SPECIFICATIONS

EDITH transplant recipient registry

Abstract

Functional and technical specifications for the EDITH transplant recipient registry

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Specifications

EDITH transplant recipient registry

This document will describe all components used and how they are used for the EDITH deceased patient registry (https://edith-project.eu/). It is not intended to be a manual for use of any of these components, those will be provided when the application is delivered.

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Introduction

Open platform

The EDITH transplant recipient registry is based on an open platform: openEHR. Open platforms are open in the sense that data can be are available is a standard format, based on open clinical models and can be wholly and freely accessed. Data and models in an openEHR based platform can be used with any vendors product that adhere to these standards. These qualities make an open platform very flexible. More on open platform in this excellent white paper by the Apperta Foundation: https://apperta.org/openplatforms/.

openEHR

'openEHR' is the name of a technology for e-health, consisting of open specifications, clinical models and software that can be used to create standards, and build information and interoperability solutions for healthcare. The various artefacts of openEHR are produced by the openEHR community and managed by the openEHR Foundation, an international non-profit organisation established in the year 2003 (https://www.openehr.org/about/what_is_openehr).

Flexibility

The openEHR platform gives the EDITH registry flexibility in setup. Besides gathering the data over a long period of time in a registry from existing registries, it is important to offer countries who do not have a registry a platform that they themselves can use for starting a registry.

The current setup is a single instance openEHR platform with a central database and a single instance front-end. However other setups are possible for instance we can keep the central database, but created a federated landscape of smaller openEHR based platforms and frontends that can deviate both on user interface, language and data collection from the central database as long as the EDITH dataset acrhetypes are incorporated in the country specific dataset. In this setup any country can create their own database based on their own specific needs and still be able to seamlessly deliver data to the central EDITH registry.

You can choose different vendors for the openEHR platform both "free" open source solutions (for instance http://ethercis.org/) or paid solutions. You can also choose to develop your own front-end, find an open source version (and extend it) or buy a solution from a vendor. We compared many solutions and came to the conclusion that an open source solution would require considerable effort to adapt to the needs of a registry, therefor it has a high initial cost, but perhaps lower running cost than a paid solution. However as the EDITH transplant recipient registry has limited funding and an unclear timeline after the project is concluded, we have opted for a paid solution.

The product we use is the Better Platform with Better Pathfinder Lite front-end application (www.better.care) it offers a lot of tools we use in our registry out of the Box. We run it ourselves in the AWS cloud in Frankfurt. At the moment Better has started to offer a SAAS solution (Azure cloud in France), which might be better fit in the future as no technical support for servers, netwerk is needed any more.

Functional Requirements

The solution is based on the requirement document EDITH design_v1_1.pdf (see Github repository).

Resources

Resources mentioned in this document can be find on our public github:

https://github.com/edith-project/deceased-registry

Components

The registry uses several components to create , in this chapter we will describe them shortly and explain how the work together to provide the functionality as described in the requirements document.

