

Safe Drugs Save Lives

# Monitoring & Evaluation Management Information System

Software Requirement Specification Document Version 1.0.0







# **APPROVED BY**

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# 1 INTRODUCTION

#### 1.1 Purpose

The purpose of this document is to present a detailed description of the Monitoring and Evaluation Management Information System (MEMIS). It will explain the purpose and features of the system, the interfaces of the system, what the system will do, the constraints under which it must operate and how the system will react to external stimuli. This document is intended for both the stakeholders and the developers of the system and will be proposed to the National Drug Authority (NDA) for its approval.

The system should address the following data need requirements:

- a) To design a planning and allocation of resources module.
- b) To design and standardize the M&E reporting module.
- c) To design the enterprise risk management module
- d) To design an on-spot GIS monitoring and reporting module
- e) To develop a project management module.

# 1.2 Scope

A complete web-based monitoring & evaluation system for NDA to that will enhance efficiency in data management, data use and timely information dissemination for decision making by the Directorates, departmental process owners and management. This system will be designed to maximize the organization productivity by providing tools to complete manage all M & E, Risk, Project and GIS processes, which would otherwise have to be performed manually. By maximizing the stakeholders work efficiency and production the system will meet their needs while remaining easy to understand and use.





# **2 FUNTIONAL REQUIREMENTS**

# 2.1 Planning Module

In planning module, the system should be able to capture the Strategic Plan for 5 years which is aligned to National Development Plan III (NDP III), extract annual implementation plan and allow the stake holders to create detailed annual work plan for current year.

#### 2.1.1 Master Data

#### 2.1.1.1 NDP III

The system records the core items in National Development Plan III.

NDP III Programme Objective	NDP III Interventions	NDA Focus Area objectives	NDA focus area Strategies to attain NDP3 programme interventions and objectives
NDP III Programme	e: Human capital d	evelopment	
NDA Focus Area: C	Core service deliver	у	
Objective 4: To improve population health, safety and management.	4.3 Improve the functionality of the health system to deliver quality and affordable preventive, promotive, curative and palliative health care services.	To improve the regulatory efficiency and effectiveness that ensure safe, efficacious and quality drugs and health products.	<ul> <li>Strengthen systems and institute regulatory actions that support local drugs manufacturing.</li> <li>Strengthen systems and institute actions that support drug regulatory compliance by human and vet practitioners.</li> <li>Strengthen the research capacity for making evidence-based drug regulatory decisions.</li> <li>Strengthen the systems, processes and procedures for pre-market authorization of drugs and healthcare products.</li> </ul>
	e: Agro-industrializ		<ul> <li>Strengthen the systems, processes and procedures for post-market authorization of drugs and healthcare products.</li> </ul>
	Core service deliver	I	
Objective 1: Increase production and productivity.	1.3 Strengthen the agricultural inputs markets and distribution systems to adhere to quality standards and grades.	To improve the regulatory efficiency and effectiveness that ensure safe, efficacious and quality drugs and health products.	<ul> <li>Strengthen systems and institute regulatory actions that support local drugs manufacturing</li> <li>Strengthen systems and institute actions that support drug regulatory compliance by human and vet practitioners.</li> </ul>
	1.9	To improve the	Strengthen systems and institute actions





Safe Drugs Save Lives			
	Strengthen	regulatory efficiency	that support drug regulatory compliance by
	systems for	and effectiveness	human and vet practitioners.
	management of	that ensure safe,	Strengthen the research capacity for
	pests, vectors	efficacious and	making evidence-based drug regulatory
	and diseases.	quality drugs and	decisions.
		health products.	Strengthen the systems, processes and
			procedures for pre-market authorization of
			drugs and healthcare products.
			Strengthen the systems, processes and
			procedures for post-market authorization
			of drugs and healthcare products.
NDP III Programm	e: Private sector de	evelopment	
NDA Focus Area: 0	Core service deliver	у	
Objective 5:	5.1.	To improve the	Strengthen systems and institute
Strengthen the	Support the	regulatory efficiency	regulatory actions that support local drugs
enabling	national	and effectiveness	manufacturing.
environment and	conformity	that ensure safe,	Strengthen the systems, processes and
enforcement <b>of</b>	assessment	efficacious and	procedures for pre-market authorization of
standards.	system to attain	quality drugs and	drugs and healthcare products.
	international	health products.	• Strengthen the systems, processes and
	recognition		procedures for post-market authorization
	through Ac-		of drugs and healthcare products.
	creditation.		
NDP III Programm	e: Manufacturing		
NDA Focus Area: 0	Core service deliver	У	
Objective 2:	2.1	To improve the	Strengthen systems and institute
Increase value	Support existing	regulatory efficiency	regulatory actions that support local drugs
addition for im-	local	and effectiveness	manufacturing.
port substitution	manufactures	that ensures safe,	
and enhanced	for both medical	efficacious and	
exports.	products and	quality drugs and	

health products.

Pharmaceuticals.





#### 2.1.1.2 Strategic Plan (5Years)

The Strategic Plan for NDA contributes to NDP III. The system records the strategic plan for 5 years. The stakeholders can view/extract the strategic plan from the system. The following details makes a strategic Plan

- a) NDP III
- b) Program
- c) Program Objectives
- d) Sub Program
- e) Focus Area
- f) NDA Strategic Objective
- g) Strategic Intervention
- h) Strategic Action

#### 2.1.1.3 Annual Implementation Plan for 5 Years

- a) Focus Area
- b) NDA Strategic Objective
- c) Strategic Intervention
- d) Strategic Action
- e) Activity / initiative
- f) Output Indicators
- g) Annual Target
- h) Internal Budget Code
- i) Unit Cost
- i) Justification for Unit Cost
- k) Government Budget Code

#### 2.1.1.4 M& E Plan (5 Years)

The purpose of this NDA Strategic M&E plan, developed by the Planning and Business Development Unit, is to assist the NDA and stakeholders to systematically monitor the performance of the Drug Authority and measure the progress over the next five (5) years towards achieving the objectives of the NDA Strategic Plan. The plan establishes a single, harmonized monitoring and evaluation platform around which the Planning and Business Development and stakeholders can coordinate and contribute to in developing a strong, effective M&E system that enhances understanding and decision-making in the Drug Authority.





The plan comprises CPI, KPI's and OPI's developed through a consultative and participatory process led by the Business Planning and Development Unit. The system records the M& E Plan for 5 years. The stakeholders can view/extract the M & E plan from the system.

#### 2.1.1.5 M & E Framework (5 Year)

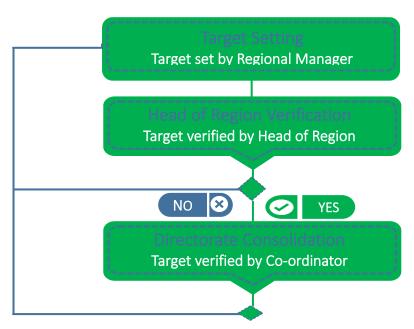
The following Details makes an M & E Framework:

- a) Focus Area
- b) Strategic Objective
- c) Health Regulatory Outcome
- d) Performance indicator
- e) Type of Indicator
- f) Indicator Formulae
- g) Indicator Definition
- h) Original Baseline (FY 19-20 Performance)
- i) Indicator classification
- j) Data Type
- k) Unit of measure
- I) Frequency of Reporting
- m) Annualized Targets for five years
- n) Means of Verification
- o) Responsibility





#### 2.1.2 Work Plan Target Collection from Region (Year before)



#### 2.1.2.1 Regional Manager Target Setting

The Regional Manager can set the quarterly targets against the annual target set by the department coordinator and submit to head of regions for verification.

Field	Field Type	M/O	Additional Remarks
Strategic Objective	Extracted from Annual	М	
	Implementation Plan		
Strategic	Extracted from Annual	М	
Intervention	Implementation Plan		
Strategic Action	Extracted from Annual	М	
	Implementation Plan		
Activity / Initiative	Extracted from Annual	M	
	Implementation Plan		
Output Indicators	Extracted from Annual	M	
	Implementation Plan		
Baseline	Extracted from Previous	М	This will be blank for first
	Performance		year
<b>Budget Code</b>	Extracted from Annual	М	
	Implementation Plan		
Unit Cost	Extracted from Annual	M	System will pop up the
	Implementation Plan		justification for unit cost
Q1 Target	User Entry. Number Field	М	
Q1 Budget	System Generated	М	Unit Cost x Q1 Target
Q2 Target	User Entry. Number Field	М	
Q2 Budget	System Generated	М	Unit Cost x Q2 Target





Q3 Target	User Entry. Number Field	M	
Q3 Budget	System Generated	M	Unit Cost x Q3 Target
Q4 Target	User Entry. Number Field	M	
Q4 Budget	System Generated	M	Unit Cost x Q4 Target
<b>Comparative Target</b>	System Generated	M	Add all quarterly targets
Budget Amount	System Generated	M	Unit Cost x Comparative
			Target

# 2.1.2.2 Head of Region Verification

Head of region can verify and approve/reject the work plan submitted by the region. Once rejected the work plan will move to the Regional Manager to update and resubmit again.

Field	Field Type	M/O	Additional Remarks
Strategic Objective	Extracted from Annual Implementation Plan	M	
Strategic Intervention	Extracted from Annual Implementation Plan	M	
Strategic Action	Extracted from Annual Implementation Plan	M	
Activity / Initiative	Extracted from Annual Implementation Plan	M	
Output Indicators	Extracted from Annual Implementation Plan	M	
Baseline	Extracted from Previous Performance	M	This will be blank for first year
<b>Budget Code</b>	Extracted from Annual Implementation Plan	M	
Unit Cost	Extracted from Annual Implementation Plan	M	System will pop up the justification for unit cost
Q1 Target	Load from the input from regional manger	M	
Q1 Budget	System Generated	М	Unit Cost x Q1 Target
Q2 Target	Load from the input from regional manger	M	
Q2 Budget	System Generated	М	Unit Cost x Q2 Target
Q3 Target	Load from the input from regional manger	M	
Q3 Budget	System Generated	М	Unit Cost x Q3 Target
Q4 Target	Load from the input from regional manger	M	
Q4 Budget	System Generated	М	Unit Cost x Q4 Target
<b>Comparative Target</b>	System Generated	М	Add all quarterly targets
<b>Budget Amount</b>	System Generated	М	Unit Cost x Comparative





			Target
Action	Dropdown (Verify/Reject)	M	The action will be applicable for the selected workplan
Comment	User Entry. Text Field	0	The comment will be applicable for the selected workplan. Comment will be mandatory once rejected. Max. characters is 500.

#### 2.1.2.3 Director Level Consolidation

M & E Coordinator can review the work plan verified by Head of Region.

Field	Field Type	M/O	Additional Remarks
Strategic Objective	Extracted from Annual Implementation Plan	M	
Strategic Intervention	Extracted from Annual Implementation Plan	M	
Strategic Action	Extracted from Annual Implementation Plan	M	
Activity / Initiative	Extracted from Annual Implementation Plan	M	
Output Indicators	Extracted from Annual Implementation Plan	M	
Baseline	Extracted from Previous Performance	M	This will be blank for first year
<b>Budget Code</b>	Extracted from Annual Implementation Plan	M	
Unit Cost	Extracted from Annual Implementation Plan	M	System will pop up the justification for unit cost
Q1 Target	Load from the input from regional manger	M	
Q1 Budget	System Generated	М	Unit Cost x Q1 Target
Q2 Target	Load from the input from regional manger	M	
Q2 Budget	System Generated	М	Unit Cost x Q2 Target
Q3 Target	Load from the input from regional manger	M	
Q3 Budget	System Generated	М	Unit Cost x Q3 Target
Q4 Target	Load from the input from regional manger	M	
Q4 Budget	System Generated	М	Unit Cost x Q4 Target
<b>Comparative Target</b>	System Generated	М	Add all quarterly targets





Budget Amount	System Generated	M	Unit Cost x Comparative Target
Action	Dropdown (Verify/Reject)	M	The action will be applicable for the selected workplan
Comment	User Entry. Text Field	0	The comment will be applicable for the selected workplan. Comment will be mandatory once rejected. Max. characters is 500.

#### 2.1.3 The 5 Year Annualized Implementation Plan

The 5 Year Annualized Implementation plan is extracted by the system from the strategic plan. This can be viewed/ printed by the stakeholders. It contains the following fields:

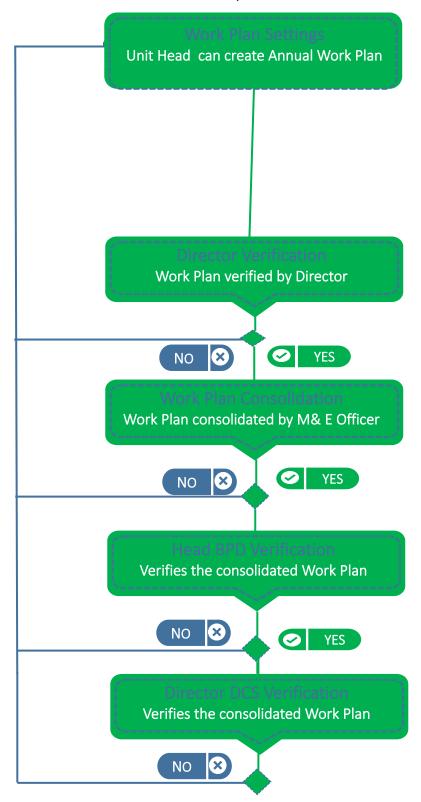
- a) Focus Area
- b) Strategic Objective
- c) Strategic Intervention
- d) Strategic Action
- e) Activities
- f) Output Indicators
- g) Output Targets
- h) Annual Target for 5 Years
- i) Means of Verification
- j) Responsible Party





#### 2.1.4 Detailed Annual Work Plan

The annual work plan will be generated from the 5 Year Annualized Implementation Plan. The department can add the comparative annual targets to the 5-year target, quarterly targets and budget information in the work plan and forward for various levels of approvals. Head of department, unit / Director can add additional activities if any.







#### 2.1.4.1 Department / Unit Work Plan Setting

The Department / Unit Coordinator creates the work plan from the Annual Implementation Plan. The department coordinator inputs the quarterly targets and budget and forward for approval. Department / Unit coordinator can add additional activities if any. The Identified risk management further actions can be added by department coordinator. It can be picked using the budget code in risk register and budget code in activity framework.

