# USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

# Digital Regulatory System Strenghening Pharmadex 2

**Database Guide & Learning Course** 

# International Version

March 2022

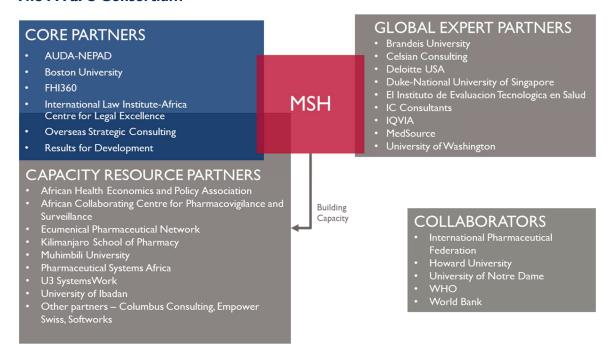


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#### **About the USAID MTaPS Program**

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to higher-performing health systems. MTaPS focuses on improving access to essential medical products and related services and on the appropriate use of medicines to ensure better health outcomes for all populations. The program brings expertise honed over decades of seminal pharmaceutical systems experience across more than 40 countries. The MTaPS approach builds sustainable gains in countries by including all actors in health care—government, civil society, the private sector, and academia. The program is implemented by a consortium of global and local partners and led by Management Sciences for Health (MSH), a global health nonprofit.

#### The MTaPS Consortium



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# **ACRONYMS AND ABBREVIATIONS**

API	Application Program Interface
HL7	A set of international standards used to transfer and share
	data between various healthcare providers. More
	specifically, HL7 helps bridge the gap between health IT
	applications and makes sharing healthcare data easier and
	more efficient when compared to older methods.
NMRA	National Medicine Regulatory Authority
MTaPS	Medicines, Technologies, and Pharmaceutical Services
URL	Universal Resource Locator
USAID	US Agency for International Development
NMRA Supervisor	The supervisor is responsible for the continuous adaption of
	Pharmadex 2 to changing needs and the management of
	NMRA users. The supervisor should know well all NMRA
	functions. A computer science qualification is appreciated,
	however, not required.

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# **PROJECT SUMMARY**

Program Name:		USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program	
Activity Start Date And End Date:		September 20, 20–September 19, 2023	
Name of Prime Implementing Partner:		Management Sciences for Health	
Contract Number:		7200AA18C00074	
MTaPS Partners	Core Partners	Boston University, FHI 360, Overseas Strategic Consulting, Results for Development, International Law Institute-Africa Centre for Legal Excellence, NEPAD	
	Global Expert Partners	Brandeis University, Deloitte USA, Duke-National University of Singapore, El Instituto de Evaluacion Technologica en Salud, ePath, IC Consultants, Imperial Health Sciences, MedSource, QuintilesIMS, University of Washington	
	Capacity Resource Partners	African Health Economics and Policy Association, Ecumenical Pharmaceutical Network, U3 SystemsWork, University of Ibadan, University of Ghana's World Health Organizations (WHO) Pharmacovigilance Collaborating Center, Kilimanjaro School of Pharmacy, Muhimbili University, Pharmaceutical Systems Africa	
	Collaborators	International Pharmaceutical Federation, Howard University, University of Notre Dame, WHO, World Bank	

## BACKGROUND

This course intends for programmers. Annex 1 contains SQL codes mentioned in the modules, Annex 2 answers to quizzes questions. All modules are mandatory. To execute modules, it is necessary to access the database. The preferable is local access. The latest database dump is available on GitHub https://github.com/MSH/Pharmadex2/tree/main/database. Alternatively, you ask MSH for it.

# **OBJECTIVE**

# MODULE I. INTRODUCTION

#### **OBJECTIVE**

The general introduction to the course.

#### SUMMARY

The Pharmadex 2 software does not need programmer's interventions to adapt to most customers' needs and requirements. It is highly configurable software grounded on the latest industry standards and best practices.

However, to implement unique customer-specific particularities or to make data available to the Data Warehouse it will be necessary to build a set of APIs or to query Pharmadex 2 database. It is a task for a qualified programmer.

To resolve this task most efficiently, a programmer should consider the following points of view to the database:

- 1. The data usage point of view:
  - 1.1. The whole data is a forest of data trees
  - 1.2. Each data tree root may be found by the URL string, like "pharmacy.site", "organization.authority", etc.
  - 1.3. Any tree is fully responsible for a data object, i.e., application configuration, dictionary, resource, organization structure, etc.
  - 1.4. Any data object may be found from the root of the tree to which this object belongs.
- 2. The API development point of view:
  - 2.1. Data access software services
  - 2.2. Data access CRUD repositories
  - 2.3. Object-Relation Mapped (ORM Hibernate) Java classes
  - 2.4. The MySQL managed relational database and SQL queries

The ability to SQL query the MySQL database is mandatory. The data access services, as well as ORM Hibernate Java classes, will be useful for Java or Kotlin programmers.

The Pharmadex 2 software codes are open. The database access codes are in a separate software library (project) "pdxmodel" Thus, Java and Kotlin programmers may use this library directly.

The main Pharmadex 2 software project "pharmadex2" is a classic Java Spring Boot REST API project. All APIs are JSON-backed. Thus, Java and Kotlin programmers may use this project as an example. In addition, it is possible to use these APIs directly from others software.

The Pharmadex 2 database "pdx2" contains Pharmadex 1 tables, Pharmadex 2 tables, views, and stored procedures. The Pharmadex 2 tables are listed as ORM Hibernate entities in package "org.msh.pdex2.model". This package can be found in the project "pdxmodel". All views and stored procedures in the database "pdx2" are solely for Pharmadex 2. Thus, a programmer can use them, regardless of the programming language.

## Quiz

- 1) The Pharmadex 2 software codes are open. What is the recommended way to adapt it to the needs of the particular NMRA?
  - a) Re-programming some source codes
  - b) Configuring Pharmadex 2
  - c) Configuring Pharmadex 2 and building particular APIs if it will be necessary
- 2) A dictionary in Pharmadex 2 is a data element represented as a graph of any reasonable depth. Which point of view is it?
  - a) Data usage
  - b) API development
- 3) I'm a .NET programmer. How can I use project "pdxmodel"?
  - a) As a software library
  - b) For reference only
- 4) Is it possible to use Pharmadex 2 software API directly from the PHP application?
  - a) Yes
  - b) No
- 5) We plan to implement the Microsoft Azure data warehouse. What is the best way to access Pharmadex 2 data from ETL (Extract, Transform, and Load) process?
  - a) The usage of API calls to Pharmadex 2
  - b) The usage of SQL queries, views, and stored procedures
  - c) The development of special APIs

## MODULE 2. THE DATA FOREST

#### **OBJECTIVE**

The objective is to learn why the tree logical model has been selected for Pharmadex 2. The general data usage recommendations are provided.

#### **SUMMARY**

The logical representation of data as a forest of data trees is widely used. Any tree keeps selfsufficient data.

An example is FHIR HL7 standard implementation. The quote from them (Figure 1) demonstrates the root of the Medicinal Product<sup>1</sup> data tree and two branches of it – Identifier and Type.

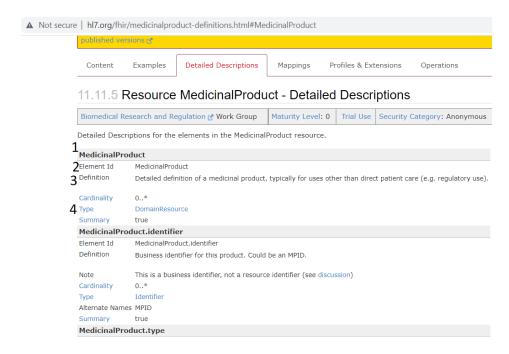


Figure 1. FHIR quote

The data organization in FHIR HL7 is compatible with SKOS standard by W3 consortium<sup>2</sup>:

The Pharmadex 2 logical data structure is compatible with SKOS standard i.e.,

- Each data element is represented by SKOS originated concept<sup>3</sup>
- Any concept is included in a tree of concepts
- A concept contains an identifier (the element ID), a preferred label, and a description

<sup>&</sup>lt;sup>1</sup> This particular example is still undergoing development and review by the appropriate Workgroups. At this time, is considered only as a draft resource not suitable for production implementation. However, for Pharmadex 2 it is the most appropriative element from HL7

<sup>&</sup>lt;sup>2</sup> https://www.w3.org/TR/skos-reference/#notations

<sup>&</sup>lt;sup>3</sup> https://www.w3.org/TR/skos-reference/#concepts

As in FHIR HL7, the root of any data tree is identified by a URI (Universal Resource Identifier). The URI implementation is a string in a dot-separated URL format. Examples are:

- organization.authority
- dictionary.responsibilities.organizations.public
- user.data

The usage of FHIR rules <a href="http://hl7.org/fhir/fhirpath.html">http://hl7.org/fhir/fhirpath.html</a> to define URLs that do not list in the FHIR is highly appreciated.

