OPTIMIZE Immunization systems and technologies for tomorrow

PATH World Health Organization

2009–2012
OPTIMIZE STRATEGY

Executive Summary

Over the past decade, the world has invested enormous resources and energy into the development of new and lifesaving vaccines. Current vaccination programs save more than three million lives per year, and new vaccines that focus on diseases disproportionately affecting those in the world's poorest countries can protect millions more. However developing new vaccines alone is not enough—we need delivery systems that are as advanced and innovative as the vaccines they support.

Optimize: Immunization systems and technologies for tomorrow, a collaboration between the World Health Organization (WHO) and PATH, has been given a unique mandate to think far into the future: to put technological and scientific advances to work, helping define the ideal characteristics and specifications for health products; and to create a vaccine supply chain that is flexible and robust enough to handle an increasingly large and costly portfolio of vaccines.

To achieve its vision, Optimize will focus on three strategic objectives and areas of work:

Innovate- Innovation is not something that happens every 30 years; it is happening all the time. By envisioning future technologies and solutions, supporting and guiding ongoing research and development activities, and creating an environment conducive to further innovation, Optimize can support countries in building logistical systems that are able to adapt to the changing needs of our changing world.

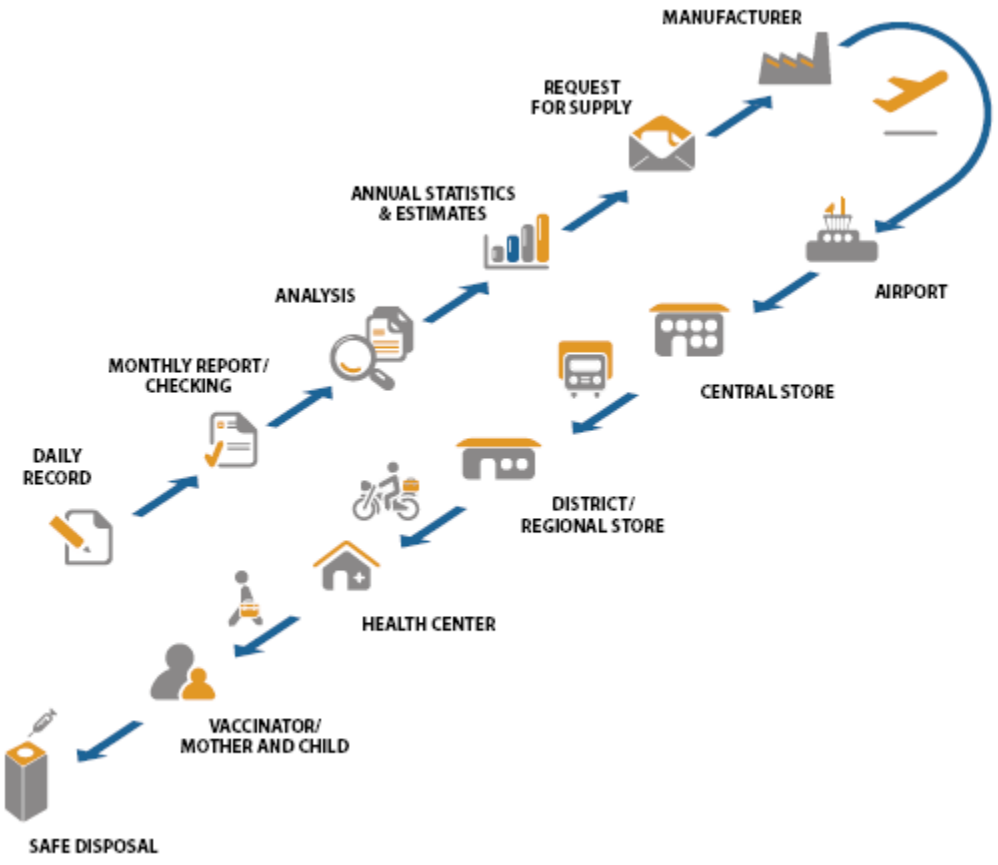
Demonstrate- New system solutions and technologies must be aligned with country circumstances and future needs, and their impacts demonstrated in country contexts. Optimize will collaborate with countries and their ministries of health to, together, define the value, benefits, and limitations of new technologies, systems, and management approaches through operations and experimental research supported by modeling. This will enable decision and policymakers to select solutions that are proven to work.