Field	Field Type	M/O	Additional Remarks
Focus Area	Extracted from Annual	М	
	Implementation Plan		
Strategic Objective	Extracted from Annual	М	
	Implementation Plan		
Strategic	Extracted from Annual	М	
Intervention	Implementation Plan		
Strategic Action	Extracted from Annual	M	
	Implementation Plan		
Activity / Initiative	Extracted from Annual	М	
	Implementation Plan		
Output Indicators	Extracted from Annual	М	
	Implementation Plan		
Baseline	Extracted from Previous	М	This will be blank for first
	Performance		year
Annual Target	Extracted from the 5 Year	M	
	Implementation Plan		
Budget Code	Extracted from Annual	М	
	Implementation Plan		
Unit Cost	Extracted from Annual	M	System will pop up the
	Implementation Plan		justification for unit cost
Q1 Output Target	User Entry. Text Field	M	
Q1 Budget	System Generated	M	Unit Cost x Q1 Target
Q2 Output Target	User Entry. Text Field	M	
Q2 Budget	System Generated	М	Unit Cost x Q2 Target
Q3 Output Target	User Entry. Text Field	М	
Q3 Budget	System Generated	M	Unit Cost x Q3 Target
Q4 Output Target	User Entry. Text Field	М	
Q4 Budget	System Generated	М	Unit Cost x Q4 Target
Comparative Target	System Generated	М	Add all quarterly targets
Justification	User Entry. Text Field	0	Justification is mandatory
			when comparative target is
			different from annual
			target





<b>Budget Amount</b>	System Generated	M	Unit Cost x Comparative
			Target

# 2.1.4.2 Department / Unit Work Plan Verification by HOD

The Head of Department / Unit verifies the work plan and approve/reject. On rejection the work plan will be sent back to the Department / Unit Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Focus Area	Extracted from Annual	М	
	Implementation Plan		
Strategic Objective	Extracted from Annual	М	
	Implementation Plan		
Strategic	Extracted from Annual	М	
Intervention	Implementation Plan		
Strategic Action	Extracted from Annual	M	
	Implementation Plan		
Activity / Initiative	Extracted from Annual	M	
	Implementation Plan		
Output Indicators	Extracted from Annual	M	
	Implementation Plan		
Baseline	Extracted from Previous	M	This will be blank for first
	Performance		year
Annual Target	Extracted from the 5 Year	M	
	Implementation Plan		
Budget Code	Extracted from Annual	М	
	Implementation Plan		
Unit Cost	Extracted from Annual	М	System will pop up the
	Implementation Plan		justification for unit cost
Q1 Output Target	Load from Work Plan by	М	
	Department / Unit		
	Coordinator		
Q1 Budget	System Generated	M	Unit Cost x Q1 Target
Q2 Output Target	Load from Work Plan by	M	
	Department / Unit		
O2 Budget	Coordinator	N 4	Halt Coat of O2 To coat
Q2 Budget	System Generated	M	Unit Cost x Q2 Target
Q3 Output Target	Load from Work Plan by	М	
	Department / Unit		
O2 Budget	Coordinator	N A	Unit Cost v O2 Torget
Q3 Budget	System Generated	M	Unit Cost x Q3 Target
Q4 Output Target	Load from Work Plan by	М	
	Department / Unit		





	Coordinator		
Q4 Budget	System Generated	М	Unit Cost x Q4 Target
<b>Comparative Target</b>	System Generated	М	Add all quarterly targets
Justification	Load from Work Plan by	0	Justification is mandatory
	Department / Unit		when comparative target is
	Coordinator		different from annual
			target
<b>Budget Amount</b>	System Generated	М	Unit Cost x Comparative
			Target
Action	Dropdown (Verified /	М	The action will be
	Reject)		applicable for the selected
			workplan
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			workplan. Comment will be
			mandatory once rejected.
			Max. characters is 500.

### 2.1.4.3 Department / Unit Work Plan Verification by Director

The Director for the Department / Unit verifies the work plan and approve/reject. On rejection the work plan will be send back to the Department / Unit Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Focus Area	Extracted from Annual	М	
	Implementation Plan		
Strategic Objective	Extracted from Annual	М	
	Implementation Plan		
Strategic	Extracted from Annual	M	
Intervention	Implementation Plan		
Strategic Action	Extracted from Annual	M	
	Implementation Plan		
Activity / Initiative	Extracted from Annual	M	
	Implementation Plan		
Output Indicators	Extracted from Annual	M	
	Implementation Plan		
Baseline	Extracted from Previous	M	This will be blank for first
	Performance		year
Annual Target	Extracted from the 5 Year	M	
	Implementation Plan		
Budget Code	Extracted from Annual	М	
	Implementation Plan		
Unit Cost	Extracted from Annual	М	System will pop up the
	Implementation Plan		justification for unit cost





Q1 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q1 Budget	System Generated	M	Unit Cost x Q1 Target
Q2 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q2 Budget	System Generated	M	Unit Cost x Q2 Target
Q3 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q3 Budget	System Generated	М	Unit Cost x Q3 Target
Q4 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q4 Budget	System Generated	M	Unit Cost x Q4 Target
<b>Comparative Target</b>	System Generated	M	Add all quarterly targets
Justification	Load from Work Plan by Department / Unit Coordinator	0	Justification is mandatory when comparative target is different from annual target
Budget Amount	System Generated	M	Unit Cost x Comparative Target
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected workplan
Comment	User Entry. Text Field	0	The comment will be applicable for the selected workplan. Comment will be mandatory once rejected.  Max. characters is 500.

# 2.1.4.4 Work Plan Consolidation by M&E Officer

The M& E Officer verifies the work plan and consolidates work plan from various directorates/departments. For modifications M & E Officer can send it back to the Department / Unit Coordinator.

Field	Field Type	M/O	Additional Remarks
Focus Area	Extracted from Annual	M	
	Implementation Plan		
Strategic Objective	Extracted from Annual	M	
	Implementation Plan		





Strategic	Extracted from Annual	М	
Intervention		IVI	
	Implementation Plan	D.A.	
Strategic Action	Extracted from Annual Implementation Plan	M	
Activity / Initiative	Extracted from Annual	M	
	Implementation Plan		
Output Indicators	Extracted from Annual	М	
	Implementation Plan		
Baseline	Extracted from Previous	М	This will be blank for first
	Performance		year
Annual Target	Extracted from the 5 Year	М	
	Implementation Plan		
<b>Budget Code</b>	Extracted from Annual	М	
	Implementation Plan		
Unit Cost	Extracted from Annual	М	System will pop up the
	Implementation Plan		justification for unit cost
Q1 Output Target	Load from Work Plan by	М	
	Department / Unit		
	Coordinator		
Q1 Budget	System Generated	М	Unit Cost x Q1 Target
Q2 Output Target	Load from Work Plan by	М	
	Department / Unit		
	Coordinator		
Q2 Budget	System Generated	М	Unit Cost x Q2 Target
Q3 Output Target	Load from Work Plan by	М	
	Department / Unit		
	Coordinator		
Q3 Budget	System Generated	М	Unit Cost x Q3 Target
Q4 Output Target	Load from Work Plan by	М	
	Department / Unit		
	Coordinator		
Q4 Budget	System Generated	М	Unit Cost x Q4 Target
<b>Comparative Target</b>	System Generated	М	Add all quarterly targets
Justification	Load from Work Plan by	0	Justification is mandatory
	Department / Unit		when comparative target is
	Coordinator		different from annual
			target
<b>Budget Amount</b>	System Generated	М	Unit Cost x Comparative
			Target
Action	Dropdown (Verified /	М	The action will be
	Reject)		applicable for the selected
			workplan
Comment	User Entry. Text Field	0	The comment will be
Comment	OSCI EITHY. TEXT TICK	U	The comment will be





applicable for the selected
workplan. Comment will be
mandatory once rejected.
Max. characters is 500.

# 2.1.4.5 Work Plan Verification by Head of BPD

The Head of BPD verifies the work plan and approve/reject. On rejection the work plan will be send back to the Department / Unit Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Focus Area	Extracted from Annual Implementation Plan	M	
Strategic Objective	Extracted from Annual Implementation Plan	M	
Strategic Intervention	Extracted from Annual Implementation Plan	M	
Strategic Action	Extracted from Annual Implementation Plan	M	
Activity / Initiative	Extracted from Annual Implementation Plan	M	
Output Indicators	Extracted from Annual Implementation Plan	M	
Baseline	Extracted from Previous Performance	M	This will be blank for first year
Annual Target	Extracted from the 5 Year Implementation Plan	M	
<b>Budget Code</b>	Extracted from Annual Implementation Plan	M	
Unit Cost	Extracted from Annual Implementation Plan	M	System will pop up the justification for unit cost
Q1 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q1 Budget	System Generated	М	Unit Cost x Q1 Target
Q2 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q2 Budget	System Generated	М	Unit Cost x Q2 Target
Q3 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q3 Budget	System Generated	М	Unit Cost x Q3 Target
Q4 Output Target	Load from Work Plan by	М	





	Department / Unit Coordinator		
Q4 Budget	System Generated	М	Unit Cost x Q4 Target
<b>Comparative Target</b>	System Generated	M	Add all quarterly targets
Justification	Load from Work Plan by Department / Unit Coordinator	0	Justification is mandatory when comparative target is different from annual target
Budget Amount	System Generated	M	Unit Cost x Comparative Target
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected workplan
Comment	User Entry. Text Field	0	The comment will be applicable for the selected workplan. Comment will be mandatory once rejected.  Max. characters is 500.

# 2.1.4.6 Work Plan Approval by Director (DCS)

The Director (DCS) verifies the work plan and approve/reject. On rejection the work plan will be send back to the Department / Unit Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Focus Area	Extracted from Annual	М	
	Implementation Plan		
Strategic Objective	Extracted from Annual	М	
	Implementation Plan		
Strategic	Extracted from Annual	М	
Intervention	Implementation Plan		
Strategic Action	Extracted from Annual	М	
	Implementation Plan		
Activity / Initiative	Extracted from Annual	М	
	Implementation Plan		
Output Indicators	Extracted from Annual	М	
	Implementation Plan		
Baseline	Extracted from Previous	М	This will be blank for first
	Performance		year
Annual Target	Extracted from the 5 Year	М	
	Implementation Plan		
<b>Budget Code</b>	Extracted from Annual	М	
	Implementation Plan		





Unit Cost	Extracted from Annual Implementation Plan	M	System will pop up the justification for unit cost
Q1 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q1 Budget	System Generated	M	Unit Cost x Q1 Target
Q2 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q2 Budget	System Generated	M	Unit Cost x Q2 Target
Q3 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q3 Budget	System Generated	M	Unit Cost x Q3 Target
Q4 Output Target	Load from Work Plan by Department / Unit Coordinator	M	
Q4 Budget	System Generated	M	Unit Cost x Q4 Target
<b>Comparative Target</b>	System Generated	M	Add all quarterly targets
Justification	Load from Work Plan by Department / Unit Coordinator	0	Justification is mandatory when comparative target is different from annual target
Budget Amount	System Generated	M	Unit Cost x Comparative Target
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected workplan
Comment	User Entry. Text Field	0	The comment will be applicable for the selected workplan. Comment will be mandatory once rejected.  Max. characters is 500.





# 2.1.4.7 Planning Module Reports

- Strategic Plan
- 5-year Annualized Implementation Plan
- Quarterly & Annual Work Plan (Filter By Directorate/ Department / Unit/Unit)
- M & E Plan (5 Years)
- M & E Annual Plan

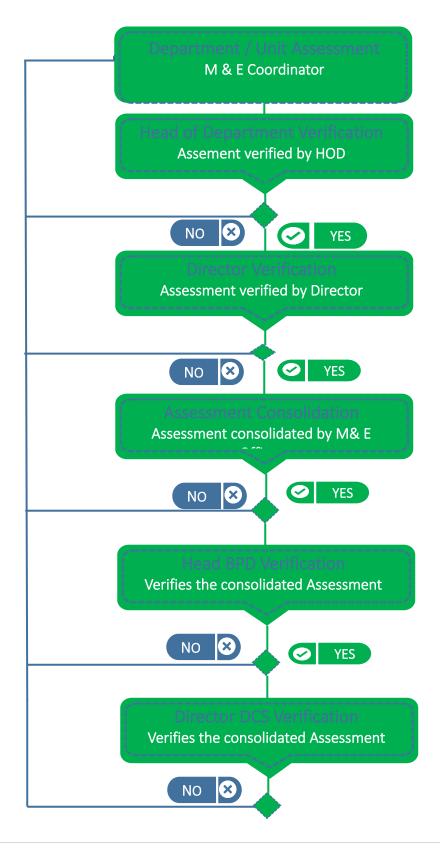




#### 2.2 M & E Module

#### 2.2.1 Activity Framework Assessment (Quarterly)

Activity Framework Assessment is based on the Annual Work Plan. All responsible departments capture the actual achieved details and actual amount spent for their activities on quarterly basis. The implementation status for each activity will be captured on annual basis.







# 2.2.1.1 Department / Unit Assessment

The M & E Coordinator capture the actual achievements, actual amount spent and justification on quarterly basis.

Field	Field Type	M/O	Additional Remarks
Strategic Intervention	Load from Work Plan	М	
Strategic Action	Load from Work Plan	М	
Activity / Initiative	Load from Work Plan	М	
Output Indicators	Load from Work Plan	М	
Annual Target	Load from Work Plan	М	
Comparative Target	Load from Work Plan	М	
Budget Code	Load from Work Plan	М	
Annual Budget	Load from Work Plan	М	
<b>Comparative Target</b>	Load from Work Plan	М	
Justification	Load from Work Plan	0	
Q1 Target	Load from Work Plan	М	
Q1 Budget	Load from Work Plan	М	
Q1 Actual	User Entry. Numeric Field	М	
Q1 Amount Spent	User Entry. Number Field	М	
Q1 Justification	User Entry. Text Field	М	Max. character is 500.
Q2 Target	Load from Work Plan	М	
Q2 Budget	Load from Work Plan	М	
Q2 Actual	User Entry. Numeric Field	М	
Q2 Amount Spent	User Entry. Number Field	М	
Q2 Justification	User Entry. Text Field	М	Max. character is 500.
Q3 Target	Load from Work Plan	М	
Q3 Budget	Load from Work Plan	M	
Q3 Actual	User Entry. Numeric Field	М	
Q3 Amount Spent	User Entry. Number Field	М	
Q3 Justification	User Entry. Text Field	М	Max. character is 500.
Q4 Target	Load from Work Plan	М	
Q4 Budget	Load from Work Plan	М	
Q4 Actual	User Entry. Numeric Field	М	
Q4 Amount Spent	User Entry. Number Field	М	
Q4 Justification	User Entry. Text Field	М	Max. character is 500.
Annual Achievement	User Entry. Text Field	М	
Total Amount Spent	User Entry. Number Field	М	
Implementation Status	Dropdown (Fully Implemented / Partially Implemented / Not Implemented)	M	
Justification	User Entry. Text Field	М	Max. character is 500.





#### 2.2.1.2 Department / Unit Assessment Verification by HOD

The Head of Department / Unit verifies the assessment submitted by M & E Coordinator and forwards to Director. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Focus Area	Load from Work Plan	М	
Strategic Objective	Load from Work Plan	М	
Strategic Intervention	Load from Work Plan	M	
Strategic Action	Load from Work Plan	М	
Activity / Initiative	Load from Work Plan	М	
Output Indicators	Load from Work Plan	М	
Baseline	Load from Work Plan	M	This will be blank for first year
Annual Target	Load from Work Plan	M	Can be modified by department
<b>Comparative Target</b>	Load from Work Plan	М	
Budget Code	Load from Work Plan	М	
Annual Budget	Load from Work Plan	М	
Q1 Target	Load from Work Plan	М	
Q1 Budget	Load from Work Plan	M	
Q1 Actual	Load from Department / Unit Assessment	M	
Q1 Amount Spent	Load from Department / Unit Assessment	M	
Comparative Target	Load from Work Plan	М	
Justification	Load from Work Plan	0	
Q1 Justification	Load from Department / Unit Assessment	M	
Q2 Target	Load from Work Plan	М	
Q2 Budget	Load from Work Plan	М	
Q2 Actual	Load from Department / Unit Assessment	M	
Q2 Amount Spent	Load from Department / Unit Assessment	M	
Q2 Justification	Load from Department / Unit Assessment	M	
Q3 Target	Load from Work Plan	М	
Q3 Budget	Load from Work Plan	М	
Q3 Actual	Load from Department / Unit Assessment	M	
Q3 Amount Spent	Load from Department / Unit Assessment	M	





Q3 Justification	Load from Department /	М	
	Unit Assessment		
Q4 Target	Load from Work Plan	М	
Q4 Budget	Load from Work Plan	М	
Q4 Actual	Load from Department /	М	
	Unit Assessment		
Q4 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q4 Justification	Load from Department /	М	
	Unit Assessment		
Annual Achievement	Load from Department /	М	
	Unit Assessment		
<b>Total Amount Spent</b>	Load from Department /	М	
	Unit Assessment		
Implementation Status	Load from Department /	М	
	Unit Assessment		
Justification	Load from Department /	М	Max. character is 500.
	Unit Assessment		
Action	Dropdown (Verified /	М	The action will be
	Reject)		applicable for the selected
			records
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			records . Comment will be
			mandatory once rejected.
			Max. characters is 500.

