

**STRATEGIC PLAN FOR RISK  
COMMUNICATION AND  
HEALTH LITERACY**

**SPRCHL**

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# Session Overview

- History and Aims
- Development Process
- Tour of (draft) Strategic Plan
- Questions for the RCAC

# History

- Strategic Plan for Risk Communication (SPRC)
- Drafted on RCAC August 2008 recommendation
  - Strengthen Science
  - Build Capacity
  - Optimize Policy
- Presented in draft to RCAC - April 2009
- Published fall 2009, monitored internally
- Accomplishments reported in web update

# Aims

- Support FDA's Strategic Priority Goal 3:  
**Promote better informed decisions about the use of FDA-regulated products**
- Involve communicators across FDA
- Use existing resources to implement existing policy, tracking and routinizing best practices



**Conduct Review**

Reviewing and analyzing relevant data in order to better inform decision making when defining outcomes and identifying performance measures.

**Deliverable → Catalogue of current activities (internal brainstorming)**

**Define Outcomes**

Identifying intended outcomes and their causal relationships to form a strategic framework that clearly express a theory of change for how a program will achieve its mission.

**Deliverable → Strategic Framework**

**Align Activities**

Identifying current and potential activities or tasks that will be taken to achieve the outcomes, associating each with relevant outcomes, and prioritizing and sequencing their implementation.

**Deliverable → Implementation Plan**

**Identify Performance Indicators**

Establishing a process and plan for measuring achievement, reflecting changes or assessing the performance of an outcome.

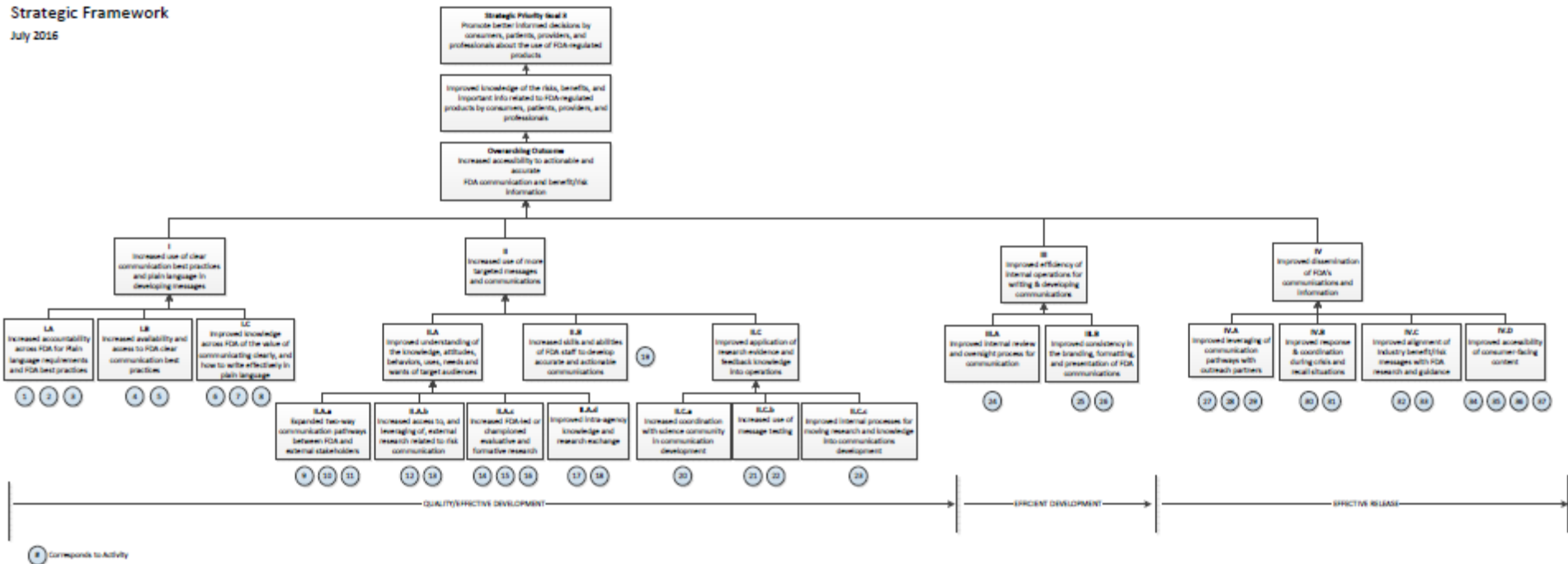
**Deliverable → Performance Monitoring Plan**

# SPRCHL Structure




- Strategic Framework
  - Outcomes
  - Activities
- Implementation Plan
- Performance Indicators/Measures
- Performance Monitoring Plan
- Narrative

# Strategic Framework

Risk Communication and Health Literacy  
Strategic Framework  
July 2016



# Implementation Plan

Lowest level Outcomes	#	Recommended Activities	Examples of Specific Steps
<b>I.A</b> Increased accountability across FDA of Plain Language requirements and FDA best practices		Develop a cross-agency approach to track health literacy actions in accord with HHS Biennial Action Plan	<ul style="list-style-type: none"> <li>• Complete annual Plain Writing Act reports</li> <li>• Develop a process for retrieving annual documents for preparation of Plain Language Annual Reports.</li> <li>• Ensure that HHS health literacy measures are included in FDA's; collect throughout the year</li> </ul>
		Incorporate plain language elements into PMAP and SES plans	<ul style="list-style-type: none"> <li>• Research a method to insert Plain Language elements into SES plans</li> <li>• Develop model Plain Language elements that can be added to Agency staff PMAP elements</li> </ul>
		Promote Plain Language Awards	<ul style="list-style-type: none"> <li>• Encourage nominations for Center-Level awards, publicize winners</li> <li>• Propose new Agency-level honor award for plain language</li> <li>• Research costs and benefits of pursuing funding and nominations for Clear Mark awards</li> </ul>



Note: Items that FDA also monitors for the HHS Biennial Action Plan for Health Literacy have asterisks (\*).

