for and access to paediatric medicines. Rendering this visible and transparent to all will foster stakeholder alignment and accountability. It is crucial to inform on performance and to identify opportunities to further set priorities, accelerate and intervene.

4

Design and implement targeted advocacy to align and mobilize key stakeholder groups: WHO Member States, affected communities and patient groups, civil society, research networks, product development partnerships, international organizations, industry, regulatory agencies and donors

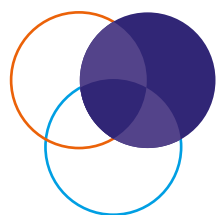
Stakeholder engagement and alignment around global priorities, needs and gaps is an important function of GAP-f, which it will achieve via robust and targeted advocacy to educate, mobilize and influence. Three main types of advocacy approaches will be implemented depending on the audience and the specific objectives – general stakeholder awareness, political engagement and technical advocacy. In addition to strengthening existing donor and partner forums, GAP-f will further engage industry and regulators to overcome significant systemic barriers.

5

Elevate and promote partner and stakeholder contributions, illustrating their roles in the GAP-f work

Each GAP-f partner plays a unique and leading role in innovation for and access to paediatric medicine. GAP-f will highlight the work partners undertake in this field and on the collaborative contribution they make to achieving GAP-f objectives. Specifically, GAP-f will continue to promote its partners' contributions in its advocacy, through webinars and other events, via publications, towards funders and investors and in stakeholder forums.





Accelerate

Strategic Objectives

1

Document and support the implementation of good practices that enable acceleration

Capitalizing on the work and experience of its partners, GAP-f will identify and document good practices for innovation of and access to paediatric medicines and promote their expansion and adaptation across therapeutic areas.

2

Facilitate the development of enabling norms, standards, regulations and policies

Lessons learned will be documented in normative documents that will set standards and promote alignment around core interventions to accelerate products through the life cycle. This work will include policy documents, implementation guidance and, when needed, dedicated technical tools to support targeted interventions.

3

Streamline regulatory pathways

GAP-f will facilitate regulatory pathways for priority paediatric medicines by helping to identify the most efficient regulatory route. GAP-f will convene and work with regulators by leveraging the established WHO Paediatric Medicines Regulators' Network and the work of the WHO Prequalification of Medical Products

team, to harmonize the requirements when possible, promote improvements and make best use of efficient regulatory pathways, including use of the collaborative registration procedure for more rapid national regulatory approval. In addition, GAP-f will promote the WHO principle of good reliance practices for a more efficient approach to regulatory oversight, thereby improving access to quality-assured, effective and safe medical products over the entire life cycle of drug development.

4

Support targeted capacity strengthening

Building on existing efforts such as those led by TDR, the Special Programme for Research and Training in Tropical Diseases, GAP-f will facilitate and leverage capacity-strengthening activities aimed at implementing high-quality paediatric-specific clinical research (such as pharmacokinetics and pharmacodynamics; modelling and simulations; and clinical trials) and enabling better use of real-world data to inform safety and efficacy.

Capacity-strengthening activities will also entail targeted interventions to facilitate technology transfer for optimal formulation development and supporting healthcare workers and affected communities for the accelerated introduction and roll-out of new paediatric medicines.

5

Introduce innovations to improve and accelerate investigation, development, introduction and access

Building on its initial and continual work on bitter receptor antagonists (also called bitter blockers), which may provide a novel approach to eliminate bitterness in paediatric drugs and thus dramatically improve treatment adherence, GAP-f will explore novel administration technologies, such as non-oral and long-acting formulations, and match them with appropriate compounds to advance the drugs and platforms that would improve the quality of care. It will engage affected communities to explore end-user

preferences and inform target product profile and preferred product characteristics that will best match the needs of children across the age and weight spectrum. It will also investigate challenges and opportunities to take these technologies to scale.

GAP-f and partners will also explore innovative methods to use artificial intelligence and analyse and use real-world data to monitor the safety and effectiveness of new paediatric medicines. In this way, it will inform global, regional and national policies and future innovation in clinical case management as well as forecasting efforts for introducing new medicines.