The full list of the roots is available using the view "tree roots" (Figure 2). The assignment of most URLs is a responsibility of a Pharmadex 2 Supervisor user.

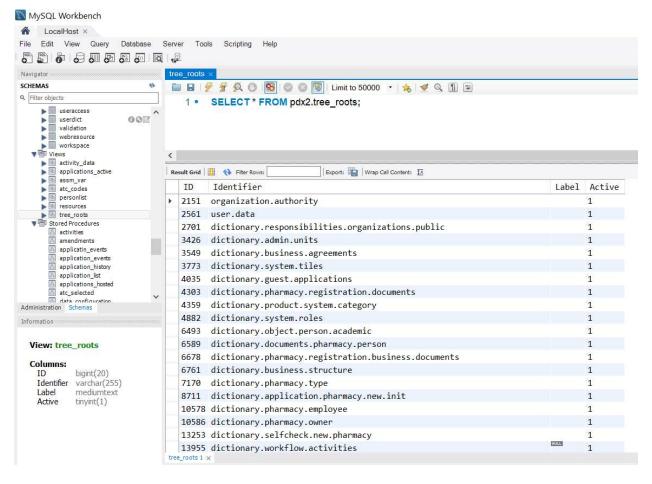


Figure 2. The forest

## The administrate features use URLs widely

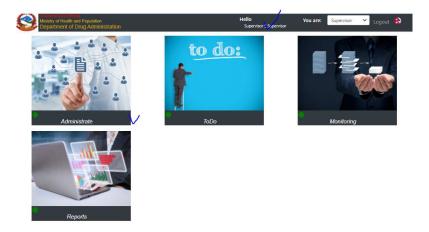


Figure 3. Administrate feature access

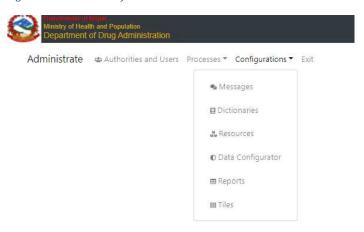


Figure 4. The configuration's feature

An example is a "Dictionaries" feature.

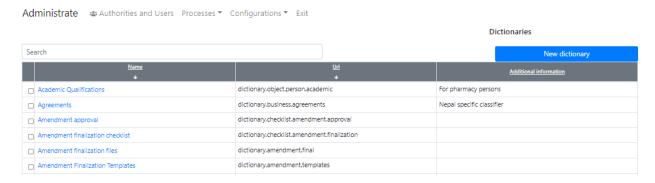


Figure 5. Dictionaries

## Quiz

- 1) The HL7 MedicinalProduct tree should be considered as a draft. Is it possible to use it in Pharmadex 2?
  - a) No, it is impossible, because Pharmadex 2 should strictly obey the current HL7
  - b) Yes, it is possible, because it is recommended to use the HL7 approach in case the HL7 standard is not available yet.
- 2) Administrative feature "Resources" shows URLs. However, it is impossible to find these URLs in the view "tree\_root". What do you think why?
  - a) These URLs are branches in some other trees
  - b) These URLs do not belong to any tree

## MODULE 3. DATA TREE IMPLEMENTATION AND EXPLORING

## **OBJECTIVE**

The objective is to study data tree implementation in the ORM and the database. The data exploration examples are provided.

#### **SUMMARY**

The Pharmadex 2 database is implemented on the MySQL relation database engine. The name of the schema is "pdx2". The URLs tree has been implemented using the "closure table" pattern (https://coderwall.com/p/lixing/closure-tables-for-browsing-trees-in-sql).

The "Closure Table" pattern is built on Concept and Closure ORM objects (Figure 6).

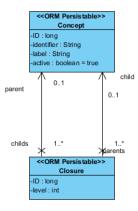


Figure 6. ORM implementation of the "closure table" database pattern

These ORM objects are backed by the database tables "concept" and "closure".

#### Concept

Field	Description	Data samples
ID	Primary key	2155
Identifier	Unique Identifier of this concept inside the branch. It may be URL, language tag, variable name, etc	en_us
Label	Any textual information related to this concept	Ministry of Health and Population
Active	Boolean value. Is this concept active?	true

#### Closure

Field	Description	Data samples
ID	Primary key	7510
ChildID	Point to child concept	2155
ParentID	Point to parent concept	2154
Level	Tree level	1

To support the trees on the service level, Pharmadex 2 provides the software implemented by org.msh.pharmadex2.service.r2.ClosureService.java. It can be found in the "pharmadex2" project.

The Pharmadex 2 provides views and stored procedures to work with the trees directly, by SQL. It is possible to explore a tree from the root or any branch or leaf.

View "tree\_root" selects roots A root URL is a concept for which the parent concept doesn't exist. (Figure 7).

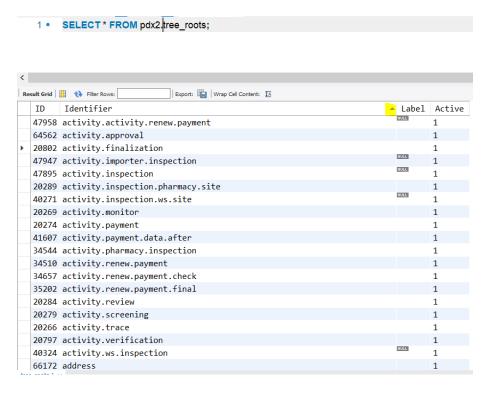


Figure 7. Tree roots sorted by URL

The stored procedure "print\_tree" allows exploring any "tree" in the "forest". The parameter of this procedure is a primary key (ID) of the concept.

Example 1. The tree exploration from the root. The tree root is "dictionary.admin.units".

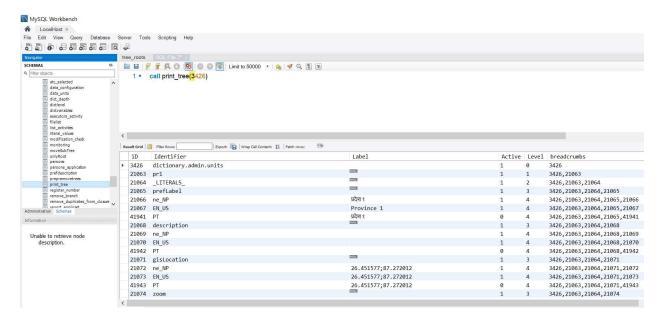


Figure 8. Explore the dictionary tree from the root

The columns are from the "concept" table. The latest column "breadcrumbs" displays the full path to the root. These are IDs of the concepts.

- 1. The concept 3426 is the tree root of the dictionary under URL "dictionary.admin.units"
- 2. Under it is 21063 is a concept "pr1". It is a branch of the tree.
- 3. Under it is a concept 21064 "\_LITERALS\_". It is a branch of multi-language labels
- 4. Under it is a concept 21065 "prefLabel". It is a label name
- 5. Under it are concepts contain values of the "prefLabel" on different languages

#### Example 2. The tree exploration from a branch or a leaf. The branch is the "images.design" resource4.

It is not the root of a tree, thus first we need to determine the ID of the related concept (Figure 9). There are two concepts with the same URL because the resource is created for two languages. Thus, these concepts are in separate branches.

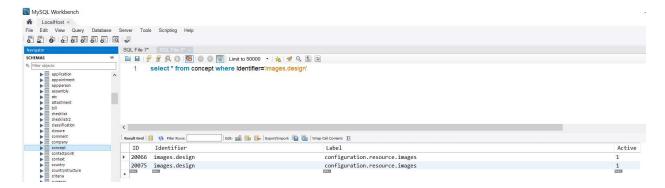


Figure 9. Find the ID of the branch inside the tree

Then, will get a path to the tree root for any of the concepts above (Figure 9), using the "print tree" stored procedure. The second concept (2074) in this path should be the language of the branch.