Facilitate- Over the next five years Optimize will facilitate a coalition of partners who will work to define the characteristics of an ideal supply chain, from health products to policies to logistics systems. By 2012 we aim to have a globally accepted "roadmap" that will make it possible to implement these innovations around the world—and the momentum and support from our partners to move forward.

October 2009

The Current Vaccine Supply Chain

The current vaccine supply chain used in most low- and middle-income countries is composed of a series of procurement, storage, and distribution activities. Once the vaccine leaves the manufacturer it must be kept within a specific temperature range. The longer it takes the vaccines to get from the manufacturer to the vaccinator, and the longer the vaccines are stored and moved around, the higher the risk of damage to the vaccine. Optimize is committed to reducing the risk and improving the efficiency of this process.



Introduction

It is estimated that immunization saves over three million lives each year, many of them in the world's poorest countries. However, millions of people in these countries remain at risk for diseases that can be prevented by vaccines.

Over the past decade major global investments of resources and time have been put towards the development of new vaccines and health technologies that can reduce or even eliminate these risks and significantly improve the health of people in the world's poorest countries. Now that these new vaccines and health technologies are becoming available, the world is facing an alarming logistical challenge. Without significant improvements in the supply chain that delivers the correct amounts of these valuable products safely and efficiently—ensuring little is wasted, lost, broken, or exposed to excessive heat or cold—they may never reach the people who need them most.

In November 2007 the Bill & Melinda Gates Foundation funded a five-year PATH - WHO joint effort to shape the future of immunization and health delivery systems which led to the creation of **Optimize: Immunization systems and technologies for tomorrow.**

Background

In 2008, Optimize carried out several landscape analyses to better understand the environment in which the project will be operating, to identify innovative and effective solutions in relevant areas, and to inform the project focus and strategy.

These landscaping efforts covered the following areas:

- Immunization logistics.
- Supply chain and logistics in the health center.
- Supply chain and logistics of perishables outside of health.
- Cool chain technologies.
- Vaccine and delivery technologies.
- Modeling.
- Information systems and technologies.
- Training and capacity building.
- Outsourcing and financing.
- Stakeholder mapping.
- Global advocacy and policy (in process).

In addition, a workshop was organized to imagine the possible future scenarios that could be encountered in 30 years time. These future scenarios, while not predictions of future immunization systems, are meant to illustrate plausible, challenging, and divergent future options that should stretch our vision and alert us to the issues that must be addressed to make future immunization systems relevant.

This strategy is informed by the above mentioned work, as well as by numerous analytical and planning efforts undertaken by the project in 2007 and 2008. This strategy will be the guiding vision for the work the project undertakes through 2012. However, the Optimize team remains open to adapting our vision as needed in order to benefit from relevant synergies and opportunities that may emerge.

Strategic Intent and Project Goals

While Optimize is a five-year project, it seeks to create momentum that will continue beyond the end of the project in 2012. As such our goals are not limited to what we can do in five years but are the first steps in establishing enduring mechanisms that promote active and collaborative looking ahead and planning, involving all stakeholders—from countries to industry.

Our vision is far reaching, and our impact should be as well. Our starting point is immunization and vaccines, but our goal is to develop and test innovations that can be applied across the health sector. We aim to significantly impact the design of health logistics systems and the characteristics of health products to meet the evolving needs of populations in low- and middle-income countries in years to come. This is a broad field, and much exciting work is already underway within it. We understand the importance of synergizing with existing efforts and focusing our efforts on areas where we can make a substantial impact.

Optimize's work over the next five years will lay the foundation to achieve its vision. We have set our long-term strategic intent in the future after the project ends. This strategic intent serves as a constant reminder that we must, in all we do, think beyond 2012, and strive to create a platform that supports innovation for decades to come.

Optimize has, therefore, defined its long-term strategic intent as follows:

By 2025, state-of-the-art health logistics and technologies meet the changing needs of a changing world.