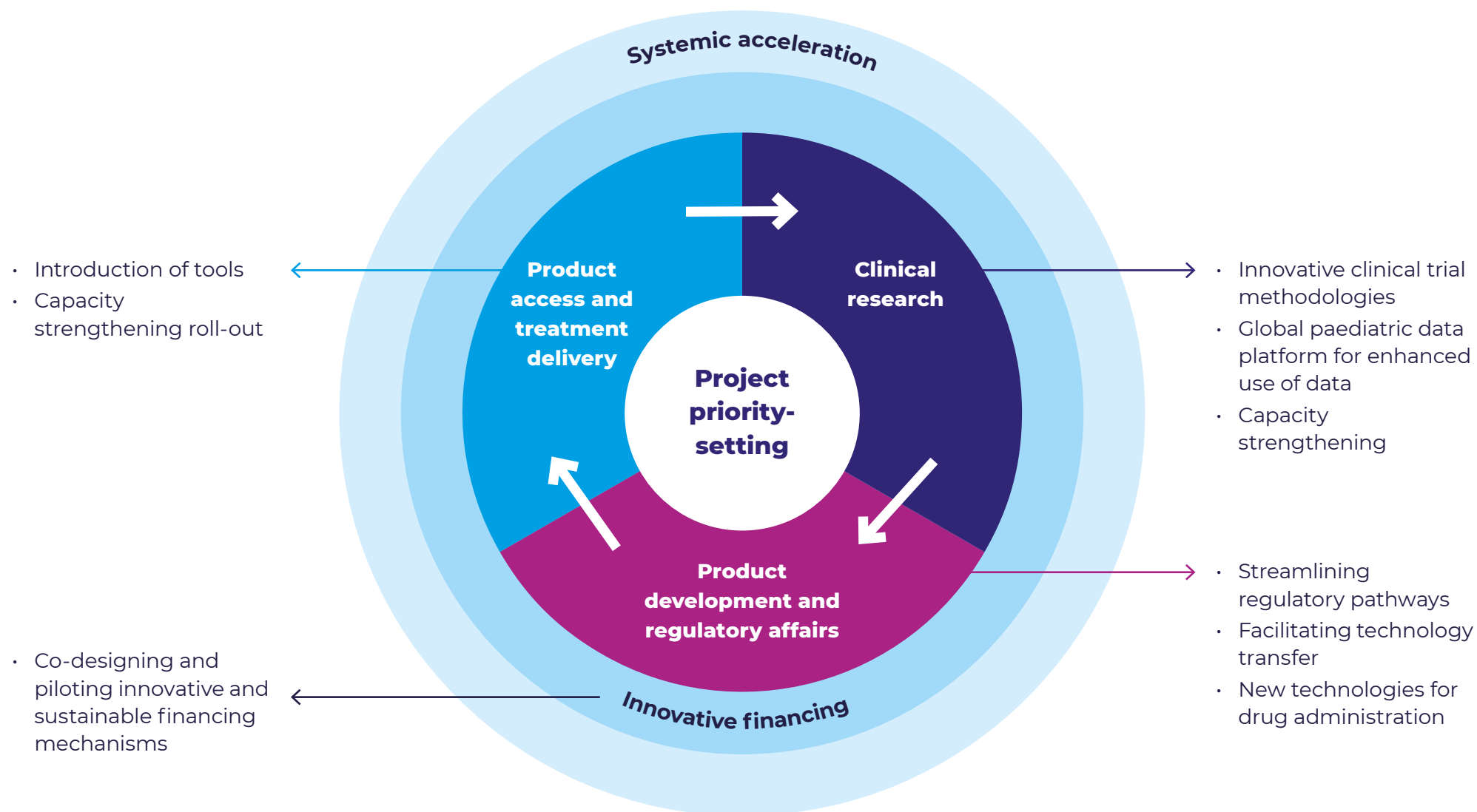
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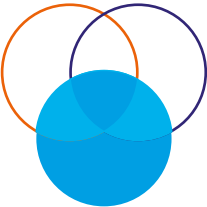
Explore innovative funding mechanisms to accelerate paediatric innovation and access

GAP-f will expand on exploratory work undertaken in its Phase 1 strategy to co-design and pilot innovative funding mechanisms. The aim, in this strategic

period, is to identify and facilitate the implementation of sustainable funding mechanisms to support the investigation, development and introduction of better paediatric medicines. In doing so, GAP-f will explore innovative funding models that both draw on experience from existing funding mechanisms and embrace the principles and structures found in funding and investment models outside public health, such as: state-sponsored models (from taxes or pension bonds); outcome- or impact-based models such as outcomes funds, development impact bonds, social impact bonds or percentages of sales models (such as royalties); various crowdfunding models; accelerator models, such as from large anchor donors (traditional and state) and venture investors; and membership or subscription models, to name a few.

2022–2024 strategic priorities for the accelerate pillar





Intervene

Based on periodic reviews of information collated in the tracking system, GAP-f will directly intervene to address product-specific gaps by facilitating, leading or fundraising for various projects in clinical research, product development, regulatory affairs, access and delivery and monitoring. With its partners, GAP-f will work to minimize or eliminate bottlenecks. The following diagram demonstrates a typography of gap-filling roles GAP-f will play.



