

# National Pharmaceutical Traceability Vision and Strategy Development Reference Note

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## USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

Version, 1.0, February 2021



# Introduction

# How To Use This Resource

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

- Vision and strategy development workshop materials and exercises
- Traceability results framework
- High-level roadmap for implementing traceability
- Guidance and framework for drafting a national pharmaceutical traceability strategy document

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.

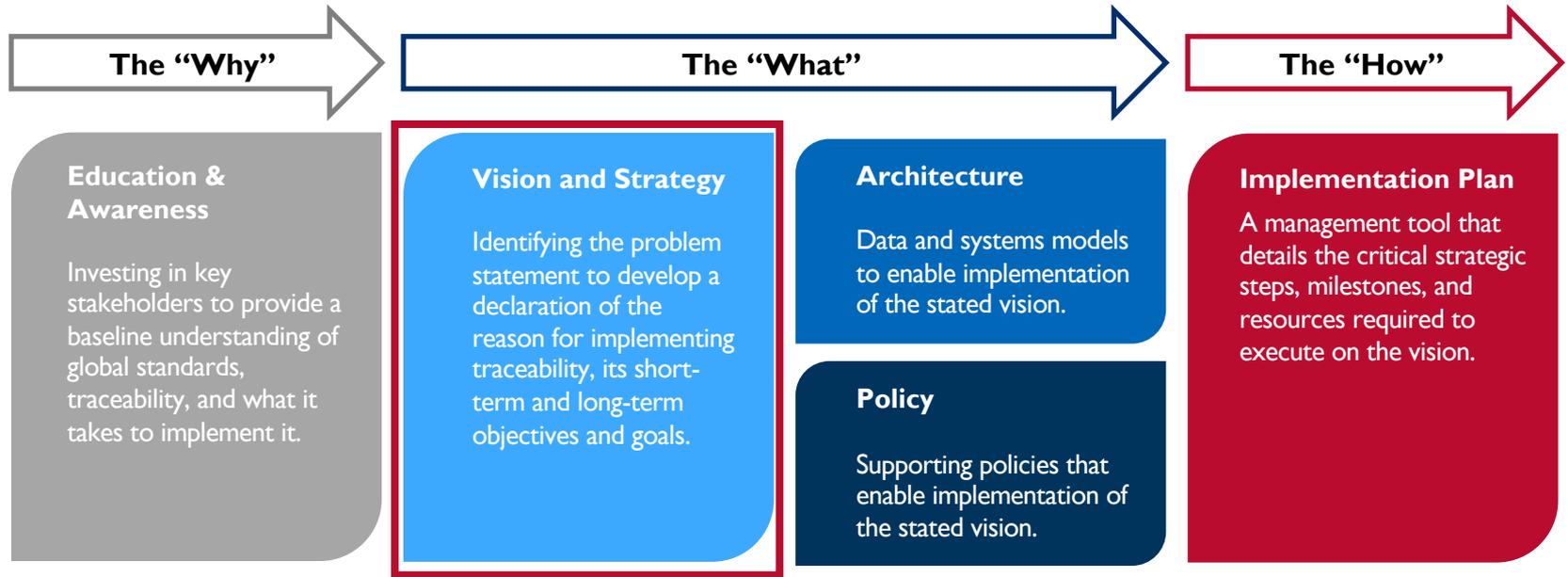
# Background

# National Pharmaceutical Traceability Strategy Development Stakeholders



# GHSC-PSM Traceability Planning Framework

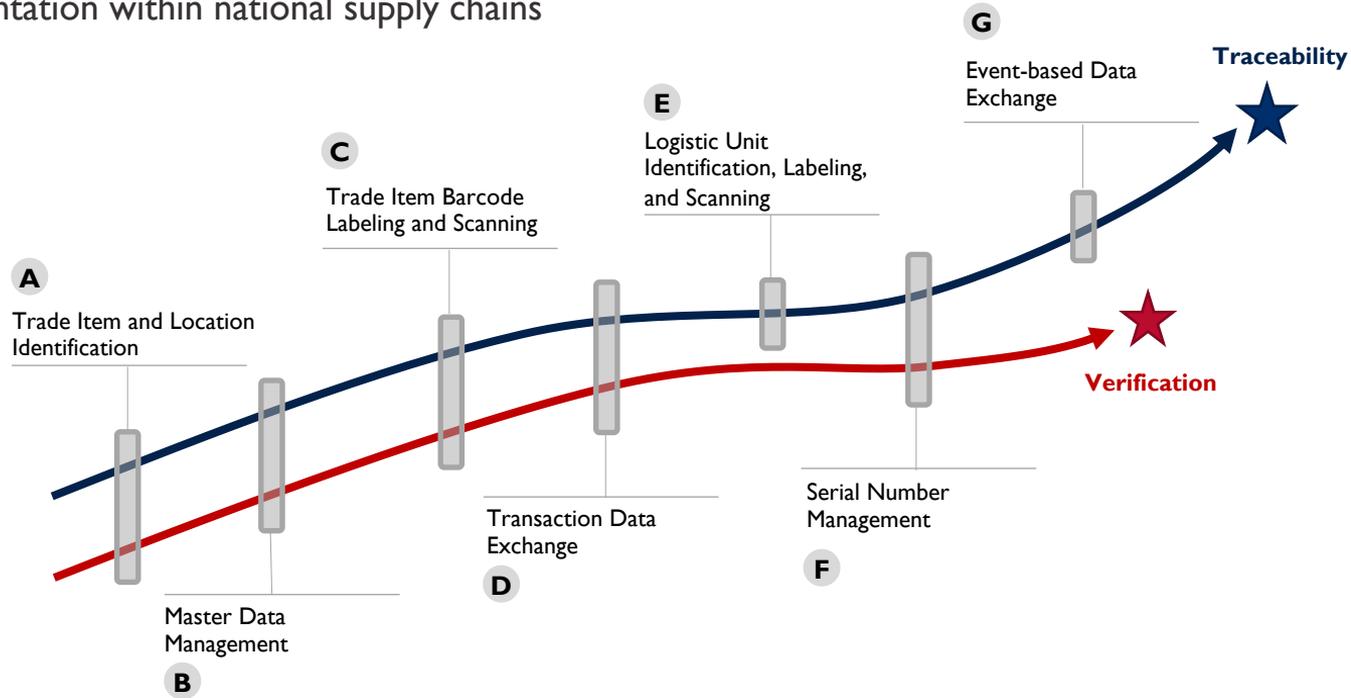
**Vision** and **Strategy** development is phase two of the GHSC-PSM's Pharmaceutical Traceability Framework



**Available:** [https://www.ghsupplychain.org/sites/default/files/2019-03/CountryImplementationGuide\\_Final.pdf](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

## Identify Country Priorities

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



