

# Top level Specification

Version 1.2, 12 December 2018, Lemoene, Apostolos

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## 1. Purpose of this document

This document establishes a top level understanding in layman language of how the Froid Middleware must meet sponsor requirements.

### 1.1 Document Convention

*Most importantly, unless specified differently:*

*LIMS = LIS The latter refers an earlier term used for clinical Patient centric LIMS*

*CSV - References all text based file exchanges with Instruments, albeit CSV TSV, XLS, XML*

*ASTM - All Ethernet communications on any of the ASTM protocols. Some instruments may require serial to Ethernet converters*

[Glossary of Terms](#)

## 2 Open Source Instrument Middleware

Open Instrument Middleware<sup>1</sup> is a long cherished goal of Open Source LIMS communities, to coordinate sporadic integration efforts e.g. in [DANT Teaching Hospital's HMIS](#) and [OpenLabConnect](#)<sup>2</sup>, into an

### Open vendor neutral Instrument Server

Interfacing all lab devices and systems

and doing so holistically, in the spirit of Ubuntu, ensuring Froid reaches those who need it most.

Froid welcomes new participants to the journey.

Since the first Froid modules will serve as blueprint for instruments to follow, the code be provided with sufficient technical and user documentation and included in the code repositories.

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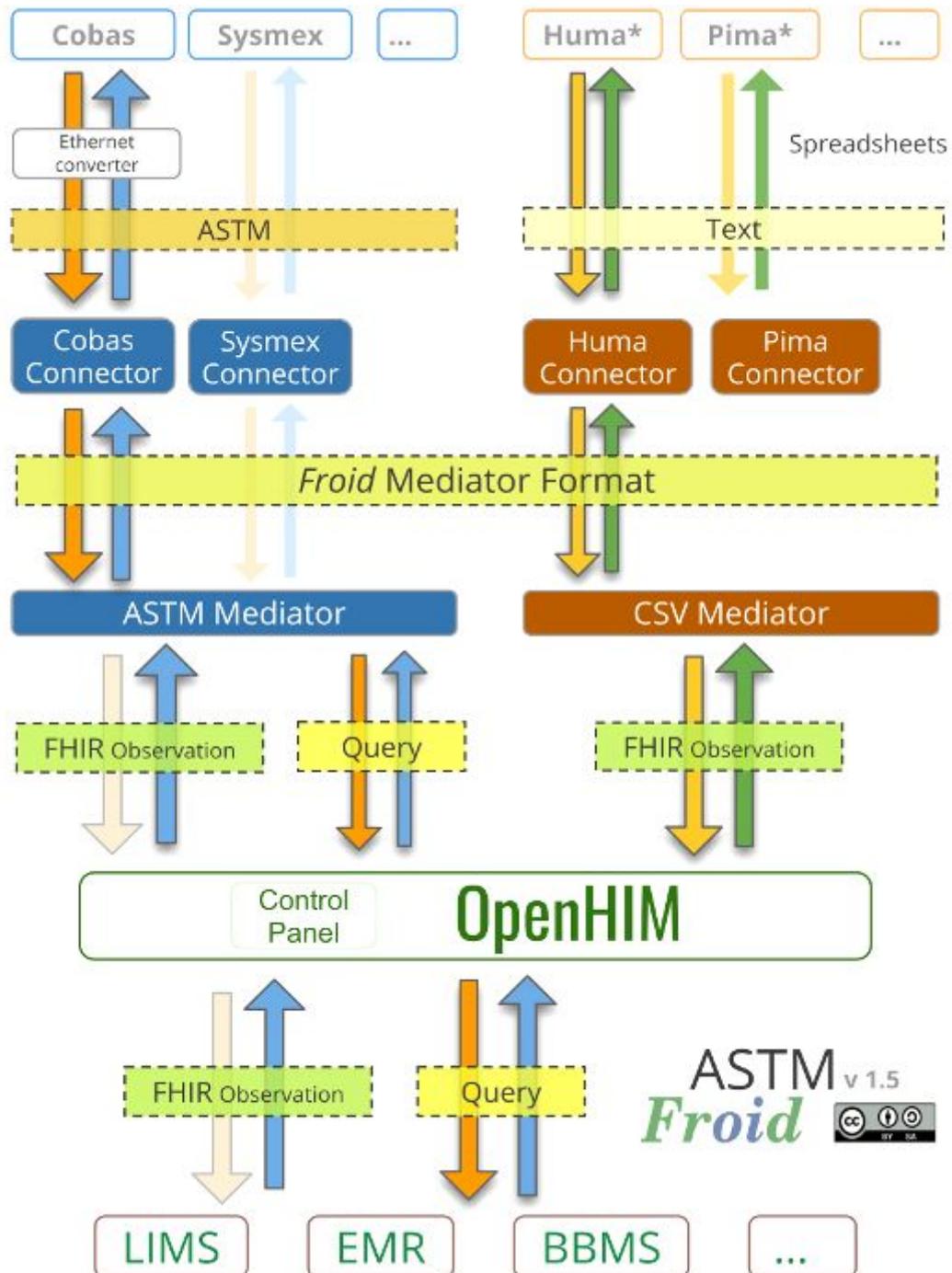
<sup>1</sup> <https://www.bikalims.org/news/bika-in-the-2015-google-summer-of-code#froid>

