

SCOMRA 2025

API database & portal

Ambele Mwafula



Unlocking Africa's Health Potential

- Continental API database is a useful tool which can be used by the AMRH, AMA, RECs and NMRA for accessing information about API manufacturers who have undergone inspection and approved by regulatory organizations and the WHO-PQ

- Duration

November, 2023 to April 2024.

System Scope

- Keep records of all important API information for regulatory purposes, research and manufacturer
- Allow uploading of evaluation report of specific APIs by EMP TC, RECs and recognized NRAs
- Allow uploading of inspection reports of API Manufacturing sites by GMP TC, RECs and recognized NRAs
- Allow updating, verification, commenting and sharing of other API information as maybe deemed necessary from time to time

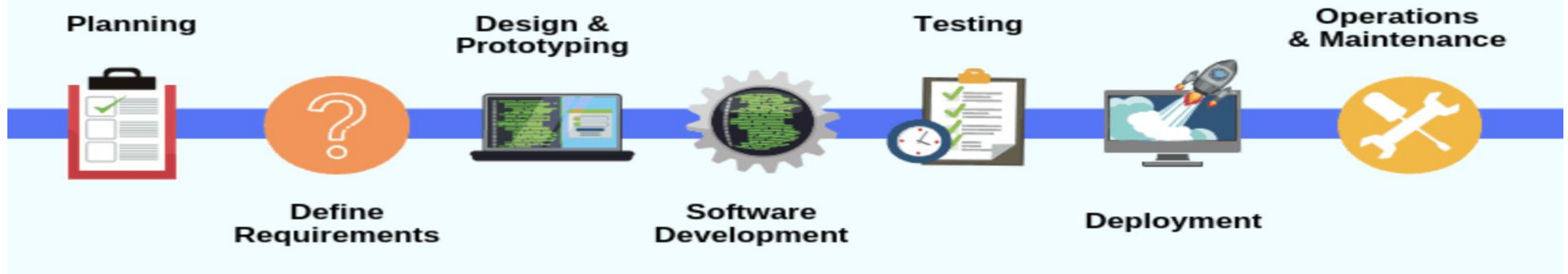


Source of Information

- EMP TC and GMP TC records of approved APIs following joint evaluation and joint GMP inspections
- Recognized RECs processes for API approval (such as Regional APIMF procedures)
- Recognized NRAs (such as NMRA with WHO ML3 and above) from the continent
- WHO PQ scheme
- Recognized Stringent Regulatory Authority outside the continent whereas access to inspection and evaluation reports is assured through agreement with AMRH
- Trusted website links (e.g WHO, EDQM) (for public domain and manufacturers)



