

National Pharmaceutical Traceability Vision and Strategy Development Reference Note

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

Version, 1.0, February 2021



USAID
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PEPFAR
U.S. President's Emergency Plan for AIDS Relief



USAID
FROM THE AMERICAN PEOPLE



U.S. President's Malaria Initiative

Introduction



How To Use This Resource

This resource provides guidance and tools that may be used in developing a traceability vision and strategy, including a:

- Vision statement and strategic objectives for implementing traceability
- Traceability results framework
- High-level roadmap for implementing traceability

We provide guidance on which stakeholders to engage, key focus areas to consider in strategy development, and exercises and templates that can be used to create a traceability results framework and high-level implementation roadmap. You can adopt and adapt these materials to conduct a vision and strategy development workshop with stakeholders.

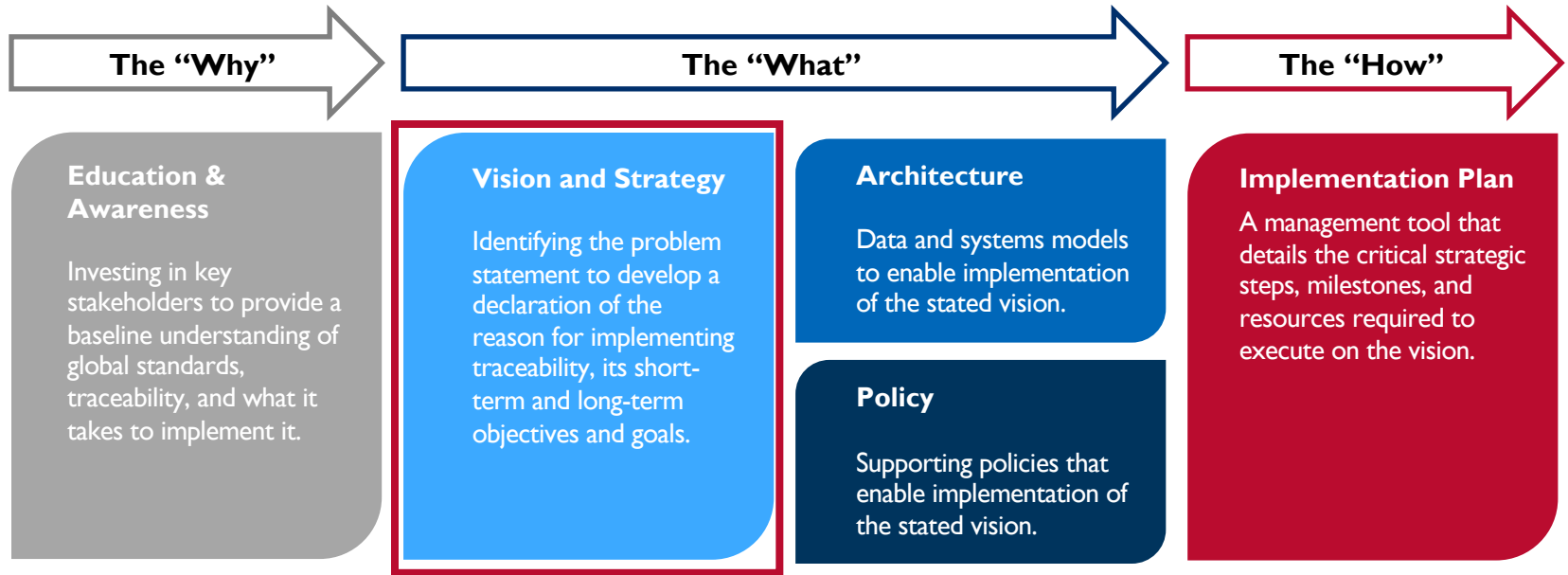
Background

National Pharmaceutical Traceability Strategy Development Stakeholders



GHSC-PSM Traceability Planning Framework

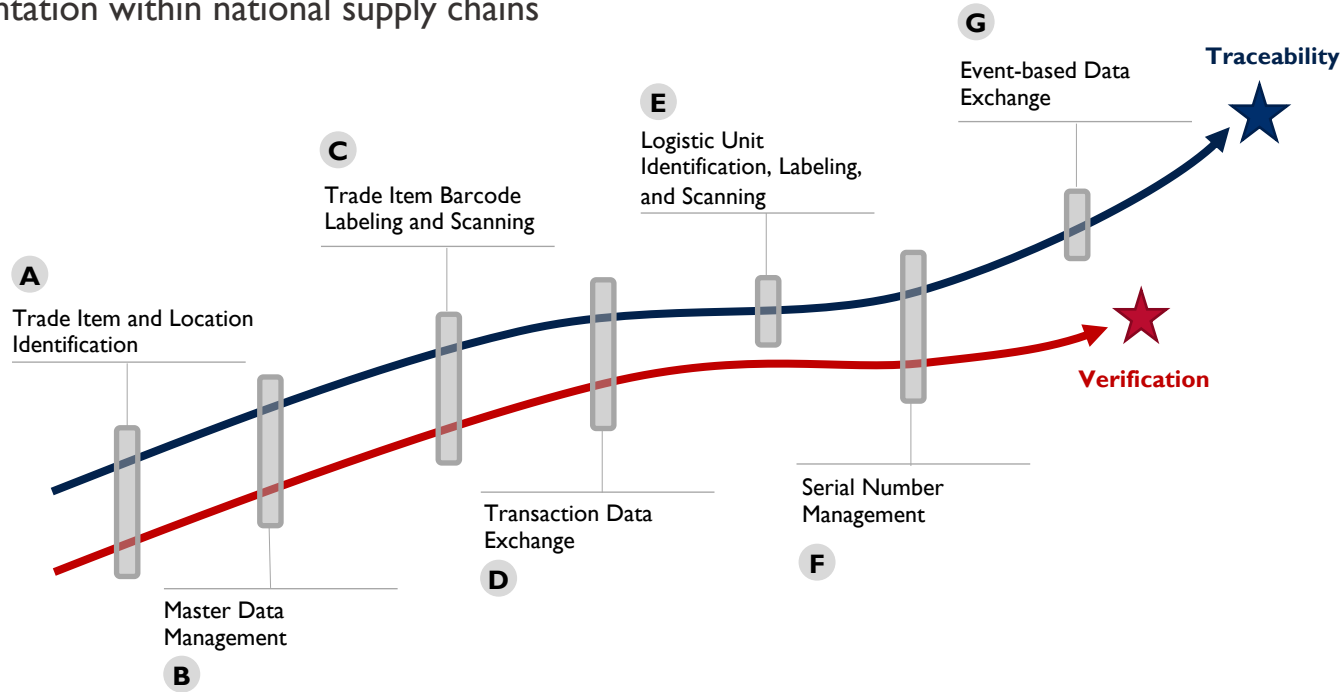
Vision and **Strategy** development is phase two of the GHSC-PSM's Pharmaceutical Traceability Framework



Available: https://www.ghsupplychain.org/sites/default/files/2019-03/CountryImplementationGuide_Final.pdf

GHSC-PSM Traceability Implementation Roadmap

Strategy development is informed by the GHSC-PSM Traceability Implementation Roadmap to enable implementation within national supply chains



What does it take? A holistic approach that includes...



Enabling Environment & Governance



Regulation & Policy



Supply Chain Operations



Systems & Technology



Service Delivery

Standards Implementation Focus Areas

Enabling Environment & Governance

Outlines the organizational structure, distribution of roles and activities, decision authority, reporting lines, and high-level relationship between the various stakeholders responsible for traceability implementation. Identifies decisions that need to be made to establish relationships and appropriate lines of communication and engagement with trading partners.

Regulation & Policy

Establishes the regulations and policies that supply chain trading partners need to adhere to for product and location identification, data capture, and data sharing to enable implementation of the country's traceability vision.