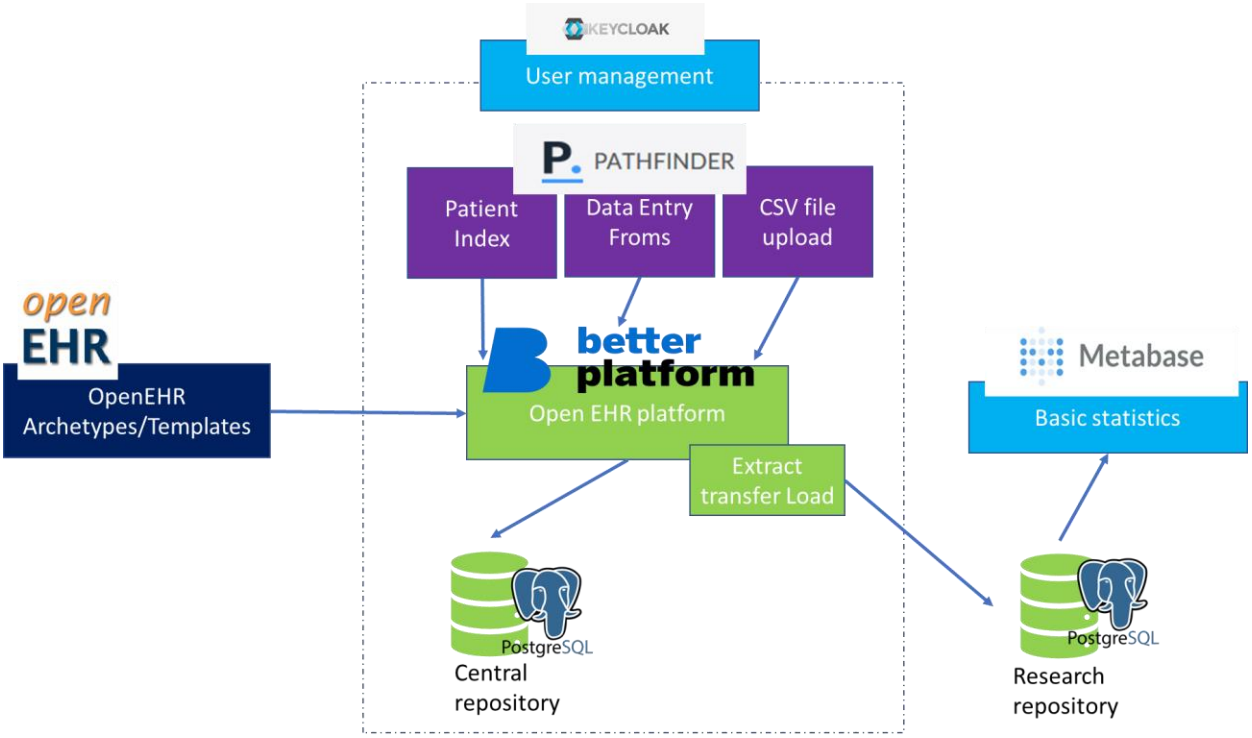


Figure 1 Schematic representation of components and how the interact

openEHR: archetypes and templates

Archteypes are the small clinical building blocks holding concepts like blood group or weight, templates describe a clinical use case. These templates can be uploaded to the openEHR platform (Better platform) which will automatically generate everything that is needed to store and access data based on these templates through open EHR API's (documentation https://specifications.openehr.org/releases/ITS-REST/latest/index.html)

Keycloak: user management

Keycloak is used to manage access to Pathfinder and Better Platform, user can use a single password to access these application. Metabase uses it own user access.

Pathfinder

Pathfinder is the front-end application that end-users (national competent authorities) will use

to enter data in an initial and a follow-up data entry form. A csv file upload is available to upload data in bulk.

Better platform

The better platform provides a clinical data repository based on openEHR, specifications, in addition it provides a form builder, ETL (Extract transfer load), EHR explorer tool voor admins to quickly manage the platform.

Metabase

Metabase is a basic statics application, it can be used to quickly generate overviews on the data. The registry will provide data export possibilities for the National Competent Authorities (NCA).

Flow between components

Short summary of a typical workflow:

1. An engineer creates user accounts in keycloak
2. A Clinical modeler (or other employee at the EU registry) creates or updates openEHR template
3. Templates are uploaded to be better platform
4. Based on the template a Form is created or updated by the Clinical modeler
5. The form is tagged for pathfinder so it immediately becomes available in pathfinder
6. Data is collected by NCA's and entered in the forms or uploaded via the bulk upload.
7. The clinical modeler designs a data query (AQL) in EHR explorer to extract data needed for research.
8. ETL is configured to use the query to extract data and the extraction is scheduled.
9. The user of an NCA can extract the data from Metabase.

AWS cloud configuration

In AWS the following components are used:

Think!EHR Explorer & Terminology adapter	EC2 Instance M5.Large
Think!EHR Platform	EC2 Instance T3.medium
Instance storage (estimate 20Gb per Instance)	EBS General Purpose SSD
PostgreSQL	Database
PostgreSQL (estimate 5Gb p/y)*	DB Storage
PostgreSQL (estimate 5Gb p/y)*	DB Backup Storage
PostgreSQL (estimate 10Gb p/y)**	Data transfer