Legend:

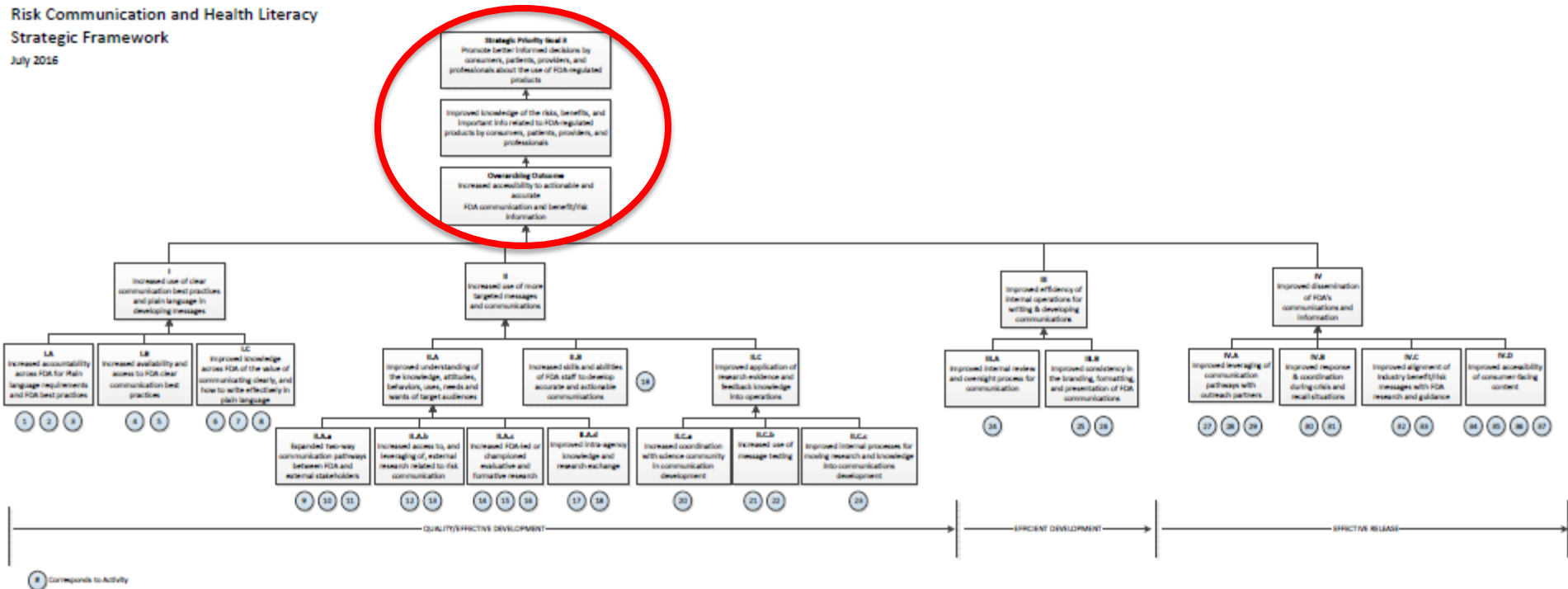
Feasibility Rating

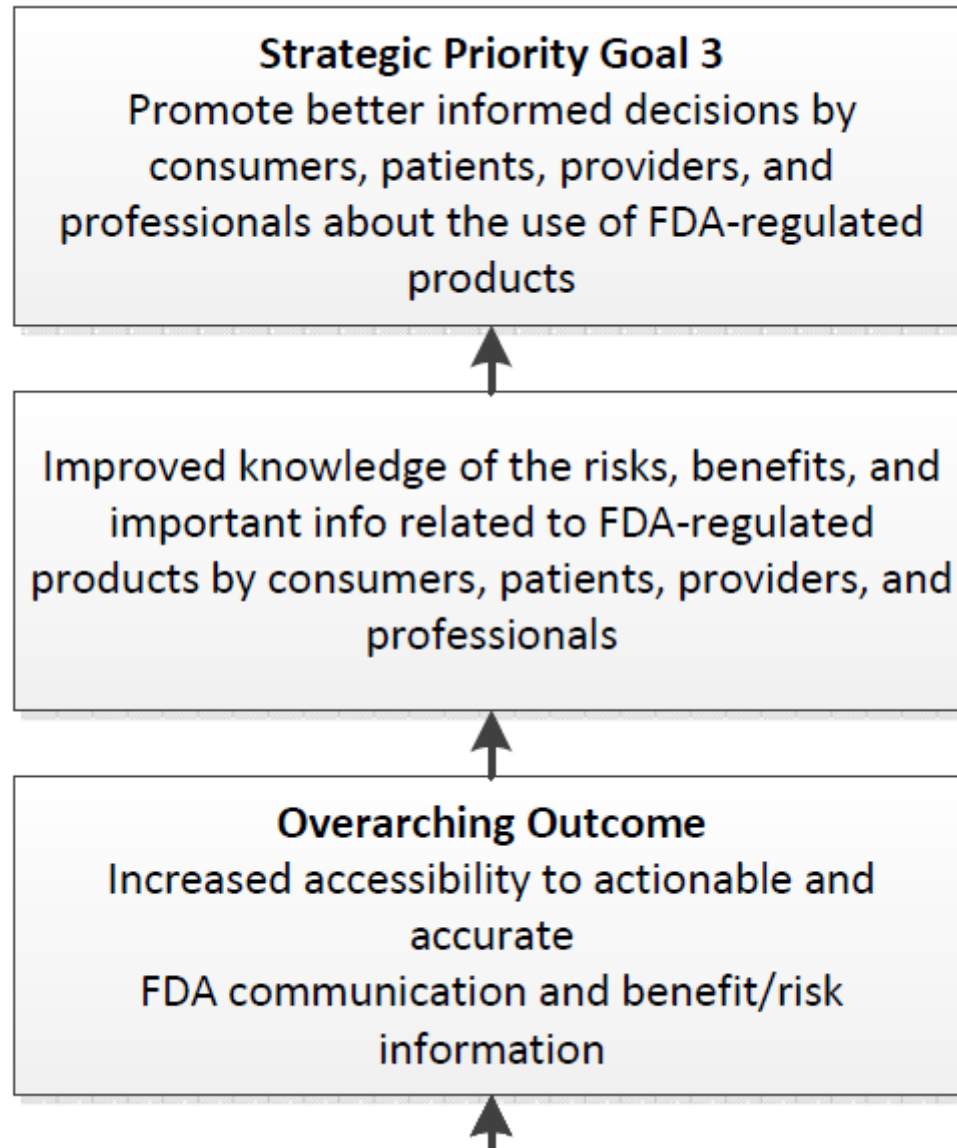
	Highly Feasible
	Feasible
	Postpone

Outcome	Feasibility	Performance Indicator
Improved knowledge of the benefits, risks, and important information related to FDA-regulated products by consumers, patients, providers, and professionals		Study, probably survey(s), of knowledge of important information on FDA-regulated products with different target audiences
		Identify any current or recent studies, including qualitative as well as quantitative methods, on beliefs about FDA and FDA-regulated products, noting any trends or retaining as baseline
Increased accessibility to actionable and accurate FDA communication and benefit/risk information		Percent of total FDA communications that are developed or revised using health literacy or plain language principles
	*	Number of FDA communications that are developed or revised using health literacy or plain language principles or tools
Increased use of clear communication best practices and plain language in developing messages		Percent of responses where an employee reports using communication best practices "frequently" in developing messages
		Percent increase/decrease of questions into call center after revising a selected piece of communication

# Strategic Framework

Risk Communication and Health Literacy  
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# Questions: Overarching Outcome