Supply Chain Operations

Identifies and provides guidance and procedural norms for processes and systems use across the supply chain operations, including procurement, importation, warehousing, inventory management, and distribution.

Systems & Technology

Identifies supply chain systems requirements, data flows, and architectures to support traceability implementation across supply chain partners. Defines norms and good practices for their use.

Service Delivery

Identifies the impacts and requirements for service delivery points, including hospitals, clinics, retail pharmacies, and community health workers in use of global standards to enable traceability.

Steps to Traceability Strategy Development

Identify Country Priorities

Identification of the priorities that you would like global standards to address in the country



1

Develop a Results Framework and Roadmap

Graphical representation of strategic objectives, Intermediate Results (IRs), outputs, and activities against realistic timeframes



5

Define Outputs and Activities

Tangible deliverables and activities to drive the traceability program



4

Define Strategic Objectives

Longer-term, higher-order changes expected from the traceability program



2

Define Intermediate Results

Medium-term, discrete results of traceability strategy that are measurable



3

Traceability Strategy Development

The traceability program should be tied to national health strategies and objectives.



Identifying Country Priorities

Traceability Strategic Objectives

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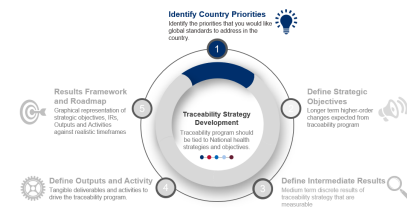
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Define Outputs and Activities

Tangible deliverables and activities to drive the traceability program.

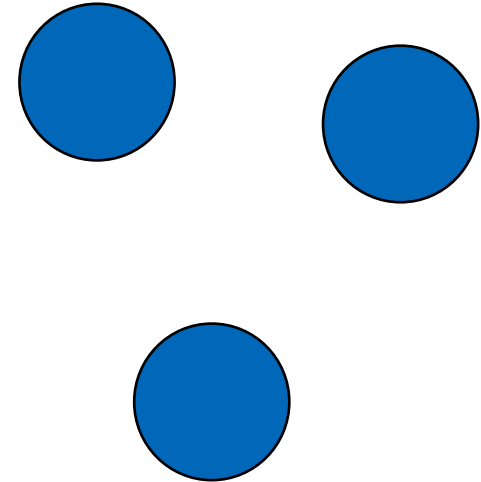


Activity: Stakeholder Priorities

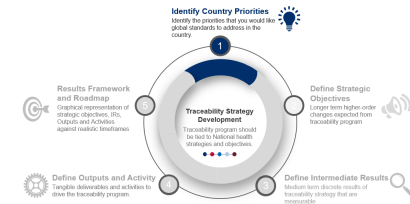


Identify the priorities that you would like global standards to address in the country. The goal is to have an initial understanding of each stakeholder's priority areas so that we can narrow the focus to what is important to achieve with global standards. Results will help guide vision and strategy development.

- Allow each person three votes.
- Review list of global standards objectives.
- Evaluate each area on your own.
- Vote for which outcomes would be important focus areas based on the reality today.
- Try not to be influenced by others' votes!



Activity: Traceability Country Priorities

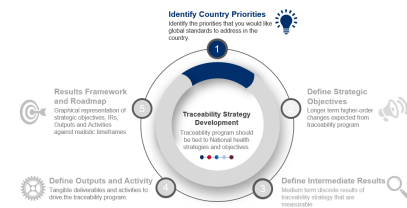


- [] Visibility of where the product is within the supply chain
- [] Efficiency of inventory management and distribution
- [] Pharmacovigilance and control of outcome of treatments
- [] Counterfeit or stolen product that is obtained by the patient/end user
- [] Counterfeit or stolen product detected in the legitimate supply chain
- [] Visibility to decrease or eliminate reimbursement fraud
- [] Visibility of product “status” (e.g., expired, recalled)
- [] Accuracy and efficiency of procurement operations
- [] Efficiency of payment and payment monitoring processes
- [] Theft or diversion of products from the legitimate supply chain
- [] Efficiency of “reverse” logistics processes (e.g., returns, recalls)
- [] Harmonized trade/customs clearance procedures

Activity

Rank in order of priority the country’s supply chain challenges that can be solved through global standards adoption.