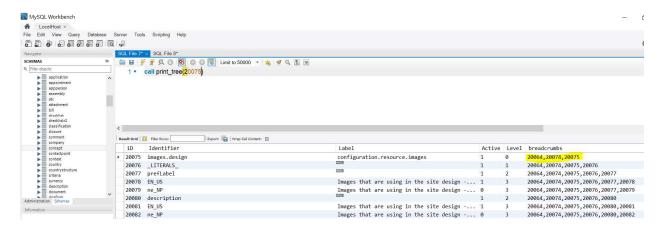


Figure 10. Find a branch inside the tree

<sup>&</sup>lt;sup>4</sup> This resource contains images that are used by Pharmadex 2 screens.

Then, will explore the concept 2074, using print\_tree (Figure 11). It is the Nepali language resource.

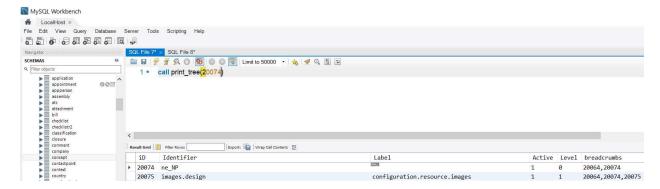


Figure 11. Find a branch of the immediate parent

Additional useful stored procedures to directly manage a tree and the forest are:

- remove\_branch() it is a correct way to remove a node in a tree. Deletion of a concept directly is not a good choice.
- moveSubTree() provides a possibility to move a branch from one tree to another.

The rest of the stored procedures are used by Pharmadex 2 software. The result of execution of them is temporary tables that may be used in SQL queries and inside other stored procedures.

It is forbidden to make changes in the procedures provided. Create and use copies instead.

# **Q**UIZ

- 1) Why the field "Level" in the "closure" table is useful?
  - a) This field is excess
  - b) This field allows avoiding recursive SQL
  - c) This field allows getting a root of a tree from any branch or leaf in a simple SQL query
- 2) Is it possible to use only the "tree\_root" view to explore a tree?
  - a) Yes
  - b) No
- 3) Is it possible to explore a tree from a leaf?
  - a) Yes
  - b) No

# MODULE 4. THE TREE IMPLEMENTATION OF MULTI-LANGUAGE STRINGS, LITERALS, NUMBERS, BOOLEANS, **DATES**

#### **OBJECTIVE**

The Pharmadex 2 provides multi-language data storage. In most cases, the data is stored for the language selected by a user in the User Interface. This feature is implemented using the data tree.

#### SUMMARY

The Pharmadex 2 provides a possibility to include to the application data the common use data types such are Strings, Literals<sup>5</sup>, Numbers, Booleans, and Dates. This data will be stored separately for the language selected by a user.

The database structure to manage them is a tree<sup>6</sup>. Below is an example of the tree from the "pharmacy.site" root.

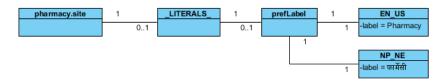


Figure 12. A literal with name prefLabel is multi-language

- The root concept with Identifier "pharmacy.site" is linked to zero or one concept with identifier \_LITERALS\_
- A concept \_LITERAL\_ is linked to a concept with identifier "prefLabel"
- A concept with the identifier prefLabel (name of the data variable) is linked to concepts with language tags identifiers
- Each language tag keeps a value in the language defined by the field "identifier".

<sup>&</sup>lt;sup>5</sup> Strings and Literals are representations of a textual strings. However, Strings unlike literals do not support the multi-language feature

<sup>&</sup>lt;sup>6</sup> The ORM diagram is unclear for this case - Figure 6

To explain the considerations above, it is possible to create a SQL<sup>7</sup> to extract values of the "prefLabel" field linked to the root concept with ID=20005. The language is en\_US.

1 • select root.ID, var.Identifier as 'varName', pref.Identifier as 'language',pref.Label as 'prefLabel' 2 from concept root 3 join closure clo on clo.parentID=root.ID and clo.Level=1 4 join concept lit on lit.ID=clo.childID and lit.Identifier=' LITERALS ' join closure clo1 on clo1.parentID=lit.ID and clo1.Level=1 join concept var on var.ID=clo1.childID and var.Identifier='prefLabel' join closure clo2 on clo2.parentID=var.ID and clo2.Level=1 join concept pref on pref.ID=clo2.childID and pref.ldentifier='EN\_US' 8 where root.ID=20005



Figure 13. Select a value of prefLabel in en\_US

<sup>&</sup>lt;sup>7</sup> This query is for learning purpose only. The real query is simplest. See Annex 1.

# **Q**UIZ

- 1) Suppose that in some country is in use Gregorian and traditional calendar. Is it possible to keep dates separately?
  - a) Yes
  - b) No
- 2) Why does Pharmadex 2 use a concept with identifier \_LITERALS\_?
  - a) It is the useless concept
  - b) To distinct common use variables from others
  - c) To improve the performance of SQL queries

# MODULE 5. THE CONFIGURATION OF THE APPLICATION DATA.

### **OBJECTIVE**

The Pharmadex 2 uses the data tree to keep application configuration data. This data is necessary for APIs creation.

#### **SUMMARY**

The Pharmadex 2 allows the Supervisor to configure application data as well as on-screen forms.

Below, is the "pharmacy.site" application data configuration.

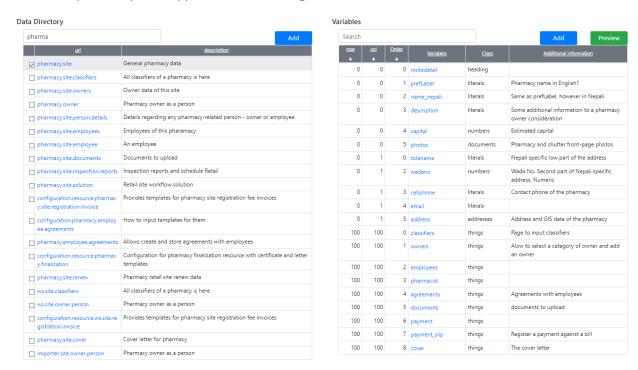


Figure 14. Data Configuration example from Pharmadex 2

Each line in this configuration is stored in the database using Concept and Assembly ORM objects. The Assembly is to store the configuration data. The Concept is to collect the configuration data to the appropriate tree and to keep language specific data in the branch "LITERALS".

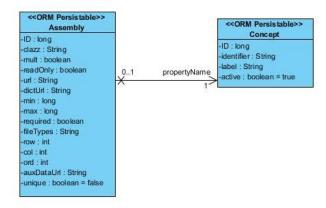


Figure 15. A line in the data configuration

The Assembly object contains many fields, because of uniformity needs. The most used of them are:

- url data configuration URL
- clazz the type of variable
- col, row, order place on the screen
- required is this data mandatory?

On the database level, the configuration data is stored to the tables "concept" and "assembly". Thus, it is possible to create SQL queries for the configuration data.

First, will find a concept that is the root of the "pharmacy.site" configuration (Figure 16). The result is two concepts – the first is the configuration data, the second is the application data.

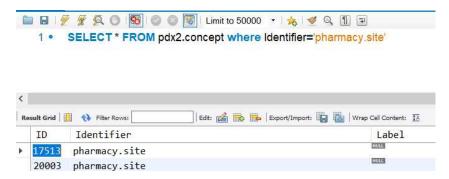


Figure 16. Find a concept by the Identifier

Then, will ensure that it is the configuration data (Figure 17).