© Fabio Nascimento, DNDi

Gap-filling across the product life cycle

Priority product	Clinical research	Product development	Regulatory approval	Introduction and procurement	Roll-out	Monitoring
A						
B						
C						
D						
E						
F						
G						

Illustrative examples:

- A illustrates a product that is not currently covered by partners and or/funding.
- B illustrates a product without partners and/or funding post regulatory approval.
- C illustrates a product undertaken by a partner whose activities do not extend beyond initial introduction.

- Blue – fulfilled: appropriate partner and funding for this phase.
- Pink – gap: lack of partner and/or funding for this phase.

Strategic Objectives

1

Define product-specific priorities for at least three additional therapeutic areas and intervene when necessary

Based on discussions with GAP-f partners, GAP-f expects to define product-specific priorities for at least three additional therapeutic areas while continuing to follow the previously defined product-specific priorities in HIV, TB and hepatitis C. It anticipates the need to intervene in the following:

- designing and implementing at least three additional clinical trials;
- developing at least four new formulations;
- introducing at least four new products; and
- monitoring the safety of five drugs among those given priority.

The GAP-f Strategy and Coordination Committee will define engagement in collaboration with GAP-f partners to ensure that ongoing and anticipated work is adequately mapped and collaborations explored.

2

Identify and engage industry partners to support and accelerate development of priority products

For development of priority products, relationships with industry partners will be key to ensuring that adequate manufacturing and supply of these products are available. GAP-f will identify innovator companies for specific products and engage with them to support paediatric development activities early enough to impact decisions such as clinical trial and formulation design. Additionally, focused, strategic business relationships with generic pharmaceutical companies will be fostered to enable accelerated product development of paediatric formulations of priority drugs.





Impact

**Holding ourselves accountable:
Impact measures of success**

GAP-f is accountable to the World Health Organization and its 194 Member States, and above all, to the children of those countries.

The ultimate impact GAP-f will deliver is to significantly decrease mortality and morbidity of children by providing access to safe, effective, quality, affordable paediatric medicines.

During this three-year strategic period, GAP-f and partners will measure the impact of this strategy through key indicators and strategic enablers.



Impact Indicators

We agree on what children need and track how we get there.

1

The global needs, framework for setting priorities and GAP-f focus areas are well defined, widely communicated, and broadly accepted. A system for global progress monitoring and tracking is in place to enable stakeholder alignment and targeted work to be undertaken to accelerate research on, development of and introduction of paediatric medicines.

We eliminate or minimize all delays.

2

Amount of time saved at each stage of prioritization, research, development, introduction and monitoring.

We leverage state-of-the-art technologies.

3

New technologies and methods matched and applied to priority paediatric medicines across multiple stages of priority-setting, research, development, introduction and monitoring.

We mobilize the resources needed.

4

Measurable increase in the funding dedicated to paediatric medicines and the number of new investors in this area: WHO and GAP-f partners are better funded to deliver against GAP-f priorities.

We get appropriate medicines to the children who need them.

5

Number of countries reporting on inclusion of formulations on the WHO Essential Medicines List for children in their national Essential Medicines Lists.

6

Number of additional children accessing better, appropriate medicines per disease area.

GAP-f's ability to achieve its strategy targets and impact depend on the ability to leverage and build upon five strategic enablers, as foundations for success.

'At UNICEF we believe that every child has the right to grow up healthy and strong. To ensure they survive and thrive, we urgently need investments in innovative child-friendly medicines and formulations, including for neglected and chronic illnesses. Through GAP-f we are pleased to join WHO and partners to ensure that every child in need is able to benefit from quality, lifesaving treatments delivered through quality, equitable health systems.'

Dr Aboubacar Kampo,
Director, Health, Programme Group, UNICEF

Strategic Enablers

1

Political commitment to ensure that improving paediatric medicines is high on global, regional and national agendas

The urgent need for paediatric medicines is prominent in current global goals and resolutions and must be translated into regional and national plans. Through its work, GAP-f will harness these commitments to ensure commensurate investment of collaborative effort and funding while continuing to advocate for increased and sustained political commitments.

2

Good governance, strong leadership, management and technical knowledge are fit for purpose

As GAP-f transitions out of its Phase 1, its governance and operating models will be refined to account for lessons learned, with a broader scope and more diverse set of objectives. The GAP-f Secretariat will increase its support, and to do this in an agile way, it will increasingly draw on WHO leadership and technical capacity residing in technical departments, partner engagement and existing expertise. Additional multisectoral partners and stakeholders, including representatives of affected communities, must be engaged in the relevant governance and operating models to ensure the participation and representation of the expertise necessary to achieve Phase 2 goals. As stated in its core principles, GAP-f and its partners will adhere to the governance principles of inclusion, participation and accountability.

