

WHO Immunization Devices

2025 – 2030 STRATEGY

July 2025



WHO Immunization Devices Prequalification

Vaccines & Immunization Devices Assessment Team (VAX)
Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)

WHO Immunization Devices (IMD) Performance, Quality and Safety (PQS)



Mission

Ensure the **availability and quality** of prequalified products to safeguard vaccines and immunization devices. In this way, the mission supports WHO's **disease elimination and eradication** efforts, as well as countries' **preparedness** for and **resilience** during health emergencies.

The WHO Immunization Devices programme sets global standards for equipment used in the safe storage, transport and administration of lifesaving vaccines—protecting the significant investments of time and resources required to develop, procure and deliver them effectively.

IMD-PQS is crucial to the success of the WHO Essential Programme on Immunization (EPI)

The World Health Organization (WHO) Immunization Devices Programme evolved from a system developed in 1979 to set standards for equipment intended to be used in the vaccine supply chain. Through its evolution, IMD-PQS has defined the standards for immunization equipment and worked together with manufacturers to ensure the availability of safe, effective equipment appropriate for low- and middle-income country settings. IMD's work supports the Immunization Agenda 2030 (IA2030) priorities, including coverage and equity and supply and sustainability.

WHO Immunization Devices adds value by:

SETTING STANDARDS that ensure immunization devices keep lifesaving vaccines potent and safe.

Rigorously VERIFYING COMPLIANCE of immunization devices with WHO standards.

Signaling market and country needs through **TARGET PRODUCT PROFILES TO HELP MANUFACTURERS** develop appropriate technologies and foster innovations.

Ensuring DEVICE DURABILITY AND RELIABILITY, raising their value across total cost of ownership.

PREQUALIFYING DEVICES that safeguard a growing range of new and more expensive vaccines, vital to the progress of WHO's EPI.

Facilitating CONSENSUAL STANDARDS DEVELOPMENT between country EPIs, WHO, UNICEF, Gavi, the Vaccine Alliance, the Pan American Health Organization's Revolving Fund, the Gates Foundation, and industry and technical experts.

WHO Immunization Devices mitigates important risks:

UNRELIABLE EQUIPMENT, which can lead to temperature excursions and reduced potency or spoiling of vaccines, possible adverse health consequences and wasted investments.

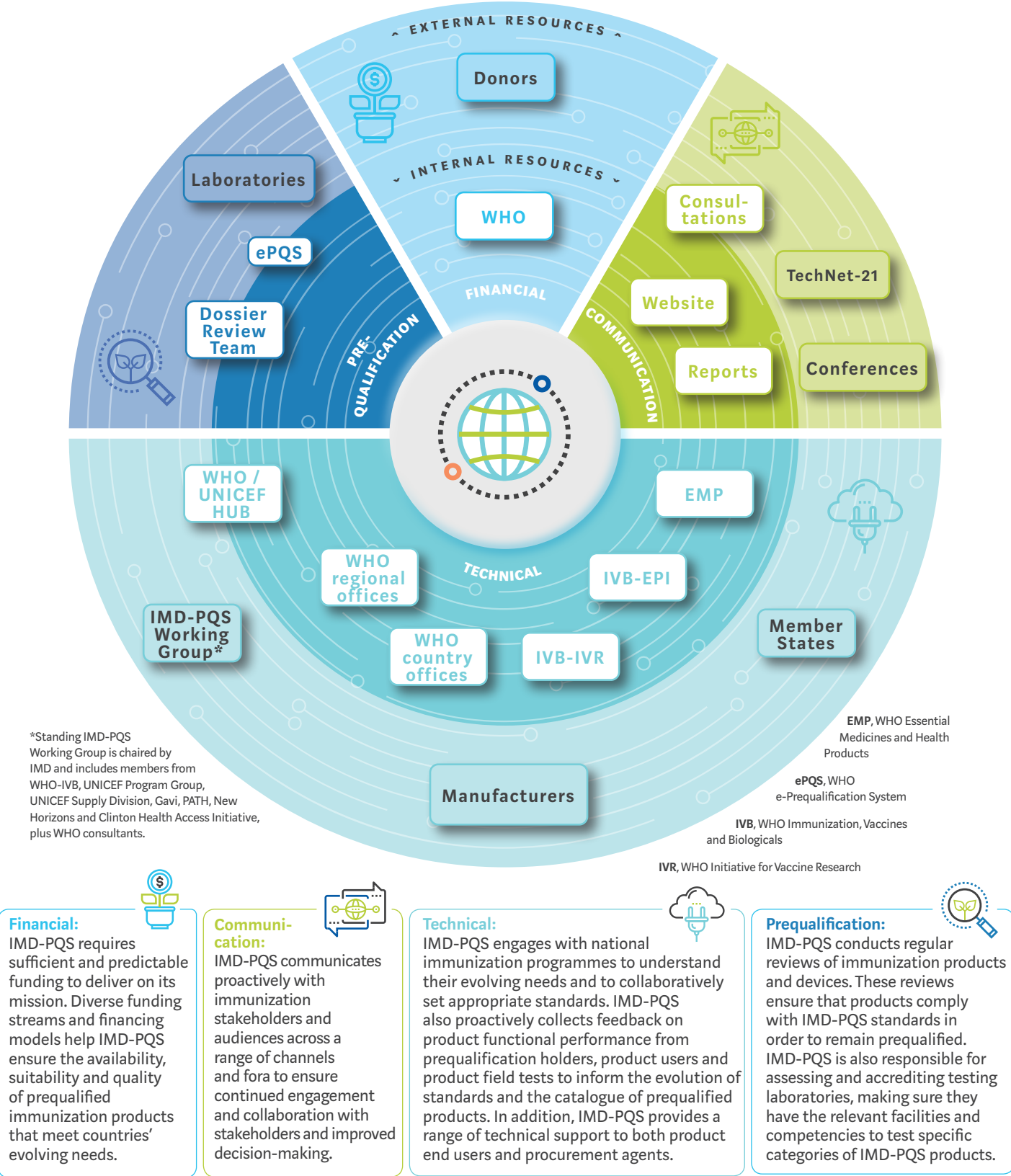
EQUIPMENT FAILURE, which can lead to costly downtime and compromised equipment. Proactive monitoring ensures early issue detection, better maintenance and extended equipment lifespan.