Optimize's success will be measured against how well we have, by 2012:

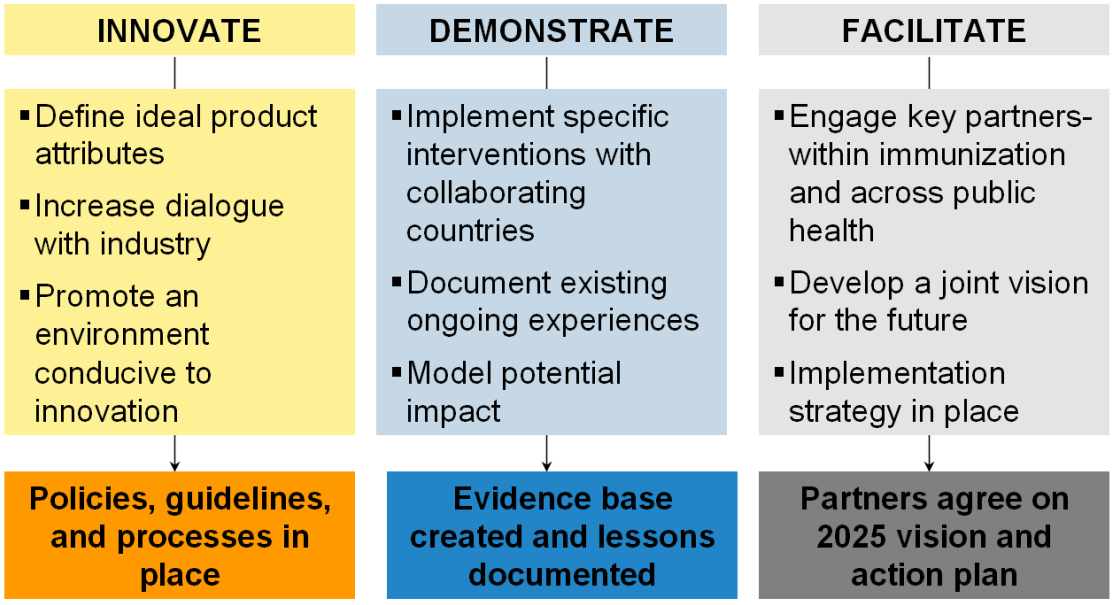
- Identified the attributes of efficient and effective health logistic systems for the future.
- Defined a set of ideal product characteristics for vaccines, delivery technologies, and cooling systems that are shared and actively supported by major stakeholders in their respective areas of influence.
- Generated the tools and evidence that support these choices.
- Developed mechanisms that support and encourage innovation, defined a pattern and practice that identifies successful methods for achieving innovation, and indentified pathways to move those innovations through the policy mechanisms.
- Created a coalition of stakeholders who are invested in the outcomes of Optimize and committed to moving the work forward post-2012.

Optimize has defined the life-of-project goal as:

By 2012 all major stakeholders share an informed vision of optimal health logistics and technologies for 2025 and are committed to its achievement.

In order to reach this goal, Optimize work will center around three complementary strategic objectives:

Innovate, Demonstrate, Facilitate



Innovate

Strategic Objective 1: ***By 2012 mechanisms and policies to drive innovation are in place.***

Optimize will promote a policy and regulatory environment conducive to innovation—one that minimizes risk and increases incentives. Our work towards furthering this goal in the areas of technologies, systems, and practices focuses on the catalyzing the following:

1.1
Policies and mechanisms that enable innovation are used to support selected technologies.

1.2
Policies and mechanisms that enable adoption of new health logistics (systems and practices) are developed and used.

Activities in this area will focus on:

- Selecting specific technologies and systems/practices to champion.
- Identifying bottlenecks in the development, introduction, and adoption pathway of these technologies and systems (e.g., regulatory, policy, financing, commercial market, advocacy, procurement, decision-making).
- Defining opportunities to remove these constraints and accelerate development; introduction; and adoption of new technologies, systems, and practices.
- Generating patterns and practices that show how innovation can successfully be achieved and supported.
- Developing and supporting the implementation of a research and development (R&D) agenda and demonstration effort for selected products, technologies, systems, and practices.
- Documenting R&D results and successes in reducing barriers and increasing incentives.
- Generating the evidence necessary for adoption of these innovations.

Vaccine Vial Monitors (VVMs)

A policy that would allow heat-stable vaccines to be used under less stringent "cold chain" requirements could:

1) free up limited cold chain space and reduce additional resources required to accommodate new vaccines, especially those in single-dose presentation (e.g., rotavirus, pneumococcal and HPV), and

2) facilitate better integration of health products and immunization supply chains.