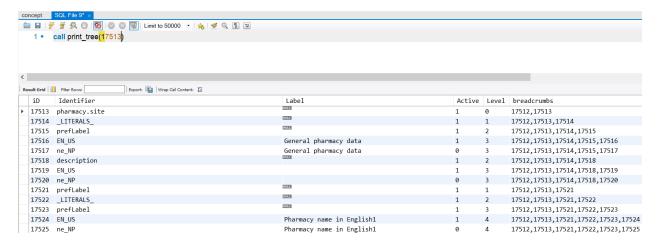


Figure 17. Data configuration tree

It is possible to create an SQL query that returns the same result (Figure 18)

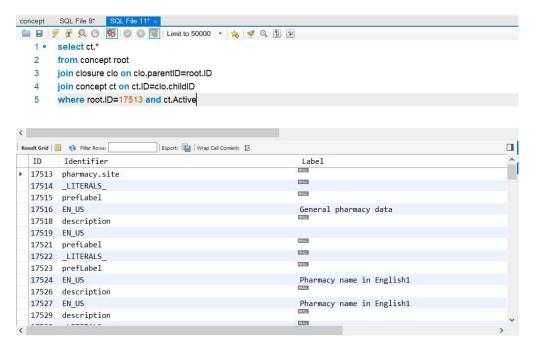


Figure 18. Data configuration selection use plain SQL select

Then will create a SQL to select the data configurations from the "assembly" table (Figure 19). Internal SQL is from the example above (Figure 18). The "clazz" column means the data type.

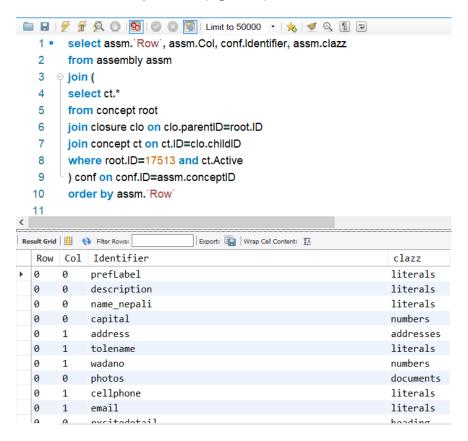


Figure 19. Select data configuration using SQL

# Quiz

- 1) Who is responsible for application data configuration?
  - a) Supervisor
  - b) Programmer
  - c) Both
- 2) Which table are not in use for data configuration?
  - a) concept
  - b) closure
  - c) activity
  - d) assembly
- 3) Does the "clazz" column is available for the Supervisor?
  - a) Yes
  - b) No

# MODULE 6. THE APPLICATION DATA

#### **OBJECTIVE**

This module explains how the application data may be found, and, then, accessed by SQL.

#### **SUMMARY**

To collaborate with NMRA the Business User should create the electronic application data and, then, send it to NMRA. The data structure of the application data has been defined by the supervisor. The application data is stored in the tree. The root concept of this tree is the application's URL. Below is an example for "pharmacy.site" application data.



Figure 20. How to application data is stored in a tree?

- 1. The concept "pharmacy.site" is the root of data of the "pharmacy. site" applications
- 2. It is linked to many concepts of applicants' emails owners of applications
- 3. Email of each applicant is linked to one or many applications data concepts (typically one)

Thus, the data of any given application may be found using the root concept of the application. The structure of the application data is defined in the configuration. Because the configuration is uniform, the data of any application can be gotten by the same SQL.

There are many approaches how to finding the root concept. Suppose, we will need "Lion and Pan pharmacy".

First, select concepts with this label "Lion and Pan pharmacy". The concepts for two languages will be selected.

- 1 · SELECT
- 2 \* FROM concept
- where Label like '%Lion and pan pharmacy%';

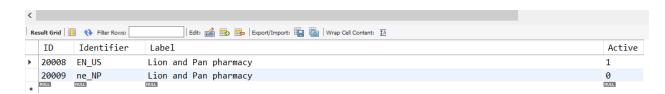


Figure 21. Search by the name

Then, will explore any concept above, using the "print\_tree", e.g. 20008

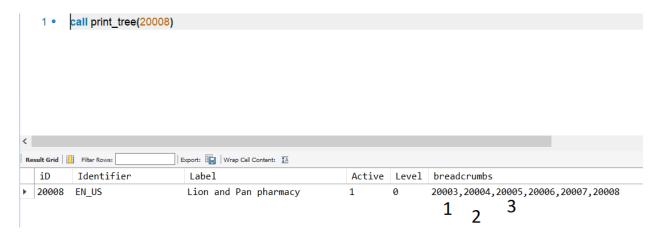


Figure 22. Search for the root concept of the application data

- The common root for all applications of this type is available in the "tree\_root" view.
- The email of the applicant.
- The root concept of the application

Then, will explore the application found. The root concept of it is 20005.

call print\_tree(20005)

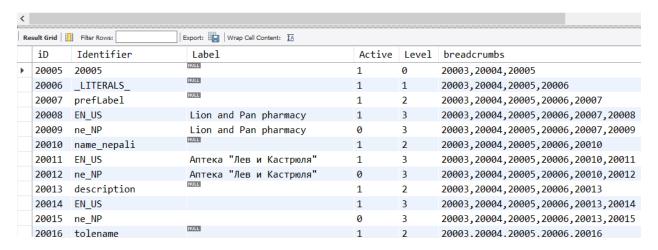


Figure 23. The application data example

The Pharmadex 2 software uses the ORM object Thing to assembly the application data. The whole ORM structure is below (Figure 24).

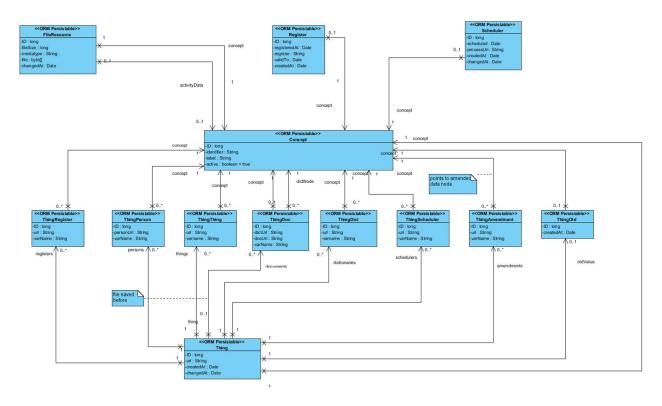


Figure 24. Full application data structure

The part of the whole ORM structure (Figure 24) are relations between the application data concept and files attached to it (Figure 25).

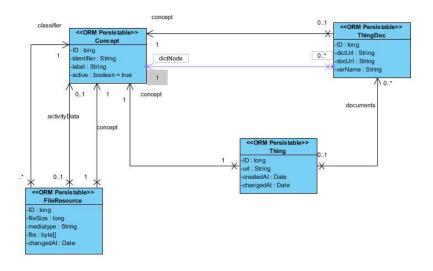


Figure 25. Files attached to the application data

- The application data concept is related to the Thing
- The Thing is related to a zero or many objects ThingDoc
- The ThingDoc is related to a file concept object and a concept object in a dictionary
- The file concept object is related to a file stored

To explain the considerations above, it is possible to create a SQL to extract all uploaded files related to the application data concept with ID=20005.

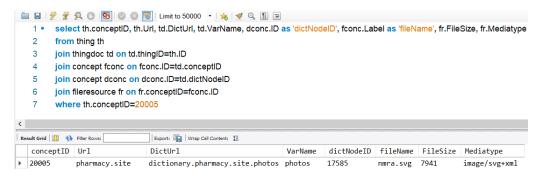


Figure 26. Uploaded file in the application data. SQL

# **Q**UIZ

- 1) The ThingDoc object relates to concept dictNode. It is a concept of a dictionary item. Why do we need this reference?
  - a) To provide a user a guide on which file should be uploaded
  - b) To check file name against a dictionary item
  - c) To attach the file to the dictionary
- 2) The query listed in Figure 26 returns more than one record. Is it possible?
  - a) Yes
  - b) No
- 3) The query listed in Figure 26 returns zero records. Is it possible?

  - b) No

# MODULE 7. THE APPLICATION DATA AND ADDITIONAL DATA

#### **OBJECTIVE**

To learn how to create a sequency of electronic forms to prepare an application. The pre-defined data components and the additional data.

#### **SUMMARY**

A typical application is a sequency of electronic forms. This sequency is configurable by the Supervisor user. An electronic form consists of pre-defined data elements. The examples of them are:

- data input field
- dictionary to select value(s)
- address to select an address and geo-data
- file uploader
- file downloader
- etc.

The pre-defined data elements are highly customizable by the Supervisor user.

The first on-screen form in an application is the application data. The others on-screen forms are additional data. Altogether is the application. Below (Figure 27), the additional data forms are highlighted, pre-defined data components are on white background.