New vaccines provide protection against more and more diseases, but also tend to cost more per dose. Safe, effective and reliable cold chain equipment is crucial to **PROTECTING THE PUBLIC HEALTH VALUE OF VACCINES**.

The IMD-PQS ecosystem

IMD-PQS work relies on the inputs and investments of a wide ecosystem of partners, mostly external to WHO. The continued success of IMD-PQS and achievement of the current five-year strategy depends on the continuation of these contributions: technical, human resources and financial.

WHO Immunization Devices adds value to the global ecosystem of operational, technical and financial contributors focused on the delivery of high-quality, well-performing equipment that safeguards vaccines in immunization programmes.



Achievements

Successes & progress

over the previous IMD-PQS strategic period (2019–2024)

- » Set new product and testing **standards**.
- » Catalyzed new product **features** and supported technical **innovation**.
- » Reacted quickly to **facilitate** the availability of new technologies necessary to manage a **global pandemic**.
- » Increased **institutional capacity, stakeholder engagement** and strengthened the immunization devices **evidence base**.

Since 2019, IMD-PQS has:

Responded effectively to the COVID-19 pandemic:

- **Reviewed a tripled influx of prequalification applications**, primarily from refrigerators and freezers, and temperature monitoring devices.
- **Responded to the need for new injection devices** due to the non-standard COVID-19 vaccine dose sizes and resulting increase in dossier reviews.
- **Developed new product standards for ultra-cold chain equipment**.
- **Advised on global supply chain needs for ultra-cold storage and emergent response to the temperature excursion incidents involving COVID-19 vaccines**, ensuring these newer, high-value vaccines were never exposed to dangerously high temperatures during storage in freezers, which would have destroyed their potency.

Prioritized environmentally focused modernization:

- **Phased out R-134a refrigerant**. To reduce hydrofluorocarbon emissions under the Kigali Amendment to the Montreal Protocol, eliminating R-134a will reduce ozone depletion, lower greenhouse gas emissions and improve climate sustainability².
- **Developed standards for solar-powered systems to be used with walk-in cold rooms and freezers**.

Specified and prequalified new product features and functionalities, including:

- **Refrigerated vehicles**. Published a product specification and a test standard for refrigerated vehicles for vaccine transport. Prequalified first product in this category.
- **Transportable refrigerators**. Published a product specification and a test standard for transportable, powered appliances for temporary storage and transport of vaccines.
- **Asset tags**. Published a product specification for labels containing unique barcodes for cold chain equipment (CCE).
- **IA2030 alignment**. Contributed to the coverage and equity priority by prequalifying equipment for the last mile.

