FHIR Data Exchange of Pharmaceutical Quality Data (DX-PQ):

Plan for Testing Event #2

Day 1 – Technical Track

2023-08-10

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# Disclaimer

All testing information should be considered public. No proprietary or confidential information will be shared or exchanged.

# Objectives

The objectives for Testing Event #2 are:

1. Demonstrate and gain hands-on experience with the interactions for PQ data on a FHIR server (submit, edit, validate and display data)
2. Explore two scenarios:
   1. Basic example – editing, adding and linking data, with MedicinalProductDefinition and PlanDefinition
      1. Search and get data
      2. Create and submit data
   2. Advanced – more detailed testing example, working with Observation data in DiagnosticReport (and will demonstrate Bundle)
      1. Search, get, update and submit Diagnostic Report
      2. Validate the data
      3. Display the data

# What do we need from participants?

Before the Testing Event, we request that the participants please perform the following:

* Review the participant pack
* Download and install or set up required tooling (in advance, if possible) – suggested tools:
  + API client - submit data and interact with the FHIR server
    - Postman - <https://www.postman.com/> (download links for Windows, Mac, Linux)
  + XML and/or JSON editor(s) (need at least one) – create and edit FHIR resource data
    - Visual Studio Code – <https://code.visualstudio.com/download>
    - Oxygen (free trial) –<https://www.oxygenxml.com/xml_editor/download_oxygenxml_editor.html>
    - (and/or other editors of choice)
  + Additional tooling that may be suggested/recommended (prior to or during the session)

On the day of the Testing Event (Day 1):

* Be prepared to use the sample data (to be provided) and tooling to interact with the FHIR server (view, create, submit and retrieve data).

# Short Description

This testing event is the second of an anticipated ongoing series to test creation, exchange and display of structured pharmaceutical quality data using the FHIR standard. These testing events will be private (i.e., limited to Accumulus members or those invited to attend) or public (e.g., open events hosted by the DX-PQ team or Connectathons hosted by HL7). This testing event is private, limited to representatives from Accumulus sponsor companies.

Each testing phase is intended to include increased scope of PQ data and increasingly complex scenarios.

# Event Details

## [Accumulus] FHIR Testing Event - Technical Track Date and Agenda

Date & Time: The Technical Track of the FHIR Testing Event (Day 1) will take place on

**August 10, 2023, from 0900 to 1200 EDT.**

|  |
| --- |
| **Technical Track Agenda** |
| 1. Introduction and Objectives (10 min) 2. Overview and verify access to the FHIR server (5 min) 3. Demonstrations and hands-on interaction    1. Part 1 – Reading, viewing, submitting, and changing data (1 hr)    2. Brief intermission (10 min)    3. Part 2 – Adding and linking data, validating data, basic searching for data in the server (1 hr) 4. Takeaway points and questions (20 min) 5. Closing remarks (10 min) |

## Technical Track Telecom Details

**MS Teams Meeting:** Join on your computer, mobile app or room device

[Click here to join the meeting](https://teams.microsoft.com/l/meetup-join/19%3ameeting_MzMxMzkxZDktNjdmOS00Mjg4LWJjMDEtZWVlZmZlNTgxZDUx%40thread.v2/0?context=%7b%22Tid%22%3a%225934dd1c-8d18-4de5-8696-4516a5707a57%22%2c%22Oid%22%3a%2240971fff-c5b6-45e4-a08e-a86dd511fa08%22%7d)

Meeting ID: 229 132 591 242   
Passcode: nQRunK

[Download Teams](https://www.microsoft.com/en-us/microsoft-teams/download-app) | [Join on the web](https://www.microsoft.com/microsoft-teams/join-a-meeting)

Or call in (audio only)

[+1 208-996-1659,,638310547#](tel:+12089961659,,638310547) United States, Boise

Phone Conference ID: 638 310 547#

[Find a local number](https://dialin.teams.microsoft.com/fc6a185e-29a9-405b-a922-7c155f9df637?id=638310547) | [Reset PIN](https://dialin.teams.microsoft.com/usp/pstnconferencing)