### 2.2.1.3 Department / Unit Assessment Verification by Director

The Director verifies the assessment forwarded by Head of Department / Unit and approve/reject. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Focus Area	Load from Work Plan	М	
Strategic Objective	Load from Work Plan	M	
Strategic Intervention	Load from Work Plan	М	
Strategic Action	Load from Work Plan	М	
Output Indicators	Load from Work Plan	М	
Baseline	Load from Work Plan	M	This will be blank for first year
Annual Target	Load from Work Plan	M	Can be modified by
			department
Budget Code	Load from Work Plan	M	
Annual Budget	Load from Work Plan	М	





<b>Comparative Target</b>	Load from Work Plan	М	
Justification	Load from Work Plan	0	
Q1 Target	Load from Work Plan	М	
Q1 Budget	Load from Work Plan	М	
Q1 Actual	Load from Department /	М	
	Unit Assessment		
Q1 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q1 Justification	Load from Department /	М	
	Unit Assessment		
Q2 Target	Load from Work Plan	М	
Q2 Budget	Load from Work Plan	М	
Q2 Actual	Load from Department /	М	
	Unit Assessment		
Q2 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q2 Justification	Load from Department /	М	
	Unit Assessment		
Q3 Target	Load from Work Plan	М	
Q3 Budget	Load from Work Plan	М	
Q3 Actual	Load from Department /	М	
	Unit Assessment		
Q3 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q3 Justification	Load from Department /	М	
	Unit Assessment		
Q4 Target	Load from Work Plan	М	
Q4 Budget	Load from Work Plan	M	
Q4 Actual	Load from Department /	M	
	Unit Assessment		
Q4 Amount Spent	Load from Department /	M	
	Unit Assessment		
Q4 Justification	Load from Department /	M	
	Unit Assessment		
Annual Achievement	Load from Department /	M	
	Unit Assessment		
Total Amount Spent	Load from Department /	M	
	Unit Assessment		
Implementation Status	Load from Department /	М	
	Unit Assessment		
Justification	Load from Department /	М	Max. character is 500.
	Unit Assessment		
Action	Dropdown (Verified /	М	The action will be applicable





	Reject)		for the selected records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			records. Comment will be
			mandatory once rejected.
			Max. characters is 500.

# 2.2.1.4 Consolidation of Assessment by M&E Officer

The M& E Officer consolidates the assessment verified by Directors of various directorates. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Focus Area	Load from Work Plan	M	
Strategic Objective	Load from Work Plan	М	
Strategic Intervention	Load from Work Plan	M	
Strategic Action	Load from Work Plan	М	
Output Indicators	Load from Work Plan	M	
Baseline	Load from Work Plan	M	This will be blank for first year
Annual Target	Load from Work Plan	M	Can be modified by department
<b>Budget Code</b>	Load from Work Plan	М	
Annual Budget	Load from Work Plan	M	
Comparative Target	Load from Work Plan	М	
Justification	Load from Work Plan	0	
Q1 Target	Load from Work Plan	М	
Q1 Budget	Load from Work Plan	M	
Q1 Actual	Load from Department / Unit Assessment	M	
Q1 Amount Spent	Load from Department / Unit Assessment	M	
Q1 Justification	Load from Department / Unit Assessment	M	
Q2 Target	Load from Work Plan	М	
Q2 Budget	Load from Work Plan	М	
Q2 Actual	Load from Department / Unit Assessment	M	
Q2 Amount Spent	Load from Department / Unit Assessment	M	
Q2 Justification	Load from Department / Unit Assessment	M	
Q3 Target	Load from Work Plan	M	





Q3 Budget	Load from Work Plan	М	
Q3 Actual	Load from Department /	М	
	Unit Assessment		
Q3 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q3 Justification	Load from Department /	М	
	Unit Assessment		
Q4 Target	Load from Work Plan	М	
Q4 Budget	Load from Work Plan	М	
Q4 Actual	Load from Department /	М	
	Unit Assessment		
Q4 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q4 Justification	Load from Department /	М	
	Unit Assessment		
Annual Achievement	Load from Department /	М	
	Unit Assessment		
<b>Total Amount Spent</b>	Load from Department /	М	
	Unit Assessment		
Implementation Status	Load from Department /	М	
	Unit Assessment		
Justification	Load from Department /	М	Max. character is 500.
	Unit Assessment		
Action	Dropdown (Verified /	М	The action will be applicable
	Reject)		for the selected records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			records. Comment will be
			mandatory once rejected.
			Max. characters is 500.

#### 2.2.1.5 Head BPD Verification

The Head BPD verifies the assessment forwarded by M&E Officer and approve/reject. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Focus Area	Load from Work Plan	М	
Strategic Objective	Load from Work Plan	М	
Strategic Intervention	Load from Work Plan	М	
Strategic Action	Load from Work Plan	М	
Output Indicators	Load from Work Plan	М	
Baseline	Load from Work Plan	М	This will be blank for first
			year





Annual Target	Load from Work Plan	М	Can be modified by
· ·			department
Budget Code	Load from Work Plan	M	
Annual Budget	Load from Work Plan	M	
Comparative Target	Load from Work Plan	M	
Justification	Load from Work Plan	0	
Q1 Target	Load from Work Plan	M	
Q1 Budget	Load from Work Plan	M	
Q1 Actual	Load from Department /	M	
	Unit Assessment		
Q1 Amount Spent	Load from Department /	М	
•	Unit Assessment		
Q1 Justification	Load from Department /	М	
	Unit Assessment		
Q2 Target	Load from Work Plan	М	
Q2 Budget	Load from Work Plan	М	
Q2 Actual	Load from Department /	M	
	Unit Assessment		
Q2 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q2 Justification	Load from Department /	М	
	Unit Assessment		
Q3 Target	Load from Work Plan	М	
Q3 Budget	Load from Work Plan	М	
Q3 Actual	Load from Department /	М	
	Unit Assessment		
Q3 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q3 Justification	Load from Department /	М	
	Unit Assessment		
Q4 Target	Load from Work Plan	М	
Q4 Budget	Load from Work Plan	М	
Q4 Actual	Load from Department /	М	
	Unit Assessment		
Q4 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q4 Justification	Load from Department /	М	
	Unit Assessment		
Annual Achievement	Load from Department /	М	
	Unit Assessment		
<b>Total Amount Spent</b>	Load from Department /	M	
	Unit Assessment		
Implementation Status	Load from Department /	M	





	Unit Assessment		
Justification	Load from Department /	М	Max. character is 500.
	Unit Assessment		
Action	Dropdown (Verified /	M	The action will be
	Reject)		applicable for the selected
			records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			records. Comment will be
			mandatory once rejected.
			Max. characters is 500.

# 2.2.1.6 Approval by Director (DCS)

The Director (DCS) verifies the assessment forwarded by Head BPD and approve/reject. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Focus Area	Load from Work Plan	М	
Strategic Objective	Load from Work Plan	М	
Strategic Intervention	Load from Work Plan	М	
Strategic Action	Load from Work Plan	М	
Output Indicators	Load from Work Plan	М	
Baseline	Load from Work Plan	M	This will be blank for first year
Annual Target	Load from Work Plan	М	Can be modified by
			department
Budget Code	Load from Work Plan	М	
Annual Budget	Load from Work Plan	М	
<b>Comparative Target</b>	Load from Work Plan	М	
Justification	Load from Work Plan	0	
Q1 Target	Load from Work Plan	М	
Q1 Budget	Load from Work Plan	М	
Q1 Actual	Load from Department / Unit Assessment	M	
Q1 Amount Spent	Load from Department / Unit Assessment	M	
Q1 Justification	Load from Department / Unit Assessment	M	
Q2 Target	Load from Work Plan	М	
Q2 Budget	Load from Work Plan	М	
Q2 Actual	Load from Department /	М	
	Unit Assessment		
Q2 Amount Spent	Load from Department /	М	





	Unit Assessment		
Q2 Justification	Load from Department /	М	
	Unit Assessment		
Q3 Target	Load from Work Plan	М	
Q3 Budget	Load from Work Plan	М	
Q3 Actual	Load from Department /	М	
	Unit Assessment		
Q3 Amount Spent	Load from Department /	М	
	Unit Assessment		
Q3 Justification	Load from Department /	М	
	Unit Assessment		
Q4 Target	Load from Work Plan	М	
Q4 Budget	Load from Work Plan	М	
Q4 Actual	Load from Department /	М	
	Unit Assessment		
Q4 Amount Spent	Load from Department /	M	
	Unit Assessment		
Q4 Justification	Load from Department /	M	
	Unit Assessment		
Annual Achievement	Load from Department /	М	
	Unit Assessment		
Total Amount Spent	Load from Department /	M	
	Unit Assessment		
Implementation Status	Load from Department /	М	
	Unit Assessment		
Justification	Load from Department /	М	Max. character is 500.
	Unit Assessment		
Action	Dropdown (Verified /	М	The action will be applicable
	Reject)		for the selected records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			records. Comment will be
			mandatory once rejected.
			Max. characters is 500.





#### 2.2.2 SDT Assessment (Monthly/Quarterly)

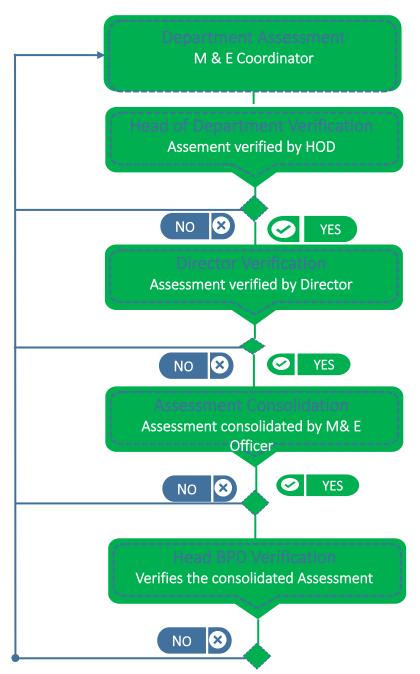
NDA has established service delivery timelines (SDT) to improve regulatory systems, processes and procedures that guarantee availability of safe, efficacious and quality drugs and health products. All the service Delivery Time lines are subsets of indicator "Proportion of SDT's implemented within the agreed timeline" under Strategic Objective One (1) in the M&E Frame work. The SDT are assessed monthly/quarterly basis. The M & E Coordinator will input the numerator and denominator to find a conclusive achievement from it.

#### **SDT Relative Evaluation Scale:**

Criteria	Rating	Methodology for the weighted score for determining overall performance	Justification for the methodology	Needed Action
Actual Performance <= Set Target	Green (1)	If the SDT is within the set target, award a score of 100%	People, Processes, Systems, Customers and Cash flow meet the basic or more than the minimum requirements	Sustain the performance
Actual Performance > set target within variance of 10%	Yellow (0.5)	If SDT is above the set target by not more than 10% variance, award a score of 50%	People, Processes, Systems, Customers and Cash flow fairly meet the basic minimum requirements	1) Review the individual transactions to identify outliers, 2) Review the entire business process if the actual result of the SDT is above the set target by 10% variance for two consecutive quarters and develop the Action plan for improvement
Actual Performance > set target above 10% variance of the SDT	Red (0.25)	If SDT is above the set target by more than 10% variance, award a score of 25%	People, Processes, Systems, Customers and Cash flow does not meet the minimum requirements	1) Review the entire business process if the actual result of the SDT is above the set target by 5 days for two consecutive quarters and develop the Action plan for improvement and 2) Develop and implement a special purpose project







#### 2.2.2.1 SDT Master

The system records all 60 Service Delivery Timelines and its measure, evaluation period, target, responsible department, numerator, denominator.

#### 2.2.2.2 Department / Unit Data Collection

The M & E Coordinator will select the month of assessment and capture numerator and denominator for each SDT. On Submission it forwards to Head of Department / Unit for Verification.

Field	Field Type	M/O	Additional Remarks
Service Delivery	Load from master	М	
Timelines (SDTs)			
Measure	Load from master	М	
Reporting Interval	Load from master	М	





Month	Dropdown (Jul – Jun)	M	The rates and target changed according to the month
Numerator	User Entry. Number Field	M	System will load the numerator description from master. User can add Numerator for each month.
Implemented within Timeline	User Entry, Numeric Field	M	
Denominator	User Entry. Number Field	M	System will load the denominator description from master. User can add Denominator for each month.
Rate	System calculates	М	Numerator / Denominator
Proportion within Timeline	System Generated	M	Implemented within Timeline/ Denominator
Target	Load from master	М	
Achievement Status	System automatically selects based on the rate	M	Achieved (1.0) /Not Achieved (0.25) /On Track (0.5)
% Variance	System Calculates the variance automatically.	M	(Rate-Target) / Target
Justification	User Entry. Text Field	М	Max. character is 500.
Rating	System calculates the rating	M	

# 2.2.2.3 Verification By HOD

The Head of Department / Unit verifies the assessment submitted by department coordinator and forwards to Director. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Service Delivery	Load from master	М	
Timelines (SDTs)			
Measure	Load from master	М	
Reporting Interval	Load from master	М	
Month	Dropdown (Jul – Jun)	М	The rates and target
			changed according to the
			month
Numerator	User Entry. Number Field	М	System will load the





			numerator description from master. User can add Numerator for each month.
Denominator	User Entry. Number Field	M	System will load the denominator description from master. User can add Denominator for each month.
Rate	System calculates	M	Numerator / Denominator
Target	Load from master	M	
Achievement Status	System automatically selects based on the rate	M	Achieved (1.0) /Not Achieved (0.25) /On Track (0.5)
% Variance	System Calculates the variance automatically.	M	(Rate-Target) / Target
Rating	System calculates the rating	M	
Justification	User Entry. Text Field	M	Max. character is 500.
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected.  Max. characters is 500.

# 2.2.2.4 Verification By Director

The Director verifies the assessment forwarded by Head of Department / Unit and approve/reject. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Service Delivery	Load from master	М	
Timelines (SDTs)			
Measure	Load from master	М	
Reporting Interval	Load from master	М	
Month	Dropdown (Jul – Jun)	M	The rates and target
			changed according to the
			month
Numerator	User Entry. Number Field	М	System will load the





			numerator description from master. User can add Numerator for each month.
Denominator	User Entry. Number Field	M	System will load the denominator description from master. User can add Denominator for each month.
Rate	System calculates	M	Numerator / Denominator
Target	Load from master	M	
Achievement Status	System automatically selects based on the rate	M	Achieved (1.0) /Not Achieved (0.25) /On Track (0.5)
% Variance	System Calculates the variance automatically.	M	(Rate-Target) / Target
Rating	System calculates the rating	М	
Justification	User Entry. Text Field	М	Max. character is 500.
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected.  Max. characters is 500.