Solar-powered refrigerators for lower carbon emission vaccine storage

Solar-powered refrigeration was incorporated into vaccine cold chains in the 1980s to bring cold storage for vaccines to locations that had no or unreliable electricity. As electric infrastructure has improved, solar power remains a climate-friendly option to power vaccine refrigerators. Over the last 20 years, solar direct-drive (SDD) refrigerators have evolved so that batteries, which are costly and problematic for disposal, are not needed. In addition, many refrigerator models generate a surplus of solar power, which clinics can use to charge mobile phones and operate small equipment.

IMD-PQS played a key role in the mainstreaming of SDD refrigerators by developing specifications and testing protocols, the first of which were published in 2007. When Gavi launched the Cold Chain Equipment Optimization Platform in 2015, 24 SDD refrigerator models had been prequalified by IMD-PQS, enabling Gavi to prioritize this climate-friendly option for country purchase.

From 2014 through 2024, UNICEF purchased nearly 120,000 SDD refrigerators with funds from various sources.

SDD refrigerators now have a strong foothold in the vaccine refrigerator market, ensuring availability of lifesaving vaccines in locations that lack access to reliable electricity, and contributing to the greening of the vaccine supply chain.

Since 2019, IMD-PQS has also:

Coordinated global partner collaboration to deliver new innovations for stronger CCE monitoring and management, such as:

- **Equipment monitoring system**. Introduced a suite of new specifications and requirements for onboard refrigerator performance data generation, which will increase availability and uniformity of data for vaccine and refrigerator performance monitoring and management.
- **Sentinel surveillance programme pilot in four countries in 2020–2021**. Developed a toolkit, including indicators, lessons learned, guidance and other tools for future programme implementation activities to support proactive equipment monitoring and maintenance.

Launched new online resources to streamline and strengthen interactions with IMD-PQS, such as:

- **New IMD-PQS website**. Refreshed the website to align with overall WHO Prequalification division website updates and to present content in a cleaner, more streamlined manner. The welcome page includes easy access to information streams for manufacturers, testing laboratories, procurement agencies, global policymakers, country-level health officials and equipment operators.
- **Electronic prequalification system (ePQS)**. Developed an ePQS to formalize and modernize the process for dossier submission by prequalification holders and applicants and standardize the interactions between IMD-PQS and dossier reviewers. The system also facilitates documentation of these interactions and will enable IMD-PQS performance tracking.

IMD-PQS progress in numbers

For the period 2019–2024

Developed	Prequalified	Accredited
 52 NEW PRODUCT SPECIFICATIONS AND VERIFICATION PROTOCOLS	 187 NEW PRODUCTS ACROSS 10 CATEGORIES	 11 NEW TESTING LABORATORIES
IMD-PQS developed standards for ultra-cold freezers and equipment monitoring systems, and revised 43 existing standards to reflect evolving technologies and program needs, including refrigerated vehicles and portable fridges.	Not all operating environments are the same and programmatic needs vary among different local contexts. More IMD-PQS–prequalified products means more options from which countries can choose to best suit their particular immunization service delivery needs.	Laboratories accredited to carry out IMD-PQS testing doubled, further ensuring that devices met required performance standards, guaranteeing reliability and quality in critical applications. Accredited labs are now available in every region except WHO’s African Region.



Challenges & future needs

Challenges remain

- » The global landscape in which immunization programmes must operate is rapidly evolving.
- » Many of the IMD-PQS structures and functions need ongoing reinforcement and expansion to ensure procured equipment continuously performs to the standards by which it was prequalified and to prequalify products that meet countries' evolving needs.

Immunization supply chain systems are evolving due to advancements in information and communication technologies, better access to vaccines and immunization data, the growing number of vaccines in immunization schedules, bulkier volumes of new vaccines requiring greater storage capacity, the inclusion of non-vaccine temperature-sensitive health products in the 'vaccine' cold chain and higher costs of some newer vaccines. In addition, the emergence of COVID-19 highlighted how global pandemics can and will impact immunization programmes and systems at both global and country levels. In the wake of this pandemic and the probability of increased climate-related adverse events, emergency preparedness has risen in importance, while adaptability and proactivity are necessary to respond to global environmental change and its cascading effects on populations worldwide. To be successful in the future, WHO IMD will need to continue to prequalify products and devices that keep pace with these changes and ensure the availability of devices that fulfill their evolving vaccine transport and storage needs.