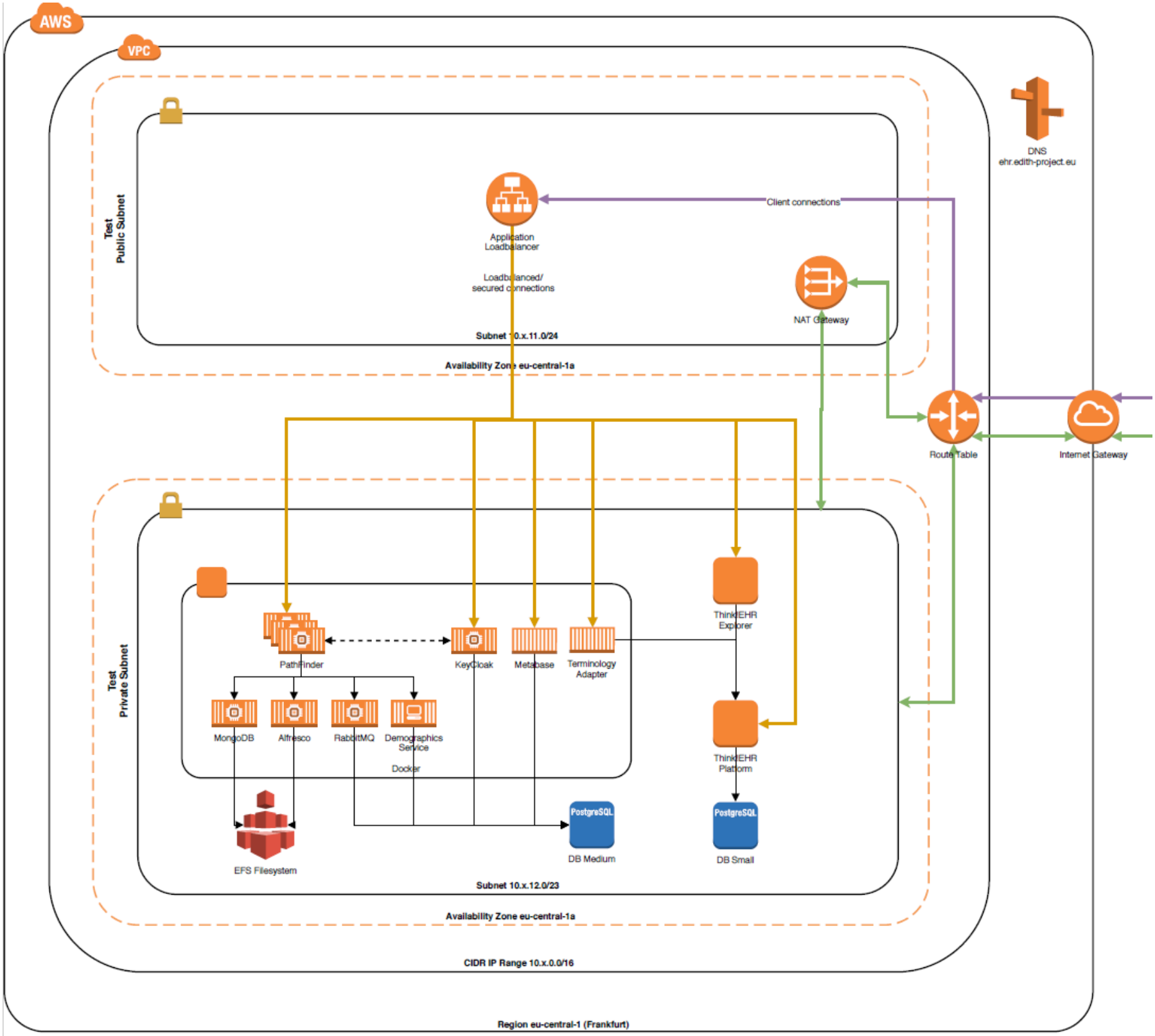
Figure 2 AWS components used per environment (test, prod)

Application Loadbalancer	
Route53 DNS	Hosted zone
VPC	VPN
Backup Storage for Instance snapshots	S3

Figure 3 Components shared between environments

On the next page you can find a schema of the implementation used for a single environment (in this case Test). The environment has its own VPC (Virtual Private Cloud) and a public and private subnet to secure the data in the private subnet. An application load balancer is used to balance client traffic, this will make the setup more flexibility as we could scale easily to extra instances of pathfinder or Better platform (formerly known as Think!EHR platform). The Pathfinder and Metabase components run on the docker instances (easier to install) while the Better platform is not yet available on docker and needs a separate server.