- 1. Looking specifically at Risk Communication and Health Literacy at FDA:**
  - a. Does the Overarching Outcome support Strategic Priority Goal 3?
  - b. Do the proposed performance indicators provide meaningful measurement of progress toward the Overarching Outcome?
  - c. Can you suggest any other indicators for us to consider?

Note: Items that FDA also monitors for the HHS Biennial Action Plan for Health Literacy have asterisks (\*).

Legend:

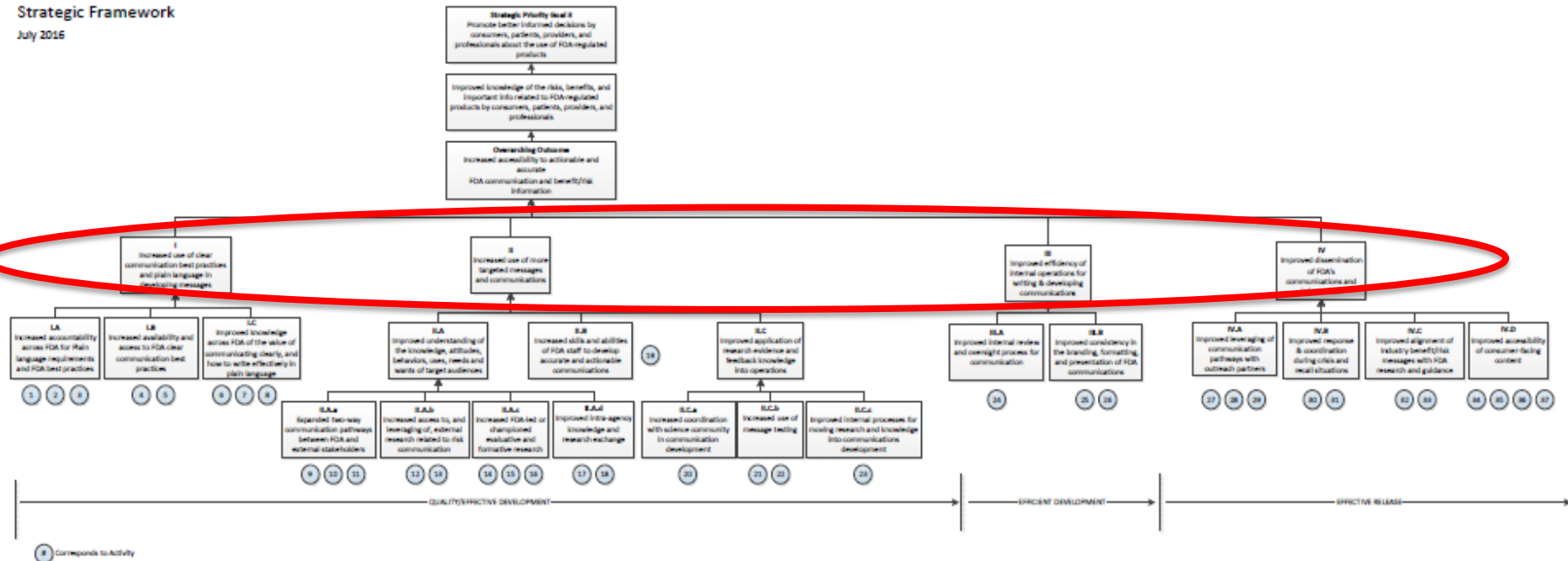
Feasibility Rating

	Highly Feasible
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	Postpone

Outcome	Feasibility	Performance Indicator
Improved knowledge of the benefits, risks, and important information related to FDA-regulated products by consumers, patients, providers, and professionals		Study, probably survey(s), of knowledge of important information on FDA-regulated products with different target audiences
		Identify any current or recent studies, including qualitative as well as quantitative methods, on beliefs about FDA and FDA-regulated products, noting any trends or retaining as baseline
Increased accessibility to actionable and accurate FDA communication and benefit/risk information		Percent of total FDA communications that are developed or revised using health literacy or plain language principles
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# Strategic Framework