WHO's strategy for prequalification of immunization devices operates within the context of broader supply chain challenges, such as:



- The emergence of COVID-19 vaccines plus an already robust pipeline of new vaccines, which is driving an anticipated increase in total volume of vaccines to be stored and transported in the cold chain.
- Continued difficulties with procuring and maintaining equipment to keep vaccines within the proper temperature range in extreme environments.
- Increased call to integrate storage of vaccines and other heat-sensitive products used in primary health care.

At the same time, the strategy must react to the rapidly evolving global landscape in which immunization programmes operate:



- » **Climate change** is projected to cause 60,000 additional deaths from malaria annually between 2030 and 2050. While a malaria vaccine is currently being piloted in three African countries, its introduction into the cold chain requires reliable CCE to protect investments and ensure vaccine potency³.



- » Robust cold chain systems, improved vaccine management processes and the ability to reach broad target populations are all crucial to ensuring rapid and effective **emergency and pandemic response** to vaccine-preventable diseases⁴.



- » From 2010 to 2019, the **global population increased** 10 percent and urban living 5 percent. Coupled with a nearly 110 percent increase in displaced persons, this elevates the urgency of immunization and increases the challenges of delivering vaccines⁵.

And ensure procured equipment continuously performs to the standards by which it was prequalified.



IMD-PQS balances efforts to adapt equipment standards to keep pace with evolving technology and stewarding the quality of existing equipment and manufacturing. Three ongoing efforts that illustrate this dual role are the implementation of new equipment monitoring standards, the post-market monitoring initiative and efforts to strengthen the manufacturer inspection process.

- » IMD-PQS initiated **equipment monitoring system (EMS)** specification development in 2017 in response to challenges and opportunities observed with existing monitoring systems and the emergence of technological advances in the so-called 'Internet of things': In 2022, IMD-PQS published a suite of new specifications that define internal *data loggers* in refrigerators that generate and record data according to accompanying *data standards* and can be displayed or transmitted by *monitoring devices*. All three of these elements work together to allow users to more easily access standardized data across their CCE inventory.
- » IMD-PQS initiated the **post-market monitoring (PMM) programme** to help close the feedback loop so that IMD-PQS would have information about how the equipment they prequalified is performing against performance specifications in real-use settings. PMM can also provide insight into the reasons for equipment failure, which can inform manufacturers and future IMD-PQS specifications and lead to improved equipment overall. PMM was piloted in four countries in the last strategic period. In the coming years, IMD-PQS hopes to expand the use of PMM, embedding it within country ministry of health CCE maintenance teams.
- » IMD-PQS is refocusing attention on **manufacturing site inspections**. This is an important step in the continued verification of prequalified product quality. When IMD-PQS carries out a site inspection, they pay special attention to the manufacturer's quality system and look for the presence of systematic controls that ensure the equipment coming off the factory line will meet the quality and performance standards of the original prequalification.

*Internet of things describes devices with sensors, processing ability, software and other technologies that connect and exchange data with other devices and systems over the internet or other communication networks.



PQS Strategy 2025-2030



- The prequalification process is more efficient and transparent, and manufacturers continue to be held accountable.
- Post-market monitoring is fully functional and benefits country management and manufacturers.
- Standards are evolving and include consideration of country needs and environmental impacts.

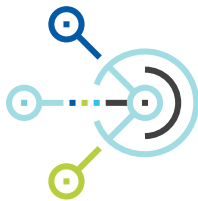
Stronger prequalification systems
Better feedback on equipment
Standards address needs

IMD-PQS TARGET

OUTCOME

OUTPUTS

2030 GOALS



01.
Streamline the prequalification process

The new IMD-PQS website and ePQS platform provide enhanced access to prequalification resources, expedite the prequalification process and improve device identification and visibility across stakeholders, ensuring country programmers, partners, prequalification holders and reviewers can efficiently interact with IMD-PQS at all stages.

- Officially launch the ePQS, facilitating its adoption through targeted training sessions, regular updates, troubleshooting support and comprehensive user guides.
- Expand dossier reviewer capacity by creating a standing request for CVs, consulting with experts, building a network of qualified professionals through platforms like TechNet-21 and collaborating with other organizations offering independent funding.
- Maintain a public repository of product standards and related guidance documentation and develop comprehensive procedural guidance for manufacturers.