Seven Phases of Software Development Life Cycle

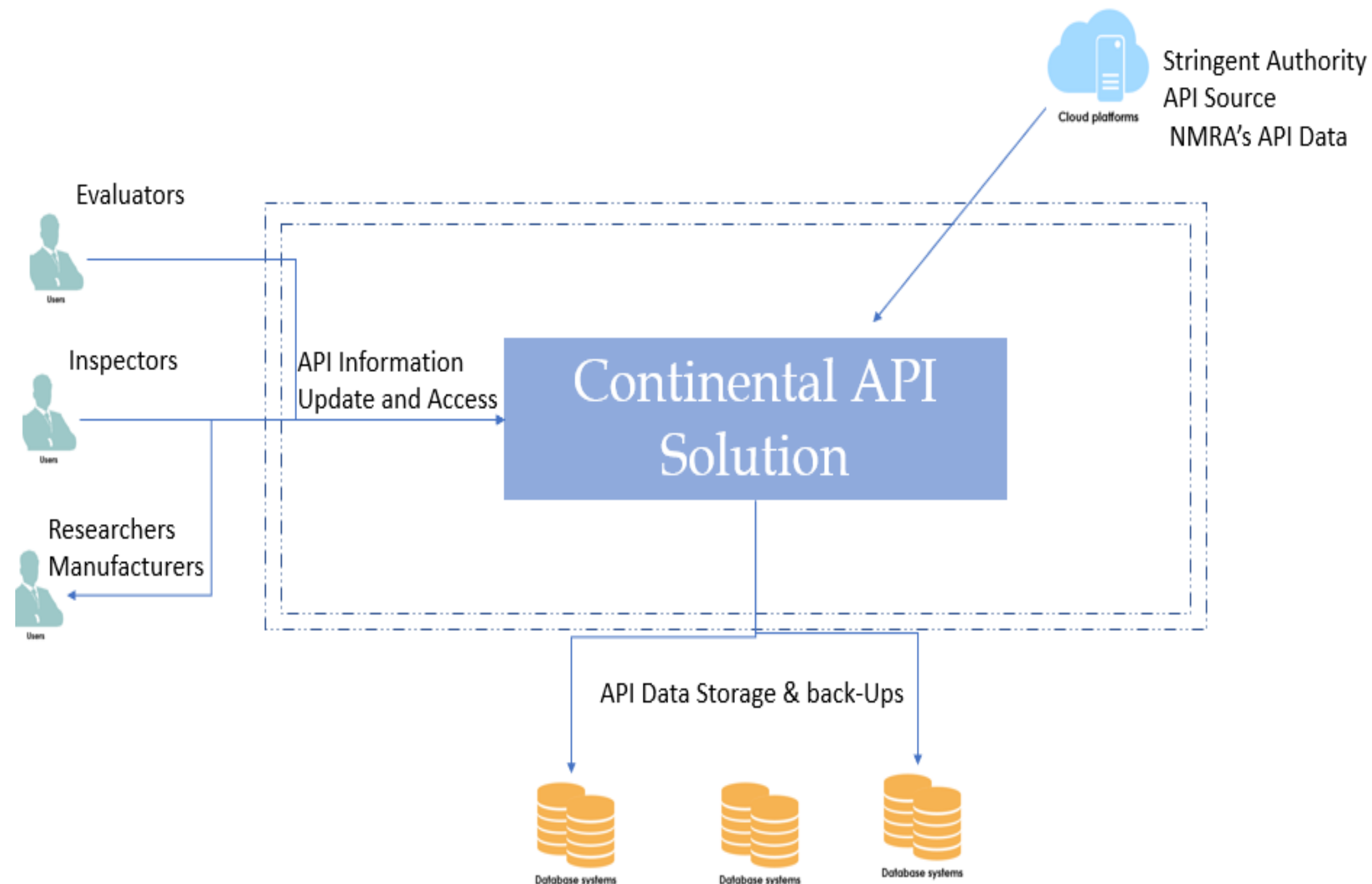


- **Reviewing** the existing API information websites
- **The Use Cases** technique
 - *A methodology used in system analysis to identify, clarify and organize system requirements*
- **Interview** different stakeholders
- Estimation methodology
 - *Expert estimation*
 - *Formal estimation model*
 - *Combination-based estimation sources*



- **Several API databases existing**
 - **Non Commercial**
 - ✓WHO
 - ✓EDQM
 - ✓[EMC](#)
 - ✓[US FDA](#)
 - ✓ANVISÁ
 - ✓[Therapeutic Goods Administration \(TGA\)](#)
 - ✓Heath Canada
 - **Commercial**
 - ✓[Chemxpert](#), Pharmazie, Pharma Source
 - ✓Subscription fees