Activity: Vision Statements



The traceability vision statement reflects a country's aspiration of the end state desired after adopting global standards for traceability.

✓ A vision statement must reflect the national health plans and traceability priorities.

A supply chain that enables every citizen to access safe and secure medicines

Example

1

Patient safety through enhanced data visibility in the supply chain

Example

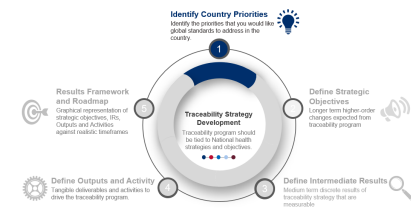
2

Every citizen has access to quality and affordable health products.

Example

3

Vision Statement Work Instructions

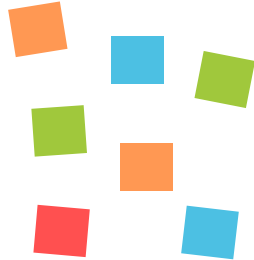


1



Review example assigned to your group.

2



Brainstorm key elements of your vision statement reflective of traceability and national priorities.

3



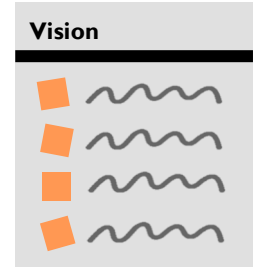
Discuss with your group; challenge one another!

4



As a group, agree on the best traceability vision statement for the country.

5



Document your vision statement.

Developing Strategic Objectives

Traceability Strategic Objectives

Identify Country Priorities

Identification of the priorities that you would like global standards to address in the country



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Define Intermediate Results

Medium-term, discrete results of traceability strategy that are measurable



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Develop a Results Framework and Roadmap

Graphical representation of strategic objectives, IRs, outputs, and activities against realistic timeframes



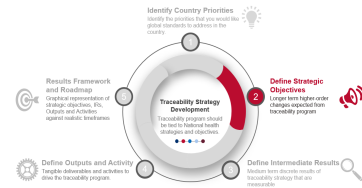
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Define Outputs and Activities

Tangible deliverables and activities to drive the traceability program



Strategic Objective



What is a strategic objective (SO)?

An objective that defines **higher-order changes** in systems, communities, or organizations that are developed by understanding the problem and defining what success looks like.

Tips for developing SOs:

- ✓ Reflect the best assessment of what can be achieved realistically and resourced in a 5- to 10-year timeframe
- ✓ State SOs clearly and precisely to lend themselves easily to objective measurement
- ✓ Emphasize the results of actions, not the actions themselves

PROBLEM

✓ What problem are we trying to solve?

✓ High levels of inefficiencies in inventory management at the central medical warehouse

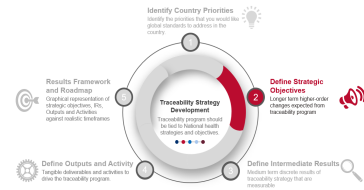
SUCCESS

✓ How will you know when the program has been successful in solving the problem?

✓ Automatic identification and data capture of pharmaceutical products



Illustrative Strategic Objectives



SO1 Governance

Example: Sustained governance structure that is accountable for implementing the traceability strategy

SO5 Service Delivery

Example: Health care providers enabled to provide safe and good-quality pharmaceutical products to the client

SO2 Regulation & Policy

Example: Expanded regulatory framework for verification and traceability of quality pharmaceutical products through legitimate supply channels

Traceability
Strategic
Objectives

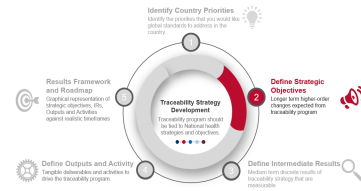
SO4 Systems & Technology

Example: Integrated information and communication technologies that support end-to-end data visibility and pharmaceutical traceability

SO3 Supply Chain Operations

Example: Efficient public and private supply chain through standardized identification, capture, and reporting of high-quality supply chain data

Strategic Objectives Group Work Instructions



1

2

3

4

5



Review example assigned to your group.