Both the docker and platform servers use a Postgress database. Databases are back-upped daily and are retained for 3 days.


AWS
VPC
Test
Public Subnet
Application
Loadbalancer
Client connections
Loadbalanced/
secured connections
NAT Gateway
Subnet 10.x.11.0/24
Availability Zone eu-central-1a
DNS
ehr.edith-project.eu
Route Table
Internet Gateway
Test
Private Subnet
PathFinder
KeyCloak
Metabase
Terminology
Adapter
ThinkEHR
Explorer
MongoDB
Alfresco
RabbitMQ
Demographics
Service
Docker
ThinkEHR
Platform
EFS Filesystem
PostgreSQL
DB Medium
PostgreSQL
DB Small
Subnet 10.x.12.0/23
Availability Zone eu-central-1a
CIDR IP Range 10.x.0.0/16
Region eu-central-1 (Frankfurt)

openEHR archetypes and templates

Description

We use openEHR templates and arcehtypes to describe our dataset and create operational templates that can be used inside an openEHR platform.

Use

We have used Better's ADL-designer to create the openEHR archetypes and templates. Most archetypes are downloaded from the international open Clinical Knowledge Manager at openEHR.org (https://www.openehr.org/ckm/). You can download Archetype and Templates files used in the project from our public Github repository.

Configuration

We have created 2 templates which intern use archetypes (both local and CKM)