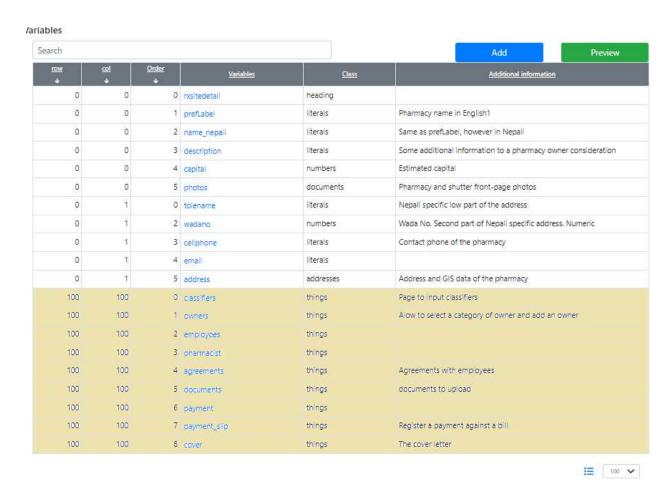


Figure 27. An application with application data and additional data

The database implementation of the additional data is on the following diagram:

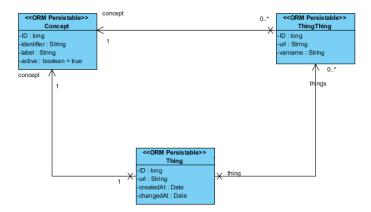


Figure 28. Representation of the application data and additional data in the database

- An application data concept object is related to a Thing object
- A thing object is related to zero or many ThingThing objects
- A ThingThing object is related to an additional data concept

To explain the considerations above, it is possible to create a SQL to extract all additional concepts for the application data concept (ID=20005).

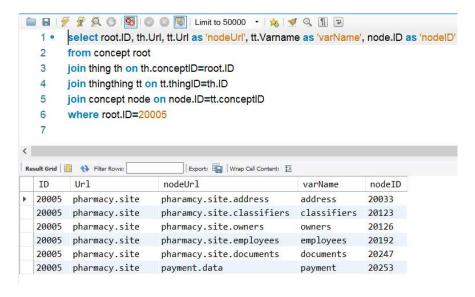


Figure 29. Additional concepts to the application data

The additional data should be configured separately. An additional data should be configured only using data components. Example is "pharmacy.site.classifiers". This additional data form consists of three dictionaries.

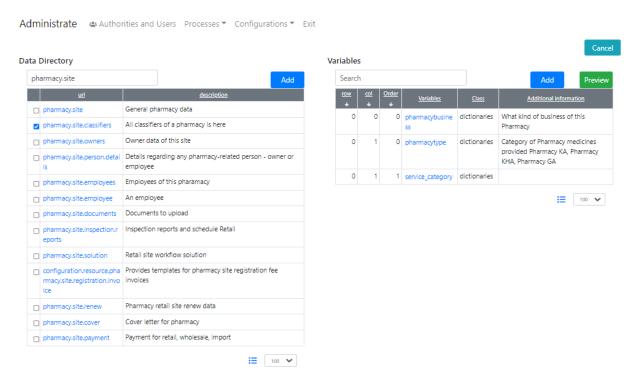


Figure 30. Additional data configuration

### **Q**UIZ

- 1) Is it possible that the application data fits in one on-screen form?
- 2) The application data consists of the application data and sixteen additional data forms.
  - a) Is it possible technically?
    - i) Yes
    - ii) No
  - b) Is it acceptable?
    - i) Yes
    - ii) No
- 3) Who is solely responsible for application data configuration?
  - a) Supervisor
  - b) Moderator
  - c) Programmer
  - d) Business User
- 4) Can I use the same "pharmacy.site.employees" additional data configuration for retail and wholesale pharmacies?
  - a) Yes
  - b) No

### **MODULE 8. MANAGE PERSONS AND INGREDIENTS**

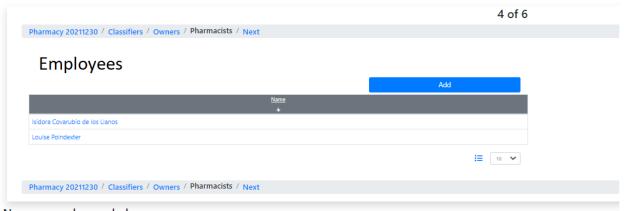
### **OBJECTIVE**

How to manage a list of persons or ingredients attached to an additional data

#### **SUMMARY**

The pre-defined data components "persons" and "ingredients" provide a list of persons or medicine ingredients. These components should be placed to the additional data. An example is a list of pharmacy employees (Figure 31).

#### New personal owned pharmacy



New personal owned pharmacy

Figure 31. The "persons" pred-defined data component in the user interface

The list above (Figure 31) is implemented by the "persons" data component included in the "pharmacy.site.employees" data configuration (Figure 32).

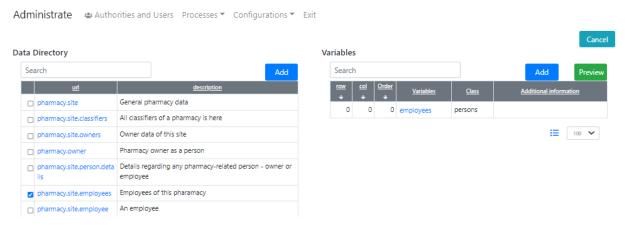


Figure 32. The pre-defined "persons" data component the additional data configuration

In its turn, this data configuration is the additional data configuration in the "pharmacy.site" application data (Figure 33).

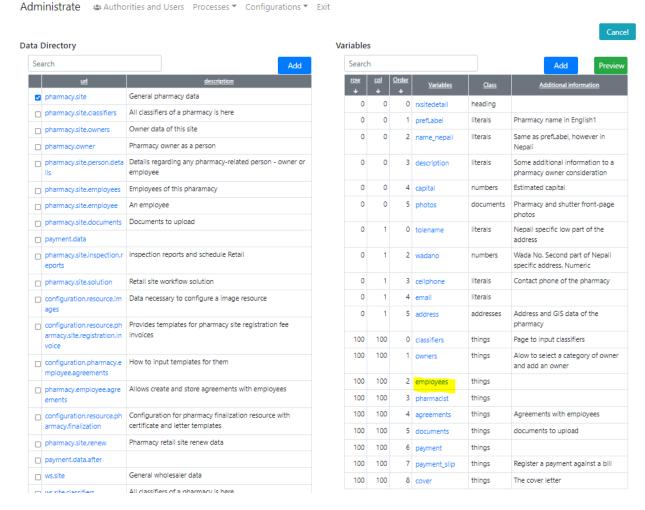


Figure 33. The list of persons is included as the additional data

The configuration parameter auxURL is required for the "persons" pred-defined data component. This parameter should be defined in the additional data "employees" of "pharmacy.site" configuration

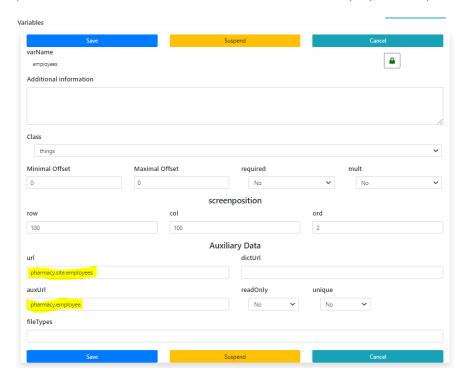


Figure 34. The auxUrl field points to the data configuration for an employee person – "pharmacy.employee"

The "pharmacy.employee" may include additional data.

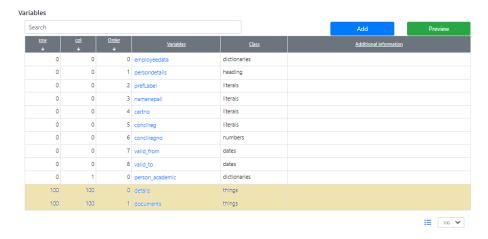


Figure 35. The additional data in "pharmacy.site.employee"

The auxURL parameter is to define the configuration and storage for one element of the list of employees (Figure 36, Figure 37).

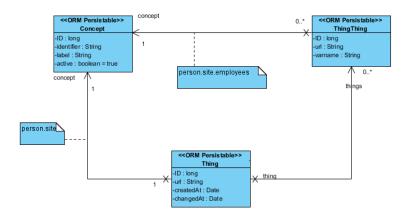


Figure 36. A concept "person.site.employees" is an additional data for application data "person.site"

A concept "person.site.employees" is linked to a concept "pharmacy.site.employee" using Thing Person.