Placing VVMs on all vaccines is a key step towards accomplishing this. The VVM is an innovative technology that helps health personnel ensure vaccine safety by identifying over-exposure to heat.

Developing the new Effective Vaccine Management (EVM) Tool

A well-organized and managed national cold store, where all vaccines are received, stored, and distributed, is critical to an efficient national vaccine supply chain and immunization system. In 2004 WHO and UNICEF launched the Effective Vaccine Store Management (EVSM) initiative—a self-assessment tool to help countries improve vaccine storage and distribution, focusing on country primary vaccine stores. The introduction of new and more costly vaccines with larger presentation volumes will put mounting pressure on the supply and cold chain systems, and especially on national cold stores. With the value of stocks in national cold stores running to millions of dollars, protecting this investment in life-saving vaccines requires highly effective national store systems and management.

In recent years the EVSM initiative has lost traction, and other vaccine management tools [namely the Vaccine Management Assessment (VMA)] that cover both the national and sub-national levels have emerged. As part of responding to current country needs with a view to the future, Optimize is working to:

- Streamline the vaccine management assessment tools by merging the EVSM and VMA into EVM, pulling the best of each tool into a combined-web based platform
- Revitalize the initiative by supporting training activities and promoting the use of the revised tool for self-assessment of vaccine management.
- Undertake a global analysis of vaccine management and develop online databases.

Innovate—indicators and measures of success:

- Existence of policies and guidelines issued by official bodies that drive innovation.
- Results from modeling that show the projected impact of proposed technologies, systems, and practices.
- Numbers of products/technologies, systems, and practices developed or advanced.
- Policy documents or published guidelines by official bodies that include adoption and access to new products, technologies, systems, and practices.
- Evidence that adoption of and access to products and technologies, new systems, and practices has been advanced by policies and mechanisms

Demonstrate

Strategic Objective 2: ***By 2012 a strong evidence base for optimal combinations of systems, technologies, and practices has been established.***

Strategic objective 2 focuses on collaboration with countries in order to demonstrate innovative processes and new technologies that can contribute to improving the efficiency, flexibility, and cost-effectiveness of immunization supply chain and logistic systems. Supply chains are not unique to immunization, and Optimize is committed to looking across all sectors to identify potential opportunities and synergies.

Based on the experience and lessons of the demonstration projects, Optimize will work with relevant groups to develop recommendations that countries can follow when looking to optimize their supply chains. For example, a reduction in the number of storage levels in a country's supply chain and a more effective inventory control management system may be keys to improving efficiency, decreasing costs, and limiting risks associated with product mishandling.

Discovering and gathering evidence to support such solutions will be instrumental in solving the enduring problems in immunization logistics and in addressing the challenges of introducing new vaccines and delivery mechanisms in the future.

Lessons from the Produce Aisle

Passively-cooled carts used to deliver fruit and vegetables to European supermarkets are one example of a new technology that could improve vaccine distribution. They may be a perfect fit for moving vaccines from one storage location to another in developing countries. The carts maintain constant temperatures and carry a significantly higher volume of vaccines than traditional cold boxes, potentially saving considerable expense in both the short and long term.

Other emerging technologies such as battery-free solar refrigerators could significantly improve the reliability of refrigeration systems at health centers and clinics and reduce maintenance requirements.

Optimize objectives in support of this work are:

2.1
Country-level interventions designed.

2.2
Country-level interventions validated.

Activities in countries and the development of a modeling tool will generate an evidence base that validates proposed changes to supply chain and logistic systems and will inform the development of future technologies.

Waste Management

Waste management is an integral component of any health system. While not a focus of Optimize's core work, the project aims to dovetail supply chain solutions with waste management initiatives. In all undertakings, Optimize is committed to the following:

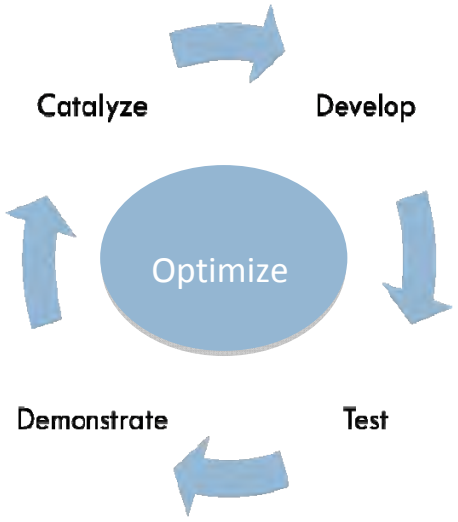
- Supporting products, technologies, and logistic solutions that prioritize waste minimization (volume and materials).
- Exploring innovative potential solutions to issues of waste management (infectious debris, sharps, etc.) such as backloading vehicles that deliver health products with medical waste, which can then be delivered to safe disposal facilities.