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



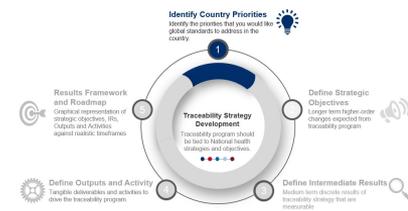
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## Define Outputs and Activities

Tangible deliverables and activities to drive the traceability program.

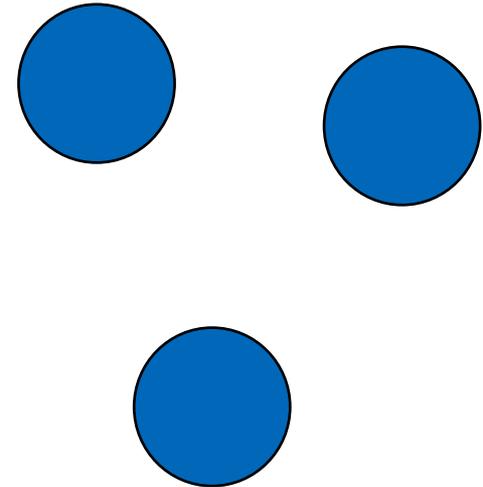


# Activity: Stakeholder Priorities

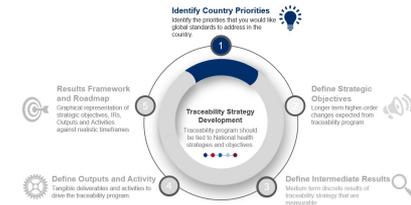


Identify the priorities that you would like global standards to address in the country. The goal is to have an initial understanding of each stakeholder's priority areas so that we can narrow the focus to what is important to achieve with global standards. Results will help guide vision and strategy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

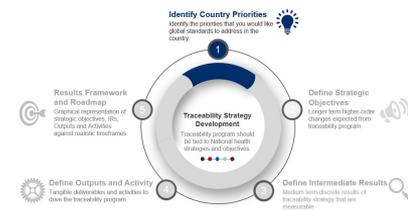


- [ ] Visibility of where the product is within the supply chain
- [ ] Efficiency of inventory management and distribution
- [ ] Pharmacovigilance and control of outcome of treatments
- [ ] Counterfeit or stolen product that is obtained by the patient/end user
- [ ] Counterfeit or stolen product detected 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

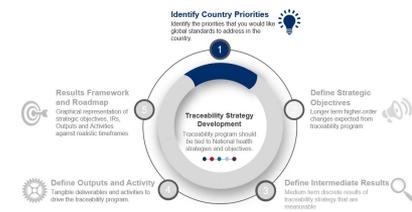
2

Every citizen has access to quality and affordable health products.