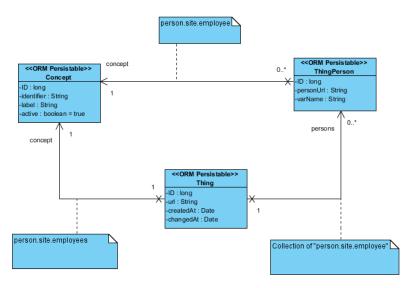


Figure 37. An application node "pharmacy.site.employees" is linked to zero or many nodes "pharmacy.site.employee"

To explain the considerations above, it is possible to create a SQL to extract all additional data concepts from "pharmacy.site.employee" linked to the "pharmacy.site.employees" concept with ID=20192 (Figure 36)

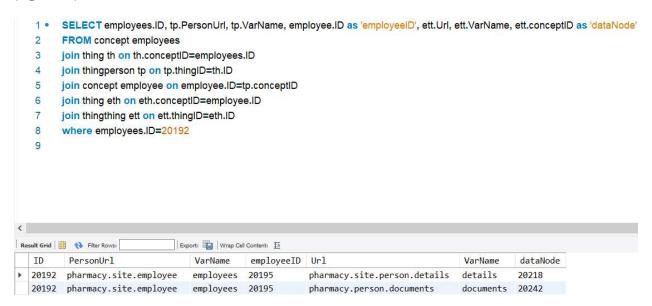


Figure 38. SQL to extract "pharmacy.site.employees" data

### Quiz

- 1) Is it possible to place a list of product manufacturers?
  - a) Yes
  - b) No
- 2) 7) Is it possible to place a text field to the on-screen form that contains the "persons" predefined data component?
  - a) Yes
  - b) No
- 3) Is it possible to use the pre-defined component "ingredients" in the additional data for medical devices?
  - a) Yes
  - b) No
- 4) A pre-defined component consists of User Interface and server-side API. Does the "persons" component API use the ThingPerson ORM class in the server-side codes?
  - a) Yes
  - b) No
- 5) Can SQL query on Figure 38 return data for all employees
  - a) Yes
  - b) No

### MODULE 9. THE WORKFLOW DATA

### **OBJECTIVE**

To study how to get data collected while application processing in NMRA.

#### **SUMMARY**

In addition to the application data defined by the applicant, the Pharmadex 2 collects applicationrelated data defined by NMRA experts. This data is a result of workflow activities execution, i.e., workflow data. Examples are:

- Certificates
- Register numbers
- Review, inspection, and laboratory reports
- Payment amounts
- Additional documents
- etc.

On the left side of Figure 39 is the workflow data

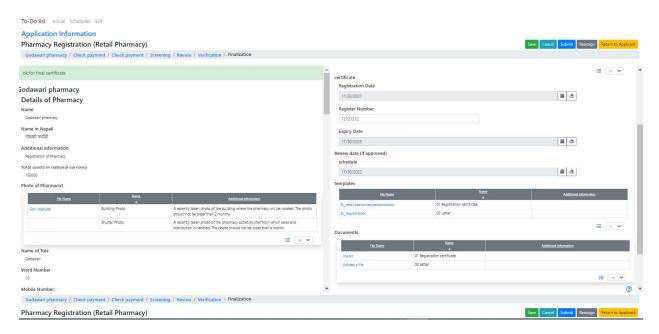


Figure 39. The workflow data in the User Interface

The workflow data and application data relation are implemented by the ORM object "History" (Figure 40)

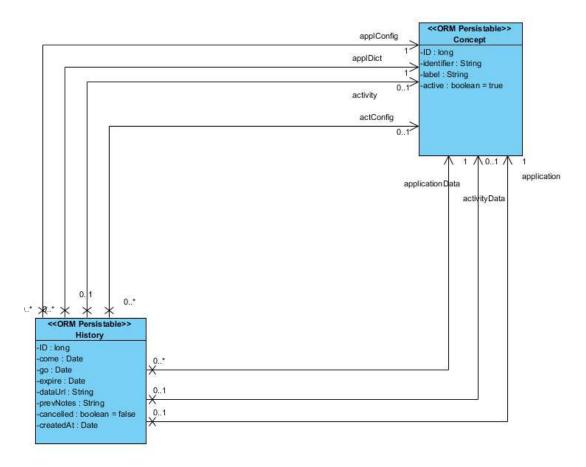


Figure 40. The History object is a hub for concepts

#### These relations are:

- applConfig a concept to manage a configuration of the workflow
- applDict a concept that belongs to dictionary item that keeps name and description of a workflow
- activity a concept to manage the activity of the workflow
- actConfig a concept to manage a configuration of the activity of the workflow.
- applicationData a concept to manage an application data
- activityData a concept to manage an activity data
- application a concept to manage the whole application

The Pharmadex 2 stores the workflow data the same way as the application data – under root URL and Owner concepts. Suppose the root URL is "pharmacy.site.renew" (Figure 41)

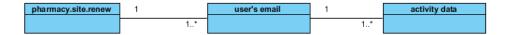


Figure 41. The workflow data is stored in the same structure as the application data

It is possible to use SQL to get all workflow data for application data with ID=20005 (Figure 42). Line 4 allows getting the root concept of the application data. The criteria "his.actConfigID is not null" allows selecting only workflow activities.

- SELECT his.applDataID as 'applDataID', actData.ID as 'activityDataID', actRoot.Identifier as 'actURL' 1 •
- 2 **FROM** history his
- 3 join concept actData on actData.ID=his.activityDataID
- 4 join closure clo on clo.childID=actData.ID and clo.Level=2
- 5 join concept actRoot on actRoot.ID=clo.parentID
- 6 where his.applDatalD=20005 and his.actConfigID is not null



Figure 42. Get all workflow data for application data ID=20005

### **Q**UIZ

- 1) Can be INN in the workflow data?
  - a) Yes
  - b) No
- 2) Line 4 in SQL in Figure 42 contains criteria "clo.Level=2". What will display in column actURL in case "clo.Level=1"?
  - a) error
  - b) owner's eMail
  - c) The ID of a concept
- 3) Line 6 contains the criteria "his.actConfigID is not null". What does it mean?
  - a) Some history records may not point to an activity of the workflow.
  - b) Some workflow activities haven't configurations

# MODULE 10. REPORTS, OR PUT IT ALL TOGETHER

### **OBJECTIVE**

The learning Pharmadex 2 basic report feature will help to get a diverse knowledge of how to query the data.

### **SUMMARY**

The basic report feature of Pharmadex 2 allows the reporting of medical products and medical sites. The medical products are medicines and medical devices. The medical sites are pharmacies, warehouses, manufactures, etc.

The reports look like Figure 43 and Figure 44



Figure 43. Medical products report

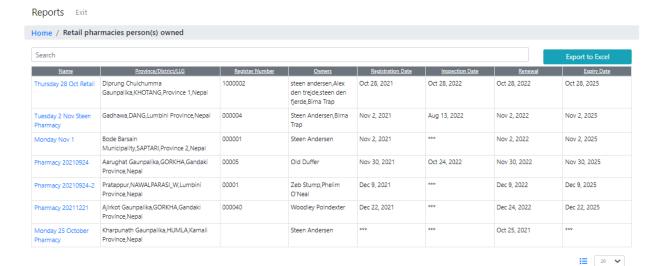


Figure 44. Medical sites report

The Supervisor should configure a report for any type of application. The report configuration feature is available in Administrate group of tasks

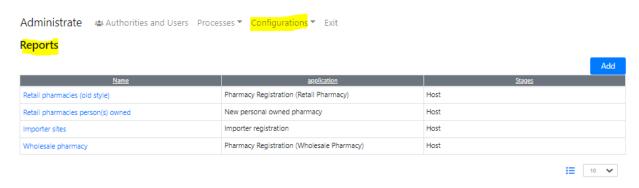


Figure 45. Reports configuration feature

All configurations are stored under the root URL "report. configuration". The description of this structure is for the Supervisor, thus beyond this course.