[Learn More](https://aka.ms/JoinTeamsMeeting) | [Meeting options](https://teams.microsoft.com/meetingOptions/?organizerId=40971fff-c5b6-45e4-a08e-a86dd511fa08&tenantId=5934dd1c-8d18-4de5-8696-4516a5707a57&threadId=19_meeting_MzMxMzkxZDktNjdmOS00Mjg4LWJjMDEtZWVlZmZlNTgxZDUx@thread.v2&messageId=0&language=en-US)

# Scope

## In-Scope for this event

PQ domains are in-scope for this testing event

* **Process Validation** (primary focus)
* Stability
* Specification
* Manufacturing Process

## Out of Scope for this event

Infrastructure (setup of FHIR servers and APIs). FHIR server and APIs will be provided.

Wave 3 PQ domains are out of scope for this event, but are expected to be tested in the fall event:

* DS/DP Characterization
* Batch Formula
* DP Composition
* Compatibility
* Reference Standards

# Participants

* Accumulus member companies
* Accumulus
* Lantana

# Recommended Background/Skill Requirements for Participants

The testing event will have content that caters to those with the following backgrounds:

* Technical subject matter expert (XML, APIs)
* FHIR subject matter expert (nice to have)
* PQ subject matter expert (nice to have)

# Testing Event Leads

Accumulus DataX Core Team: Rita Algorri (Amgen), Sheetal Gaiki (Janssen), Colin Wood (AstraZeneca), Mike Abernathy (Amgen), Craig Anderson (Pfizer)

Lantana Consulting: Rik Smithies, Rob Hausam, Ola Fakorede, Kit Cooper

# Technical Details

## **FHIR Version**

FHIR Release 5.0.0

## **Specification**

Link to the draft DX-PQ FHIR Implementation Guide: <https://build.fhir.org/ig/HL7/uv-dx-pq/>

## Testing Environment

A FHIR server will be accessible for use during the testing event. Please note that the server is for testing only and anything exchanged over the server is public. No log-in will be required. Keep in mind that content will be loaded into the server closer to the Testing Event, but we ask that participants please check that they have access to the server.

To access the server, use either of the following links:

* <https://dx-pq.lantanagroup.com/> (server base)
* <https://dx-pq.lantanagroup.com/fhir> (server base FHIR endpoint)
* <https://dx-pq.lantanagroup.com/fhir/metadata> (server capability statement endpoint)

## **Artifacts (i.e., Sample data)**

The artifacts for this testing event will be located in the HL7 GitHub repository for the [dx-PQ](https://github.com/HL7/uv-dx-pq) FHIR Implementation Guide (IG) at this [link](https://github.com/HL7/uv-dx-pq/tree/master/additional_data/testing_event_2023-08-10). This folder includes the participant pack (with a copy of this document) and any additional documentation and resources for the testing event, including a set of sample data that is available for use. [The MS Word files have been set to Read Only for the purpose of this event.]

If your team is not able to access this data, please email Rita Algorri ([malgorri@amgen.com](mailto:malgorri@amgen.com)).

Profiles for the in-scope PQ domains are located under the Artifacts Index page of the [dx-PQ](https://build.fhir.org/ig/HL7/uv-dx-pq/artifacts.html) IG.

### **Testing Details**

Sample FHIR data examples will be provided for the PQ domains in scope under the testing scenarios. Each testing step will consist of an initial demonstration, followed by an opportunity for individual hands-on experience and exploration of the topic:

1. Create
2. Upload
3. Searc
4. Add/update
5. Verify

# PQ Test Scenario #1: Basic – Adding, editing, and linking data around MedicinalProductDefinition and PlanDefinition

## Goal:

* Demonstrate data exchange for selected resources using FHIR – focusing on MedicinalProductDefinition and PlanDefinition and associated linked resources.

## Scenario:

* Search for a MedicinalProductDefinition or PlanDefinition resource on the server (if necessary, you may submit an example resource first).
* In this search (or additional searches) return linked Observation, Organization and other associated resources.
* Display the returned resources. Display and explore (navigate) linkages between the resources.
* Create one or more new Observation and Organization resource instances and submit (POST) them to the server.
* Link the newly created resources to the previously existing MedicinalProductDefinition or PlanDefinition resource(s) and display/navigate the new links.