### 2.2.2.5 Consolidation By M& E Officer

The M& E Officer consolidates the assessment verified by Directors of various directorates. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Service Delivery	Load from master	М	
Timelines (SDTs)			
Measure	Load from master	М	
Reporting Interval	Load from master	М	
Month	Dropdown (Jul – Jun)	M	The rates and target changed according to the month
Numerator	User Entry. Number Field	M	System will load the numerator description from master. User can add





			Numerator for each month.
Denominator	User Entry. Number Field	M	System will load the denominator description from master. User can add Denominator for each month.
Rate	System calculates	М	Numerator / Denominator
Target	Load from master	М	
Achievement Status	System automatically selects based on the rate	M	Achieved (1.0) /Not Achieved (0.25) /On Track (0.5)
% Variance	System Calculates the variance automatically.	M	(Rate-Target) / Target
Rating	System calculates the rating	M	
Justification	User Entry. Text Field	М	Max. character is 500.
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected.  Max. characters is 500.

### 2.2.2.6 Verification by Head of BPD

The Head BPD verifies the assessment forwarded by M&E Officer and approve/reject. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Service Delivery	Load from master	М	
Timelines (SDTs)			
Measure	Load from master	М	
Reporting Interval	Load from master	М	
Month	Dropdown (Jul – Jun)	M	The rates and target changed according to the month
Numerator	User Entry. Number Field	M	System will load the numerator description from master. User can add Numerator for each month.





Denominator	User Entry. Number Field	M	System will load the denominator description from master. User can add Denominator for each month.
Rate	System calculates	M	Numerator / Denominator
Target	Load from master	М	
Achievement Status	System automatically selects based on the rate	M	Achieved (1.0) /Not Achieved (0.25) /On Track (0.5)
% Variance	System Calculates the variance automatically.	M	(Rate-Target) / Target
Rating	System calculates the rating	М	
Justification	User Entry. Text Field	M	Max. character is 500.
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected.  Max. characters is 500.

#### 2.2.3 M& E Assessment (Annually)

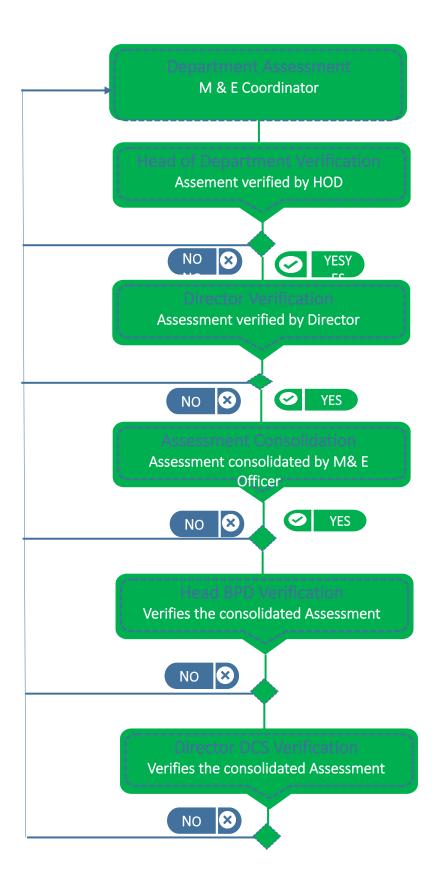
The NDASP performance monitoring plan and Evaluation, including: Type of Indicator, Indicator Formulae, Indicator Definition, Original Baseline, Indicator Classification, Data Type, Unit of measure, Frequency of Reporting, Annualized Targets for five years, Means of Verification and Responsibility. The performance indicators have been categorized in three levels;

- 1. **Core Performance Indicators:** These are high level indicators that are measuring the higher-level results especially the goal of an organization.
- 2. **Key Performance Indicators:** These are measures that NDA uses to gauge its performance over time and its progress towards achieving its goals.
- 3. **Operational Performance Indicators:** These are process indicators that are mainly measuring the Service Delivery Timelines for different processes in different directorates. All the operational indicators are supporting the achievement of one Key Performance Indicator in the M&E Framework under Strategic objective 1.





The M& E Framework indicators are assessed on annual basis. The M & E Coordinator will input the numerator and denominator to find a percentage of achievement from it.







#### 2.2.3.1 Department / Unit Assessment

The system will load the respective Performance Indicators for each department. The M & E Coordinator will select the KPI for assessment and capture numerator and denominator to find the percentage. On Submission it forwards to Head of Department / Unit for Verification.

Field	Field Type	M/O	Additional Remarks
Performance indicator	Load from M& E Plan	М	
Type of Indicator	Load from M& E Plan	М	
Indicator Formulae	Load from M& E Plan	М	
Indicator Definition	Load from M& E Plan	М	
Original Baseline	Load from M& E Plan	М	
Indicator classification	Load from M& E Plan	М	
Data Type	Load from M& E Plan	М	
Unit of measure	Load from M& E Plan	М	
Frequency of Reporting	Load from M& E Plan	М	
Annualized Target	Load from M& E Plan	М	System will load the target
			based on the year selected
Numerator	User Entry. Number Field	М	
Denominator	User Entry. Number Filed	М	
Achieved	System will calculate	М	Numerator/Denominator
	based on numerator and		
	denominator		
Justification	User Entry. Text Field	0	Max. character is 500.
Means of Verification	Load from M& E Plan	М	
Responsibility	Load from M& E Plan	М	

#### 2.2.3.2 Department / Unit Assessment Verification by HOD

The Head of Department / Unit verifies the assessment submitted by M & E Coordinator and forwards to Director. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Performance indicator	Load from M& E	М	
	Department / Unit		
	Assessment		
Type of Indicator	Load from M& E	М	
	Department / Unit		
	Assessment		
Indicator Formulae	Load from M& E	М	
	Department / Unit		
	Assessment		
Indicator Definition	Load from M& E	М	
	Department / Unit		





	Assessment		
Original Baseline	Load from M& E	M	
	Department / Unit		
	Assessment		
Indicator classification	Load from M& E	M	
	Department / Unit		
	Assessment		
Data Type	Load from M& E	M	
	Department / Unit		
	Assessment		
Unit of measure	Load from M& E	M	
	Department / Unit		
	Assessment		
Frequency of Reporting	Load from M& E	M	
	Department / Unit		
	Assessment		
Annualized Target	Load from M& E	M	
	Department / Unit		
	Assessment		
Numerator	Load from M& E	M	
	Department / Unit		
	Assessment		
Denominator	Load from M& E	M	
	Department / Unit		
	Assessment		
Achieved	Load from M& E	M	
	Department / Unit		
	Assessment		
Justification	Load from M& E	0	
	Department / Unit		
	Assessment		
Means of Verification	Load from M& E	М	
	Department / Unit		
	Assessment		
Responsibility	Load from M& E	M	
	Department / Unit		
	Assessment		
Action	Dropdown (Verified /	М	The action will be
	Reject)		applicable for the selected
			records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			records. Comment will be
			mandatory once rejected.





	Max. characters is 500.
	maxi characters is see.

#### 2.2.3.3 Department / Unit Assessment Verification by Director

The Director verifies the assessment forwarded by Head of Department / Unit and approve/reject. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Performance indicator	Load from M& E	M	
	Department / Unit		
	Assessment		
Type of Indicator	Load from M& E	M	
	Department / Unit		
	Assessment		
Indicator Formulae	Load from M& E	M	
	Department / Unit		
	Assessment		
Indicator Definition	Load from M& E	M	
	Department / Unit		
	Assessment		
Original Baseline	Load from M& E	M	
	Department / Unit		
	Assessment		
Indicator classification	Load from M& E	M	
	Department / Unit		
	Assessment		
Data Type	Load from M& E	M	
	Department / Unit		
	Assessment		
Unit of measure	Load from M& E	M	
	Department / Unit		
	Assessment		
Frequency of Reporting	Load from M& E	M	
	Department / Unit		
	Assessment		
Annualized Target	Load from M& E	M	
	Department / Unit		
	Assessment		
Numerator	Load from M& E	M	
	Department / Unit		
	Assessment		
Denominator	Load from M& E	M	
	Department / Unit		
	Assessment		





Achieved	Load from M& E Department / Unit Assessment	M	
Justification	Load from M& E Department / Unit Assessment	0	
Means of Verification	Load from M& E Department / Unit Assessment	M	
Responsibility	Load from M& E Department / Unit Assessment	M	
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected. Max. characters is 500.

### 2.2.3.4 Consolidation of Assessment by M&E Officer

The M& E Officer consolidates the assessment verified by Directors of various directorates. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Performance indicator	Load from M& E	М	
	Department / Unit		
	Assessment		
Type of Indicator	Load from M& E	М	
	Department / Unit		
	Assessment		
Indicator Formulae	Load from M& E	М	
	Department / Unit		
	Assessment		
Indicator Definition	Load from M& E	M	
	Department / Unit		
	Assessment		
Original Baseline	Load from M& E	М	
	Department / Unit		
	Assessment		
Indicator classification	Load from M& E	М	
	Department / Unit		





	Assessment		
Data Type	Load from M& E	M	
	Department / Unit		
	Assessment		
Unit of measure	Load from M& E	M	
	Department / Unit		
	Assessment		
Frequency of Reporting	Load from M& E	M	
	Department / Unit		
	Assessment		
Annualized Target	Load from M& E	M	
	Department / Unit		
	Assessment		
Numerator	Load from M& E	M	
	Department / Unit		
	Assessment		
Denominator	Load from M& E	М	
	Department / Unit		
	Assessment		
Achieved	Load from M& E	М	
	Department / Unit		
	Assessment		
Justification	Load from M& E	0	
	Department / Unit		
	Assessment		
Means of Verification	Load from M& E	M	
	Department / Unit		
	Assessment		
Responsibility	Load from M& E	M	
	Department / Unit		
	Assessment		
Action	Dropdown (Verified /	М	The action will be
	Reject)		applicable for the selected
			records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			records. Comment will be
			mandatory once rejected.
			Max. characters is 500.





#### 2.2.3.5 Head of BPD Verification

The Head BPD verifies the assessment forwarded by M&E Officer and approve/reject. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Performance indicator	Load from M& E	M	
	Department / Unit		
	Assessment		
Type of Indicator	Load from M& E	M	
	Department / Unit		
	Assessment		
Indicator Formulae	Load from M& E	M	
	Department / Unit		
	Assessment		
Indicator Definition	Load from M& E	M	
	Department / Unit		
	Assessment		
Original Baseline	Load from M& E	M	
	Department / Unit		
	Assessment		
Indicator classification	Load from M& E	M	
	Department / Unit		
	Assessment		
Data Type	Load from M& E	M	
	Department / Unit		
	Assessment		
Unit of measure	Load from M& E	M	
	Department / Unit		
	Assessment		
Frequency of Reporting	Load from M& E	M	
	Department / Unit		
	Assessment		
Annualized Target	Load from M& E	M	
	Department / Unit		
	Assessment		
Numerator	Load from M& E	M	
	Department / Unit		
_	Assessment		
Denominator	Load from M& E	M	
	Department / Unit		
	Assessment		
Achieved	Load from M& E	M	





	5 /		
	Department / Unit		
	Assessment		
Justification	Load from M& E	0	
	Department / Unit		
	Assessment		
Means of Verification	Load from M& E	M	
	Department / Unit		
	Assessment		
Responsibility	Load from M& E	M	
	Department / Unit		
	Assessment		
Action	Dropdown (Verified /	M	The action will be
	Reject)		applicable for the selected
			records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			records. Comment will be
			mandatory once rejected.
			Max. characters is 500.

### 2.2.3.6 Approval by Director (DCS)

The Director (DCS) verifies the assessment forwarded by BPD. On rejection the assessment will be send back to the M & E Coordinator to update and submit again.

Field	Field Type	M/O	Additional Remarks
Performance indicator	Load from M& E	М	
	Department / Unit		
	Assessment		
Type of Indicator	Load from M& E	М	
	Department / Unit		
	Assessment		
Indicator Formulae	Load from M& E	M	
	Department / Unit		
	Assessment		
Indicator Definition	Load from M& E	М	
	Department / Unit		
	Assessment		
Original Baseline	Load from M& E	M	
	Department / Unit		
	Assessment		
Indicator classification	Load from M& E	М	
	Department / Unit		
	Assessment		





Data Tymo	Lood from NAC E	N A	
Data Type	Load from M& E	M	
	Department / Unit		
	Assessment		
Unit of measure	Load from M& E	M	
	Department / Unit		
	Assessment		
Frequency of Reporting	Load from M& E	М	
	Department / Unit		
	Assessment		
Annualized Target	Load from M& E	М	
	Department / Unit		
	Assessment		
Numerator	Load from M& E	М	
Numerator		IVI	
	Department / Unit		
	Assessment		
Denominator	Load from M& E	M	
	Department / Unit		
	Assessment		
Achieved	Load from M& E	M	
	Department / Unit		
	Assessment		
Justification	Load from M& E	0	
	Department / Unit		
	Assessment		
Means of Verification	Load from M& E	М	
	Department / Unit		
	Assessment		
Responsibility	Load from M& E	М	
	Department / Unit		
	Assessment		
Action		M	The action will be
Action	Dropdown (Verified /	IVI	
	Reject)		applicable for the selected
			records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the selected
			records. Comment will be
			mandatory once rejected.
			Max. characters is 500.





### 2.2.3.7 M & E Reports

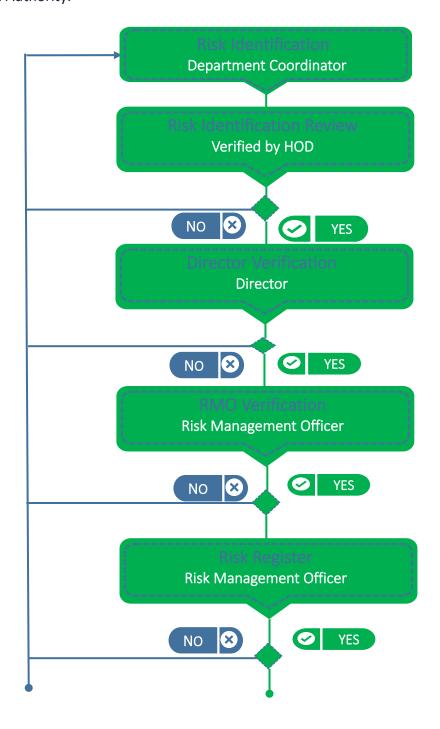
- Activity Framework Quarterly and Annual Report
- SDT Monthly, Quarterly and Annual Report
- M& E Annual Performance Report





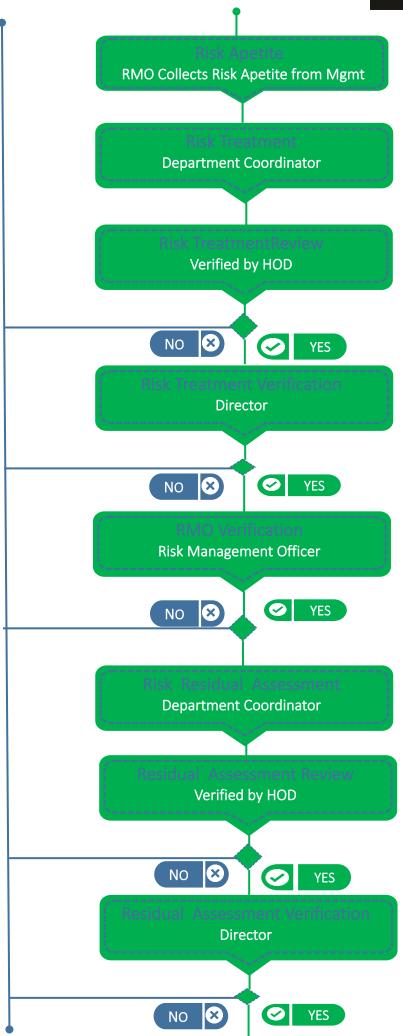
#### 2.3 Risk Management Module

The National Drug Authority just concluded the process of developing its strategic plan 2020/2021-20242025. The successful implementation of the objectives as laid out in the strategic plan will depend of how the authority will be able to identify and manage its risks. There is need to manage risks proactively and adapt, quickly, to the mutation or changing nature of risk in the given environment. NDA adopted Enterprise Risk Management Framework as an appropriate approach to identify, assess, treat, monitor, review and report risks. The ISO 31000 framework has been adopted as a standard for risk Management with in the Authority.