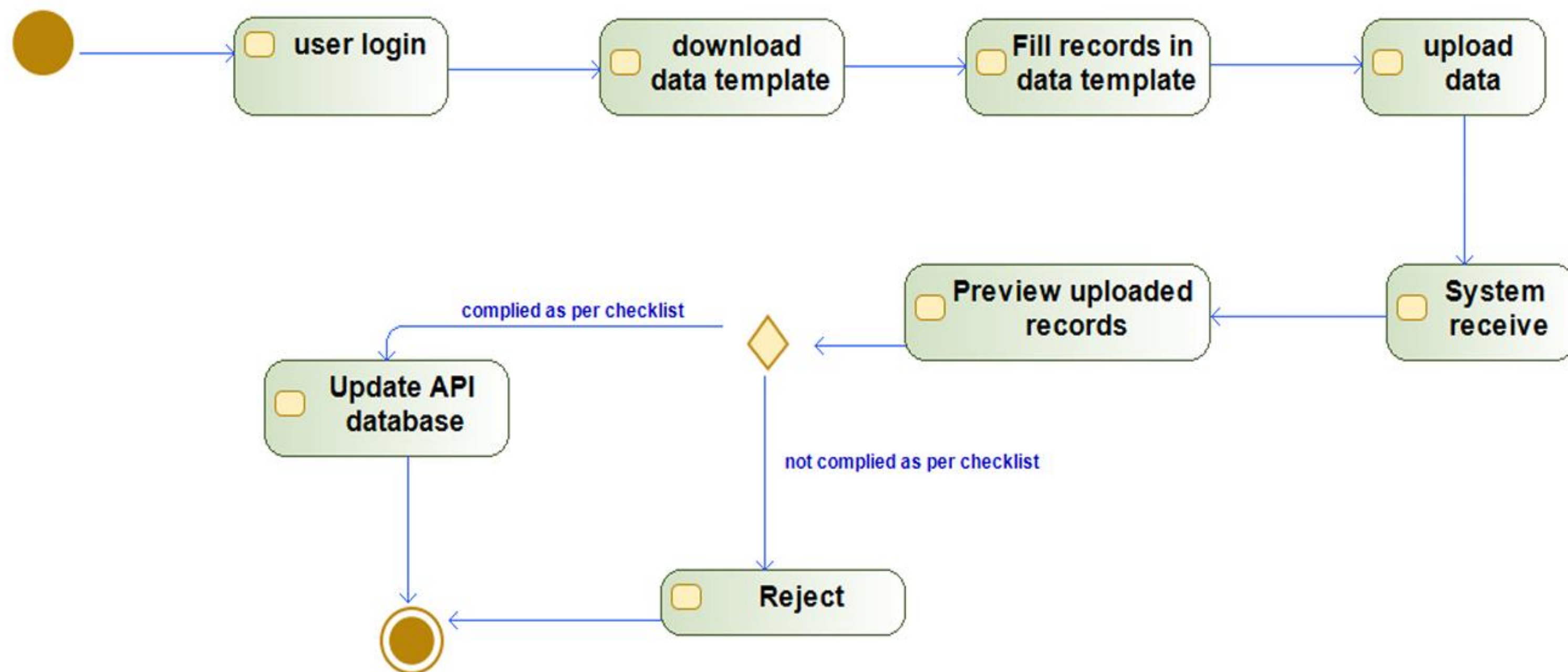
System Architecture:
multi-tier architecture

Development Framework
:full stack Laravel
framework for both front
end and backend.