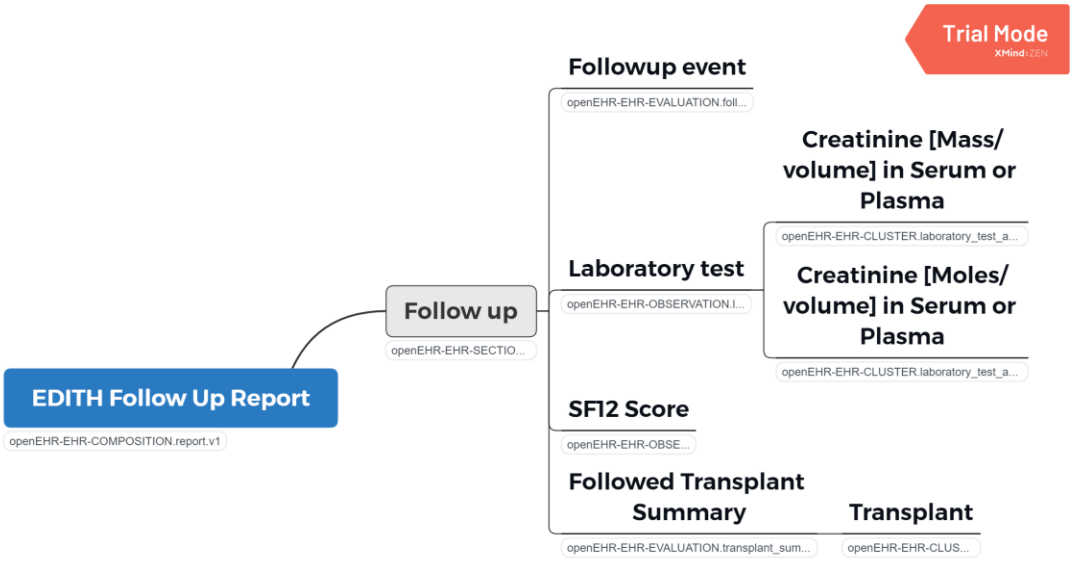


Figure 4 EDITH Follow Up archetypes mind map

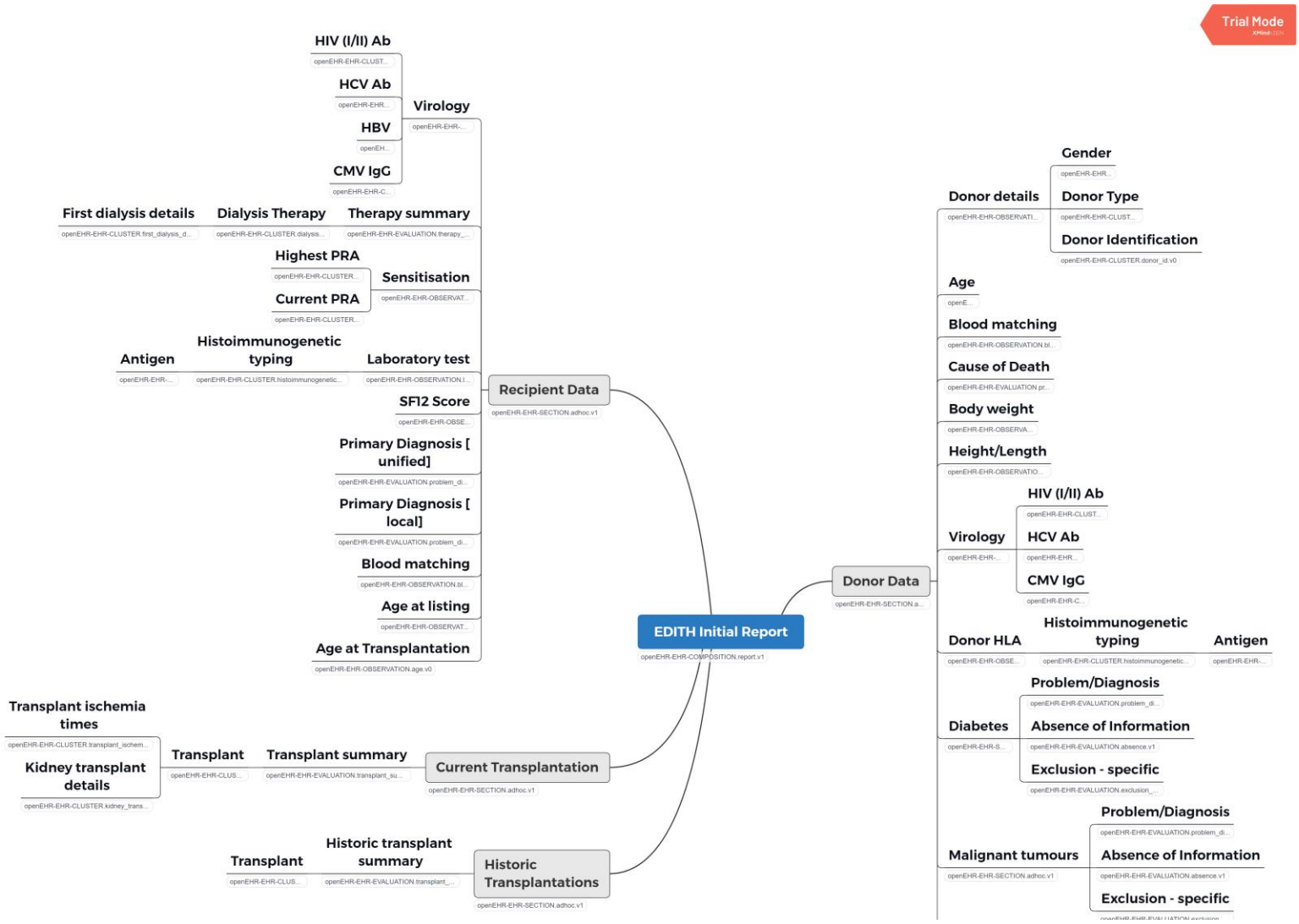


Figure 5 EDITH Initial archetypes mind map

1. EDITH Initial, describes an initial follow-up record to be recorded as the first record after transplantations. Its fields contains information on donor, recipient and transplant for a kidney transplant
2. EDITH Follow Up, describes information on the patients gathered by phycians on regular intervals. Also used to record death of a patient and failure of a transplanted graft.

User management

Description

For user management KeyCloak is used for authorizing users to the Better and Pathfinder applications. For Metabase the internal .user management is used.

Use

KeyCloak is configured by the Technical admin of the platform

Configuration

We have three user levels:

1. NCA users (users that can enter and access data on country level), these users can access data including the local subject ID (patient ID that was defined by the NCA). NCA's can download statistics from metabase with patient ID for there own country, but without ID for all transplants.
2. Europe functional admins (can access patients for all countries)
3. Admins can configure and setup components described in this document.

openEHR platform (Better)

Description

Within this project we are using Better platform (formerly known as Think!EHR) version 2.4.3.