Example

3

# Vision Statement Work Instructions

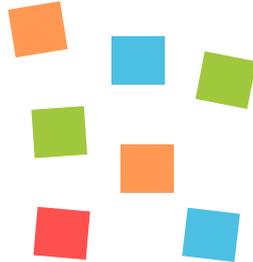


1



Review example assigned to your group.

2



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

3



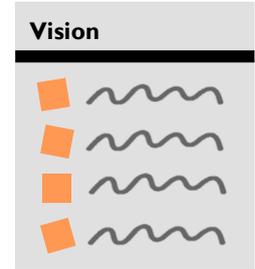
Discuss with your group; challenge one another!

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



1

## Define Strategic Objectives

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



2

## Traceability Strategy Development

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



4

## Define Intermediate Results

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



3

## Develop a Results Framework and Roadmap

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



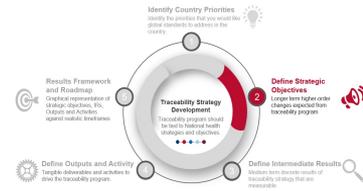
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## Define Outputs and Activities

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

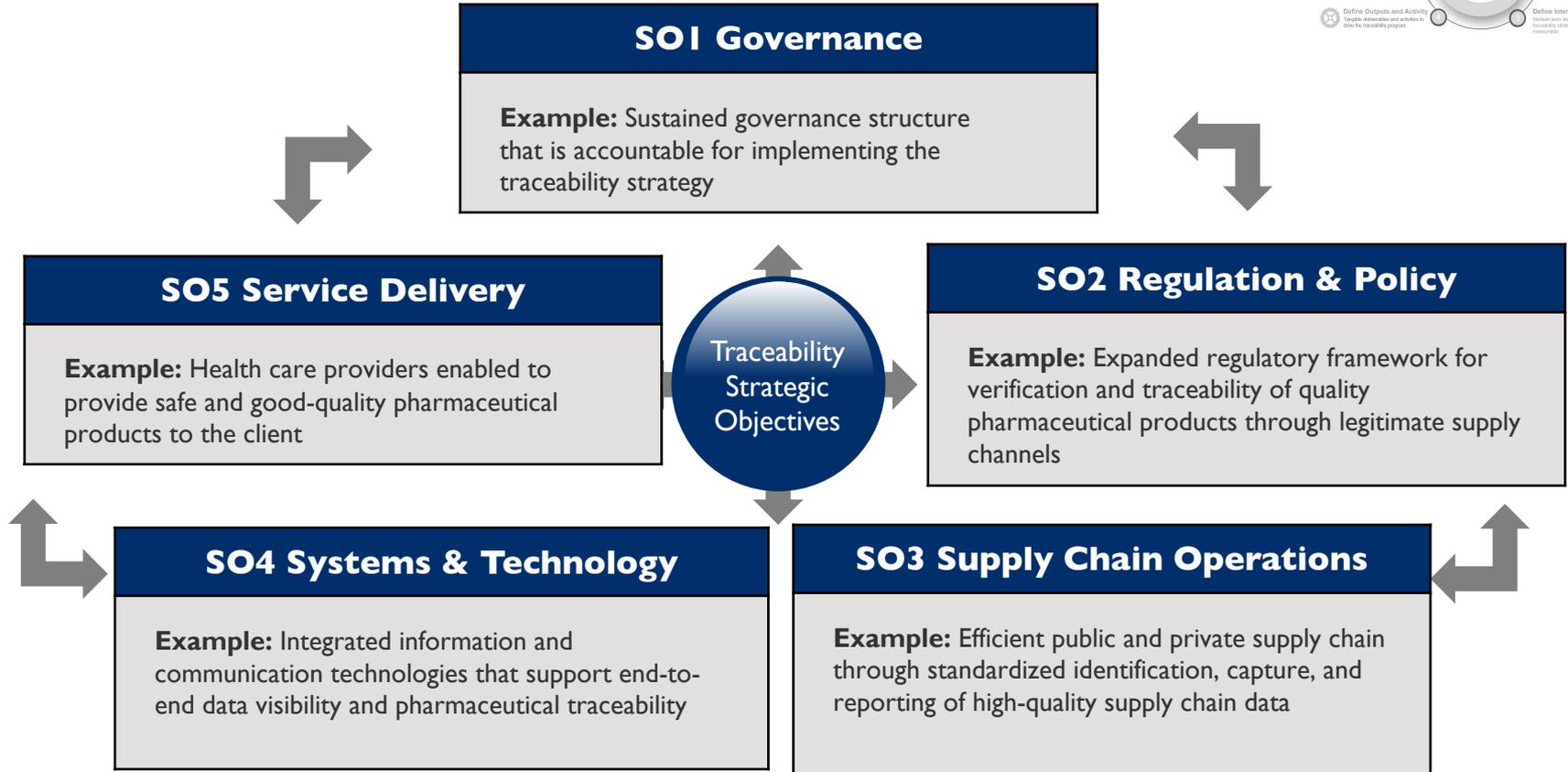
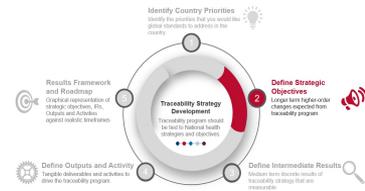
### SUCCESS