The IMD-PQS prequalification process is transparent, efficient and responsive to evolving health needs worldwide, with improved access to resources and an optimized user experience for country programmers, partners, prequalification holders and reviewers.

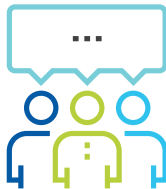


02.
Facilitate effective communication & transparency

IMD-PQS continues to serve as a link between CCE manufacturers and the countries that use this equipment for storage, monitoring and transport of vaccines.

- Formalize and strengthen the complaints management process by introducing a structured method to log and allocate all complaints efficiently.
- Enhance collaboration and engagement with key stakeholders, including the EPI, Gavi and UNICEF, through regular meetings, joint initiatives and ongoing partnership development.
- Launch an open application programming interface to ePQS to improve access to public data and integration, allowing stakeholders to interact more easily with PQS data.
- Monitor the performance and usage metrics of the new website to target outreach and assess the effectiveness of communication strategies based on data insights.
- Address the lag between annual review updates and publication of new IMD-PQS data, ensuring that manufacturers and other users receive timely, up-to-date information.

IMD-PQS data are reliable, robust and easily accessible to prequalification holders and country programmes. Communication channels are clear and effective, fostering stronger collaboration and informed decision-making among stakeholders.



03.
Maintain stakeholder engagement

Strong, ongoing involvement of manufacturers, laboratories and other relevant stakeholders in the development and maintenance of product specifications and testing protocols is sustained, ensuring that engagement remains effective and relevant.

- Maintain regular communication with manufacturers and country programmes to ensure their continued quality input into evolving specifications and testing requirements.
- Explore the establishment of a technician network through PMM, allowing technicians to report their experiences with equipment and share insights, utilizing the EPI email contact list and potentially incorporating this into in-country IMD-PQS Working Group meetings.
- Explore leveraging regular EPI meetings with regional offices to communicate IMD-PQS-related talking points, ensuring consistent messaging and alignment with regional needs.
- Continue holding IMD-PQS Working Group meetings in countries (at least one meeting per year) to maintain local engagement and gather feedback for standards setting.
- Explore opportunities for direct communication between country colleagues and the IMD-PQS team, strengthening regional connections and ensuring local perspectives are integrated.

IMD-PQS standards evolve in alignment with programme needs and industry innovations, maintaining a strong, ongoing partnership with stakeholders through sustained engagement and clear communication of changes via target product profiles.



04.
Increase post-market monitoring

A comprehensive system for PMM integrates real-time performance reporting, trends analysis and data from sentinel surveillance and other immunization sources, ensuring continuous improvement of CCE performance.

- Enforce performance issues reporting in real-time and as part of the annual review process, ensuring timely feedback and action.
- Complete implementation of the Open Data Kit software, encouraging countries to share real-time data with IMD-PQS to improve monitoring and data-driven decision-making.
- Roll out the sentinel surveillance project in target countries with the goal of embedding it within EPI management processes, ensuring sustained monitoring and oversight of CCE performance.
- Gather preliminary feedback on uptake of the EMS requirements, assessing its impact on maintenance and use of CCE.
- Codify complaints to identify emerging trends and systemic issues, establishing a structured coding process for complaints that is fully integrated into the complaint management system.

Consistent, reliable and real-time data on equipment performance are integrated from routine PMM across selected countries, enabling continuous improvement in equipment maintenance and use based on comprehensive and actionable performance data.



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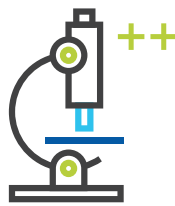
Stronger prequalification systems
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IMD-PQS TARGET

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05.
Expand laboratory testing capabilities

Laboratory testing capabilities are enhanced across all geographies.

- Explore laboratory capacity in underserved regions, identifying opportunities for expansion and capability building through feedback from local stakeholders, and testing needs.
- Increase testing capacity and capability for E003 and E006 EMS devices, ensuring laboratories can accommodate more complex and varied testing requirements.

Equipment testing options are expanded to accommodate a diverse range of equipment and tests, ensuring efficient and comprehensive testing of IMD-PQS products in both established and underserved regions.



06.
Strengthen quality management systems

Technical support for quality management system (QMS) inspections is increased and extended to new product categories.