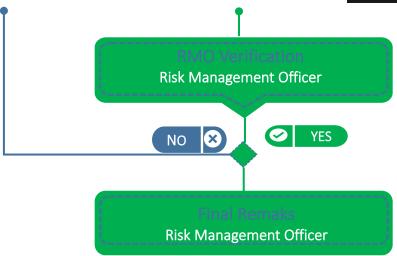












#### 2.3.1 Risk Identification

Risks and opportunities shall be identified at both a strategic and operational level (in all core drug regulatory and support processes). The Risk coordinator will capture the risk identified in their respective department. On submission it will be forwarded to head of department to confirm.

Field	Field Type	M/O	Additional Remarks
Date of Identification	User Entry, Date Field	М	
Focus Area	User Entry, Dropdown	М	List from Strategic Plan
Strategic Objective	User Entry, Dropdown	М	List from Strategic Plan
Activity	User Entry, Dropdown	0	List from Work Plan
Budget Code	User Entry, Text Field	М	
Risk Description	User Entry, Text Field	М	
Event(s)	User Entry, Text Filed	М	
Risk Source(s)	User Entry, Text Filed	М	
Cause of Risk (s)	User Entry, Text Filed	М	
Risk Consequence	User Entry, Text Filed	М	
Risk Owner	System Automatically Record	М	
Risk Analysis			
Risk Consequence	User Entry, Dropdown,	М	
	[Insignificant/Minor/Moderate/Major		
	/ Catastrophic]		
Risk Likelihood	User Entry, Dropdown ,	М	
	[Rare/ Unlikely / Possible / Likely /		
	Almost Certain]		
Risk Score	System generated.	М	System will generate the
			score from quantitative
			risk matrix
Risk Rank	System generated	М	System will select the
			Rank based on risk score
<b>Evaluation Criteria</b>	System generated	M	System will show the
			evaluation criteria based
			on risk rank.





	Qualitative Risk Matrix						
		Risk Consequence					
		Insignificant	Minor	Moderate	Major	Catastrophic	
	Rare	Very low	Very low	Very low	Very low	Low	
po	Unlikely	Very low	Very low	Low	Low	Medium	
Likelihood	Possible	Very low	Low	Medium	Medium	High	
	Likely	Very low	Low	Medium	Very High	Very High	
Risk	Almost Certain	Low	Medium	High	Very High	Very High	

	Quantitative Risk Matrix (5 x 5 Scale)						
		Risk Consequence					
		1	1 2 3 4 5				
	1	1	2	3	4	5	
Risk Likelihood	2	2	4	6	8	10	
ikelil	3	3	6	9	12	15	
Risk I	4	4	8	12	16	20	
	5	5	10	15	20	25	

Score	Risk rank	Evaluation Criteria (Management Control Action (MCA)
1 to 4	Very Low	No mitigation, no action is required, the risk is ALARP. Monitor to ensure that the risk remains tolerable at this level.
5 to 8	Low	Maintain assurance that the risk remains tolerable at this level. Monitor and manage by routine procedures, unlikely to need specific application of resources (managers and key staff).
9 to 12	Medium	Tolerable if the cost of reduction would exceed the improvement gained.  Mitigate through management by specific reviews and monitoring of procedures (Managers) but regular monitoring should occur.





Score	Risk rank	Evaluation Criteria (Management Control Action (MCA)
13 to 15	High	Tolerable only if risk reduction is impractical or if cost is disproportionate to the improvement gained. Mitigate by implementing controls to reduce the risk to as low as is reasonably practicable. Where this cannot happen, continual monitoring should occur.
16 to 25	Very High	Intolerable, the risk cannot be justified, expect in extraordinary circumstances. Mitigate by ceasing all related activities.

#### 2.4 Risk Identification Review

The head of department will review the identified risk captured by risk coordinator and approve/ reject. If approved will be forwarded to director.

Field	Field Type	M/O	Additional Remarks
Date of Identification	Load from Risk Identification	М	
Risk Description	Load from Risk Identification	М	
Event(s)	Load from Risk Identification	М	
Risk Source(s)	Load from Risk Identification	М	
Cause of Risk (s)	Load from Risk Identification	М	
Risk Consequence	Load from Risk Identification	М	
Risk Owner	Load from Risk Identification	М	
Risk Analysis			
Risk Consequence	Load from Risk Identification	M	
Risk Likelihood	Load from Risk Identification	М	
Risk Score	Load from Risk Identification	М	
Risk Rank	Load from Risk Identification	М	
Evaluation Criteria	Load from Risk Identification	M	
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected. Max. characters is 500.





#### 2.4.1 Risk Identification Verification

The director will verify the identified risk forwarded by the head of department. On approval the risk will be forwarded to Risk Management Officer.

Field	Field Type	M/O	Additional Remarks
Date of Identification	Load from Risk Identification	М	
Risk Description	Load from Risk Identification	М	
Event(s)	Load from Risk Identification	М	
Risk Source(s)	Load from Risk Identification	М	
Cause of Risk (s)	Load from Risk Identification	М	
Risk Consequence	Load from Risk Identification	М	
Risk Owner	Load from Risk Identification	М	
Risk Analysis			
Risk Consequence	Load from Risk Identification	M	
Risk Likelihood	Load from Risk Identification	М	
Risk Score	Load from Risk Identification	М	
Risk Rank	Load from Risk Identification	М	
Evaluation Criteria	Load from Risk Identification	М	
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected. Max. characters is 500.

#### 2.4.2 RMO Verification

The Risk Management Officer will verify the identified risk forwarded by the director. Risk Management Officer will present the high risks to peer committee and capture the committee comments in the system. On Approval from officer, the risk will be registered in risk register.





Field	Field Type	M/O	Additional Remarks
Date of Identification	Load from Risk Identification	М	
Risk Description	Load from Risk Identification	М	
Event(s)	Load from Risk Identification	М	
Risk Source(s)	Load from Risk Identification	М	
Cause of Risk (s)	Load from Risk Identification	М	
Risk Consequence	Load from Risk Identification	М	
Risk Owner	Load from Risk Identification	М	
Risk Analysis			
Risk Consequence	Load from Risk Identification	M	
Risk Likelihood	Load from Risk Identification	M	
Risk Score	Load from Risk Identification	М	
Risk Rank	Load from Risk Identification	М	
Evaluation Criteria	Load from Risk Identification	M	
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected. Max. characters is 500.

# 2.4.3 Risk Register

The risks verified by RMO will be added to the risk register.

Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	М	
Risk Reference Code/Number	System Generated	M	
Risk description	Load from Risk Identification	М	
Risk Category	Load from Risk Identification	М	
Risk Driver/Root cause	Load from Risk Identification	М	
Consequence/Impact definition	Load from Risk Identification	M	





Existing Mitigation	Load from Risk Identification	M	
Likeli-hood (L)	Load from Risk Identification	M	
Consequence (C)	Load from Risk Identification	М	
Inherent risk rating	Load from Risk Identification	М	
Activity / Additional mitigation strategies	Load from Risk Treatment	M	
Opportunity	Load from Risk Treatment	М	
Review/Implementation	Load from Risk Treatment	М	
date			
Risk Owner	Load from Risk Identification	М	

### 2.4.4 Risk Tolerance Level / Risk Appetite

The Risk Tolerance Level will be set by the department risk coordinator and risk appetite will be set by RMO after receiving advice from management. The department level tolerance should be reviewed by Head of Department / Unit and Director.

Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	М	
Risk Reference Code/Number	System Generated	M	
Risk description	Load from Risk Identification	М	
Risk Category	Load from Risk Identification	М	
Risk Driver/Root cause	Load from Risk Identification	М	
Consequence/Impact definition	Load from Risk Identification	M	
Existing Mitigation	Load from Risk Identification	M	
Likeli-hood (L)	Load from Risk Identification	M	
Consequence (C)	Load from Risk Identification	М	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level	User Entry, Dropdown	М	By Management
Risk Appetite	User Entry, Dropdown	М	By Board
Justification	User Entry, Text Field	M	





#### 2.4.5 Risk Treatment

Risk treatment involves identifying the options for treating each risk, evaluating those options, assigning accountability for the medium, high and very high risks and taking relevant action. For each risk, the Risk Owner must establish an appropriate level of treatment. Control measures in addition to those already existing may be needed to achieve this level of mitigation. Any risk above tolerance level 8 should be treated.

Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	М	
Risk Reference	System Generated	М	
Code/Number			
Risk description	Load from Risk Identification	M	
Risk Category	Load from Risk Identification	M	
Risk Driver/Root cause	Load from Risk Identification	M	
Consequence/Impact definition	Load from Risk Identification	M	
Existing Mitigation	Load from Risk Identification	M	
Likeli-hood (L)	Load from Risk Identification	M	
Consequence (C)	Load from Risk Identification	М	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level	Load from Risk Tolerance	М	
Risk Appetite	Load from Risk Tolerance		
Additional Mitigation Measure /Activities	User Entry. Text Field	M	
By when (expected date/period of implementation)	User Entry. Text Field	M	
Resources Required for effective risk management	User Entry. Text Field	M	

#### 2.4.6 Risk Treatment Review by Head of Department / Unit

The head of department reviews the treatment details captured by Risk Coordinator. Forwards the details to director for verification.





Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	M	
Strategic Objective	Load from Risk Identification	М	
Risk Reference	System Generated	М	
Code/Number	1 16 5:111 ::5: ::		
Risk description	Load from Risk Identification	M	
Risk Category	Load from Risk Identification	M	
Risk Driver/Root cause	Load from Risk Identification	M	
Consequence/Impact definition	Load from Risk Identification	M	
Existing Mitigation	Load from Risk Identification	M	
Likeli-hood (L)	Load from Risk Identification	М	
Consequence (C)	Load from Risk Identification	M	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	М	
Additional Mitigation Measure / Activities	Load from Risk Treatment	М	
By when (expected date/period of implementation)	Load from Risk Treatment	M	
Resources Required for effective risk management	Load from Risk Treatment	М	
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected. Max. characters is 500.

### 2.4.7 Risk Treatment Verification by Director

The director verifies the treatment details forwarded by head of department. Forwards the details to RMO for verification.





Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	М	
Risk Reference Code/Number	System Generated	M	
Risk description	Load from Risk Identification	М	
Risk Category	Load from Risk Identification	М	
Risk Driver/Root cause	Load from Risk Identification	М	
Consequence/Impact definition	Load from Risk Identification	M	
Existing Mitigation	Load from Risk Identification	M	
Likeli-hood (L)	Load from Risk Identification	M	
Consequence (C)	Load from Risk Identification	М	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	M	
Additional Mitigation Measure /Activities	Load from Risk Treatment	M	
By when (expected date/period of implementation)	Load from Risk Treatment	M	
Resources Required for effective risk management	Load from Risk Treatment	M	
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected. Max. characters is 500.

### 2.4.8 Risk Treatment Verification by RMO

The RMO verifies the treatment details forwarded by director. For any corrections it can be send back to the coordinator.

Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	M	
Strategic Objective	Load from Risk Identification	M	





Risk Reference Code/Number	System Generated	М	
Risk description	Load from Risk Identification	М	
Risk Category	Load from Risk Identification	М	
Risk Driver/Root cause	Load from Risk Identification	М	
Consequence/Impact definition	Load from Risk Identification	M	
Existing Mitigation	Load from Risk Identification	M	
Likeli-hood (L)	Load from Risk Identification	M	
Consequence (C)	Load from Risk Identification	М	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	M	
Additional Mitigation Measure /Activities	Load from Risk Treatment	M	
By when (expected date/period of implementation)	Load from Risk Treatment	M	
Resources Required for effective risk management	Load from Risk Treatment	М	
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected. Max. characters is 500.

### 2.4.9 Risk Monitoring and Review

The Risk Coordinator captures the monitoring details of risk treatment action plans. It will be submitted to HOD for review.

Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	М	
Risk Reference	System Generated	М	
Code/Number			
Risk description	Load from Risk Identification	М	
Risk Category	Load from Risk Identification	М	
Risk Driver/Root cause	Load from Risk Identification	М	





Consequence/Impact definition	Load from Risk Identification	M	
Existing Mitigation	Load from Risk Identification	M	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	M	
Additional Mitigation Measure /Activities	Load from Risk Treatment	M	
By when (expected date/period of implementation)	Load from Risk Treatment	M	
Resources Required for effective risk management	Load from Risk Treatment	M	
Action Plan			
Action undertaken to mitigate risk	User Entry, Text Field	M	
Date (Actual date/period of implementation)	User Entry, Text Field	M	
By Whom	User Entry, Text Field	М	

# 2.4.10 Risk Monitoring and Review by Head of Department / Unit

The HOD verifies the monitoring details of risk treatment action plans. It will be submitted to Director.

Field	Field Type	M/O	Additional Remarks
Focus Area	Load from Risk Identification	M	
Strategic Objective	Load from Risk Identification	М	
Risk Reference Code/Number	System Generated	M	
Risk description	Load from Risk Identification	М	
Risk Category	Load from Risk Identification	М	
Risk Driver/Root cause	Load from Risk Identification	М	
Consequence/Impact definition	Load from Risk Identification	M	
Existing Mitigation	Load from Risk Identification	M	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	M	
Additional Mitigation Measure /Activities	Load from Risk Treatment	M	
By when (expected date/period of implementation)	Load from Risk Treatment	M	
Resources Required for effective risk management	Load from Risk Treatment	M	





Action Plan			
Action undertaken to mitigate risk	User Entry, Text Field	М	
Date (Actual date/period of implementation)	User Entry, Text Field	M	
By Whom	User Entry, Text Field	М	
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected. Max. characters is 500.

### 2.4.11 Risk Monitoring and Review by Director

The Director verifies the monitoring details of risk treatment action plans. It will be submitted to RMO.

Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	М	
Risk Reference Code/Number	System Generated	M	
Risk description	Load from Risk Identification	M	
Risk Category	Load from Risk Identification	M	
Risk Driver/Root cause	Load from Risk Identification	М	
Consequence/Impact definition	Load from Risk Identification	M	
Existing Mitigation	Load from Risk Identification	M	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	M	
Additional Mitigation Measure /Activities	Load from Risk Treatment	M	
By when (expected date/period of implementation)	Load from Risk Treatment	M	
Resources Required for effective risk management	Load from Risk Treatment	M	
Action Plan			
Action undertaken to mitigate risk	User Entry, Text Field	M	
Date (Actual date/period of implementation)	User Entry, Text Field	M	





By Whom	User Entry, Text Field	М	
Action	Dropdown (Verified / Reject)	М	The action will be
			applicable for the
			selected records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the
			selected records.
			Comment will be
			mandatory once
			rejected. Max.
			characters is 500.

### 2.4.12 Risk Monitoring and Review by RMO

The RMO verifies the monitoring details of risk treatment action plans. It will be submitted to peer committee for review and RMO will capture the comments in the system.

Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	М	
Risk Reference Code/Number	System Generated	M	
Risk description	Load from Risk Identification	М	
Risk Category	Load from Risk Identification	М	
Risk Driver/Root cause	Load from Risk Identification	М	
Consequence/Impact definition	Load from Risk Identification	M	
Existing Mitigation	Load from Risk Identification	M	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	M	
Additional Mitigation Measure /Activities	Load from Risk Treatment	M	
By when (expected date/period of implementation)	Load from Risk Treatment	M	
Resources Required for effective risk management	Load from Risk Treatment	M	
Action Plan			
Action undertaken to mitigate risk	User Entry, Text Field	M	
Date (Actual date/period of implementation)	User Entry, Text Field	M	





By Whom	User Entry, Text Field	М	
Review of effectiveness of actions taken	User Entry, Text Field	M	
Reviewed By	User Entry, Text Field	М	

#### 2.4.13 Residual Assessment

The Risk Coordinator will conduct the residual assessment to evaluate the risk after treatment.

Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	M	
Risk Reference Code/Number	System Generated	M	
Risk description	Load from Risk Identification	M	
Risk Category	Load from Risk Identification	М	
Risk Driver/Root cause	Load from Risk Identification	М	
Consequence/Impact definition	Load from Risk Identification	М	
Existing Mitigation	Load from Risk Identification	M	
Inherent risk rating	Load from Risk Identification	M	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	M	
Additional Action	Load from Risk Treatment	M	
Opportunity	Load from Risk Treatment	М	
Treatment	Load from Risk Treatment	M	
Justification	Load from Risk Treatment	М	
Residual Likelihood	User Entry, Dropdown	M	
Residual Consequences	User Entry, Dropdown	М	
Residual Score	System Generate the Score	M	

### 2.4.14 Residual Assessment Review by HOD

The head of department reviews the assessment details captured by Risk Coordinator. Forwards the details to director for verification.





Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	M	
Strategic Objective	Load from Risk Identification	M	
Risk Reference Code/Number	System Generated	M	
Risk description	Load from Risk Identification	M	
Risk Category	Load from Risk Identification	М	
Risk Driver/Root cause	Load from Risk Identification	M	
Consequence/Impact definition	Load from Risk Identification	М	
Existing Mitigation	Load from Risk Identification	M	
Inherent risk rating	Load from Risk Identification	M	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	М	
Additional Action	Load from Risk Treatment	M	
Opportunity	Load from Risk Treatment	M	
Treatment	Load from Risk Treatment	M	
Justification	Load from Risk Treatment	M	
Residual Likelihood	Load from residual assessment	М	
Residual Consequences	Load from residual assessment	M	
Residual Score	Load from residual assessment	М	
Action	Dropdown (Verified / Reject)	M	The action will be applicable for the selected records.
Comment	User Entry. Text Field	0	The comment will be applicable for the selected records. Comment will be mandatory once rejected. Max. characters is 500.

### 2.4.15 Residual Assessment Verification by Director

The director verifies the assessment details forwarded by head of department. Forwards the details to RMO for verification.





Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	М	
Risk Reference	System Generated	M	
Code/Number Risk description	Load from Risk Identification	M	
Risk Category	Load from Risk Identification	M	
Risk Driver/Root cause	Load from Risk Identification	M	
Consequence/Impact	Load from Risk Identification	M	
definition	Load Holli Risk identification	IVI	
Existing Mitigation	Load from Risk Identification	M	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	M	
Additional Action	Load from Risk Treatment	М	
Opportunity	Load from Risk Treatment	М	
Treatment	Load from Risk Treatment	М	
Justification	Load from Risk Treatment	М	
Residual Likelihood	Load from residual assessment	М	
Residual Consequences	Load from residual assessment	М	
Residual Score	Load from residual assessment	М	
Action	Dropdown (Verified / Reject)	М	The action will be
			applicable for the
			selected records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the
			selected records.
			Comment will be
			mandatory once
			rejected. Max.
			characters is 500.

### 2.4.16 Residual Assessment Verification by RMO

The RMO verifies the assessment details forwarded by director. For any corrections it can be send back to the coordinator.





Field	Field Type		Additional Remarks
		M/O	
Focus Area	Load from Risk Identification	М	
Strategic Objective	Load from Risk Identification	М	
Risk Reference	System Generated	M	
Code/Number Risk description	Load from Risk Identification	M	
Risk Category	Load from Risk Identification	M	
Risk Driver/Root cause	Load from Risk Identification	M	
Consequence/Impact	Load from Risk Identification	M	
definition	Load Holli Risk identification	IVI	
Existing Mitigation	Load from Risk Identification	М	
Inherent risk rating	Load from Risk Identification	М	
Tolerance Level /Risk Appetite	Load from Risk Tolerance/Appetite	M	
Additional Action	Load from Risk Treatment	М	
Opportunity	Load from Risk Treatment	М	
Treatment	Load from Risk Treatment	М	
Justification	Load from Risk Treatment	М	
Residual Likelihood	Load from residual assessment	М	
Residual Consequences	Load from residual assessment	М	
Residual Score	Load from residual assessment	М	
Action	Dropdown (Verified / Reject)	М	The action will be
			applicable for the
			selected records.
Comment	User Entry. Text Field	0	The comment will be
			applicable for the
			selected records.
			Comment will be
			mandatory once
			rejected. Max.
			characters is 500.

#### 2.4.17 Final Remarks by RMO

The risk remain high after residual assessment will be forwarded to management outside system by RMO. The management decision and final remarks will be captured in the system by RMO. Management decision status (Implemented / Partially Implemented / Not Implemented) should be updated at a later stage by RMO.





#### 2.4.18 Risk Register Updating

The Risk Register carryforwards from the previous year. The register carries forward risk with Risk Ref. Code /Number, Risk description and Risk Category. The residual assessment of the previous year becomes the current year inherent rating.

#### **2.4.19 Reports**

- Risk Register
- Risk Treatment Report
- Risk Monitoring Reports





### 2.5 GIS Module

The GIS module will have on-spot data capturing facility. The data will be captured by the regional officers and shared with the central database accessed by the directorate.

# 2.5.1 Inspections/support supervisions/enforcement activity

#### 2.5.1.1 Pre-inspection [New Drug Shop]

Regional Officers can capture the details of activity as specified below.

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Applicant	User Entry, Text Field	М	
Name of Business	User Entry, Text Field	М	
<b>Physical Location of Prem</b>	ises of the Business		
Road/Street	User Entry, Text Field	М	
Zone	User Entry, Text Field	М	
Village	User Entry, Text Field	М	
Country	User Entry, Text Field	М	
District	User Entry, Dropdown	М	
Tel. No.	User Entry, Text Field	М	
Email	User Entry, Text Field	М	
<b>GPS Location</b>	System get current location	М	
Product Classification	User Entry, Dropdown	М	Others, please specify
	[Human/Vet/Other]		
Particulars of nearest pha	rmacy to the proposed premise	es.	
Name	User Entry, Text Field	М	
Road/Street	User Entry, Text Field	М	
Distance from the	System Generated	М	GPS Location will be added by the
proposed drug shop premises (km)			system
	shop to the proposed premise	es	
Name	User Entry, Text Field	М	
Road/Street	User Entry, Text Field	M	
Distance from the	System Generated	M	GPS Location will be added by the
proposed drug shop	.,		system
premises (km)			,
Name of Inspector	User Entry, Text Field	M	[A
Approval by Head Regions/Regional	User Entry, Dropdown	M	[Approved/Not Approved]
Manager			
Comments	User Entry, Text Field	0	





Approval by Director	User Entry, Dropdown	M	[Approved/Not Approved]
Comments	User Entry, Text Field	0	

# 2.5.1.2 Pre-inspection [New Pharmacy]

Regional Officers can capture the details of activity as specified below.

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Applicant	User Entry, Text Field	M	
Name of Business	User Entry, Text Field	М	
<b>Physical Location of Prem</b>	ises of the Business		
Road/Street	User Entry, Text Field	М	
Zone	User Entry, Text Field	M	
Village	User Entry, Text Field	М	
Country	User Entry, Text Field	М	
District	User Entry, Dropdown	М	
Tel. No.	User Entry, Text Field	М	
Email	User Entry, Text Field	М	
<b>GPS Location</b>	System get current location	М	
Category of Premises	User Entry, Dropdown	М	
	[Retail/Wholesale/Medical		
	Device/Annex Store]		
<b>Product Classification</b>	User Entry, Dropdown	M	Others, please specify
	[Human/Vet/Other]		
Particulars of nearest pha	armacy to the proposed premise	s [prov	ision to add more]
Name	User Entry, Text Field	М	
Road/Street	User Entry, Text Field	М	
Distance from the	System Generated	M	GPS Location will be added by the
proposed pharmacy premises (km)			system
Name of Inspector	User Entry, Text Field	M	
Inspector's	User Entry, Text Field	M	
Recommendation	oser zirery, rexerrera		
Approval by Head	User Entry, Dropdown	M	[Approved/Not Approved]
Regions/Regional Manager			
Comments	User Entry, Text Field	0	
Approval by Director	User Entry, Dropdown	M	[Approved/Not Approved]
Comments	User Entry, Text Field	0	C 11 - 21, 21 (PP-2123)
	1/ - 10		

### 2.5.1.3 Pre-inspection [New Manufacturing Unit]

Regional Officers can capture the details of activity as specified below.





Field	Field Type		Additional Remarks	
		M/O		
Inspection Date	User Entry, Date Field	М		
Inspection Time	User Entry, Time Field	М		
Name of Applicant	User Entry, Text Field	М		
Name of Business	User Entry, Text Field	М		
Physical Location of Premises of the Business				
Road/Street	User Entry, Text Field	М		
Zone	User Entry, Text Field	М		
Village	User Entry, Text Field	М		
Country	User Entry, Text Field	М		
District	User Entry, Dropdown	М		
Tel. No.	User Entry, Text Field	М		
Email	User Entry, Text Field	М		
GPS Location	System get current location	М		
Category of Premises	User Entry, Dropdown [FPP	М		
	API			
	Herbal			
	Surgical Instruments]			
Product Classification	User Entry, Dropdown	М	Others, please specify	
	[Human/Vet/Other]			
Recommendation	User Entry, Text Field	М		
Name of Inspector	User Entry, Text Field	М		

# 2.5.1.4 Relocation [New Pharmacy]

Regional Officers can capture the details of activity as specified below.

Field	Field Type		Additional Remarks	
		M/O		
Inspection Date	User Entry, Date Field	М		
Inspection Time	User Entry, Time Field	М		
Name of Applicant	User Entry, Text Field	М		
Name of Business	User Entry, Text Field	М		
Current Physical Location of Premises of the Business				
Road/Street	User Entry, Text Field	М		
Zone	User Entry, Text Field	М		
Village	User Entry, Text Field	М		
Country	User Entry, Text Field	М		
District	User Entry, Dropdown	М		
Tel. No.	User Entry, Text Field	М		
Email	User Entry, Text Field	М		
GPS Location	System get current location	М		
Proposed new location of premises of the business				





are error			
Road/Street	User Entry, Text Field	М	
Zone	User Entry, Text Field	М	
Village	User Entry, Text Field	М	
Country	User Entry, Text Field	М	
District	User Entry, Dropdown	М	
Tel. No.	User Entry, Text Field	М	
Email	User Entry, Text Field	М	
<b>GPS Location</b>	System get current location	М	
Category of Premises	User Entry, Dropdown	М	
	[Retail/Wholesale/Medical		
	Device/Annex Store]		
Product Classification	User Entry, Dropdown	М	Others, please specify
	[Human/Vet/Other]		
Particulars of nearest pha	rmacy to the proposed premise	s [prov	ision to add mre]
Name	User Entry, Text Field	М	
Road/Street	User Entry, Text Field	М	
Distance from the	System Generated	М	GPS Location will be added by the
proposed pharmacy premises (km)			system
Name of Inspector	User Entry, Text Field	М	
Inspector's	User Entry, Text Field	М	
Recommendation			
Approval by Head	User Entry, Dropdown	M	[Approved/Not Approved]
Regions/Regional Manager			
Comments	User Entry, Text Field	0	
Approval by Director	User Entry, Dropdown	М	[Approved/Not Approved]
Comments	User Entry, Text Field	0	

### 2.5.1.5 Relocation [Drug Shop]

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Applicant	User Entry, Text Field	М	
Name of Business	User Entry, Text Field	М	
<b>Current Physical Location</b>	of Premises of the Business		
Road/Street	User Entry, Text Field	М	
Zone	User Entry, Text Field	М	
Village	User Entry, Text Field	М	
Country	User Entry, Text Field	М	
District	User Entry, Dropdown	М	
Tel. No.	User Entry, Text Field	М	





Email	User Entry, Text Field	М	
<b>GPS Location</b>	System get current location	М	
Proposed new location of	premises of the business		
Road/Street	User Entry, Text Field	М	
Zone	User Entry, Text Field	М	
Village	User Entry, Text Field	М	
Country	User Entry, Text Field	М	
District	User Entry, Dropdown	М	
Tel. No.	User Entry, Text Field	М	
Email	User Entry, Text Field	М	
GPS Location	System get current location	М	
Product Classification	User Entry, Dropdown	М	Others, please specify
	[Human/Vet/Other]		
Particulars of nearest pha	rmacy to the proposed premise	S	
Name	User Entry, Text Field	М	
Road/Street	User Entry, Text Field	М	
Distance from the	System Generated	М	GPS Location will be added by the
proposed drug shop premises (km)			system
	g shop to the proposed premise	S	
Name	User Entry, Text Field	М	
Road/Street	User Entry, Text Field	М	
Distance from the	System Generated	М	GPS Location will be added by the
proposed drug shop	,		system
premises (km)	Llean Fotos, Taut Field	D 4	•
Name of Inspector	User Entry, Text Field	M	
Inspector's Recommendation	User Entry, Text Field	M	
Approval by Head	User Entry, Dropdown	М	[Approved/Not Approved]
Regions/Regional			
Manager Comments	Hear Entry Toyt Field	0	
Approval by Director	User Entry, Text Field		[Approved/Not Approved]
Comments	User Entry, Dropdown	M	[Approved/Not Approved]
Comments	User Entry, Text Field	0	