3

Active and transparent engagement of GAP-f partners and stakeholders

GAP-f's entire model depends on active collaboration and participation of partners and stakeholders fulfilling, and perhaps strengthening, their individual organizational missions while contributing to the collective vision and mission of GAP-f. Convening and coordinating multisectoral partners and stakeholders, GAP-f provides the collaborative platform and resources for this engagement. Partners' engagement is required, and the collective return on investment depends on it.

4

Financial resources

'To improve access to medicines for children, government funding, development assistance, and philanthropic funding must be leveraged by shaping paediatric markets, attracting investors, and increasing funding available for innovative approaches to expand access to paediatric products in LMICs' (19) and globally. GAP-f's Donor Forum will expand and transform into a Funders and Investors Forum to promote alignment in order to address global needs. In addition to ramping up advocacy on the financial needs and gaps, GAP-f is exploring innovative funding mechanisms. Its resource mobilization strategy is threefold and interlinked: ensure resources for the GAP-f Secretariat so that its coordination function and specific GAP-f activities are sufficient to carry out its strategy; increase overall investment and mobilize resources for GAP-f partners through global advocacy on the needs and gaps, spotlighting the partners that need resources to accelerate paediatric medicine priorities; and support the piloting and creation of innovative funding mechanisms.

5

Effective strategic partnerships and alliances with public and private partners

Crucial to accelerating research on, development of and delivery of paediatric medicines, GAP-f will facilitate partnerships and alliances across the paediatric medicines landscape to align all groups, overcome barriers and/or fill gaps. GAP-f is at a critical junction of the full range of public and private actors, and its operating model is key to its ability to unify the landscape.



**Ready to scale:
learning and evolving
from Phase 1 by reinforcing
the foundations of the
GAP-f collaboration
model**

GAP-f has now completed its foundational Phase 1, with an initial strategy, business plan and seed funding. Together with WHO, GAP-f's co-founders are the Clinton Health Access Initiative, the Elizabeth Glaser Pediatric AIDS Foundation, the Medicines Patent Pool and Penta Child Health Research. GAP-f's WHO-staffed Secretariat, embedded in WHO's Science Division, and GAP-f's Steering Group, co-hosted by WHO and the Clinton Health Access Initiative, have actively worked towards shaping GAP-f operations and priorities to date.

Within WHO, the GAP-f Secretariat has engaged across multiple departments and divisions, through an agile team of paediatric focal points to provide critical contributions to GAP-f, convene disease specific collaborations and ensure country engagement. GAP-f's External Advisory Committee, convened by WHO, has provided ad hoc strategic guidance.

Finally, a Donor Forum, co-chaired by WHO and Unitaid, has been established to ensure that awareness of gaps and priorities are shared among donors; to provide a framework for expansion to diversify the funding and financing actors involved; and to increase the overall funding and investment for paediatric medicines.

'We must ensure that all children have access to adapted lifesaving treatment, wherever they live. Unitaid has always been at the forefront of accelerating access for paediatric medicines. Supporting the GAP-f is a step forward in this endeavor and is crucial to Unitaid's mission and public health.'

Dr Philippe Duneton,
Executive Director, Unitaid

GAP-f PHASE 1 (2020–2021)

30 institutional partners

04 product life cycle–targeted working groups

03 disease areas (HIV, TB and hepatitis C), support on guidance (PADO) and targeted product support (formulations for weight bands, pharmacokinetics and taste improvements)

03 additional exploratory disease areas (childhood cancer, neglected tropical diseases and antimicrobial resistance)

Comprehensive assessment of WHO Essential Medicines List for children (EMLc) initiated

Four working groups have sparked collaborations across three disease areas – HIV, TB and hepatitis C – as well as key cross-cutting activities supporting product priority-setting, regulatory guidance, more efficient, high-quality clinical research and increased coordination of product development and introduction efforts. For Phase 1, HIV, TB and hepatitis C were identified as priority therapeutic areas to leverage some of the similarities and explore synergy among initial partners. Innovations to deliver medicines for children have been explored, and new projects have been facilitated to optimally match technologies to needs. Initial exploration of innovative financing models for paediatric medicines is reaching completion. GAP-f also launched key advocacy and communication activities and a webinar series to proactively engage with an extended group of stakeholders on specific thematic areas.

Through piloting in this first phase, GAP-f has recognized the paramount importance of systematic global setting of priorities among needs and identifying gaps in the paediatric medicines landscape. GAP-f experience shows that the lessons learned and successes in paediatric HIV can and should be applied to other paediatric indications, harnessing the power of working across multiple disease areas. However, for the efforts required for targeted products in specific disease areas, a one-size-fits-all approach is not feasible.