- Continue conducting QMS inspections for E003 and E006 devices to ensure compliance with established quality standards.
- Explore how to embed QMS oversight as a core element of IMD-PQS processes, integrating it fully within the WHO inspection system to streamline and standardize inspections across product categories.
- Continue optimizing the inspection process by increasing capacity, and continue to focus on high-volume manufacturers and risk basis.
- Identify ways to improve QMS oversight.

QMS oversight is fully integrated into the IMD-PQS system, strengthening the capacity to conduct routine and comprehensive inspections of manufacturing sites and testing laboratories, ensuring that equipment manufacturers consistently meet high quality standards.



07.
Evolve product standards

Shifting global health challenges are anticipated and addressed by evolving product specifications and prequalification processes as appropriate. Product standards are adapted to emerging programmatic needs, evolving technologies and changing contexts, and consider the practicalities of expanding cold chain use and ensuring that specifications remain sufficient and effective for protecting and maintaining vaccine potency.

- Establish systematic touchpoints with emergency response colleagues within WHO to ensure coordination and alignment on evolving needs.
- Strengthen links with the EPI to align specifications with the evolving landscape of health emergencies and responses.
- Develop an expedited pathway for prequalification during emergencies, including rolling submissions, and codify this process for efficient, timely reviews.
- Revise IMD-PQS specifications to meet the needs of immunization programmes, with guidance from WHO Immunization, Vaccines and Biologicals/EPI regarding integration of temperature-sensitive non-vaccine products within the vaccine cold chain.
- Continue with the target product profile process and maintain responsiveness to country needs.

IMD-PQS is adaptable and responsive to changing landscapes and global health emergencies as the result of evolving product specifications that accommodate new technologies and changing programmatic needs while ensuring the integrity of the cold chain.



08.
Address environmental concerns

Key climate change mitigation and adaptation tactics that are within the ability of IMD-PQS to influence are identified, such as reducing use of harmful materials in products and enabling sustainable energy practices.

- Review relevant WHO environmental guidance documents and engage with experts in environmental sustainability to explore the development of an IMD-PQS ecosystem-aligned environmental approach.

Publication of a comprehensive and appropriate environmental strategy to guide ongoing actions and improvements.



Critical success factors

The following elements are essential for IMD-PQS to achieve its five-year mission.