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# Major Contributing Outcomes

- I. Clear Communications
- II. More Targeted Communications
- III. Efficient Operations
- IV. Dissemination

## Questions: Major Contributing Outcomes

### **2. Consider the four major Contributing Outcomes, which all feed into the Overarching Outcome**

- a. Collectively, do they support the Overarching Outcome, “Increased accessibility to actionable and accurate FDA communication and benefit/risk information?” Are there gaps in support?
- b. Do the proposed performance indicators provide meaningful measurement of progress toward the Contributing Outcomes? Can you suggest any others for us to consider?



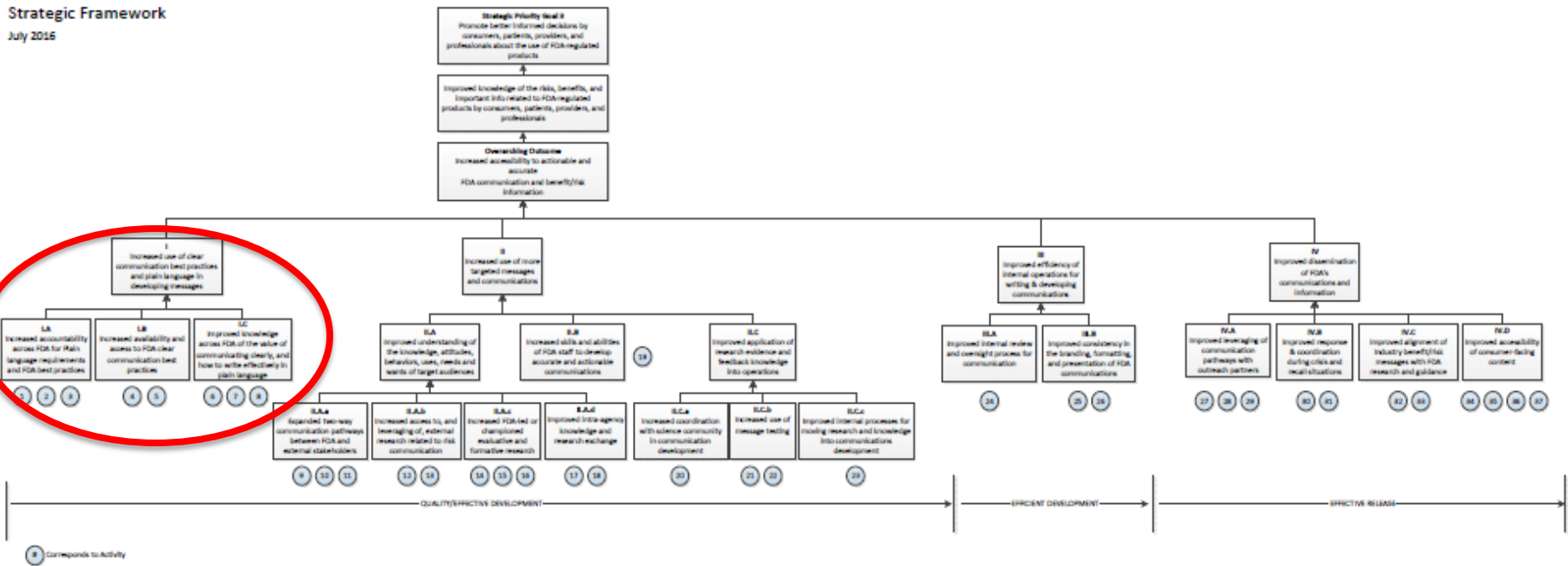
# Lower Level Outcomes and Actions

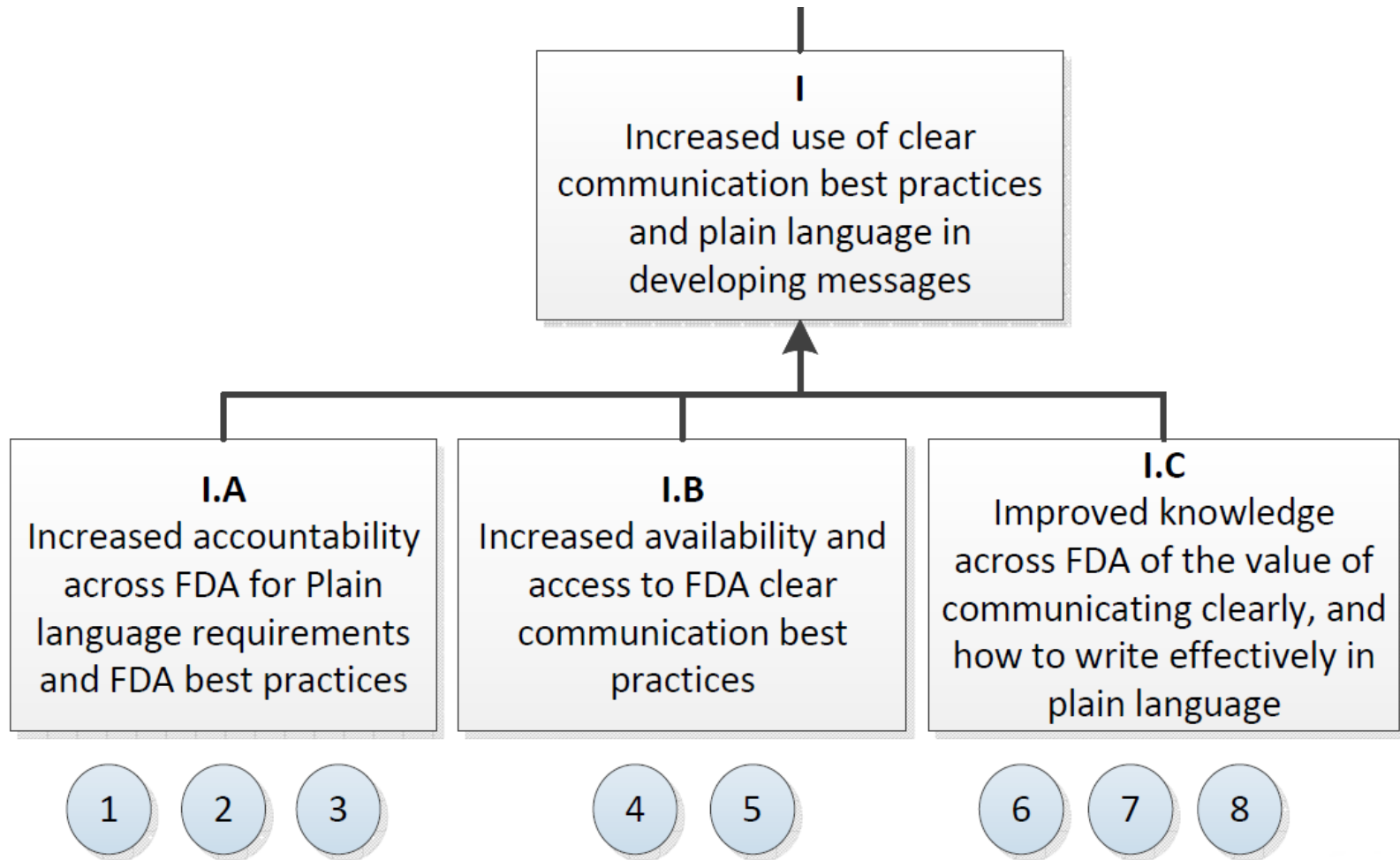
## 3. Taking each major Contributing Outcome I through IV in turn, please consider the questions:

- a. Do the lower level contributing outcomes support this outcome? Are there gaps in support?