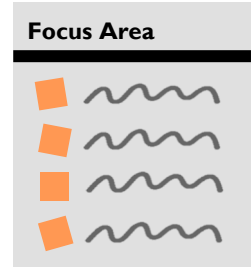
Write down your individual thoughts and recommendations.



Discuss with your group; challenge one another!



As a group, agree to a strategic objective.



Document your consensus-recommended strategic objective.

Developing Intermediate Results

Traceability Strategic Objectives

Identify Country Priorities

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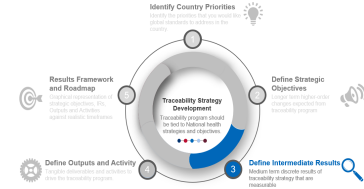
Develop a Results Framework and Roadmap

Graphical representation of strategic objectives, IRs, outputs, and activities against realistic timeframes



5

Intermediate Result



What is an Intermediate Result?

A set of **discrete results** that create causal links in the results chain and bridge the gap between the current state and the desired SO.

Tips for developing IRs:

- ✓ Establish a clear link between your proposed IRs and your SO
- ✓ Develop multiple IRs to achieve each SO
- ✓ Ensure IRs are SMART
- ✓ Emphasize the results of activities and outputs, but not the activities and outputs themselves

| | | |
|-----------------|--|---|
| PROBLEM | ✓ What problem are we trying to solve? | ✓ Poor visibility into where the product is within the supply chain, limiting efficiency of reverse logistics |
| SUCCESS | ✓ How will you know when the program has been successful in solving the problem? | ✓ End-to-end visibility of product information within the supply chain |
| DISCRETE RESULT | ✓ How will you measure that success? | ✓ Harmonized product master data enabled through interoperable National Product Catalogue |



Intermediate Results Group Work Instructions



1



Review example assigned to your group.

2



Write down your individual thoughts and recommendations.

3



Discuss with your group; challenge one another!

4



As a group, agree on **three to five** well-defined IRs for your SO.

5

| Focus Area | | |
|---------------|---------------|--------------|
| IR | Outputs | Activities |
| Orange square | Blue square | Pink square |
| Orange square | Yellow square | Green square |
| Orange square | Blue square | Pink square |
| Orange square | Blue square | Pink square |

Document your consensus-recommended IRs.

Developing Outputs and Activities

Traceability Strategic Objectives

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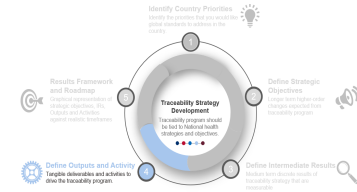
5

Define Outputs and Activities

Tangible deliverables and activities to drive the traceability program



Outputs & Activities



Output

What is an output?

Completed and delivered product of a specific activity. Outputs should be specific and tangible products or services.

Tips for developing outputs:

- Each output should be discrete and contained
- Output information does not tell you anything about the actual results achieved or the consequences of the products and services delivered
- Outputs are important to show the scope or size of what the inputs and activities produce

Example: Establish a Steering Committee for traceability

Activity

What is an activity?

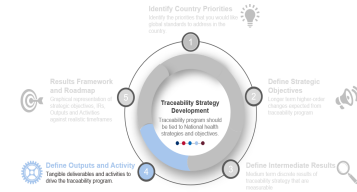
An individual task to be executed by an organization; typically, the smallest unit of work that needs to be completed to develop a specific output.