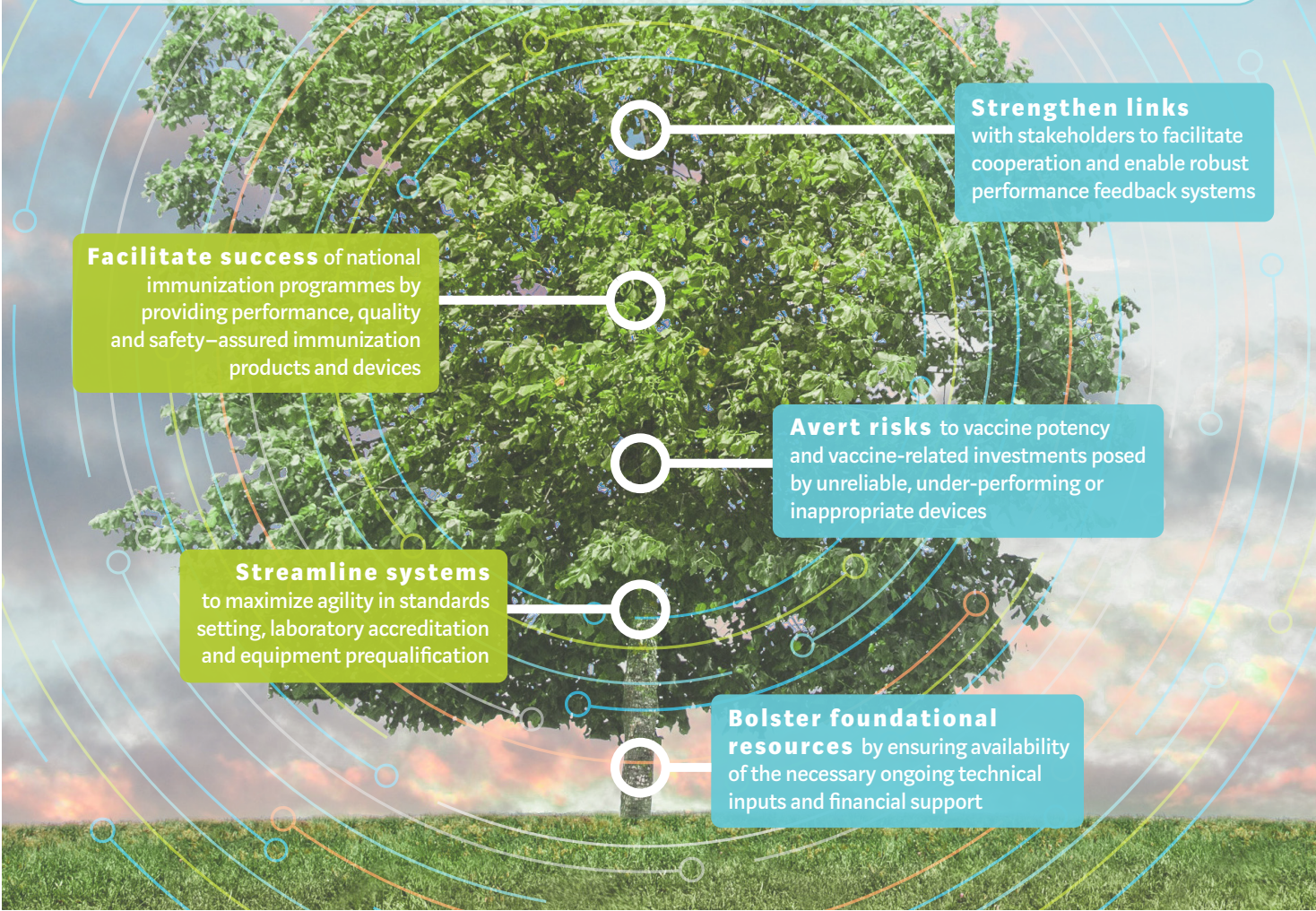
	 INVESTMENT <i>New versus current sources of IMD-PQS funding</i>	 HUMAN RESOURCES <i>Reinforced IMD-PQS Secretariat</i>	 TECHNICAL COOPERATION <i>Expanded list of collaborative partners</i>	 CONTINUOUS PERFORMANCE MONITORING <i>IMD-PQS SMART indicators*</i>
 BENEFITS TO INVESTMENT	+ Long-term predictability for PMM systems and QMS inspections. + Development of IMD-PQS evidence base.	+ More robust and efficient IMD-PQS processes. + Strengthened CCE technical community around IMD-PQS.	+ Extends IMD-PQS's access to technical expertise. + Provides insight into market needs and latest innovations to inform standards and target product profiles.	+ Targeting of interventions according to need. + Identification and implementation of mitigation strategies. + Systematic tracking of progress against 2030 goals.
 RISKS OF STATUS QUO	- o Dependence/reliance on partners to lead PMM and QMS inspections. - o Ad-hoc QMS inspections based on partner timelines and budgets.	- o Limited interaction with the CCE technical community. - o Slower and limited IMD-PQS processes and approaches.	o Missed opportunities to leverage CCE innovations in target product profile development.	- o Harder to identify or implement mitigation strategies if targets are not set and met for this strategic period. - o Ad-hoc approach.

* **SMART indicators:** Specific, measurable, achievable, relevant and time-bound metrics used to track progress and evaluate the effectiveness of programmes or projects.



Envisioning a healthy IMD-PQS ecosystem

IMD-PQS must **maintain its ability to adapt, future-proof the immunization cold chain** and **safeguard vaccines in an unpredictable landscape**



References

1. Brooks A, Habimana D, Huckerby G. Making the leap into the next generation: a commentary on how Gavi, the Vaccine Alliance is supporting countries' supply chain transformations in 2016–2020. *Vaccine*. 2017;35(17):2110–2114. <https://doi.org/10.1016/j.vaccine.2016.12.072>

2. The Kigali Amendment: The amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer agreed by the Twenty-Eighth Meeting of the Parties (Kigali, 10–15 October 2016). Accessed 13 March 2025. <https://ozone.unep.org/treaties/montreal-protocol/amendments/kigali-amendment-2016-amendment-montreal-protocol-agreed>

3. World Health Organization (WHO). *Immunization Agenda 2030: A Global Strategy to Leave No One Behind*. Geneva: WHO; 2020. <https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/ia2030>

4. UNICEF. *Immunization Roadmap to 2030*. New York: UNICEF; 2023. <https://www.unicef.org/documents/unicef-immunization-roadmap-2030>

5. World Health Organization (WHO). *Global Vaccine Action Plan*. Geneva: WHO; 2020. <https://www.who.int/publications/i/item/global-vaccine-action-plan-monitoring-evaluation-accountability-secretariat-annual-report-2020>