- b. Do the listed activities and sample specific actions for each contributing outcome implement the outcome? Can you suggest other activities we might consider, if possible?
- c. Do the proposed performance indicators provide meaningful measurement of progress toward the outcomes? Can you suggest any others for us to consider?

# Strategic Framework

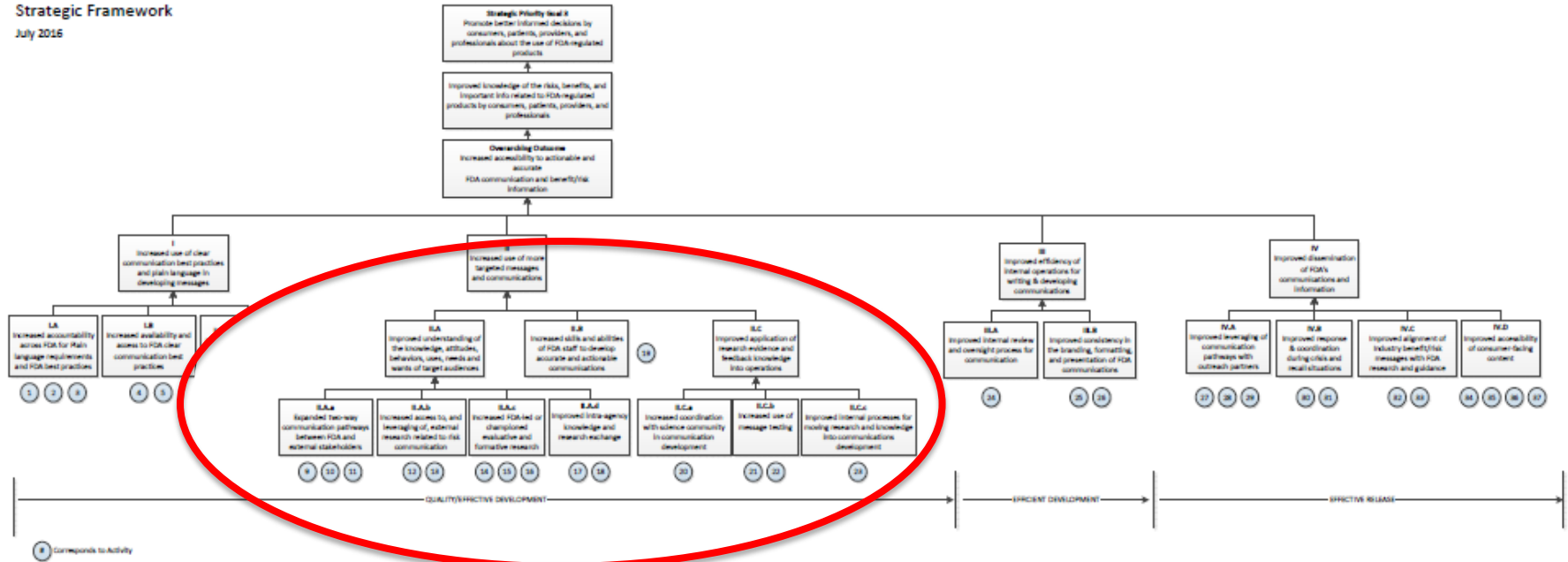
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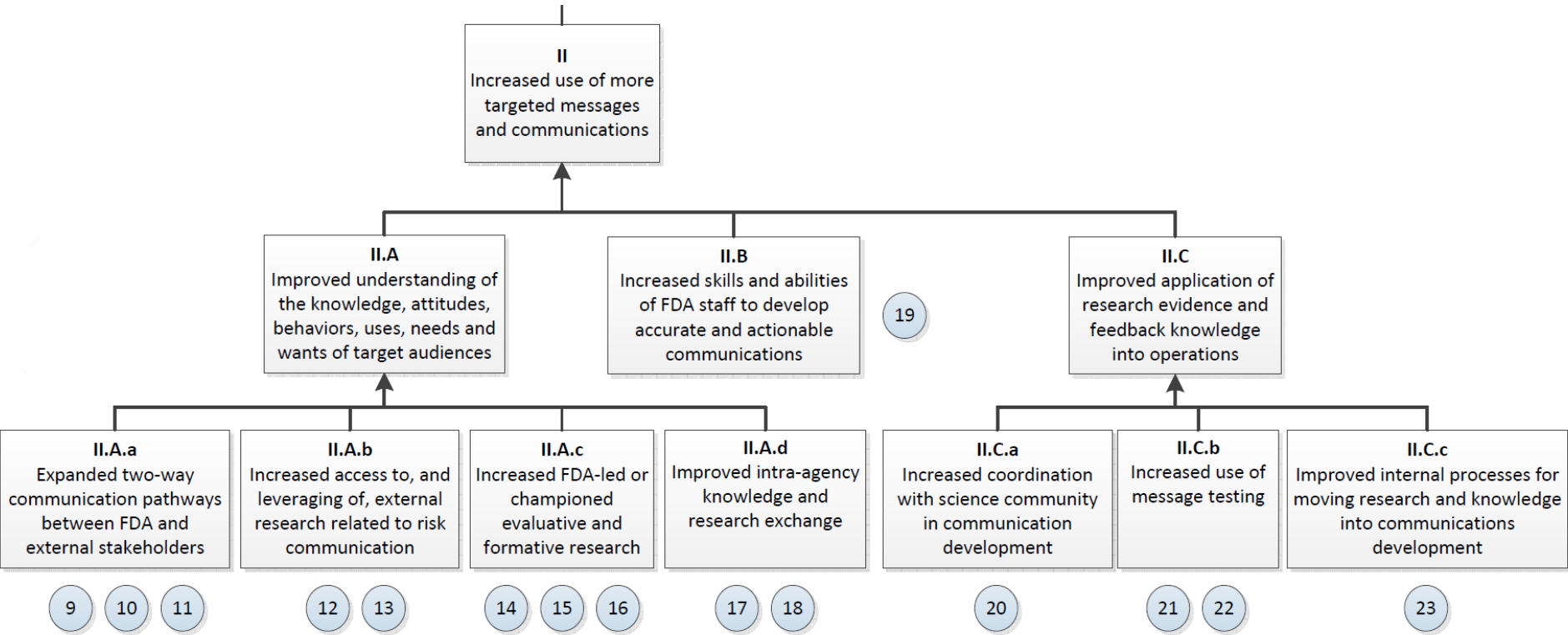