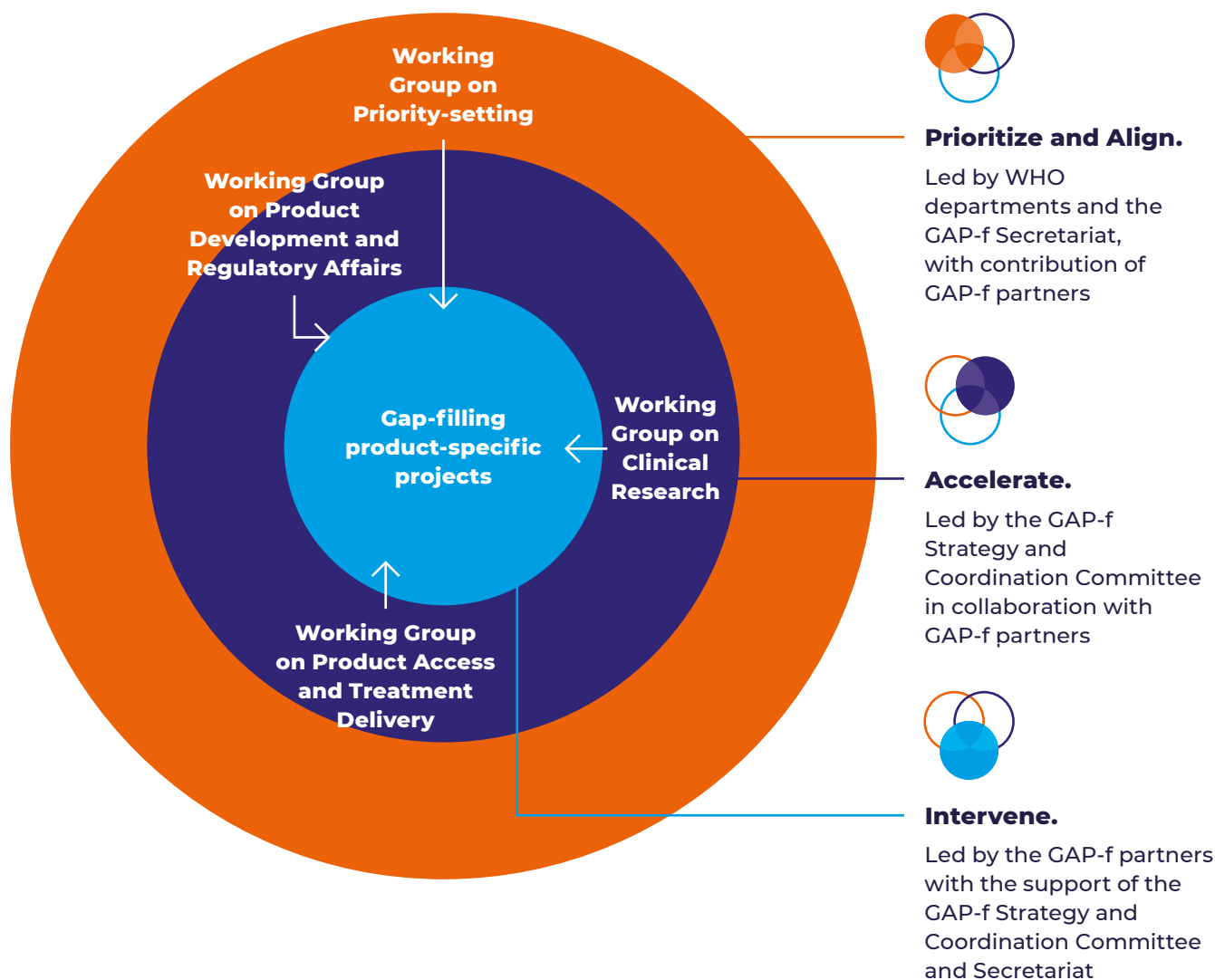
GAP-f partners are all key drivers of progress in important areas of advocacy for, research on, development of and delivery of paediatric medicines. By interrogating the complementary role and added value of GAP-f for these partners and others, GAP-f has fine-tuned its approach to leveraging existing initiatives to benefit all. The expertise among the GAP-f partners has the potential to provide cross-cutting solutions to meet the ultimate objective of GAP-f, which is securing children's equitable access to the medicines they need. This is only possible if a concerted, non-siloed approach is taken. In addition, individual initiatives are generally underfunded and require much greater visibility, which GAP-f can and should provide. Finally, matching priorities with partners and funding is a role that GAP-f is uniquely positioned to fulfil and has led to a new strategic approach for this current Phase 2.

With the momentum created by its now 30 institutional partners (see page 9) ranging from United Nations agencies and disease-focused initiatives to humanitarian, development and advocacy

nongovernmental organizations to non-profit product development partnerships and academic institutes, GAP-f is now ready to take the achievements and lessons learned in Phase 1 to effectively move to a refined strategic approach for expansion in Phase 2, 2022–2024.