Tips for developing activities:

- Each activity should be discrete
- Each activity should directly influence the output
- Activities should be scoped so that resource inputs can be defined

Example: Develop training materials for global standards and traceability; train trainers in curriculum delivery

Output Group Work Instructions

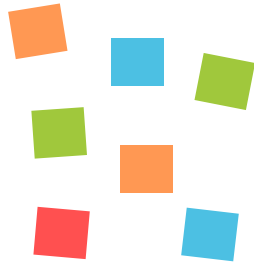


1



Review example assigned to your group.

2



Brainstorm **one to two outputs** and corresponding activities for each IR.

3



Discuss with your group; challenge one another!

4



As a group, agree on outputs and **at least one activity** per output.

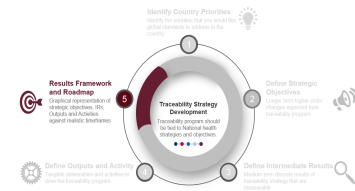
5

| Focus Area | | |
|---------------|---------------|--------------|
| IR | Outputs | Activities |
| Orange square | Blue square | Pink square |
| Orange square | Yellow square | Green square |
| Orange square | Blue square | Pink square |
| Orange square | Yellow square | Green square |
| Orange square | Blue square | Pink square |

Document your objectives and activities.

Developing a Results Framework & Roadmap

Traceability Results Framework and Roadmap



Identify Country Priorities

Identification of the priorities that you would like global standards to address in the country.



Develop a Results Framework and Roadmap

Graphical representation of strategic objectives, IRs, outputs, and activities against realistic timeframes



Define Outputs and Activities

Tangible deliverables and activities to drive the traceability program.



Traceability Strategy Development

The traceability program should be tied to national health strategies and objectives.



Define Strategic Objectives

Longer-term, higher-order changes expected from traceability program



Define Intermediate Results

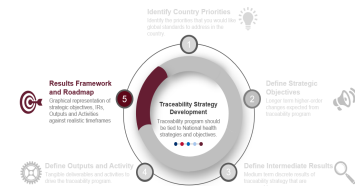
Medium-term, discrete results of traceability strategy that are measurable



Results Framework

What is a Results Framework?

A graphical representation of the cause-and-effect linkages between the different levels of changes expected to be achieved from a traceability program.



A Results Framework includes:

Vision Statement

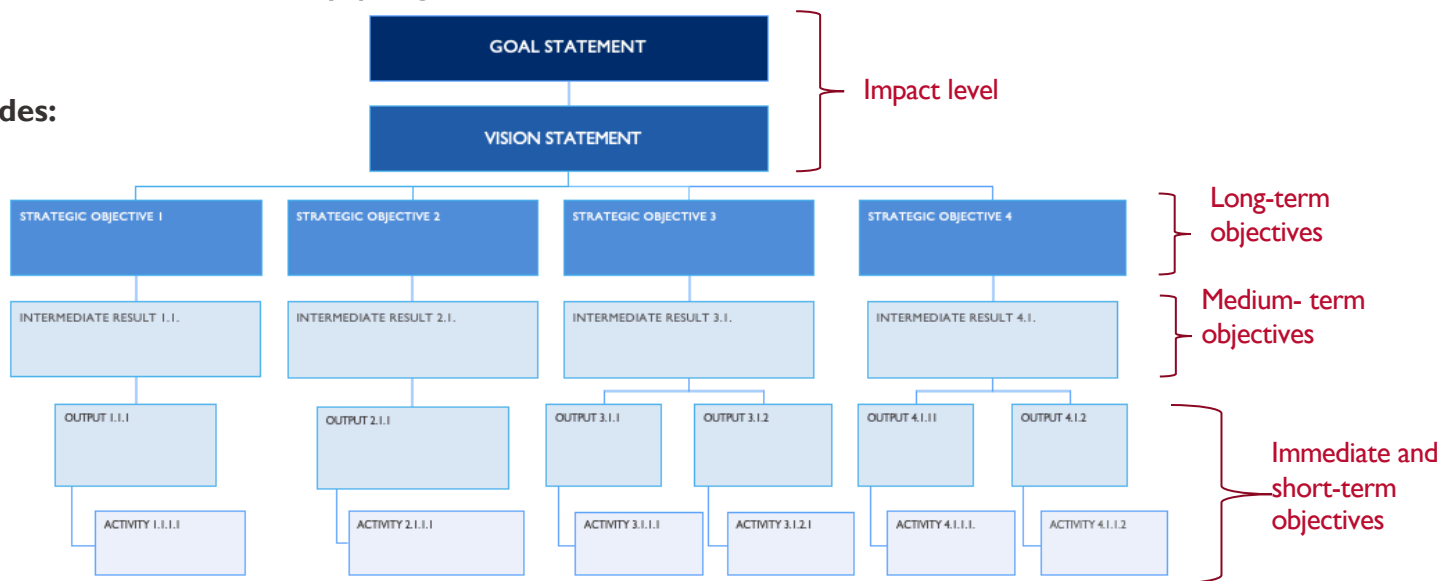
Goal Statement

Strategic Objective

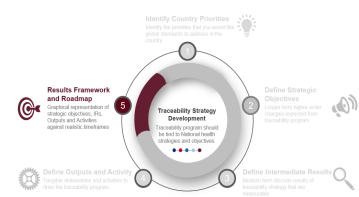
Intermediate Results

Outputs

Activities

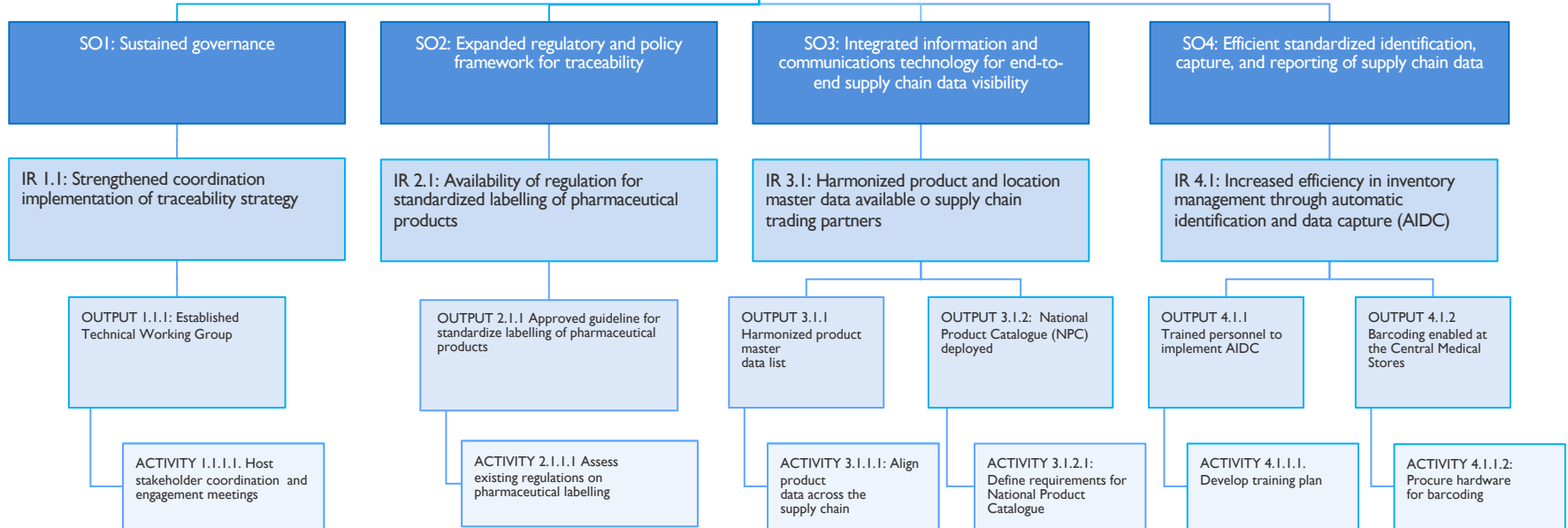


Illustrative Traceability Results Framework

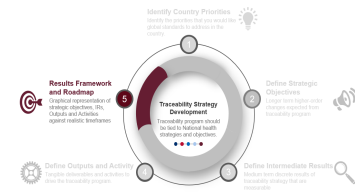


Goal: Improved health and quality of life for all citizens

Vision: A supply chain that enables safe and equal access to safe and secure medicines



Traceability Roadmap



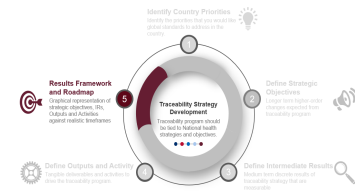
What is a Traceability Roadmap?

A **management tool** that details a high-level overview of critical steps mapped against strategic objectives with timelines and activity owners required to **execute the traceability strategy**.

Tips for developing IRs:

- ✓ Ensure the Traceability Roadmap is developed and managed by the championing body of the traceability initiative (e.g., health ministry, regulatory body, or cross-sector steering committee).
- ✓ Consider reasonable timelines and resources required by various sector stakeholders and trading partners to meet implementation requirements.

Traceability Roadmap Development Group Work Instructions



1



Review example assigned to your group.

2



Write down your individual thoughts and recommendations.

3



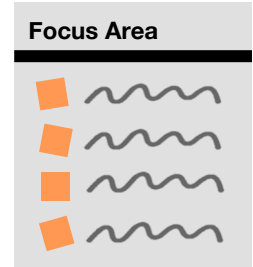
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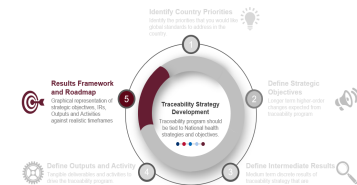
As a group, agree on reasonable timelines and initiative owners at the output level for each SO.

5




Document your consensus-recommended timelines and initiative owners.

Roadmap Example



| Level and Description | Owner (Output) & Timeline (Activity) | | |
|---|--------------------------------------|-------------|-------|