## Scope of Testing:

* Demonstrate effective data exchange (data components, formats, standardization) for this subset of the PQ Domain Scope
* Operational aspects are out of scope (e.g., who generates the data, when is data generated, etc.)

## Detailed PQ Domain Scope:

1. Product info: name, other identifiers, strength, dosage form
2. Batch info: #, mfg date, packaging, (can be multiple batches in a single stability study)
3. Specifications- identifier (country/region), list of tests to be conducted, reference to test methods, and acceptance criteria
4. Stability study design: storage conditions (temperature, humidity, light, chemical exposure, etc.) and time points
5. Stability study info: protocol #/ identifier, start date
6. Results: individual results, Pass/Fail against acceptance criteria
7. Overall study conclusion
8. Proposed shelf life- storage condition and duration allowed (can be based on conclusions from multiple stability studies)

## Steps:

* Each step (as outlined in the above scenario in 11.2) will consist of:
  + An initial demonstration of the step by the DX-PQ team.
  + Assistance by the DX-PQ team for the participants to complete the step, using the provided example data (or additionally their own data or modified example data, if they so choose).

# PQ Test Scenario #2: Advanced – Testing Observation examples around Diagnostic Report plus Bundle (demonstration)

## Goal:

* Demonstrate data exchange for selected resources using FHIR – focusing on DiagnosticReport and associated Observation resources and resource Bundle instances.

## Scenario:

* Search for a DiagnosticReport resource on the server (if necessary, you may submit an example data containing a DiagnosticReport resource first).
* In this search (or additional searches) return linked resources.
* Display the returned resources and links.
* Update one or more data elements in the DiagnosticReport resource and re-submit (POST) it to the server.
* Display the updated resource and verify that the expected updates were successfully made.
* Update and submit (POST) one or more Observation or Organization resource instances and verify that the expected updates were successfully made.
* Optional – Create and link one or more new resources to the previously existing DiagnosticReport and display the new data.
* Validate the resources modified and created above based on the corresponding [dx-PQ](file:///Users/rhausam/Library/CloudStorage/GoogleDrive-rob@hausamconsulting.com/My%20Drive/Clients/Lantana/Accumulus-IG-Development/test%20event%202/Bundle%20–%20Drug%20Product%20Stability%20dx-PQ) IG profiles.
* Will demonstrate Bundle example(s) (pre-assembled) containing DiagnosticReport and associated resources conforming to the [Bundle – Drug Substance Stability dx-PQ](https://build.fhir.org/ig/HL7/uv-dx-pq/StructureDefinition-Bundle-drug-substance-stability-dxpq.html) or [Bundle – Drug Product Stability dx-PQ](https://build.fhir.org/ig/HL7/uv-dx-pq/StructureDefinition-Bundle-drug-product-stability-dxpq.html) profiles.

## Scope of Testing:

* Demonstrate effective data exchange (data components, formats, standardization) for this subset of the PQ Domain Scope
* Operational aspects are out of scope (e.g., who generates the data, when is data generated, etc.)

## Detailed PQ Domain Scope:

1. Product info: name, other identifiers, strength, dosage form
2. Batch info: #, mfg date, packaging, (can be multiple batches in a single stability study)
3. Specifications- identifier (country/region), list of tests to be conducted, reference to test methods, and acceptance criteria
4. Stability study design: storage conditions (temperature, humidity, light, chemical exposure, etc.) and time points
5. Stability study info: protocol #/ identifier, start date
6. Results: individual results, Pass/Fail against acceptance criteria
7. Overall study conclusion
8. Proposed shelf life- storage condition and duration allowed (can be based on conclusions from multiple stability studies)

## Steps:

* Each step (as outlined in the above scenario in 12.2) will consist of:
  + An initial demonstration of the step by the DX-PQ team.
  + Assistance by the DX-PQ team for the participants to complete the step, using the provided example data (or additionally their own data or modified example data, if they so choose).