‘Every day, we see children struggle when treatments are not adapted to their needs. For paediatricians, healthcare workers, parents and caretakers, we know that only true collective action can address this challenge. We cannot be complacent; we owe it to the kids to do all that we can.’

Dr Agnes Mahomva Chief Coordinator,
National Response to the COVID-19
Pandemic and former Permanent
Secretary for the Ministry of Health
and Child Care, Zimbabwe



This Phase 2 strategic period is indeed critical to maintaining existing commitments, taking on new disease areas that bring both diverse challenges and new opportunities, testing broader funding and financing mechanisms, and finally, adapting the GAP-f governance and operating models to be fit-for-purpose to these objectives. These cover opportunities in childhood cancer, antibiotics and selected neglected tropical diseases in addition to HIV, TB, hepatitis C, and urgent needs related to emerging pathogens of international concern such as SARS-CoV-2. The lessons learned and progress in Phase 2 will then inform the transition to a consolidation phase to realize GAP-f's full potential across the spectrum of essential medicines for children.

As GAP-f shifts from start-up mode to expanding activities of priority-setting and acceleration for impact, its model must adapt.



An evolving model, fit for purpose

This new strategy will also require increasing representational governance, partnership and stakeholder engagement.

GAP-f is part of WHO, which is accountable to and governed by the World Health Assembly and its 194 Member States. The WHO-staffed GAP-f Secretariat reports to the Research for Health Department of the Science Division and brings together the leadership from multiple departments and divisions across WHO in relation to paediatric medicines in specific therapeutic areas. It represents the interface of WHO with external partners and leads GAP-f strategy implementation in coordination with its Strategy and Coordination Committee and by collaboration with its partners through four thematic working groups (see diagram on page 35), internal and external advisory groups and stakeholder forums. To better serve the current strategy and the targeted expansion, the following changes will be implemented.

- The GAP-f Secretariat will be strengthened with an increase in technical, financial and administrative support.
- The GAP-f Steering Group, as it was called in Phase 1, will be expanded to reflect the scoping and priority-setting of new therapeutic areas.

With broader representation, this group will now become the GAP-f Strategy and Coordination Committee, with two workstreams – strategy and operations – to be better equipped to implement the strategy, benefitting from greater cross-fertilization of expertise.

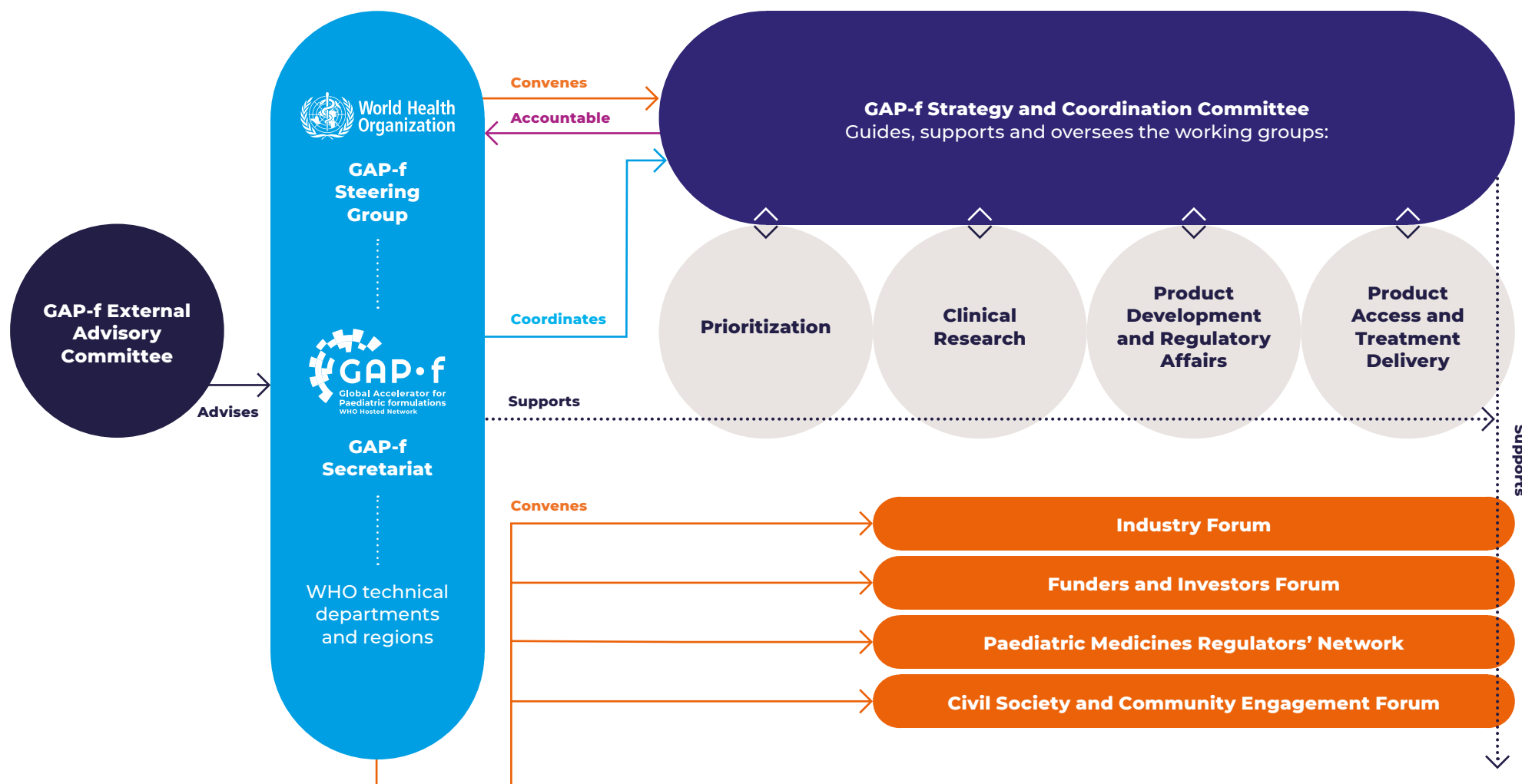
- Four strategic forums will be further expanded or newly developed: the existing Donors Forum will explore a new *modus operandi* for a broader Funders and Investors Forum for Paediatric Medicines; an Industry Forum will be formalized; close collaboration will be maintained with the WHO Paediatric Medicines Regulators' Network; and a specific Civil Society and Community Engagement Platform will evolve from the previous stakeholder engagement activities.
- GAP-f's External Advisory Committee will be fortified according to expertise and strategic input needed for expansion.
- The four GAP-f working groups will maintain their thematic areas, and each group will develop three-year objectives in accordance with this strategy. They will be co-led by partners and will ensure broad stakeholder involvement in their activities.