Database engine: MySQL



<https://capi.auda-nepad.org>

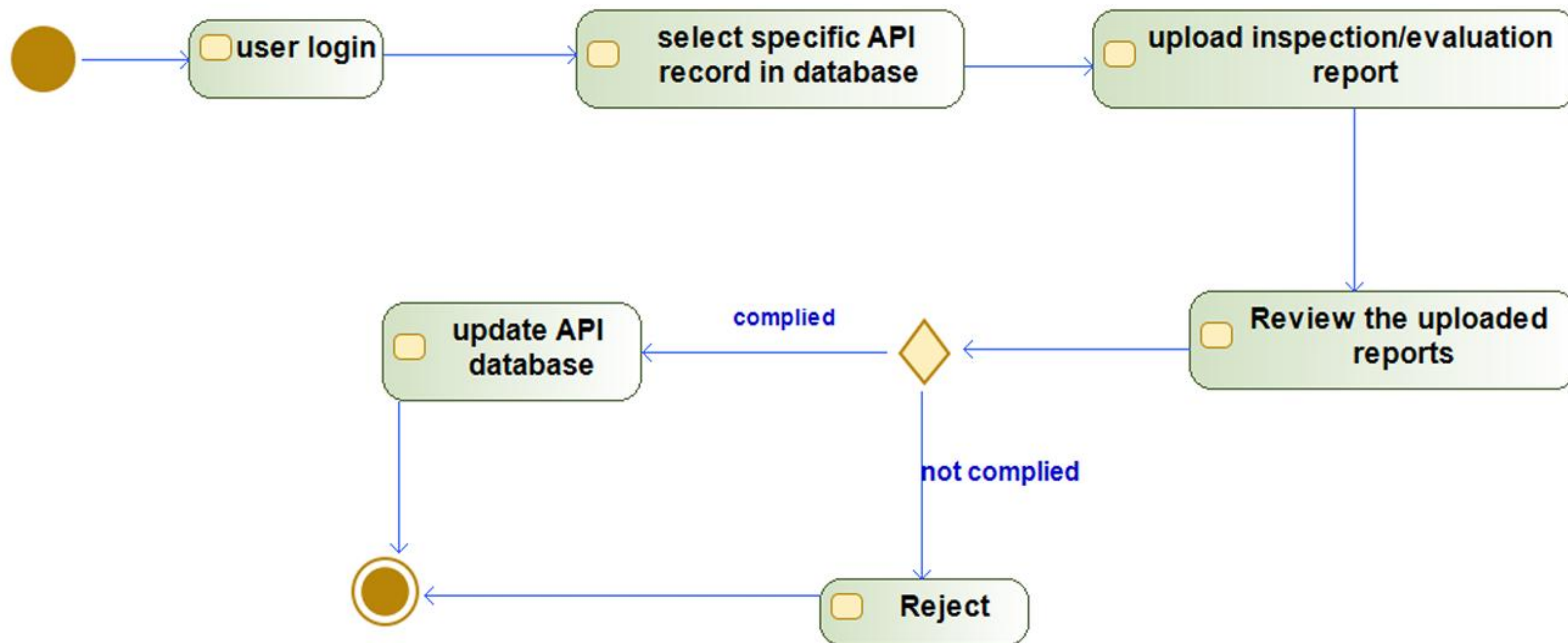


Unlocking Africa's Health Potential





<https://capi.auda-nepad.org>



Unlocking Africa's Health Potential

SYSTEM- Public page

Search API Information by Chemical/INN/Compendia Name,CAS Number and Category

Q

EXPORT TO EXCEL

CATEGORY	SOURCE	REFERENCE NO	MANUFACTURING SITE	CHEMICAL NAME	INN NAME	CAS NUMBER	MOLECULAR FORMULA	MOLECULAR WEIGHT
Target Organs (Respiratory drugs)	In-house	2024/TO/0001	Hanna Jackson	Acetylsalicylic acid	Aspirin	50-78-2	C9H8O4	180.16
Biotechnological Origins (Cell therapies)	In-house	2024/BO/0001	Blythe Morton	Lisinopril	Lisinopril	76547-98-3	C21H31N3O5	405.5
Therapeutic Classes (Antibiotics)	In-house	2024/TC/0001	Ambele	Ibuprofen	Ibuprofen	15687-27-1	C13H18O2	206.29
Chemical Structures (Peptides)	In-house	2024/CS/0002	test1test	test1	test1	test1	test1	test1
Pharmacological Actions (ACE inhibitors)	Compendia	2024/PA/0006	ALPHONCE	Metronidazole	Metronidazole	443-48-1	cooh	100

Showing 1 to 5 of 17 results

<

1

2

3

4

>

API By Category

Therapeutic Classes 7

API by Continent

Africa 0

API by Manufacturer

Test 2

SYSTEM -languages

API Database

[Home](#)

[About](#)

[Sources](#)

[User Guide](#)

[Contact](#)

[Log in](#)

[Register](#)

Select language ▾

English

French

Search API Information by Chemical/INN/Compendia Name,CAS Number and Category

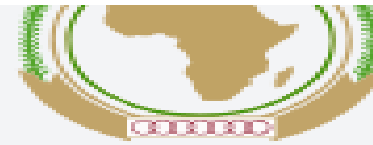


 EXPORT TO EXCEL

CATEGORY	SOURCE	REFERENCE NO	MANUFACTURING SITE	CHEMICAL NAME	INN NAME	CAS NUMBER	MOLECULAR FORMULA	MOLECULAR WEIGHT
Target Organs (Respiratory drugs)	In-house	2024/TO/0001	Hanna Jackson	Acetylsalicylic acid	Aspirin	50-78-2	C9H8O4	180.16

Select language

SYSTEM -Access Control



Continental Active Pharmaceutical Ingredients Repository

Account Type

Choose Account Type



Organization

Search Organization



First Name

First Name

Middle Name

Middle Name

Last Name

Last Name

Email

Email

Phone Number

+XXX XXX XXXX

Password

Password

Confirm Password

Confirm Password

[Already registered?](#)

REGISTER

SYSTEM- Access Control



AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Continental Active Pharmaceutical Ingredients Repository