<sup>2</sup> <https://www.bikalims.org/blog/1st-openlabconnect-release-open-source-instrument-middle-ware>

### 3 Overview

#### 3.1 OpenHIM

Robust and scalable [OpenHIM<sup>3</sup>](http://openhim.org/) offers secure [HL7 FHIR®](#) message routing to web service APIs, via REST interface architecture widely accepted by LIMS and EMR, and is utilised in Froid without having to redevelop and validate these functions to the standards required in health care.



<sup>3</sup> <http://openhim.org/>

Through its control panel, OpenHIM visualises request logs and provides ongoing metrics of data passing through.

Applications using OpenHIM are open to other participating projects, epidemiology, patient and caregiver registries, HIS, image servers and mobile platforms.

[OpenHIM Features](#)<sup>4</sup>. Backed by a big team at [Jembi](#)<sup>5</sup>, Cape Town.

OpenHIM configuration required for Froid, tech and user manuals are to be part of the Froid repositories.

### 3.2 Middleware. Froid

The Middleware converts all communications between Instruments and downstream systems to HL7 FHIR® format, using OpenHIM as interoperability layer.

It does so in an *Instrument Connector* per format, addressing serial instruments in ASTM.

The Connectors pass results data in Froid's uniform instrument format to a *Mediator* per ASTM and CSV data stream, converting the results to HL7 FHIR before posting it to the instrument's channel in OpenHIM.

In communications from the LIMS to the Instrument, its FHIR post is routed through OpenHIM to the ASTM and CSV Mediators for unpacking, conversion to instrument format and passed to the Instrument's Connector. The Connector converts the data to ASTM before feeding the Instrument.

### 3.3 LIMS

Some instruments may run in *Results only* mode, but often the lab analyst kicks the procedure off in the LIMS by compiling a worksheet of Samples to be analysed on the instrument and then exports it to the Instrument.

Instruments often follow this up with real-time requests for more information.

The LIMS finally receives analysis results returned from the Instrument in FHIR format, unpacks it to the LIMS DB and injects the results in its standard QC and verification/retraction workflow.

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<sup>4</sup> <http://openhim.org/#features>

<sup>5</sup> <https://www.jembi.org/>

The LIMS also interprets confirmation and error messages from OpenHim, and presents it to authorised LIMS users.

## 4 Use Cases

A list here only.

### 4.1 Instrument barcode scanning

This would be an option for instruments where only results export to LIMS is available as direct interface.

Some instruments are capable of scanning barcodes on containers, alternatively analysts can do so hands free per mounted auto-reading scanner, swiping samples while loading the instrument.

### 4.2 Analysis Requests from LIMS

The Analyst compiles a Worksheet in the LIMS for the Samples to be analysed, and then exports it to the Instrument.

### 4.3 Results export to LIMS

When results become available on the instrument and the analyst confirms, they are transmitted to the LIMS.

### 4.4 Duplicate results

For retesting, or in error, results transmitted to the LIMS for Samples that already have results in the LIMS, are handled in the LIMS and does not impact Froid.