Lessons to be learned from COVID-19:

GAP-f's launch period coincided with the COVID-19 pandemic, during which there has been unprecedented research and development acceleration for vaccines, therapeutics and diagnostics with the global challenge of achieving equitable access for all. In addition to sharing its experience for application in the context of COVID-19 (20), GAP-f will leverage the lessons learned from multisectoral collaboration and adapt them to difficult areas in developing and introducing paediatric drugs: new trial methodologies, more collaboration between the private and public sectors, an agile regulatory environment and increasing use of data collection.

All these adjustments will be laid out in more detail in the initial months of this strategic period and in the GAP-f 2022–2024 business plan, ultimately leading to the target governance and operating model and accountability framework to take GAP-f to the next phase.





Overview of the 2022–2024 GAP-f strategic framework

Vision	All children have equitable access to the medicines they need.									
Mission	Remove barriers to developing and delivering appropriate, quality, affordable and accessible medicines for children and contribute to universal health coverage by spurring collaboration across stakeholders to identify gaps, set priorities for needs and accelerate product investigation, development and delivery to improve and save the lives of children.									
Shared principles	Action anchored in global goals and frameworks – Sustainable Development Goal 3, universal health coverage, United Nations Convention on the Rights of the Child and WHO resolution WHA69.20	Effective coordination, collaboration and synergy among multisectoral stakeholders	Agile and efficient mechanism supporting the rapid development of high-quality, effective medicines	Innovative thinking for solutions to shared problems	Knowledge sharing and dialogue to rapidly respond purposefully and with urgency to change	Leverage existing efforts and minimize overlap and duplication	Good governance that is inclusive, transparent, and accountable	Equitable access to therapeutics that leaves no child behind		
Strategic enablers	Political commitment to ensure that improving paediatric medicines is high on global, regional and national agendas		Good governance, strong leadership, management and technical knowledge are fit for purpose		Active and transparent engagement of GAP-f partners and stakeholders		Financial resources		Effective strategic partnerships and alliances with public and private partners	
Value statement	GAP-f identifies gaps and sets priorities for the needs in paediatric medicines and formulations worldwide while both leveraging and elevating the important work undertaken by public and private stakeholders in this field. As a unique interface between WHO and its technical departments and paediatric medicines product developers, implementers and funders and civil society, GAP-f: <ul style="list-style-type: none">• leverages the expertise and resources needed to target and optimize investment of time, personnel, effort and funds;• accelerates the time needed to investigate, develop and deliver priority products through synchronized action; and• directly intervenes when needs remain unaddressed.									
Overarching goals	Prioritize & Align <ul style="list-style-type: none">• Set global priorities for therapeutic areas and missing formulations• Communicate global gaps and priorities through targeted advocacy• Align stakeholders' priorities and action to respond to global needs• Monitor and track global research and development pipelines, gaps, stakeholders & investments				Accelerate <ul style="list-style-type: none">• Facilitate collaborative efforts and mobilize partners to minimize barriers that inhibit innovation and access to paediatric formulations and stimulate activities for acceleration• Identify and promote best practices to accelerate clinical research, product development and delivery activities• Support innovations to advance the development of original research methodologies, novel technologies and innovative financing				Intervene <ul style="list-style-type: none">• Address gaps by facilitating, leading or fundraising for product-specific projects on clinical research, development, regulatory, access and delivery• Support GAP-f partners and engage public and private stakeholders to minimize or eliminate product-specific bottlenecks	