6. World Health Organization (WHO) and UNICEF. *Temperature-sensitive health products in the Expanded Programme on Immunization cold chain: A WHO-UNICEF joint statement encouraging greater health commodity supply chain integration for temperature-sensitive pharmaceuticals where appropriate*. Geneva: WHO; 2020. https://www.who.int/publications/i/item/WHO-2019-nCov-Immunization-Cold_Chain-2020.1



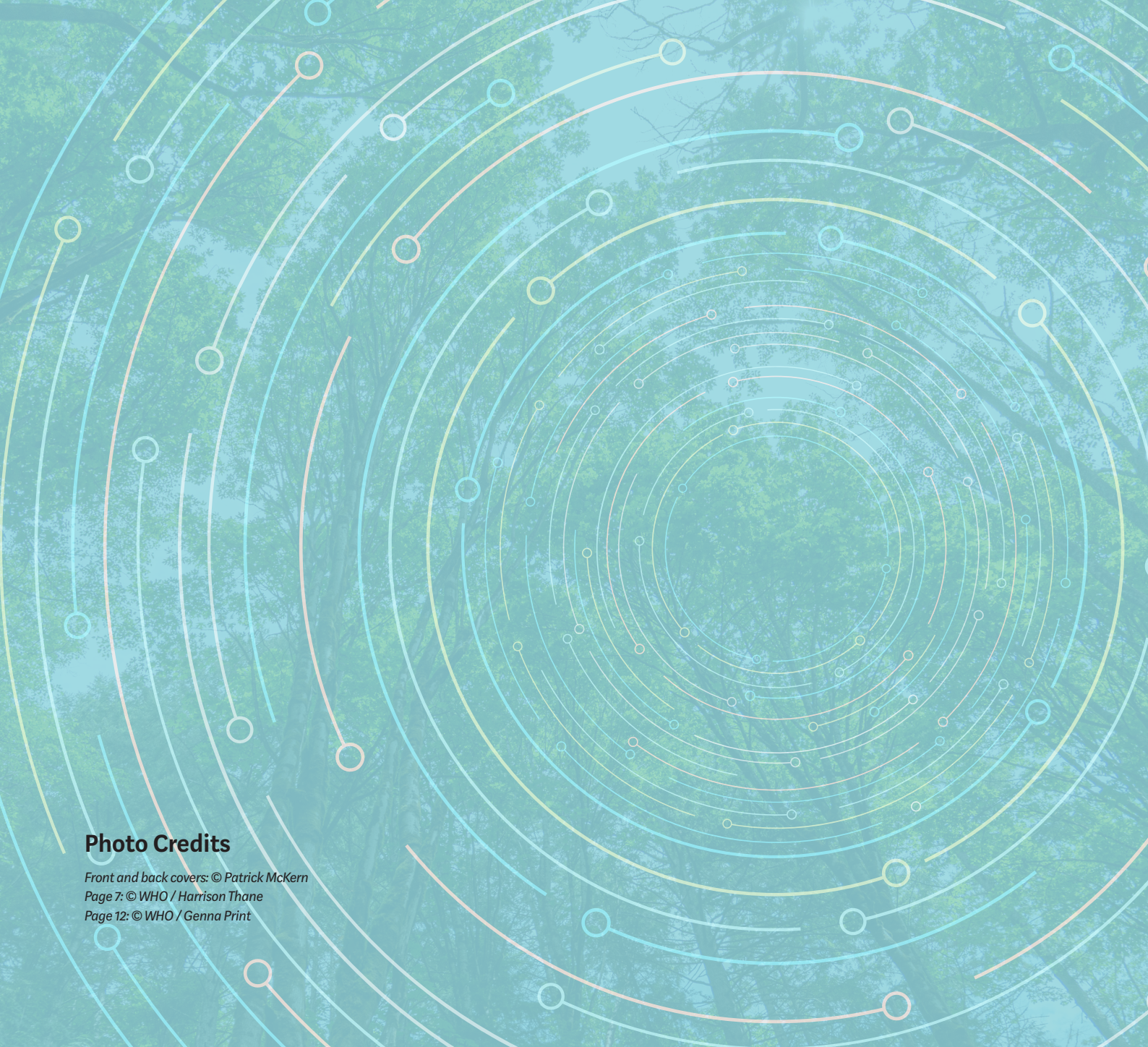


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