To query data for reports, Pharmadex 2 provides a set of stored procedures. These stored procedures are in the database "pdx2". The final reports will be produced by:

- report\_products
- report\_sites

The reports are uniform. This uniformity is backed by the tree data model and parameters of the stored procedures.

The Pharmadex 2 distinguishes product reports and the site reports by the "addressURL" parameter in the report configuration. The "addressURL" parameter is the site property.

The report\_products procedure requires parameters:

Parameter	Description	Value example
data_url	Root URL of application data	marketing.auth
state_url	Any application data in any given moment is in some workflow. This workflow may be either started or scheduled to start. The workflow implements a lifecycle stage of the application data. Workflows for the same stage are listed in the same dictionary. The URL of this dictionary is a state URL.	<ul> <li>The possible URLs are:</li> <li>"dictionary.guest.applications" – new not approved</li> <li>"dictionary.host.applications" – approved</li> <li>dictionary.shutdown.applications – canceled or discharged, however existing in the database</li> </ul>

Parameter	Description	Value example
applicant_url	URL under which applicant data has been	marketing.auth.applicant
	stored. The applicant data may be	
	configured by Supervisor. The text field	
	"prefLabel" is mandatory <sup>8</sup>	
register_url	URL under which the registration number	register.marketing.auth.cert
	has been stored. This URL is particular for	
	the application.	
	This URL can be found in the	
	appropriative workflow data	
	configuration	
lang	The language	en_US

### An example is below

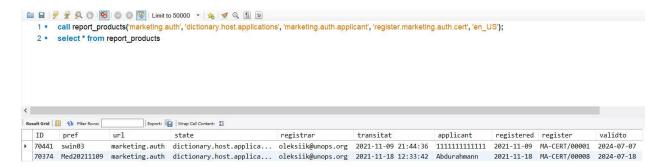


Figure 46. An example of report\_products call

<sup>&</sup>lt;sup>8</sup> The SKOS originated requirement. See https://www.w3.org/2012/09/odrl/semantic/draft/doco/skos\_prefLabel.html

The report\_sites procedure requires parameters:

Parameter	Description	Value example
site_url	Root URL of application data	pharmacy.site
dict_stage_url	Any application data in any given moment is in some workflow. This workflow may be either started or scheduled to start. The workflow implements a lifecycle stage of the application data. Workflows for the same stage are listed in the same dictionary. The URL of this dictionary is a state URL.	The possible URLs are:      "dictionary.guest.applications" –     new not approved      "dictionary.host.applications" –     approved      "dictionary.shutdown.applications" –     canceled or discharged, however     existing in the database
addr_url	The URL under which the address of a site is stored. Can be found in the data configuration.	pharamcy.site.address
owner_url	The URL under which owners of the site are stored. Can be found in the data configuration.	pharmacy.site.owners
appl_inspection_url	The URL under which the site inspection schedule is stored. This URL can be found in the appropriative workflow data configuration	application.pharmacy.inspection
appl_renew_url	The URL under which the site renewal schedule is stored. This URL can be found in the appropriative workflow data configuration	application.pharmacy.renew
appl_cert_url	The URL under which the site certificate register is stored. This URL can be found in the appropriative workflow data configuration	pharmacy.site.certificate
lang	The language	en_US

#### An example is below:

49110 Steen Another Phar...

58525 Kumar Pharmacy

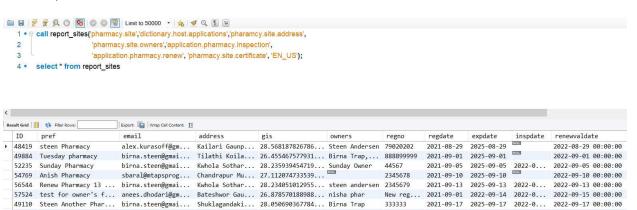
36100 RedHill Pharmacy

36665 Bhishma Pharmacy 38824 Swin and Pharmacy

59525 Birnas Pharmacy

45478 Kathmandu Pharmacy

62762 Sharad Pharmacy



333333

333334

333335

123456

332131231

1234567

2021-09-17

2021-09-18 2025-09-18

2021-09-19 2025-09-19

2021-09-19 2025-09-19

2021-09-21 2025-09-21 2022-1...

2022-09-17 00:00:00

2022-09-18 00:00:00

2022-09-19 00:00:00

2022-09-21 00:00:00

2021-09-17 2025-09-17 2022-0... 2022-09-17 00:00:00

2021-09-19 2025-09-19 2022-0... 2022-09-19 00:00:00

2021-10-06 2025-10-06 2022-1... 2022-10-06 00:00:00

*Figure 47. An example of report\_sites call* 

birna.steen@gmai...

The stored procedures report products and report sites call others stored procedures and finally compose the result. These procedures are a good starting point to study the Pharmadex 2 data querying.

Shuklagandaki... 28.050690367784... Birna Trap

birna.steen@gmai... Lalitpur Metr... 27.680501946851... Birna Trap,...

sbaral@mtapsprog... Bhaktapur Mun... 27.677162576810... Samrat Baral

oleksiik@unops.org Dangisharan,D... 28.096452490677... Alexey Kura...

adhodari-consult... Chandrapur Mu... 27.112562070752... Anish Dhodari

birna.trap@gmail... Lalitpur Metr... 27.680516788236... Birna Trap

deepabajracharya... Kirtipur Muni... 27.682055995187... bhisma

sharad2044@gmail... Tokha Municip... 27.744887543571... Akash

### **Q**UIZ

- 1) Is it mandatory to follow SKOS "prefLabel" recommendations to configure any application data?
  - a) Yes
  - b) No
- 2) Is it possible to get a list of all sorts of product applications using the "report\_products" procedure?
  - a) Yes
  - b) No
- 3) Is it possible to create a uniform data query for all sorts of medical sites using the "report\_sites" procedure?
  - a) Yes
  - b) No
- 4) May I change the existing stored procedures?
  - a) Yes
  - b) No

## **ANNEX I. SQL CODES**

### FIGURE 18. DATA CONFIGURATION SELECTION USE PLAIN SQL SELECT

select ct.\*
from concept root
join closure clo on clo.parentID=root.ID
join concept ct on ct.ID=clo.childID
where root.ID=17513 and ct.Active

### FIGURE 19. SELECT DATA CONFIGURATION USING SQL

select assm.`Row`, assm.Col, conf.Identifier, assm.clazz from assembly assm join (
select ct.\*
from concept root
join closure clo on clo.parentID=root.ID
join concept ct on ct.ID=clo.childID
where root.ID=17513 and ct.Active
) conf on conf.ID=assm.conceptID
order by assm.`Row

### FIGURE 13. SELECT A VALUE OF PREFLABEL IN EN US

An original query:

select root.ID, var.Identifier as 'varName', pref.Identifier as 'language',pref.Label as 'prefLabel' from concept root join closure clo on clo.parentID=root.ID and clo.Level=1 join concept lit on lit.ID=clo.childID and lit.Identifier='\_LITERALS\_' join closure clo1 on clo1.parentID=lit.ID and clo1.Level=1 join concept var on var.ID=clo1.childID and var.Identifier='prefLabel' join closure clo2 on clo2.parentID=var.ID and clo2.Level=1 join concept pref on pref.ID=clo2.childID and pref.Identifier='EN\_US' where root.ID=20005

The simplest version of it:

select root.ID, var.Identifier as 'varName', pref.Identifier as 'language',pref.Label as 'prefLabel' from concept root join closure clo1 on clo1.parentID=root.ID and clo1.Level=2 join concept var on var.ID=clo1.childID and var.Identifier='prefLabel' join closure clo2 on clo2.parentID=var.ID and clo2.Level=1 join concept pref on pref.ID=clo2.childID and pref.Identifier='EN\_US' where root.ID=20005

#### FIGURE 21. SEARCH BY THE NAME

SELECT

\* FROM concept

### FIGURE 26. UPLOADED FILE IN THE APPLICATION DATA. SQL

select th.conceptID, th.Url, td.DictUrl, td.VarName, dconc.ID as 'dictNodeID', fconc.Label as 'fileName', fr.FileSize, fr.Mediatype from thing th join thingdoc td on td.thingID=th.ID

join concept fconc on fconc.ID=td.conceptID join concept dconc on dconc.ID=td.dictNodeID

join fileresource fr on fr.conceptID=fconc.ID

where th.conceptID=20005

### FIGURE 29. ADDITIONAL CONCEPTS TO THE APPLICATION DATA

select root.ID, th.Url, tt.Url as 'nodeUrl', tt.Varname as 'varName', node.ID as 'nodeID' from concept root join thing th on th.conceptID=root.ID join thingthing tt on tt.thingID=th.ID join concept node on node.ID=tt.conceptID where root.ID=20005