# Strategic Framework

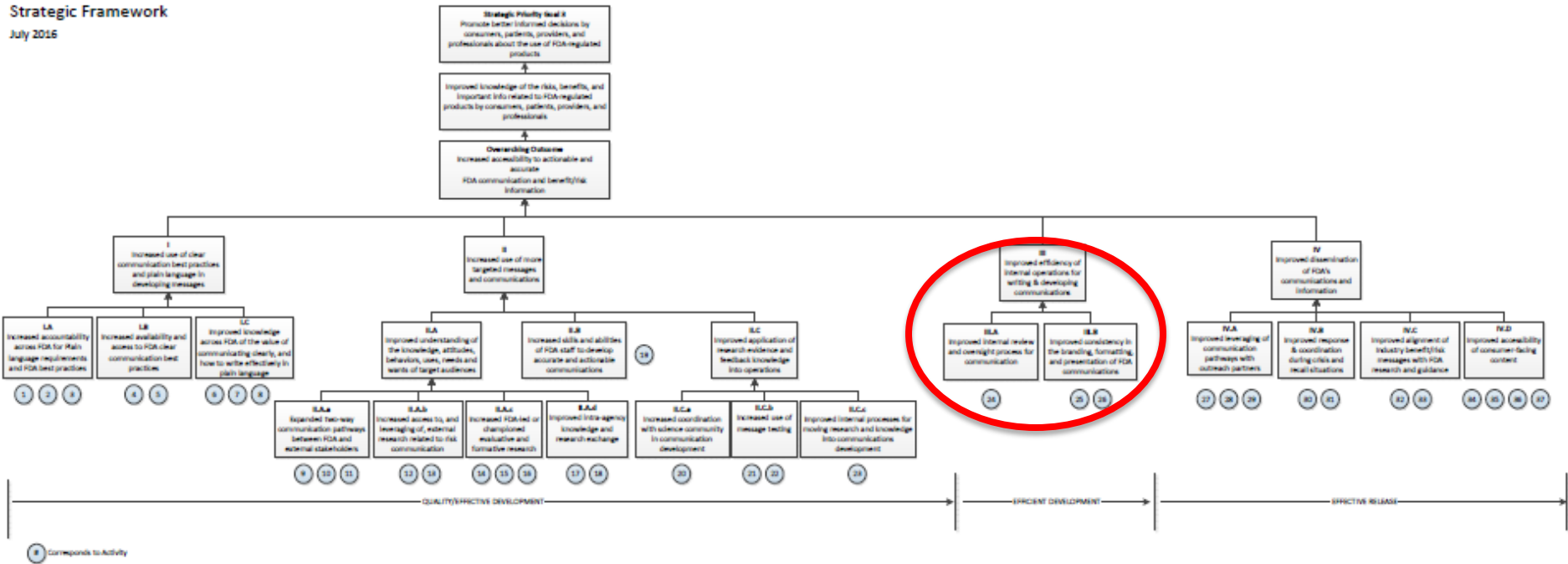
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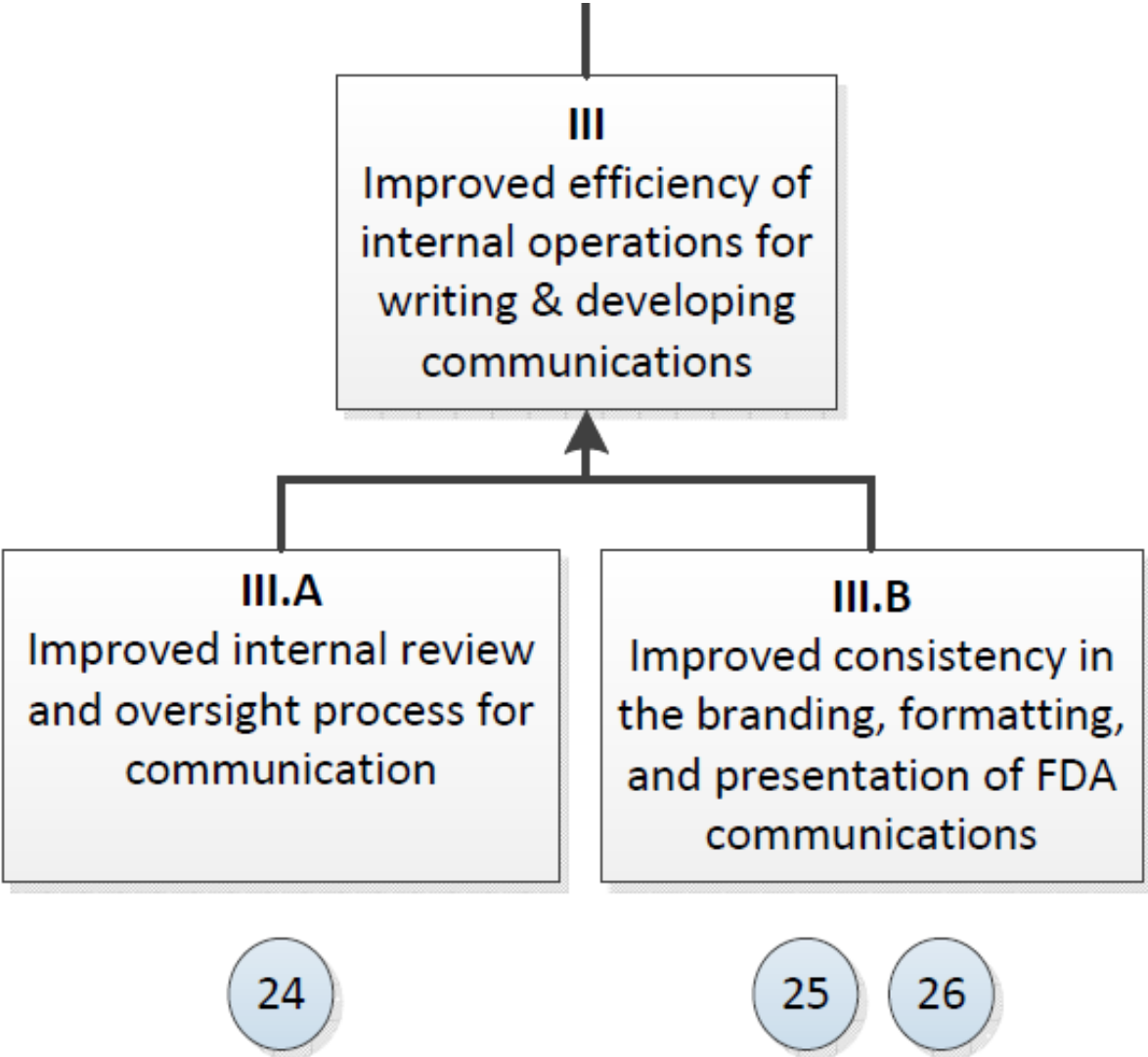