✓ 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



# Strategic Objectives Group Work Instructions



1

2

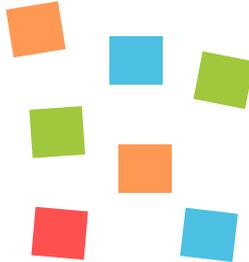
3

4

5



Review example assigned to your group.



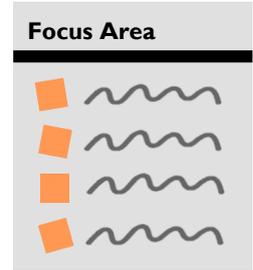
Write down your individual thoughts and recommendations.



Discuss with your group; challenge one another!



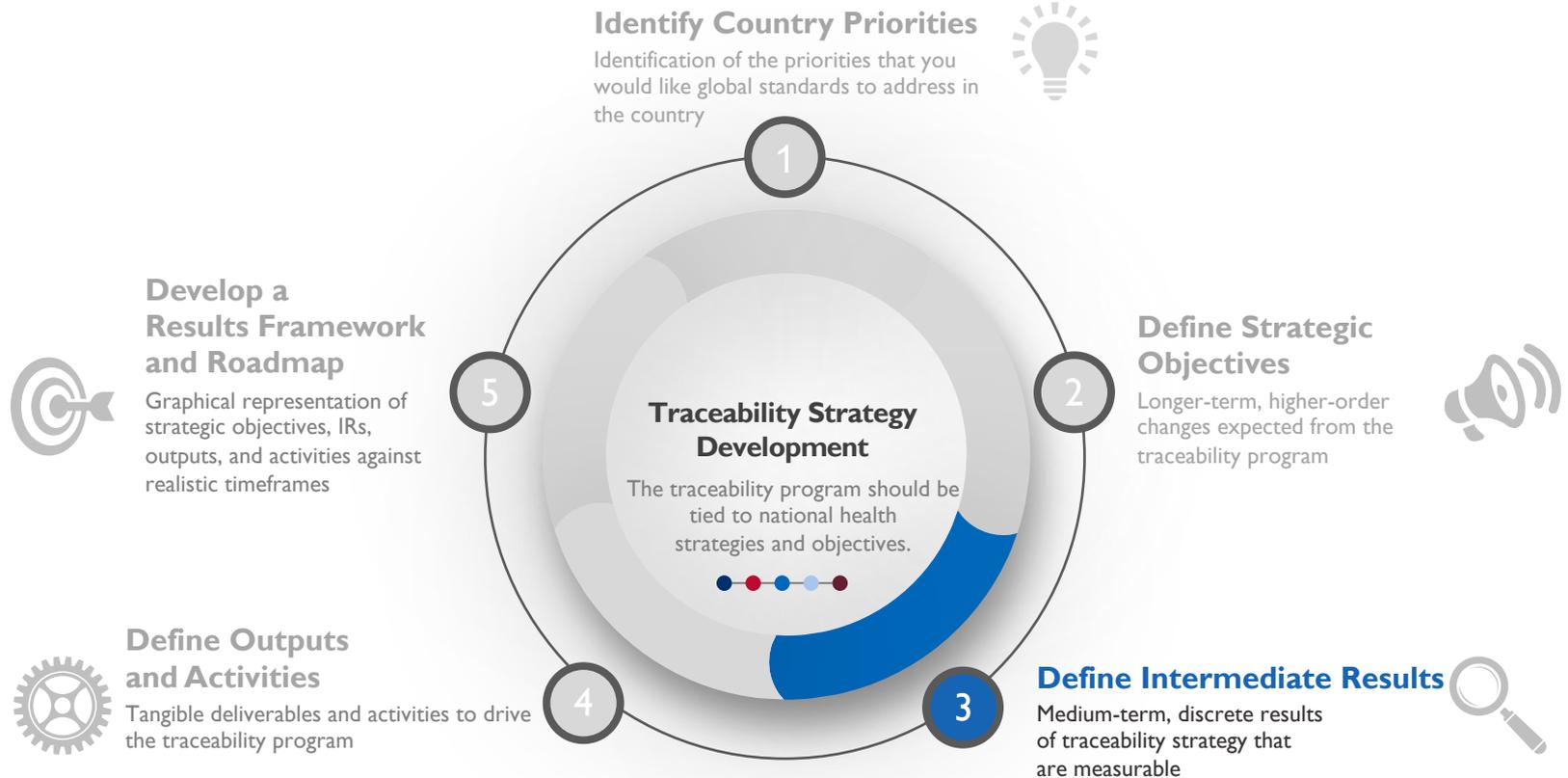
As a group, agree to a strategic objective.