Email

Password

☐ Remember me

[Forgot your password?](#) **LOG IN**

SYSTEM -Authorized page



Dashboard

Not Submitted API

Submitted API

Published API

Dashboard

Ambele Test LastName

API SUBMITTED
24

ACCEPTED API - CONTINENTAL SOURCE
9

ACCEPTED API-GLOBAL SOURCES
4

+ ADD API

DOWNLOAD EXCEL TEMPLATE

UPLOAD API FROM EXCEL

EXPORT TO EXCEL

Search for API

CHEMICAL NAME	COMPENDIA NAME	CAS NUMBER	CATEGORY	REFERENCE NO	ACTION
testupload	testupload	testupload	Alkaloids	2024/CS/0006	EDIT
test	test	test	Amines	2024/CS/0005	EDIT
Daniel	Daniel	666-12-1	Analgesics	2024/PA/0009	EDIT
Text1	Text1	Text1	Analgesics	2024/TC/0014	EDIT
Text1	Text1	Text1	Analgesics	2024/TC/0015	EDIT

Submitted for Review

API Reviewed and published

API not submitted for review

SYSTEM- Adding API data

International Nonproprietary Name(INN) 	Compendia Name
Chemical Name 	Brand Name
CAS Number Enter CAS number (e.g., 123-45-6)	Molecular Formula Enter molecular formula (e.g., H2O)
Molecular Weight Enter molecular weight (e.g., g/mol)	Chemical/Physical Variation Choose variation
Shelf Life Enter shelf life (e.g., 6 months or 2 years)	Storage Conditions Enter Conditions (e.g., 25°C or 37°C) Select Unit
Intermediate Manufacturer 	Starting Material Manufacturer
Primary Packaging Enter details (e.g., bottle, blister pack)	Secondary Packaging Enter packaging details (e.g., carton, case)
Tertiary Packaging Enter packaging details (e.g., pallet, shipping container)	

SYSTEM- Adding API data

Category

Therapeutic Classes

Antibiotics

Reference Information

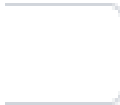
Reference Informations

Source Information

In-house

Quality Standard

Quality Standard Used



NEXT

SYSTEM- Adding API data

APIMF Version Number

Open Part

Closed Part

Specification Number

NEXT

SYSTEM- Adding API data

DMF Holder Information

Name

DMF Holder Name

Address

Physical Address

Contact Person

Contact Person

Contact Email

Contact Email

Contact Phone

Contact Phone

Country

Choose Country

City

City

CANCEL

SAVE

SYSTEM- Adding API data

Manufacturer Site Information

Name

Site Name

Location

Site Location

Facility Type

Site Capacity

Country

Choose Country

City

CANCEL

SAVE

SYSTEM- Adding API data

Step 6 of 6

To avoid duplication of information, please follow these steps:

- 1. Use the search box to find if the record exists.
- 2. If the record does not exist in our database, type in the Organisation in the text box and use the add button to provide the information.

☐ Is this API approved by any institution/ regulatory body (e.g., NMRA, WHO etc)

Organization

Search Organization

Approval Description

Certificate number/ WHOPQ number etc

Approval/Issue Date

dd / mm / yyyy

Upload Certificate/Licence/Permit

Browse...

No file selected.

ORGANIZATION	DESCRIPTION	DATE	FILE
--------------	-------------	------	------

No Regulatory Approval

SYSTEM- Adding API data

API Information

Basic Information

- INN: test
- Compendia Name: test
- Chemical Name: test
- Brand Name: test
- CAS Number: test
- Molecular Formula: test
- Molecular Weight: test
- Chemical/Physical Variation: Salt

Storage Information

- Shelf Life: test
- Storage Conditions: test

Other Details

- Category: Therapeutic Classes-Analgesics
- Reference Information:
- Source Information: In-house
- Quality Standard: test
- Reference Number: 2024/TC/0003

Packaging Information

- Primary Packaging: test
- Secondary Packaging: test
- Tertiary Packaging: test

APIMF Versioning

- Version Number: test
- Open Part: test
- Closed Part: test
- Specification Number: test

DMF HOLDER INFORMATION

Name	TEST
Address	TEST
Contact Person	test1
Contact Email	test1@gmail.com
Contact Phone	0888888
Country	Armenia
City	dar