### 2.5.1.6 Compliance Support Supervision

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Inspector	System loads from login details	M	
<b>GPS Location</b>	System get current location	М	





ave Lives			
Region	User Entry, Dropdown	M	Regions will load from Region Master
District	User Entry, Dropdown	M	District will load from District
			Master
Facility Details	·	1	
Name of Facility	User Entry, Text Field	M	
Facility Status	User Entry, Dropdown	M	[Open/ Closed].
			If closed no other data will be
			collected.
Person found at facility	User Entry, Dropdown	M	[In-charge / (Attendant/Operator)]
Name	User Entry, Text Field	M	
Contact	User Entry, Text Field	M	
Qualifications	User Entry, Text Field	M	
Category of Facility	User Entry, Dropdown	M	[ Wholesale Pharmacy
			Retail Pharmacy
			Drug Shop
			External stores
			Hospital
			HCIV
			HCIII
			Clinic
			Herbal selling outlet
			Shift Market
			Pharmaceutical/Medical Device
			Manufacturing premise
Lineare d / United and		D.4	Others]
Licensed/Unlicensed	User Entry, Dropdown	M	[Licensed / Un-Licensed / Not-
			Applicable (for outlets not licensed
			by NDA)  If licensed collect license number.
			If unlicensed, indicate was
			previously licensed / illegal
Category of Drugs	User Entry, Dropdown	M	[Medical Device
Satebory of Drugs	osci Entry, Diopuowii	141	Veterinary drugs
			Human drugs
			Public Healthcare products
			Herbal drugs]
Compliance Support Supe	ervision Details		7101201 01060]
Condition of Premises	User Entry, Dropdown	M	Poor
			Fair
			Good
			Excellent
Record Keeping	User Entry, Dropdown	M	Poor





			Fair Good
			Excellent
Class of Drugs	User Entry, Dropdown	M	A/B/C
Unregistered Drugs	User Entry, Dropdown	М	Present/Not Present
Actions	User Entry, Dropdown	M	Closed Outlet abandoned by owner Impounded Suspect arrested No action taken

#### 2.5.1.7 Renewal

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Inspector	System loads from login	М	
	details		
GPS Location	System get current location	М	
Region	User Entry, Dropdown	М	Regions will load from Region
			Master
District	User Entry, Dropdown	М	District will load from District
			Master
Facility Details			
Name of Facility	User Entry, Text Field	М	
Facility Status	User Entry, Dropdown	М	[Open/ Closed].
			If closed no other data will be
			collected.
Person found at facility	User Entry, Dropdown	М	[In-charge / (Attendant/Operator)]
Name	User Entry, Text Field	М	
Contact	User Entry, Text Field	М	
Qualifications	User Entry, Text Field	М	
Category of Facility	User Entry, Dropdown	М	[ Wholesale Pharmacy
			Retail Pharmacy
			Drug Shop
			External stores
			Surgical Instruments Outlets]
Licensed/Unlicensed	User Entry, Dropdown	М	[Licensed / Un-Licensed / Not-
			Applicable (for outlets not licensed
			by NDA)
			If licensed collect license number.





			If unlicensed, indicate was
			previously licensed / illegal
Category of Drugs	User Entry, Dropdown	М	[Medical Device
			Veterinary drugs
			Human drugs
			Public Healthcare products
			Herbal drugs
			Surgical Instruments]
Licensing Details			
Condition of Premises	User Entry, Dropdown	М	Poor
			Fair
			Good
			Excellent
Record Keeping	User Entry, Dropdown	М	Poor
			Fair
			Good
			Excellent
Recommendation for	User Entry	М	For Licensing / Not Recommended
Licensing			for Licensing

#### 2.5.1.8 Enforcement

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Inspector	System loads from login	М	
	details		
<b>GPS Location</b>	System get current location	М	
Region	User Entry, Dropdown	М	Regions will load from Region
			Master
District	User Entry, Dropdown	M	District will load from District
			Master
Facility Details			
Name of Facility	User Entry, Text Field	М	
Facility Status	User Entry, Dropdown	М	[Open/ Closed].
			If closed no other data will be
			collected.
Person found at facility	User Entry, Dropdown	М	[In-charge / (Attendant/Operator)]
Name	User Entry, Text Field	М	
Contact	User Entry, Text Field	М	
Qualifications	User Entry, Text Field	М	





Category of Facility	User Entry, Dropdown	M	[ Wholesale Pharmacy Retail Pharmacy Drug Shop External stores Hospital HCIV HCIII Clinic Herbal selling outlet Shift Market Operator Pharmaceutical/Medical Device Manufacturing premise Others[Specify Others]]
Licensed/Unlicensed	User Entry, Dropdown	M	[Licensed / Un-Licensed / Not- Applicable (for outlets not licensed by NDA) If licensed collect license number. If unlicensed, indicate was previously licensed / illegal
Category of Drugs	User Entry, Dropdown	M	[Medical Device Veterinary drugs Human drugs Public Healthcare products Herbal drugs]
Enforcement Action Taken	User Entry, Dropdown [Select many]	M	Impound Arrest Close Initiated Court Case No action taken Caution Warning Letter
Comments	User Entry, Text Field	0	

### 2.5.1.9 GPP(Good Pharmaceutical Practice)

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Inspector	System loads from login	М	
	details		
<b>GPS Location</b>	System get current location	М	
Region	User Entry, Dropdown	М	Regions will load from Region





			Master
District	User Entry, Dropdown	М	District will load from District
			Master
Facility Details		1	
Name of Facility	User Entry, Text Field	M	
Facility Status	User Entry, Dropdown	М	[Open/ Closed].
			If closed no other data will be
			collected.
Person found at facility	User Entry, Dropdown	М	[In-charge / (Attendant/Operator)]
Name	User Entry, Text Field	М	
Contact	User Entry, Text Field	M	
Qualifications	User Entry, Text Field	М	
Category of Facility	User Entry, Dropdown	М	[ Retail Pharmacy
			Drug Shop
			Hospital
			HCIV
			HCIII
			Clinic
			]
Licensed/Unlicensed	User Entry, Dropdown	М	[Licensed / Un-Licensed / Not-
			Applicable (for outlets not licensed
			by NDA)
			If licensed collect license number.
			If unlicensed, indicate was
			previously licensed / illegal
Category of Drugs	User Entry, Dropdown	М	[Medical Device
			Veterinary drugs
			Human drugs
			Public Healthcare products
			Herbal drugs]
GPP Details			
Facility Type	User Entry, Dropdown	М	Public Facility
			Private Facility
Certification Status	User Entry, Dropdown	М	Certified
			Not certified
Recommended for GPP	User Entry, Dropdown	М	GPP Certification
			Not recommended for GPP
			Certification

#### 2.5.1.10 GDP(Good Distribution Practice)





Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	M	
Name of Inspector	System loads from login	M	
	details		
<b>GPS Location</b>	System get current location	М	
Region	User Entry, Dropdown	M	Regions will load from Region
			Master
District	User Entry, Dropdown	M	District will load from District
			Master
Facility Details			
Name of Facility	User Entry, Text Field	M	
Facility Status	User Entry, Dropdown	M	[Open/ Closed].
			If closed no other data will be
			collected.
Person found at facility	User Entry, Dropdown	M	[In-charge / (Attendant/Operator)]
Name	User Entry, Text Field	M	
Contact	User Entry, Text Field	M	
Qualifications	User Entry, Text Field	M	
Category of Facility	User Entry, Dropdown	M	[ Wholesale Pharmacy
			Retail Pharmacy
			Drug Shop
			External stores
			Hospital
			HCIV
			HCIII
			]
Licensed/Unlicensed	User Entry, Dropdown	M	[Licensed / Un-Licensed / Not-
			Applicable (for outlets not licensed
			by NDA)
			If licensed collect license number.
			If unlicensed, indicate was
			previously licensed / illegal
Category of Drugs	User Entry, Dropdown	М	[Medical Device
			Veterinary drugs
			Human drugs
			Public Healthcare products
			Herbal drugs]
GDP Details			
Facility Type	User Entry, Dropdown	M	Public Facility
			Private Facility
		_	·





Certification Status	User Entry, Dropdown	M	Certified Not certified
Recommended for GDP	User Entry, Dropdown	М	GDP Certification
			Not recommended for GDP
			Certification

### 2.5.1.11 Herbal Inspections

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	M	
Inspection Time	User Entry, Time Field	M	
Name of Inspector	System loads from login	M	
GPS Location	details	D 4	
Region	System get current location	M	Pagions will load from Pagion
Region	User Entry, Dropdown	M	Regions will load from Region Master
District	User Entry, Dropdown	M	District will load from District
			Master
Facility Details			
Name of Facility	User Entry, Text Field	M	
Facility Status	User Entry, Dropdown	M	[Open/ Closed].
			If closed no other data will be
			collected.
Person found at facility	User Entry, Dropdown	M	[In-charge / (Attendant/Operator)]
Name	User Entry, Text Field	M	
Contact	User Entry, Text Field	M	
Qualifications	User Entry, Text Field	M	
Category of Facility	User Entry, Dropdown	M	[ Herbal Selling Outlet
			Herbal Manufacturing Unit
			1
Licensed/Unlicensed	User Entry, Dropdown	M	[Licensed / Un-Licensed / Not-
			Applicable (for outlets not licensed
			by NDA)
			If licensed collect license number.
			If unlicensed, indicate was
			previously licensed / illegal
Activity Carried Out	Table, Tick the options	M	[Cultivation of medicinal plant
			materials
			Collection and storage of medicinal
			plant material
			Manufacture of API





			Manufacture of herbal medicine
			Packaging
			Importing
			Laboratory testing
			Herbal Selling to the community
			Other
Recommendation			
Recommended for Herbal	User Entry, Dropdown	М	Herbal Certification Recommended
Certification			Not recommended for Herbal
			Certification
			Pending CAPA
Comment		0	

#### 2.5.1.12 Post Market Surveillance Activity

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Inspector	System loads from login details	М	
<b>GPS Location</b>	System get current location	М	
Region	User Entry, Dropdown	М	Regions will load from Region Master
District	User Entry, Dropdown	М	District will load from District Master
Facility Details			
Name of Facility	User Entry, Text Field	М	
Facility Status	User Entry, Dropdown	M	[Open/ Closed].  If closed no other data will be collected.
Person found at facility	User Entry, Dropdown	М	[In-charge / (Attendant/Operator)]
Name	User Entry, Text Field	М	
Contact	User Entry, Text Field	М	
Qualifications	User Entry, Text Field	М	
Category of Facility	User Entry, Dropdown	M	[ Wholesale Pharmacy Retail Pharmacy Drug Shop External stores Hospital





iave Lives			
			HCIV HCIII Clinic Herbal selling outlet Shift Market Pharmaceutical/Medical Device Manufacturing premise Others]
Licensed/Unlicensed	User Entry, Dropdown	M	[Licensed / Un-Licensed / Not- Applicable (for outlets not licensed by NDA) If licensed collect license number. If unlicensed, indicate was previously licensed / illegal
PMS Activity Carries Out	User Entry, Dropdown	M	Sampling Follow-up on recall Complaint investigation Others (Specify) None
Category of Drugs	User Entry, Dropdown	M	[Medical Device Veterinary drugs Human drugs Public Healthcare products Herbal drugs]
Sampling			
Category of Product Samples	User Entry, Dropdown	M	Medical Device Veterinary drugs Human drugs Public Healthcare products Herbal drugs
Name of Product Sampled	User Entry, Text Field	M	
Number of Samples Collected	User Entry, Number Field	M	
Batch Number of Samples Collected	User Entry, Text Field	M	
Follow up on recall			
Product being followed up	User Entry, Text Field	M	
Comment on over all follow up	User Entry, Text Field	M	
Complaint investigation			
Product complaint investigated	User Entry, Text Field	M	
Others			
Specify Activity	User Entry, Text Field	M	





### 2.5.2 Radio Talk Shows

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Inspector	System loads from login	М	
	details		
<b>GPS Location</b>	System get current location	М	
Region	User Entry, Dropdown	М	Regions will load from Region
			Master
District	User Entry, Dropdown	М	District will load from District
			Master
Name of Radio Company	User Entry, Text Field	М	
Topic of Discussion	User Entry, Dropdown	М	

# 2.5.3 Sensitization Meetings

Field	Field Type		Additional Remarks
		M/O	
Inspection Date	User Entry, Date Field	М	
Inspection Time	User Entry, Time Field	М	
Name of Inspector	System loads from login	М	
	details		
<b>GPS Location</b>	System get current location	М	
Region	User Entry, Dropdown	М	Regions will load from Region
			Master
District	User Entry, Dropdown	М	District will load from District
			Master
Venue/Location	User Entry, Text Field	М	
Topic of Discussion	User Entry, Dropdown	М	
Number of Participants	User Entry, Numeric Field	М	

# 2.5.4 Reports

- Report on each activity
- Map Report on each activity based on GIS coordinates





# 2.6 Project Management Module

#### 2.6.1 Project Initiation

The M& E officer can create a project and assign a project manager at the stage of initiation.

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	User Entry, Text Field	М	
Туре	User Entry, Dropdown	М	[Construction/ Service / Work
			Programs]
Project Section	User Entry, Text Field	М	
Program	User Entry, Dropdown	М	
Sub Program	User Entry, Dropdown	М	
Department / Unit	User Entry, Dropdown	М	Select from department master.
Directorate	System load from	М	
	Department / Unit Master		
Description	User Entry, Text Field	М	
Project Manager	User Entry, Dropdown	М	Select from User Master
Project Start Date	User Entry, Date Filed	М	
Project End Date	User Entry, Date Field	М	
Duration (Days)	System Generated	М	It will only consider the working
			days
Project Members	User Entry, Text Field	М	
Budget Code	User Entry, Text Field	М	
Total Budgeted Cost	User Entry, Numeric Field	М	

#### 2.6.2 Project Plan

The Project Manager can create a project plan including activities, resources, risk, and cost based.

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	Load from Project Initiation	М	
Туре	Load from Project Initiation	М	
Program	Load from Project Initiation	М	
Sub Program	Load from Project Initiation	М	
Department / Unit	Load from Project Initiation	М	Select from department master.
Directorate	Load from Project Initiation	М	
Description	Load from Project Initiation	М	
Project Manager	Load from Project Initiation	М	Select from User Master
Project Start Date	Load from Project Initiation	М	
Project End Date	Load from Project Initiation	М	
Duration (Days)	Load from Project Initiation	М	





Project Members	Load from Project Initiation	М	
Budget Code	Load from Project Initiation	М	
Total Budgeted Cost	Load from Project Initiation	М	
Project Plan Date	User Entry, Date Field	М	
Activity Plan			
Activity	User Entry, Text Field	М	
Start Date	User Entry, Date Field	М	
End Date	User Entry, Date Field	М	
Days	System Find No. Days based	М	
	on start date and end date		
Responsible Person	User Entry, Text Field	М	
Cost	User Entry, Numeric Field	М	
Resources Required			
Risks Identified			
Risk Description	User Entry, Text Field	М	
Risk Rank	User Entry, Dropdown	М	
Payment Schedule			
Amount	User Entry, Numeric Field	М	
Due Date	User Entry, Date Field	М	
Activity	User Entry, Dropdown	М	Select from the list of activities
Documents	Attach Documents	М	

### 2.6.3 Project Implementation

Project Manager can concurrently update the project status based of activities, payment basis.