2022–2024 strategic objectives	Prioritize & Align <ol style="list-style-type: none"> 1. Develop a global priority-setting approach, informed by global disease burden and anticipated public health needs, that will result in timely engagement across therapeutic areas and a list of prioritized missing formulations and indications 2. Prioritize products needed within at least three new therapeutic areas 3. Facilitate a system to monitor and track global paediatric-focused research and development, including gaps, actors and financing 4. Design and implement targeted advocacy to align and mobilize key stakeholder groups: WHO Member States, affected communities and patient groups, civil society, research networks, product development partnerships, international organizations, industry, regulatory agencies and donors 5. Elevate and promote partner and stakeholder contributions, illustrating their roles in the GAP-f work 	Accelerate <p>Convene and support acceleration efforts via stand-alone projects or through GAP-f's working groups (Clinical Research; Product Development and Regulatory Affairs; and Product Access and Treatment Delivery) to collaborate on issues that cut across multiple therapeutic areas. Depending on the priorities defined, objectives will include:</p> <ol style="list-style-type: none"> 1. Document and support the implementation of good practices that enable acceleration 2. Facilitate the development of enabling norms, standards, regulations and policies 3. Streamline regulatory pathways 4. Support targeted capacity strengthening 5. Introduce innovations to improve and accelerate investigation, development, introduction and access 6. Explore innovative funding mechanisms to accelerate paediatric innovation and access 	Intervene <ol style="list-style-type: none"> 1. Define product-specific priorities for at least three additional therapeutic areas and intervene when necessary. For the product-specific priorities identified, GAP-f will facilitate, implement or seek funding to support several targeted interventions to accelerate these products through clinical research, regulatory processes, uptake and access. This will likely involve targeted interventions in: <ol style="list-style-type: none"> 1a. Designing and implementing at least three additional clinical trials 2a. Developing at least four new formulations 3a. Introducing at least four new products 4a. Monitoring the safety of five drugs among those given priority. 2. Identify and engage industry partners to support and accelerate development of priority products. For development of priority products, relationships with industry partners will be key to ensuring that adequate manufacturing and supply of these products are available. GAP-f will identify innovator companies for specific products and engage with them to support paediatric development activities early enough to impact decisions such as clinical trial and formulation design. Additionally, focused, strategic business relationships with generic pharmaceutical companies will be fostered to enable accelerated product development of paediatric formulations of priority drugs.
Impact of the GAP-f 2022–2024 Strategy	<p>The ultimate outcome GAP-f seeks is to reduce mortality and morbidity among children by providing access to safe, effective, high-quality, affordable paediatric essential medicines.</p> <p>During this three-year strategic period, GAP-f will measure its impact by GAP-f's and its partners' contributions to the following:</p> <ol style="list-style-type: none"> 1. The global needs, framework for setting priorities, and GAP-f focus areas are well-defined, widely communicated, and broadly accepted. A system for global progress monitoring and tracking is in place to enable stakeholder alignment and targeted work to be undertaken to accelerate research on, development of and introduction of paediatric medicines 2. Amount of time saved at each stage of prioritization, research, development, introduction and monitoring 3. New technologies and methods matched and applied to priority paediatric medicines across multiple stages of priority-setting, research, development, introduction and monitoring 4. Measurable increase in the funding dedicated to paediatric medicines and the number of new investors in this area: GAP-f partners are better funded to deliver against GAP-f priorities 5. Number of countries reporting on inclusion of formulations on the WHO Essential Medicines List for children in their national Essential Medicines Lists 6. Number of additional children accessing better and appropriate medicines per disease area 		

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Thank you

GAP-f is only as strong as its partners. WHO sincerely thanks all contributors to GAP-f's work for their dedication, insights, trust and engagement. We are grateful for the staunch support of our funding partners, who have provided intellectual and monetary resources for this endeavour. Finally, the GAP-f Steering Group and founders have provided the guidance and nurturing of this initiative since it was launched, enabling growth and vision going forward so that we can **be together, stronger, for kids.**





GAP-f: Together stronger for kids

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