Depending on the LIMS:

For results captured and verified earlier

the LIMS may report and not complete the import, or

assume it to be a secondary request on the same Sample and create a new Analysis Request for it

If the earlier results have not been verified, it can be

overwritten or

retracted and recorded as retests, carrying both results

### 4.5 LIMS Instrument Panel

OpenHIM already includes a control panel<sup>6</sup> where users can track progress and be alerted to issues, and rerun imports. For analyst users contained to the LIMS, confirmations and alerts need to be facilitated in logs for the Instrument

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<sup>6</sup> <http://openhim.org/#features>

The screenshot shows the OpenHIM Admin Console interface. The top header includes the OpenHIM logo, 'Admin Console', and a user profile 'root@openhim.org'. The left sidebar contains a navigation menu with items: Dashboard, Transaction log, Audit log, Clients, Channels, Tasks, Visualizer, Contact Lists, Mediators, Users, Certificates, and Export/Import. The main content area is titled 'Transactions Log' and features a 'Filter Settings' section with 'List Settings' and 'Toggle Advanced Filters' options. The 'Basic Filters' section includes dropdowns for 'Status' (set to 'Don't filter'), 'Channel' (set to 'Don't filter'), 'Date Range' (with 'to' input), and 'Limit' (set to '10'). A 'Clear Filters' button is located in the bottom right of the filter area. Below the filters are two buttons: 'Re-run Selected Transactions' and 'Re-run all transaction that match current filters'. A table below displays transaction data with columns: #, HTTP Method, Host, Port, Path, Request Params, Channel, Status, and Request Time. The table contains 10 rows of data, with the first row showing a 'Processing' status and the remaining 9 rows showing 'Successful' status.

#	HTTP Method	Host	Port	Path	Request Params	Channel	Status	Request Time
-	POST	localhost	5001	/queue		queue	Processing	2015-10-09 15:55:04 +0200
1	POST	localhost	5001	/queue		queue	Successful	2015-10-09 15:54:04 +0200
2	POST	localhost	5001	/queue		queue	Successful	2015-10-09 15:54:03 +0200
3	POST	localhost	5001	/queue		queue	Successful	2015-10-09 15:54:02 +0200
4	POST	localhost	5001	/queue		queue	Successful	2015-10-09 15:54:02 +0200
5	POST	localhost	5001	/queue		queue	Successful	2015-10-09 15:53:26 +0200
6	POST	localhost	5001	/queue		queue	Successful	2015-10-09 15:53:24 +0200
7	POST	localhost	5001	/queue		queue	Successful	2015-10-09 15:53:23 +0200
8	POST	localhost	5001	/queue		queue	Successful	2015-10-09 15:53:23 +0200
9	POST	localhost	5001	/queue		queue	Successful	2015-10-09 15:49:29 +0200

*OpenHIM visualizes requests in its admin console as transmissions travel through the system as well as load and success rate metrics such*

## Glossary of Terms

Based on the [Bika Glossary of LIMS terms](#)<sup>7</sup>

### An. Analysis

These are the tests included on Analysis Requests ordered by clients, they are date-stamped copies of the Analysis Services configured in the LIMS set-up - they'll be completed with results, to be published to clients after verification

One Analysis, many Analyses

### AR - Analysis Request

The collection of Analyses or tests requested for a specific sample, an 'analyses order', the most important building block in Bika LIMS

<sup>7</sup> <https://www.bikalims.org/glossary/bika-open-source-lims-glossary>



## ASTM

ASTM's laboratory testing standards are instrumental in specifying the standard dimensions, design, and make of the various equipment and instruments used in the laboratory for scientific experiments and procedures. These standards help laboratories, manufacturers, and other users and producers of such apparatuses in ensuring good quality and workmanship. [ASTM.org](https://www.astm.org)<sup>8</sup>

## EHR/EMR

Electronic Health/Medical Records system, e.g. Meditech, Cerner and OpenMRS, GnuHealth, OpenEMR, Vista

## ERP

Enterprise Resource Planner, e.g. SAP or Open Source Odoo, Tryton

## FHIR®

Fast Healthcare Interoperability Resources. FHIR®, unlike older document-centric approaches, directly exposes data elements. For LIMS, Patients, their Samples and Analyses, can be retrieved and manipulated via their own URLs.

## HIS

Hospital Information Systems. Similar to EMR, but hospital specific

## HL7

Health Level 7. A specification for a health data interchange standard

## LIS

Traditionally, Patient centric LIMS for clinical labs only

## LIMS

Multidisciplinary Sample centric LIMS. Modern LIMS provides both Sample and Patient Centric perspectives in clinical settings

## WS. Worksheet

A collection of analyses grouped together to be executed at the same workstation, on the same instrument or by the same analyst. QC Samples are included on WSs for easy verification of Analyses in context

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<sup>8</sup> <https://www.astm.org/Standards/laboratory-testing-standards.html>