Modeling Future Scenarios

Optimize modeling work will focus on supporting country partners. It will include components such as vaccine volumes for specific countries; multi-level estimates of resources; and costs for storage capacity, transport, and stock management. This model will help predict the impact of scenarios such as:

- Changes in the frequency of vaccine delivery.
- Increases in volume and storage needs over time.
- The use of various transport options and technologies.
- International regional warehousing and/or bypassing some levels of the system versus upgrading all levels of the system.
- The use of vaccines out of the cold chain.

Building on data generated in the country demonstration projects, the baseline model will be expanded to serve a broader range of scenarios and country situations.



Demonstrate—indicators and measures of success:

- Existence of data proving and documenting optimal systems.
- Menu of systems solutions and technologies ready for country presentation.
- Demonstration project design finalized and collaborative agreements signed with countries.
- Required country baseline data compiled.
- Comprehensive data from demonstration projects supports expected changes.
- Number of countries using the revised Effective Vaccine Management Assessment tool and undertaking corrective actions based on the results.
- Modeling results project the impact of proposed technologies, systems, and practices.
- Attributes of ideal health technologies and systems for tomorrow identified based on concrete evidence and clear rationale.

Facilitate

Strategic Objective 3: ***By 2012, global-level commitment to the advancement and adoption of optimal health logistics and technologies is obtained.***

The third strategic objective aims to create a shared global vision for the future of health logistic systems—a vision in which a seamless and smooth process supports the creation of new technologies and allows vaccines and other health products to be safely, efficiently, and cost-effectively managed, stored, and delivered to people who need them, when they need them, no matter where they live.

Optimize will engage the many individuals and organizations whose passion and expertise is essential to ensuring that improved logistic systems are able to respond to evolving needs. Stakeholders include public health policymakers; national governments; civil society, including nongovernmental organizations (NGOs) and academia; immunization system stakeholders; regulators; vaccine manufacturers; and relevant private-sector service providers and companies.

Initial attributes that are considered critical to a vision of optimal health logistics include:

<u>Supply systems</u>

- Increased efficiency of the supply chain system, with fewer steps, increased speed, minimized risk, and the ability to move greater quantities of vaccines.
- A maximum proportion of the target population reached on time, with quality vaccines, through quality services.
- Integration of immunization supply chain with the supply of other health commodities.

<u>Technologies</u>

- Products are more heat/freeze stable.
- Products are more compact, and vaccines are integrated with delivery devices.
- Other desirable product attributes that meet specific program needs such as:
  - Safe administration.
  - Minimizing waste and environmental impact.
  - Facilitating integration with the supply of other health products.
  - Maximizing access to the target population (e.g., enabling delivery by a wide range of personnel).

Optimize will work towards promoting those by focusing on the following intermediate objectives:

3.1
Support from the global health community obtained as a result of effective communication.

3.2
Core partners share a jointly developed vision for optimal health logistics and technologies for 2025, with plans in place to support its achievement.

Facilitate—indicators and measures of success:

- Partners involved in activities that work towards realizing a vision of optimal health logistics.
- Evidence of positive messaging and knowledge about the vision in the global health community.
- Resources from the global health community support Optimize efforts.
- Number of effective collaborations formally established.
- Number of partners with capabilities and interests relevant to the project involved in Optimize work.
- Inclusion of goals and responsibilities in 2012 partner strategic plan that are aligned with the Optimize vision.

Achieving Optimize goals and objectives by 2012 is ambitious; achieving the 2025 vision even more so. Reaching goals and achieving the vision require a clear plan of action, with markers along the way that provide opportunities to assess progress and adjust directions as needed.