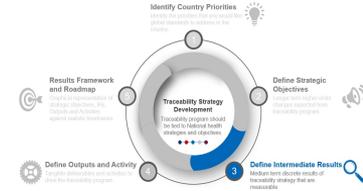
Document your consensus-recommended strategic objective.

# Developing Intermediate Results

# Traceability Intermediate Results



# 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

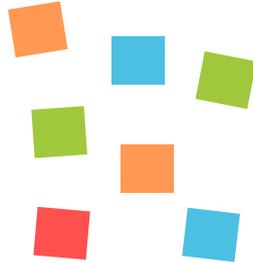


1



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.

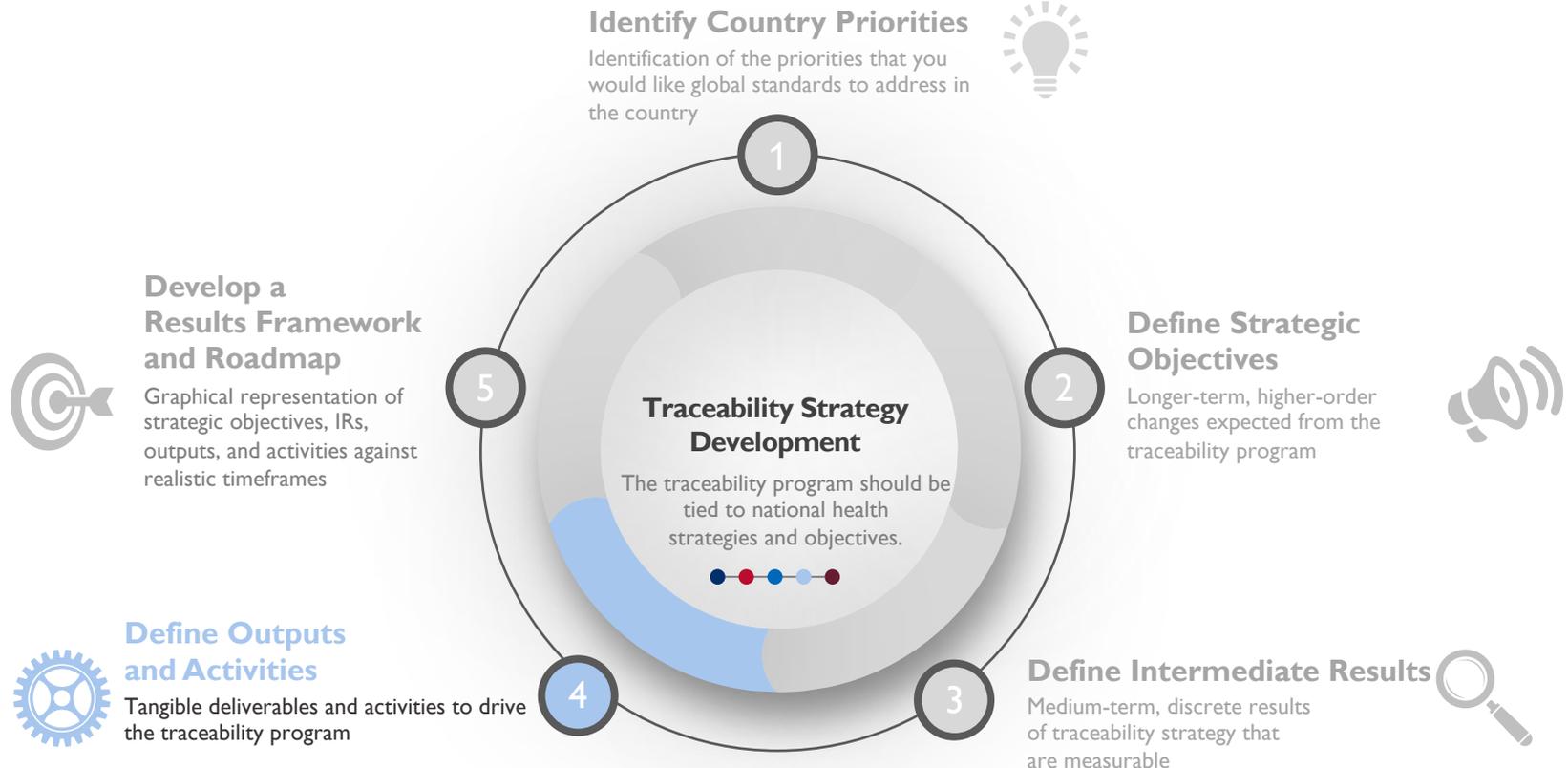
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Focus Area		
IR	Outputs	Activities
Orange square	Blue square	Pink square
Orange square	Yellow square	Green square
Orange square	Blue square	Pink square
Orange square	Blue square	Pink square