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	Load from Project Initiation	М	
Туре	Load from Project Initiation	М	
Project Section	User Entry, Text Field	М	
Program	Load from Project Initiation	М	
Sub Program	Load from Project Initiation	М	
Department / Unit	Load from Project Initiation	М	Select from department master.
Directorate	Load from Project Initiation	М	
Description	Load from Project Initiation	М	
Project Manager	Load from Project Initiation	М	Select from User Master
Project Start Date	Load from Project Initiation	М	
Project End Date	Load from Project Initiation	М	
Duration (Days)	Load from Project Initiation	М	
Project Members	Load from Project Initiation	М	
Budget Code	Load from Project Initiation	М	
Total Budgeted Cost	Load from Project Initiation	М	





Project Plan Date	Load from Project Plan	М	
Plan			
Activity	Load from Project Plan	М	
Start Date	Load from Project Plan	M	
	•		
Days	Load from Project Plan	М	
End Date	Load from Project Plan	M	
Responsible Person	Load from Project Plan	М	
Completion Status	User Entry, Dropdown	M	[Completed / Partially Completed / Not Started]
<b>Completion Percentage</b>	User Entry, Numeric Field	M	
Actual Completion Date	User Entry, Date Field	М	
Justification	User Entry, Text Field	0	
Risks Identified			
Risk Description	Load from Project Plan	М	
Risk Rank	Load from Project Plan	М	
Risk Status	User Entry, Dropdown	М	[ Mitigated / Not Mitigated]
Justification	User Entry, Text Field	0	
Payment Schedule			
Description	Load from Project Plan	М	
Amount	Load from Project Plan	М	
Due Date	Load from Project Plan	М	
Payment Status	User Entry, Dropdown	М	[Paid / Not Paid]
Payment Date	User Entry, Date Field	М	
Overall Comments	User Entry, Text Field	0	
Documents	Attach Documents	М	

### 2.6.4 Project Submittal Tracker

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	Load from Project Initiation	М	
Туре	Load from Project Initiation	М	
Project Section	User Entry, Text Field	М	
Program	Load from Project Initiation	М	
Sub Program	Load from Project Initiation	М	
Department / Unit	Load from Project Initiation	М	Select from department master.
Directorate	Load from Project Initiation	М	
Description	Load from Project Initiation	М	
Project Manager	Load from Project Initiation	М	Select from User Master
Project Start Date	Load from Project Initiation	М	
Project End Date	Load from Project Initiation	М	
Duration (Days)	Load from Project Initiation	М	





Project Members	Load from Project Initiation	M	
Budget Code	Load from Project Initiation	M	
Total Budgeted Cost	Load from Project Initiation	M	
Project Plan Date	Load from Project Plan	M	
Submittal Tracker			
Submittal description	User Entry, Text Field	M	
Task Owner	User Entry, Text Field	M	
Task Description	User Entry, Text Field	M	
Date Submittal Received	User Entry, Date Field	M	
Date Action Taken	User Entry, Date Field	M	
Date Submittal Paid/communicated	User Entry, Date Field	0	
Expected Days for Submittal to be paid/communicated	User Entry, Numeric Field	M	
variance (days)	System Generated	M	
Status	User Entry, Dropdown [Paid / Not Paid]	М	
Amount Requested	User Entry, Numeric Field	M	
Amount Paid	User Entry, Numeric Field	M	

# 2.6.5 Project Activity Schedule

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	Load from Project Initiation	M	
Туре	Load from Project Initiation	М	
Project Section	User Entry, Text Field	М	
Program	Load from Project Initiation	М	
Sub Program	Load from Project Initiation	М	
Department / Unit	Load from Project Initiation	M	Select from department master.
Directorate	Load from Project Initiation	М	
Description	Load from Project Initiation	М	
Project Manager	Load from Project Initiation	М	Select from User Master
Project Start Date	Load from Project Initiation	М	
Project End Date	Load from Project Initiation	М	
Duration (Days)	Load from Project Initiation	M	
Project Members	Load from Project Initiation	М	
Budget Code	Load from Project Initiation	М	
Total Budgeted Cost	Load from Project Initiation	M	
Activity Schedule			
Task	User Entry, Text Field	М	
Task Owner	User Entry, Text Field	М	





Start Date	User Entry, Date Field	М	
End Date	User Entry, Date Field	М	
Status	User Entry, Dropdown [Done/On Progress/ Not Done]	M	
Progress(%)	System Generated	М	

### 2.6.6 Project Monitoring and Controlling Tool

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	Load from Project Initiation	М	
Туре	Load from Project Initiation	M	
Project Section	User Entry, Text Field	М	
Program	Load from Project Initiation	M	
Sub Program	Load from Project Initiation	М	
Department / Unit	Load from Project Initiation	M	Select from department master.
Directorate	Load from Project Initiation	М	
Description	Load from Project Initiation	M	
Project Manager	Load from Project Initiation	М	Select from User Master
Project Start Date	Load from Project Initiation	M	
Project End Date	Load from Project Initiation	М	
Duration (Days)	Load from Project Initiation	M	
Project Members	Load from Project Initiation	М	
Budget Code	Load from Project Initiation	М	
Total Budgeted Cost	Load from Project Initiation	M	
Monitoring & Control			
Task Name	User Entry, Text Field	М	
Duration	User Entry, Numeric Field	М	
Start Date	User Entry, Date Field	М	
End Date	User Entry, Date Field	М	
Implementation Status	User Entry, Dropdown	М	
	[Completed/Work on		
	Progress/ Not Started]		
Closure/Completed Date	User Entry, Date Field	M	
Status	System Generated [Still Time	М	
	/ Due Today/ Overdue]		
Overdue	System Generated	M	Today – Finish Date
Late By	System Generated	M	Completed Date – Finish Date





## 2.6.7 Project Stakeholder Management

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	Load from Project Initiation	М	
Туре	Load from Project Initiation	M	
Project Section	User Entry, Text Field	М	
Program	Load from Project Initiation	М	
Sub Program	Load from Project Initiation	М	
Department / Unit	Load from Project Initiation	M	Select from department master.
Directorate	Load from Project Initiation	М	
Description	Load from Project Initiation	М	
Project Manager	Load from Project Initiation	М	Select from User Master
Project Start Date	Load from Project Initiation	M	
Project End Date	Load from Project Initiation	М	
Duration (Days)	Load from Project Initiation	М	
Project Members	Load from Project Initiation	М	
Budget Code	Load from Project Initiation	М	
Total Budgeted Cost	Load from Project Initiation	М	
Stake Holder Managemer	nt Matrix	_	
Stakeholder Name	User Entry, Text Field	М	
Contact Person – Name	User Entry, Text Field	М	
Contact Person – Email	User Entry, Text Field	М	
Contact Person – Phone	User Entry, Text Field	М	
Contact Person – Address	User Entry, Text Field	М	
Contact Person – Website	User Entry, Text Field	М	
Impact	User Entry , Dropdown	М	
	[High/Medium/Low]		
Influence	User Entry , Dropdown	М	
	[High/Medium/Low]		
What is important to the stakeholder?	User Entry, Text Field	M	
How could the stakeholder contribute to the project?	User Entry, Text Field	M	
How could the stakeholder block the project?	User Entry, Text Field	M	
Strategy for engaging the stakeholder	User Entry, Text Field	M	





## 2.6.8 Project Risk Management

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	Load from Project Initiation	M	
Туре	Load from Project Initiation	М	
Project Section	User Entry, Text Field	M	
Program	Load from Project Initiation	М	
Sub Program	Load from Project Initiation	М	
Department / Unit	Load from Project Initiation	М	Select from department master.
Directorate	Load from Project Initiation	М	
Description	Load from Project Initiation	М	
Project Manager	Load from Project Initiation	М	Select from User Master
Project Start Date	Load from Project Initiation	М	
Project End Date	Load from Project Initiation	М	
Duration (Days)	Load from Project Initiation	М	
Project Members	Load from Project Initiation	М	
Total Budgeted Cost	Load from Project Initiation	М	
Budget Code	Load from Project Initiation	М	
Risk Management			
Stage	User Entry, Text Field	М	
Risk Description	User Entry, Text Field	М	
Risk Assessment –	User Entry, Dropdown	М	
Likelihood	[Remote/Possible/Likely]		
Risk Assessment –	User Entry, Dropdown	М	
Severity	[Minor/Severe/Extreme]		
Risk Assessment – Rating	User Entry, Dropdown [	М	
	Low/Medium/High]		
Consequence	User Entry, Text Field	М	
Mitigation	User Entry, Text Field	М	
Cost of Implementing the	User Entry, Text Field	М	
risk mitigation	Harris Tayler II		
Ownership	User Entry, Text Field	M	

## 2.6.9 Project Issue Log

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	Load from Project Initiation	М	
Туре	Load from Project Initiation	М	
Project Section	User Entry, Text Field	М	
Program	Load from Project Initiation	М	





Sub Program	Load from Project Initiation	М	
Department / Unit	Load from Project Initiation	М	Select from department master.
Directorate	Load from Project Initiation	М	
Description	Load from Project Initiation	М	
Project Manager	Load from Project Initiation	M	Select from User Master
Project Start Date	Load from Project Initiation	М	
Project End Date	Load from Project Initiation	М	
Duration (Days)	Load from Project Initiation	М	
Project Members	Load from Project Initiation	М	
Budget Code	Load from Project Initiation	М	
Total Budgeted Cost	Load from Project Initiation	M	
Issue Log			
ID	Auto Generated	M	
Issue Description	User Entry, Text Field	M	
Priority	User Entry, Dropdown	M	
	[Critical/High/Medium/Low]		
Assigned To Owner	User Entry, Text Field	M	
Expected Resolution Date	User Entry, Date Field	M	
Current Status	User Entry, Dropdown [Open	M	
	/Work in Progress /Closed]		
Escalation Required	User Entry, Dropdown	M	
	[Yes/No]		
Impact Summary	User Entry, Text Field	M	
Action Steps	User Entry, Text Field	M	
Issue Type	User Entry, Dropdown	M	
	[Informational / Procedural /		
	System/ Other]		
Date Identified	User Entry, Date Field	M	
Assoc ID	User Entry, Text Field	M	
Entered By	User Entry, Text Field	M	
Actual Resolution Date	User Entry, Date Field	M	
Final Resolution & Rationale	User Entry, Text Field	М	

# 2.6.10 Project Closing

Field	Field Type		Additional Remarks
		M/O	
Project Code	System Generated	М	
Project Name	Load from Project Initiation	М	
Туре	Load from Project Initiation	М	
Project Section	User Entry, Text Field	М	
Program	Load from Project Initiation	М	





ve Lives			
Sub Program	Load from Project Initiation	M	
Department / Unit	Load from Project Initiation	M	Select from department master.
Directorate	Load from Project Initiation	M	
Description	Load from Project Initiation	M	
Project Manager	Load from Project Initiation	M	Select from User Master
Project Start Date	Load from Project Initiation	M	
Project End Date	Load from Project Initiation	M	
Duration (Days)	Load from Project Initiation	M	
Project Members	Load from Project Initiation	M	
Budget Code	Load from Project Initiation	M	
Total Budgeted Cost	Load from Project Initiation	М	
Project Plan Date	Load from Project Plan	М	
Plan			
Activity	Load from Project Plan	M	
Start Date	Load from Project Plan	M	
Days	Load from Project Plan	M	
End Date	Load from Project Plan	M	
Responsible Person	Load from Project Plan	M	
Completion Status	Load from Project	M	
	Implementation		
<b>Completion Percentage</b>	Load from Project	M	
	Implementation		
Actual Completion Date	Load from Project	М	
	Implementation		
Justification	Load from Project	0	
	Implementation		
Risks Identified			
Risk Description	Load from Project Plan	M	
Risk Rank	Load from Project Plan	M	
Risk Status	Load from Project	M	
	Implementation		
Justification	Load from Project	0	
	Implementation		
Payment Schedule			
Description	Load from Project Plan	M	
Amount	Load from Project Plan	M	
Due Date	Load from Project Plan	M	
Payment Status	Load from Project	M	[Paid / Not Paid]
	Implementation		
Payment Date	Load from Project	M	
	Implementation		
Project Closing			
Project Closing Date	User Entry, Date Field	M	





Challenges Faced	User Entry, Text Field	М	
Recommendation & Lessons Learned	User Entry, Text Field	M	
Other Comments	User Entry, Text Field	М	
Documents	Attach Documents	М	

#### 2.6.11 Researches

The M&E department can capture researched conducted related to projects.

Field	Field Type		Additional Remarks
		M/O	
Research Code	System Generated	М	
Topic	User Entry, Text Field	М	
Agenda			
Objective	User Entry, Text Field	М	
Recommendation	User Entry, Text Field	М	
Actions Done	User Entry, Text Field	М	
Status	User Entry, Dropdown	М	[Completed / Not Completed]
Agenda	Attach Documents	М	
Research Report	Attach Document		

#### **2.6.12 Reports**

- Project List
- Project Status
- Project Implementation Report
- Project Budget Variances
- Project Issue Log
- Project Progress Report
- Project Final Report
- Project Review Report
- Research Reports
- Issue Log Report [Total No. of Issues, Issues Addressed, Issues Pending, Not Implemented, Timeline]

#### 2.6.13 Reference Documents to attach

- o Contract/ MOU
- Project Review Report (Analysis of Gaps)
- o Project Commencement Letter
- o Inception Report
- User Manuals





- As-built Drawings
- Project Design Flow Chart
- Project Organogram
- o Project Completion Certificate
- o Post Completion Progress Report
- o Impact Evaluation Report
- Concept
- o Inception Plan
- o Work Plan
- Project Review Report
- o End of Program Report
- Project Charter [Project Inception]
- o Contract Management Reports
- o Project Handover Report
- Contract Management Report





# **3 NON - FUNTIONAL REQUIREMENTS**

Non-functional	Requirement Description			
Requirement				
Operational	Specific in-country operational / process requirements will need to be			
Requirement	taken into account.			
Supportability /	The system must be as generic as possible so that it can be plugged into			
Maintainability	supporting peripherals with minimum changes			
Reliability	24 x 7 availability			
Backup	<ul> <li>This should be carried out as per current processes for backend NDA systems.</li> </ul>			
Disaster Recovery (DR)	<ul> <li>This should be carried out as per current processes for backend NDA systems.</li> </ul>			
Performance	The product should conform to industry &NDA standards			
Learning / Training	<ul> <li>Users/ Operator: FTL will train all NDA Key users/operators to use the system.</li> <li>Admin Training: FTL will train the IT staff to administer and trouble shoot the system.</li> </ul>			
Security	<ul> <li>The product will need to conform to NDA Security standards and policies.</li> <li>The proposed system shall have an auditing tool to track activities in the system.</li> <li>The proposed system shall enable management of security access rights</li> </ul>			
Confidentiality /	The product will need to conform to NDA Risk and Fraud standards and			
Availability / Integrity	policies, both from a business process and technology perspective.			
Compliance and	The product will need to conform to any in-country regulatory /			
Legislative	legislative requirements.			
D I	The product will also need to conform to the NDA standards and policies			
Reports	The system will aid in preparing/extracting Reports.			





### 3.1 Software Specification

- Database: Microsoft SQL Server 2019(NDA shall have to obtain licensed version of database).
- Operating System: Windows Server 2019 or later.
- Reporting Software: Crystal Report 11.0(Embedded within Gateway).
- Antivirus Software: Any Antivirus software.
- Additional Tools: Microsoft Office

## 3.2 Hardware Specification

- Processor requirements: Quad Core Intel/AMD 2.0 GHZ+ 64-bit CPU
- RAM requirements: Minimum 16GB Recommended 32 GB
- Storage: Minimum 500GB (2 Partitions (each 250 GB))