### FIGURE 38. SQL TO EXTRACT "PHARMACY.SITE.EMPLOYEES" DATA

SELECT employees.ID, tp.PersonUrl, tp.VarName, employee.ID as 'employeeID', ett.Url, ett.VarName, ett.conceptID as 'dataNode' FROM concept employees join thing th on th.conceptID=employees.ID join thingperson tp on tp.thingID=th.ID join concept employee on employee.ID=tp.conceptID join thing eth on eth.conceptID=employee.ID join thingthing ett on ett.thingID=eth.ID where employees.ID=20192

### FIGURE 42. GET ALL WORKFLOW DATA FOR APPLICATION DATA ID=20005

SELECT his.applDataID as 'applDataID', actData.ID as 'activityDataID', actRoot.Identifier as 'actURL'

FROM history his

join concept actData on actData.ID=his.activityDataID

join closure clo on clo.childID=actData.ID and clo.Level=2

join concept actRoot on actRoot.ID=clo.parentID

where his.applDataID=20005 and his.actConfigID is not null

## **ANNEX 2. QUIZ ANSWERS**

#### MODULE I

- 1) The Pharmadex 2 software codes are open. What is the recommended way to adapt it to the needs of the particular NMRA?
  - a) Re-programming some source codes
  - b) Configuring Pharmadex 2. This answer is right, however only on the first stage of implementation.
  - c) Configuring Pharmadex 2 and building particular APIs if it will be necessary. This answer is the most appropriate.
- 2) A dictionary in Pharmadex 2 is a data element represented as a graph of any reasonable depth. Which point of view is it?
  - a) Data usage. The "graph" and "depth of graph" are from the logical model. For API development it is Concepts and Closures.
  - b) API development
- 3) I'm a .NET programmer. How can I use project "pdxmodel"?
  - a) As a software library
  - b) For reference only
- 4) Is it possible to use Pharmadex 2 software API directly from the PHP application?
  - a) Yes. Like any other JSON REST API
  - b) No
- 5) We plan to implement a Microsoft Azure data warehouse. What is the best way to access Pharmadex 2 data from ETL (Extract, Transform, and Load) process?
  - a) The usage of API calls to Pharmadex 2
  - b) The usage of SQL queries, views, and stored procedures. It is the most appropriate approach.
  - c) The development of special APIs

### MODULE 2

- 1) The HL7 MedicinalProduct tree should be considered as a draft. Is it possible to use it in Pharmadex 2?
  - a) No, it is impossible, because Pharmadex 2 should strictly obey the current HL7
  - b) Yes, it is possible, because it is recommended to use the HL7 approach in case the HL7 standard is not available yet. The EMA thinks the same way.
- 2) Administrative feature "Resources" shows URLs. However, it is impossible to find these URLs in the view "tree\_root". What do you think why?
  - a) These URLs are branches in some other trees. It is the right answer. Any concept is in a tree.
  - b) These URLs do not belong to any tree

#### MODULE 3

- 1) Why the field "Level" in the "closure" table is useful?
  - a) This field is excess
  - b) This field allows avoiding recursive SQL. This answer is the most appropriate.
  - c) This field allows getting a root of a tree from any branch or leaf in a simple SQL query. This answer is also right

- 2) Is it possible to use only the "tree\_root" view to explore a tree?
  - a) Yes
  - b) No. This view shows only the roots of the trees.
- 3) Is it possible to explore a tree from a leaf?
  - a) Yes. The print\_tree procedure allows it.
  - b) No

#### MODULE 4

- 1) Suppose, that in some country is in use Gregorian and traditional calendar. Is it possible to keep dates separately?
  - a) Yes. Theoretically, it is possible, however, the current input control does not allow any traditional calendar.
  - b) No
- 2) Why does Pharmadex 2 use a concept with identifier \_LITERALS\_?
  - a) It is the useless concept
  - b) To distinct common use variables from others. Right answer. The \_LITERALS\_ creates a separate branch in a tree for the common use variables only.
  - c) To improve the performance of SQL queries

#### MODULE 5

- 1) Who is responsible for application data configuration?
  - a) Supervisor. Right answer. It is strongly unrecommended to re-programming the Pharmadex 2.
  - b) Programmer
  - c) Both
- 2) Which table are not in use for data configuration?
  - a) concept
  - b) closure
  - c) activity
  - d) assembly
- 3) Does the "clazz" column is available for a supervisor?
  - a) Yes. It can be found in the user interface for the Supervisor
  - b) No

#### MODULE 6

- 1) The ThingDoc object relates to concept dictNode. It is a concept of a dictionary item. Why do we need this reference?
  - a) To provide a user a guide on which file should be uploadeRight answer. It is a common way how the file uploader works.
  - b) To check file name against a dictionary item
  - c) To attach the file to the dictionary
- 2) The query listed in Figure 26 returns more than one record. Is it possible?
  - a) Yes. It is possible if the file uploader will ask to upload more than one file or there are many file uploaders.
  - b) No
- 3) The query from Figure 26 returns zero records. Is it possible?
  - a) Yes. The file uploader is not defined in the configuration.

b) No

#### Module 7

- 1) Is it possible that the application data fits in on-screen form?
  - a) Yes. It should be a simple application
  - b) No
- 2) The application data consists of the application data and sixteen additional data forms.
  - a) Is it possible technically?
    - i) Yes. Right answer. There is no limit for the additional data
    - ii) No
  - b) Is it acceptable?
    - i) Yes
    - ii) No. Right answer. Seventeen forms to fill out are completely unacceptable for a business user.
- 3) Who is solely responsible for application data configuration?
  - a) Supervisor.
  - b) Moderator
  - c) Programmer
  - d) Business User
- 4) Can I use the same "pharmacy.site.employees" additional data configuration for retail and wholesale pharmacies?
  - a) Yes. It is a right answer
  - b) No

#### MODULE 8

- 1) Is it possible to place a list of product manufacturers?

  - b) No. There is no pre-defined data component for this.
- 2) Is it possible to place a text field to the on-screen form that contains the "persons" pre-defined data component?
  - a) Yes. There is any restriction to place any other pre-defined data component along with the "persons"
  - b) No
- 3) Is it possible to use the pre-defined component "ingredients" in the additional data for medical devices?
  - a) Yes. There is no restriction where to place "ingredients" and "persons"
  - b) No
- 4) A pre-defined component consists of User Interface and server-side API. Does the "persons" component API use the ThingPerson ORM class in the server-side codes?
  - a) Yes. It should make operation with this class.
  - b) No
- 5) Can SQL query on Figure 38 return data for all employees
  - a) Yes. This query is for this.
  - b) No

#### MODULE 9

1) Can be INN in workflow data?

- a) Yes
- b) No. It is hard to imagine that an NMRA user will input INN instead of a business user.
- 2) Line 4 in SQL in Figure 42 contains criteria "clo.Level=2". What will display in column actURL in case "clo.Level=1"?
  - a) Error
  - b) Owner's eMail. Please, see it in Figure 41
  - c) The ID of a concept
- 3) Line 6 contains the criteria "his.actConfigID is not null". What does it mean?
  - a) Some history records may not point to an activity of the workflow.
  - b) Some activities have no configurations. Yes, it is possible. The null value is allowable for this field, see Figure 40

### MODULE 10

- 1) Is it mandatory to follow SKOS "prefLabel" recommendations to configure any application data?
  - a) Yes. It is presumed in the reports stored procedures. Additionally, it will be a good idea to get a uniform data source for the title of the application.
  - b) No
- 2) Is it possible to get a list of all sorts of product applications using the report\_products procedure?
  - a) Yes
  - b) No. The "report\_products" procedure allows only one application data URL parameter.
- 3) Is it possible to create a uniform data query for all sorts of medical sites using the "report sites" procedure?
  - a) Yes
  - b) No. The "report\_sites" procedure allows only one application data URL parameter.
- 4) May I change the existing stored procedures?
  - a) Yes
  - b) No. These procedures are used internally by Pharmadex 2. Create a copy with another name instead.