Document your consensus-recommended IRs.

# Developing Outputs and Activities

# Traceability Outputs and Activities



# 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

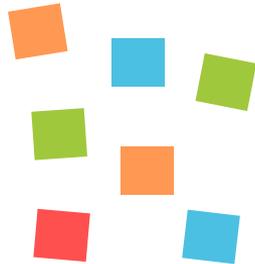


1



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.



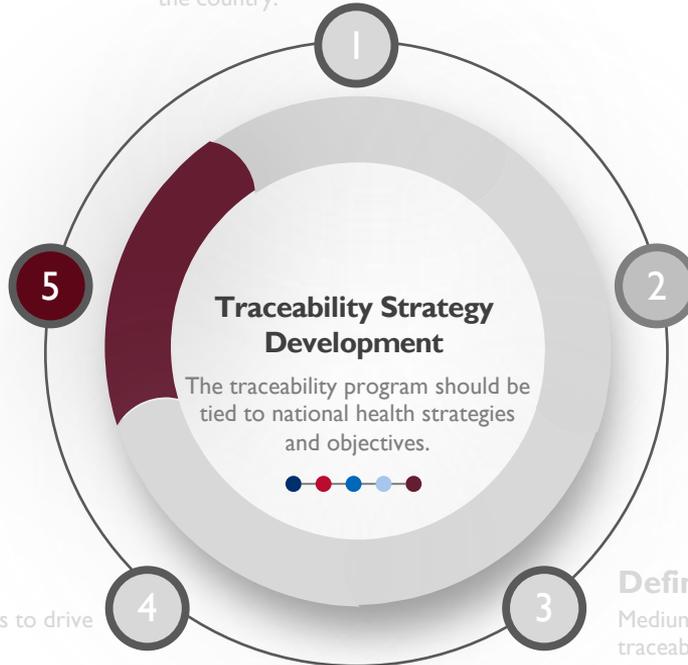
## Develop a Results Framework and Roadmap

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.