| | 2020 | 2021 - 2022 | 2023+ |
| STRATEGIC OBJECTIVE 1: Sustained governance structure that is accountable for implementing the traceability strategy | | | |
| INTERMEDIATE RESULT 1.1: Strengthened coordination, resource mobilization, and oversight of implementation of traceability strategy | | | |
| OUTPUT 1.1.1: Approved national traceability strategy for implementation | Ministry of Health | | |
| ACTIVITY 1.1.1.1: Finalize national traceability strategy, inclusive of participant feedback, and submit to Minister for approval or endorsement | X | | |
| OUTPUT 1.1.2: Established Global Standards & Traceability Steering Committee Group | Ministry of Health | | |
| ACTIVITY 1.1.2.1: Develop Terms of Reference for Steering Committee and seek approval from the Ministry of Health | X | | |
| OUTPUT 1.1.3: Costed implementation plan | Global Standards & Traceability TWG | | |
| ACTIVITY 1.1.3.1: Identify implementation requirements by stakeholder and document roles and responsibilities | X | | |
| STRATEGIC OBJECTIVE 2: Expanded regulatory framework for verification, traceability, and pharmacovigilance of quality pharmaceutical products through legitimate supply channels | | | |
| INTERMEDIATE RESULT 2.1: Expanded existing regulatory framework to encompass medicines, verification, and traceability under the mandate | | | |
| OUTPUT 2.1.1: Regulation updated to encompass SF medicines, verification, and traceability | Food and Drug Administration | | |
| ACTIVITY 2.1.1.1: Develop a draft statutory instrument to include SFs, verification, and traceability | X | | |



The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership. For more information, visit ghsupplychain.org.

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