# Strategic Framework

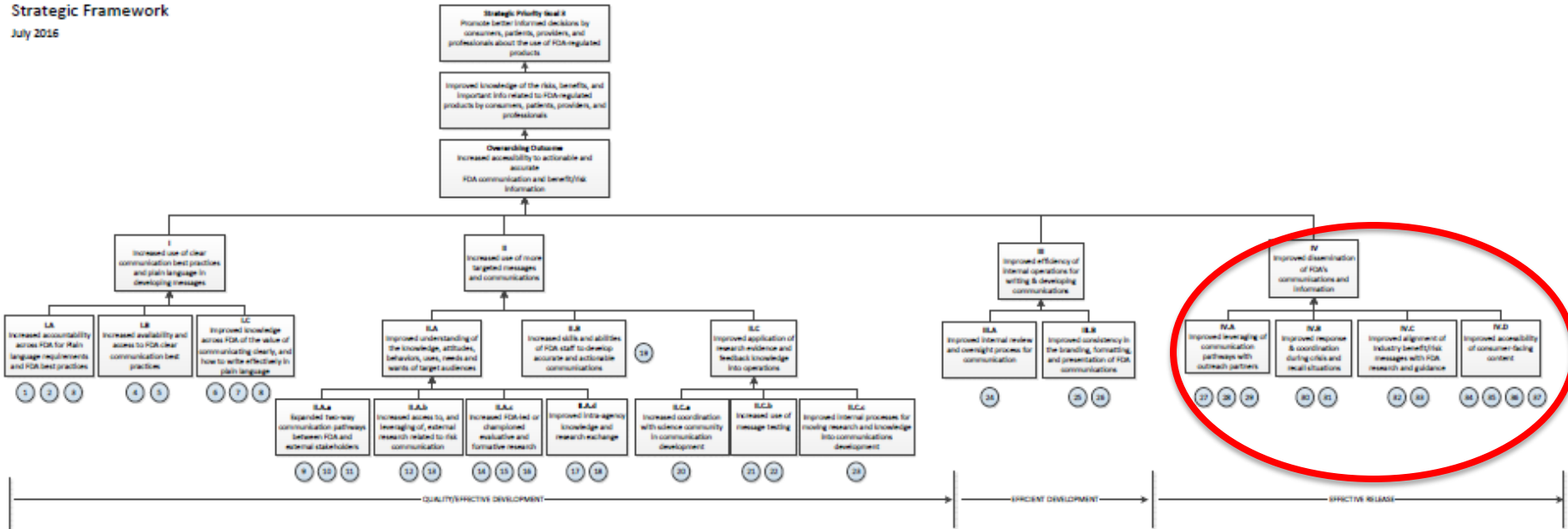
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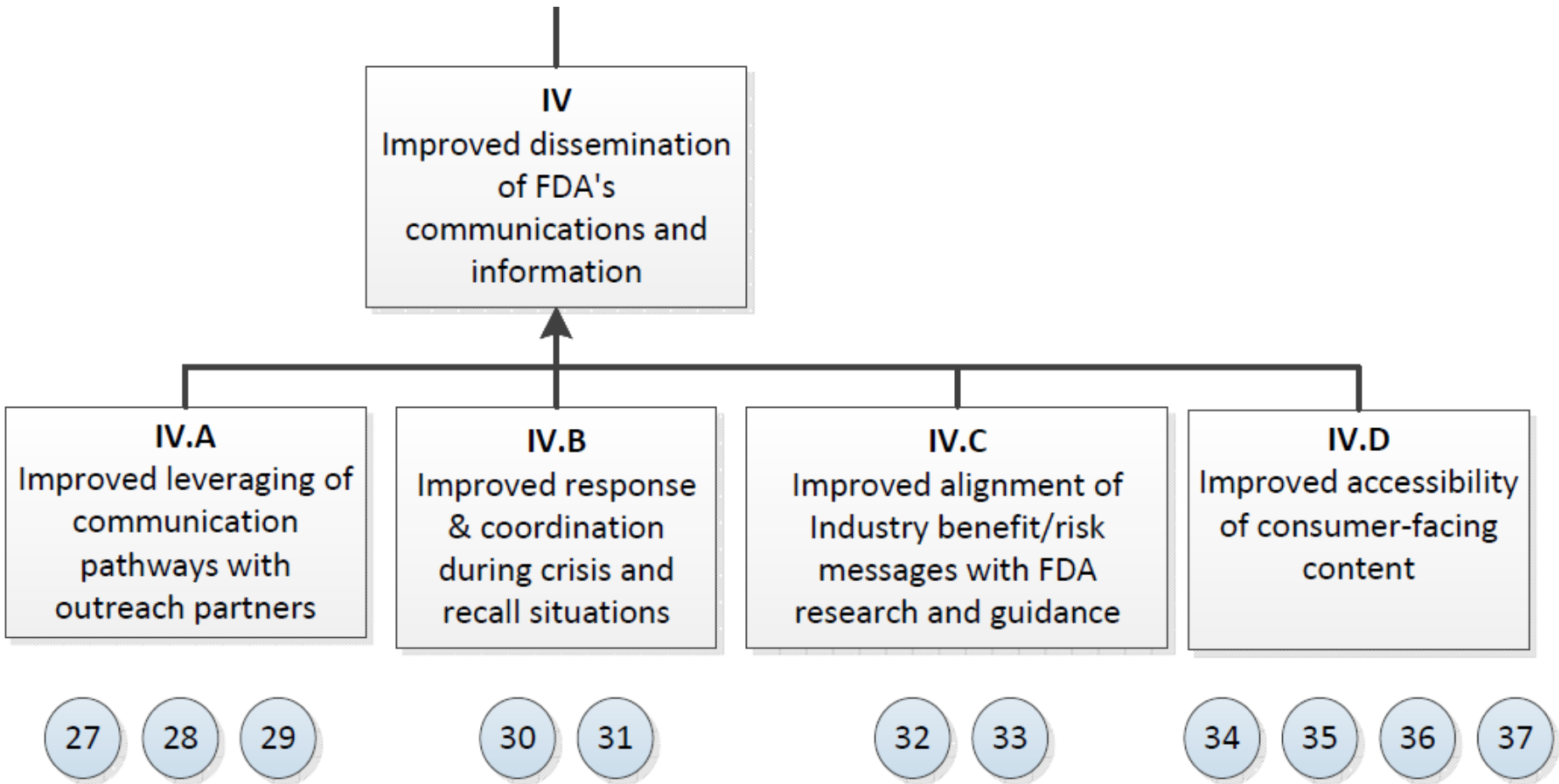
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Ⓢ corresponds to Activity





# Lower Level Outcomes and Actions

## 3. Taking each major Contributing Outcome I through IV in turn, please consider the questions:

- a. Do the lower level contributing outcomes support this outcome? Are there gaps in support?
- b. Do the listed activities and sample specific actions for each contributing outcome implement the outcome? Can you suggest other activities we might consider, if possible?
- c. Do the proposed performance indicators provide meaningful measurement of progress toward the outcomes? Can you suggest any others for us to consider?

# Next Steps for SPRCHL

- Seek RCAC Advice
- Modify Draft SPRCHL
- FDA Leadership Clearance
- Publish on FDA Website
- Execute and Monitor



**And in closing:**

**Thank you for your  
attention and advice**