MANUFACTURER SITE INFORMATION

Name	test1
Site Location	test1
Facility Type	test1
GMP Compliance	Compliant
ISO Standards	test1
Capacity	test1
Country	Tanzania
City	Dodoma

UPLOAD REPORT +

Inspection and Evaluation Report

ORGANIZATION TYPE DESCRIPTION DATE FILE

No Evaluation/Inspection Report

Regulatory Approval for API/Manufacturing Site

ORGANIZATION DESCRIPTION DATE FILE

TEST,Afghanistan	6777/mp/900	2024-04-17	DOWNLOAD 
TEST,Afghanistan	6777/mp/900	2024-04-17	DOWNLOAD 

Click the button

SYSTEM- Adding API data

API Information

Basic Information

- INN: test
- Compendia Name: test
- Chemical Name: test
- Brand Name: test
- CAS Number: test
- Molecular Formula: test
- Molecular Weight: test
- Chemical/Physical Variation: Salt

Storage Information

- Shelf Life: test
- Storage Conditions: test

Other Details

- Category: Therapeutic Classes-Analgesics
- Reference Information:
- Source Information: In-house
- Quality Standard: test
- Reference Number: 2024/TC/0003

Packaging Information

- Primary Packaging: test
- Secondary Packaging: test
- Tertiary Packaging: test

APIMF Versioning

- Version Number: test
- Open Part: test
- Closed Part: test
- Specification Number: test

DMF HOLDER INFORMATION

Name	TEST
Address	TEST
Contact Person	test1
Contact Email	test1@gmail.com
Contact Phone	08888888
Country	Armenia
City	dar

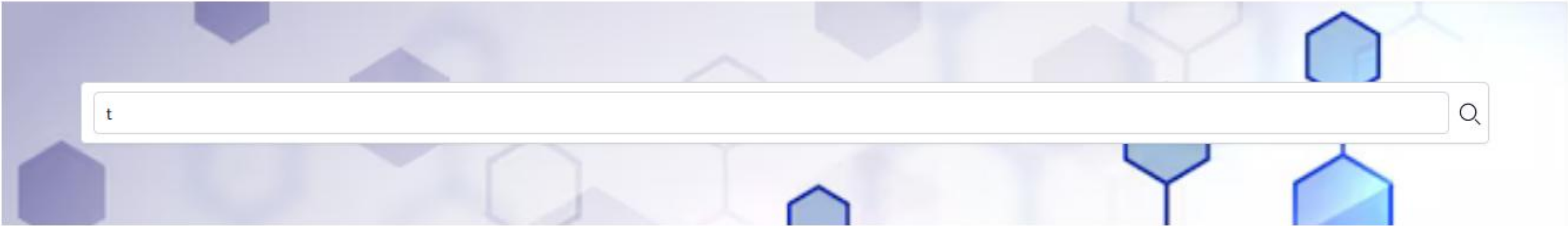
MANUFACTURER SITE INFORMATION

Name	test1
Site Location	test1
Facility Type	test1
GMP Compliance	Compliant
ISO Standards	test1
Capacity	test1
Country	Tanzania
City	Dodoma

Click button to make API data visible to public

PUBLISH API +

THANK YOU



CATEGORY	SOURCE	REFERENCE NO	MANUFACTURING SITE	CHEMICAL NAME	INN NAME	CAS NUMBER	MOLECULAR FORMULA	MOLECULAR WEIGHT
Target Organs (Respiratory drugs)	In-house	2024/TO/0001	Hanna Jackson	Acetylsalicylic acid	Aspirin	50-78-2	C9H8O4	180.16
Biotechnological Origins (Cell therapies)	In-house	2024/BO/0001	Blythe Morton	Lisinopril	Lisinopril	76547-98-3	C21H31N3O5	405.5
Generics vs. Innovator Drugs (Innovator APIs)	In-house	2024/GI/0001	Ishmael Olson	Mercedes Henson	Cameron Green	859	Temporibus nostrud a	Id natus consectetur
Chemical Structures (Peptides)	In-house	2024/CS/0002	test1	test1	test1	test1	test1	test1
Natural vs. Synthetic (Synthetic APIs)	In-house	2024/NS/0002	Jackson Livingston	Maggy Gonzalez	Maya Curtis	855	Et qui earum sint nu	Accusantium placeat