## 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

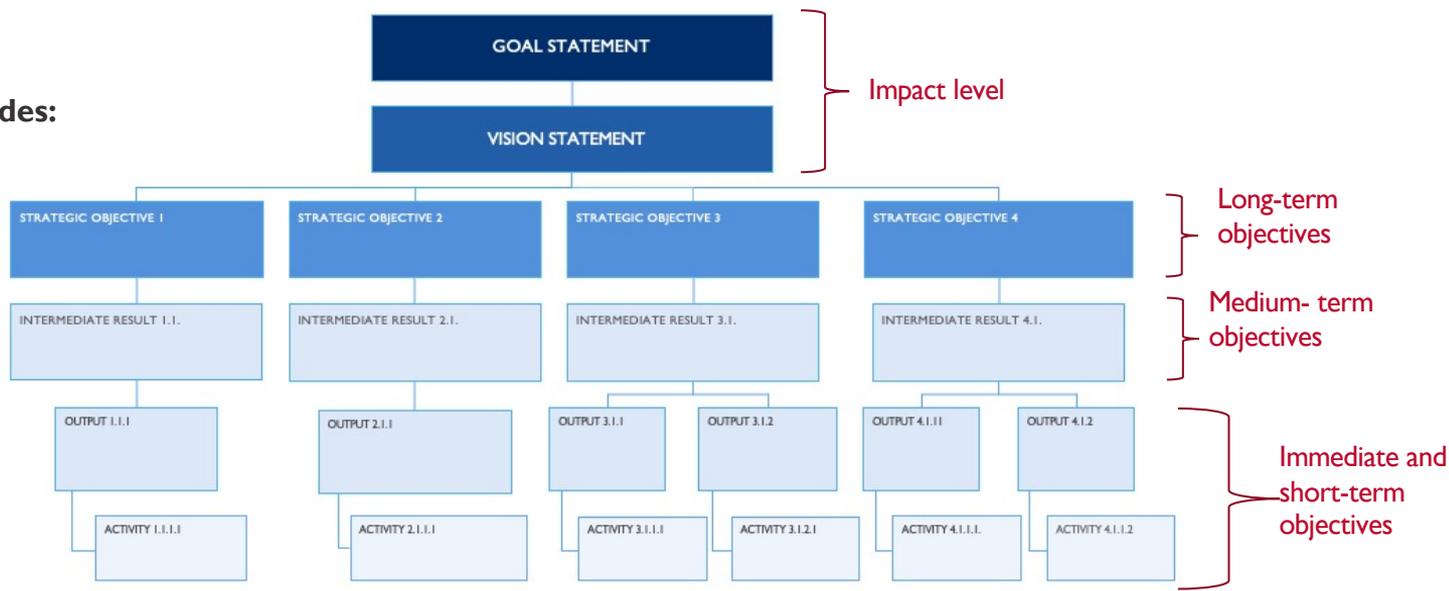
Goal Statement

Strategic Objective

Intermediate Results

Outputs

Activities

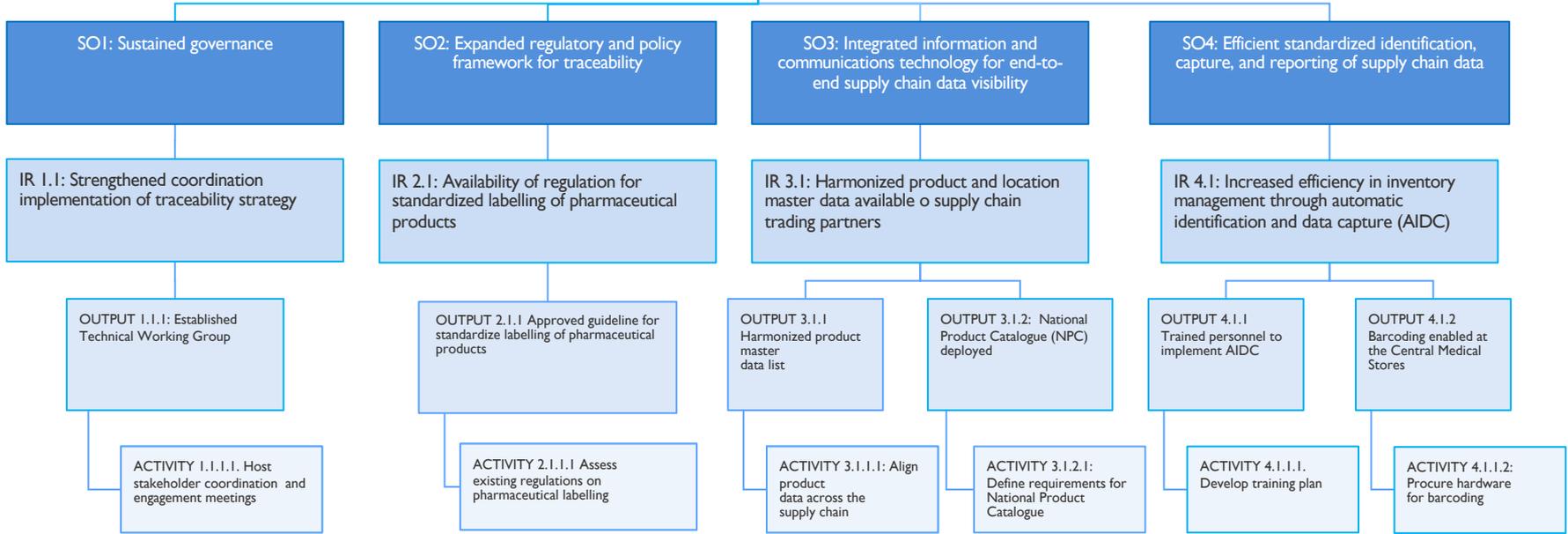


# Illustrative Traceability Results Framework

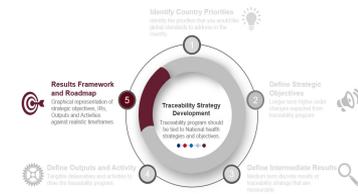


**Goal: Improved health and quality of life for all citizens**

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



# Traceability Roadmap



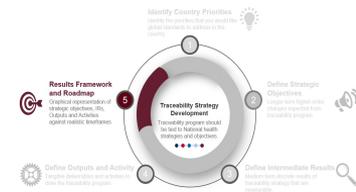
## What is a Traceability Roadmap?