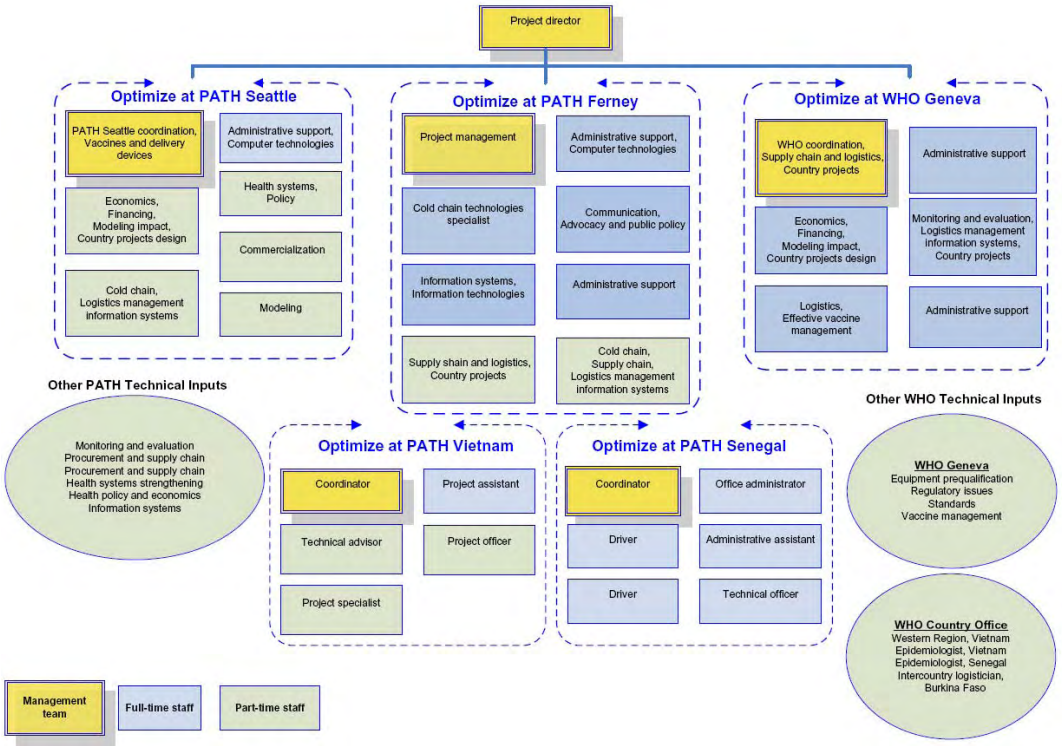
Optimize will move along the path from where we are today to a new era in logistics, always keeping in mind the ultimate goal of the ideal logistics system.

Management

Optimize is a PATH-WHO joint collaboration, formalized through a cooperative agreement between the two agencies.

Technical staff from WHO and PATH contribute to the project within their respective areas of expertise. PATH provides specific expertise and experience in technology development, vaccines and vaccine formulations, modeling, advocacy, policy and communications, and business development and commercialization. WHO staff contribute expertise in the areas of immunization, health economics, norms and standards, regulatory issues, vaccine management and immunization logistics, and monitoring and impact analysis.

Staff members are based in Geneva, Ferney-Voltaire, and Seattle. They communicate as a team on a fortnightly basis through telephone and video conferences.



A management committee reflecting WHO and PATH high-level engagement in this project, reviews and approves the project strategy, annual work plans, and annual budgets, as well as project reports.

The project also benefits from an advisory group made up of specialists in the fields of health technologies, logistics, management systems, and development. The Project Advisory Group (PAG) provides technical input and advises project leadership on vaccine and technology research, development, and implementation; supply chain and logistics systems; and linkages with other public health efforts.

Guiding Principles

The following principles, adopted by the project team in July 2008, will guide the work of Optimize:

- **Visionary**
  We maintain a broader health system perspective and remain mindful of our mandate to create and work towards a vision for the year 2025.
- **Inclusive**
  We value and respect the perspectives of all stakeholders. We create open channels of communication within our team and with our partners, and we are transparent with regard to project plans, activities, and results.
- **Bold**
  We challenge ourselves, we are prepared to work outside of our comfort zones, and we are willing to accept failure as a consequence of having taken risks.
- **Ecologically conscious**
  We focus on solutions that are environmentally friendly, and we adopt work practices that minimize our carbon footprint.
- **Sustainable**
  In our demonstration projects, we focus on practical and sustainable solutions and pay special attention to local needs, limits, and potential.