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

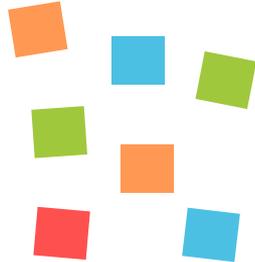


1



Review example assigned to your group.

2



Write down your individual thoughts and recommendations.

3



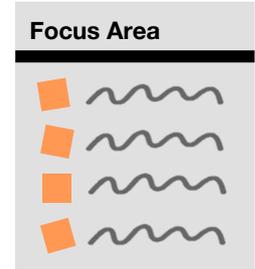
Discuss with your group; challenge one another!

4



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+
<b>STRATEGIC OBJECTIVE 1: Sustained governance structure that is accountable for implementing the traceability strategy</b>			
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		
<b>STRATEGIC OBJECTIVE 2: Expanded regulatory framework for verification, traceability, and pharmacovigilance of quality pharmaceutical products through legitimate supply channels</b>			
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		

# National Pharmaceutical Traceability Strategy Document

# Traceability Strategy Document Assumptions

## Market Context

Accounts for local market dynamics, including local legal requirements, technological sophistication, trade practices and other similar dynamics.

## Standards Adoption

National authorities will leverage the GS1 system of standards to advance traceability objectives.

## Traceability Model Section

Traceability model (track & trace, verification or both) that will be implemented is not defined when the document is initially developed, but will be through the strategy implementation process

# Notional Traceability Strategy Document Outline

■ Executive Summary	01
■ Introduction	02
■ Approach	03
■ Traceability Planning Framework	04
■ Global Standards Adoption	05
■ National Traceability Results Framework	06
■ Strategic Objectives, Intermediate Results and Outputs	07
■ Traceability Roadmap	08
■ Glossary of Terms	09

Strategy Outline	Description
01 Executive Summary	High level summary of the strategy including vision statement, key priorities, strategic objectives and expected outcomes that are anchored on existing national health policy.
02 Introduction	Highlights the national health priorities as defined in the national health strategy, current initiatives undertaken for the adoption of global standards for traceability, and overview of traceability objectives.
03 Approach	Summary of the scope of the document and what is out of scope that must be informed by market assessments, additional stakeholder consultation, and reference implementations. For example, selection of traceability model and the specific products and locations subject to traceability efforts.
04 Traceability Planning Framework	Framework to systematically organize towards the execution of the strategy leveraging GSI standards. <i>Reference:</i> <a href="https://www.ghsupplychain.org/implementation-guidance-pharmaceutical-traceability-leveraging-gsi-global-standards">https://www.ghsupplychain.org/implementation-guidance-pharmaceutical-traceability-leveraging-gsi-global-standards</a>
05 Global Standards Adoption	Summary of how global standards will contribute to achieving the strategic objectives for traceability. It is recommended for countries to reference GSI identify, capture, share and use standards as defined by GSI ( <a href="https://www.gsi.org/sites/default/files/docs/architecture/AG_Flyer_final.pdf">https://www.gsi.org/sites/default/files/docs/architecture/AG_Flyer_final.pdf</a> ).
06 National Traceability Results Framework	A graphical representation of the strategy document depicting expected change from traceability implementation at each level of implementation including Mission, Vision, Strategic Objectives, Intermediate Results and Outputs.
07 Strategic Objectives, Intermediate Results and Outputs	Description of the strategic objectives, intermediate results, and outputs described in the results framework and the approach for implementing each of these. It is recommended for a country to take a holistic approach to the development of its strategy to advance traceability across the entire health system, phasing implementation and scaling based on lessons learned.
08 Traceability Roadmap	A time-phased roadmap focused on initiatives that should be accomplished to achieve the set vision as aligned with national fiscal year and plans and detailing illustrative activities to initiate implementation of the strategy.
09 Glossary of Terms	Definition of terms use din the strategy. It is recommended that interested parties consult the <a href="#">GSI General Specification</a> and use references and terms therein whenever available.



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](https://ghsupplychain.org).

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