Use

The platform can be configured by Admins

The following artefacts are uploaded to run the application:

- Templates (see openEHR archetypes and templates)

Forms (see

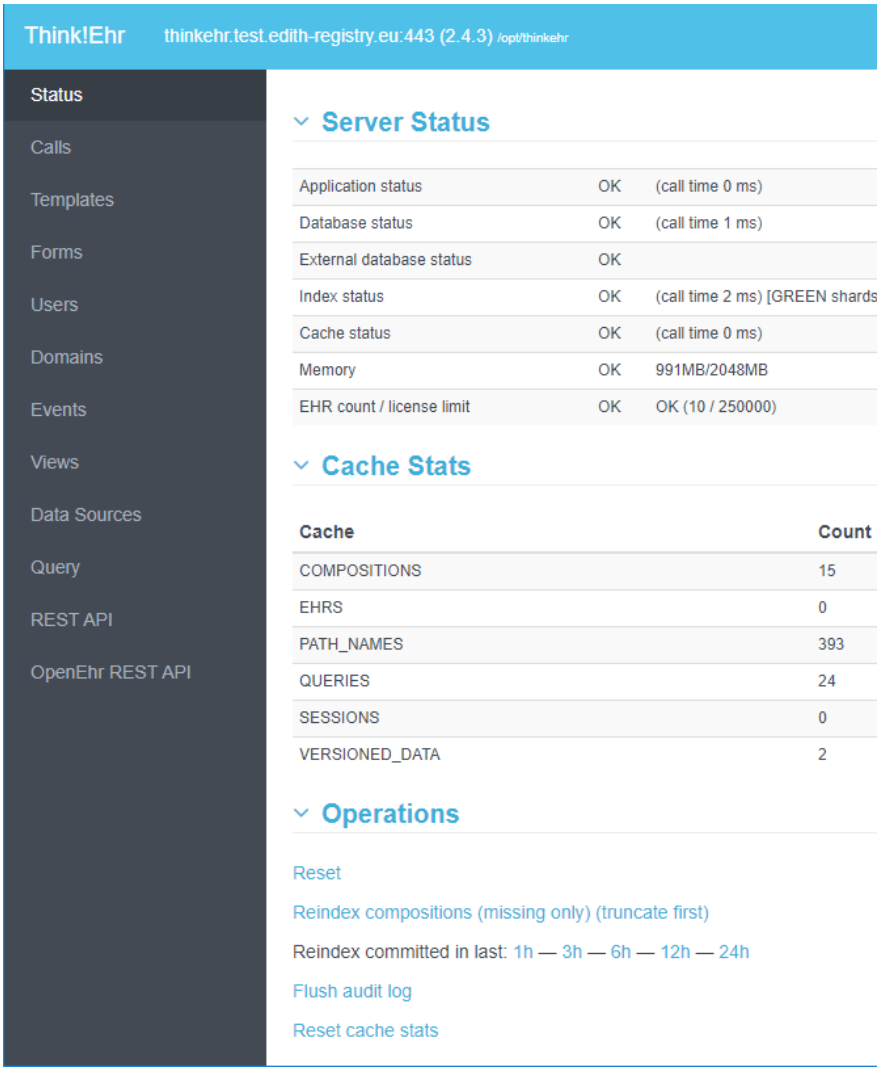


Figure 6 Admin console Better platform

- Form builder)
- Views; a view is created based on a AQL query (the openEHR query language) to create the patient list in the pathfinder application.

Configuration

The Better platform runs on a dedicated Linux server with a dedicated Postgress database.

It is a single node instance (but this platform can be clustered if needed)

It contains user account information for admins. Also a service account was created for the ETL user with only read access to the platform.

ETL

Description

The Extract Transfer Load (ETL) tool from the Better platform is a tool to quickly access the data from a Better platform via an AQL query and transfer data to an relational database. As most statistics tools cannot access openEHR platforms directly it is an easy way to get data in to a database that the statistics application can use. ETL tool from Better version 1.1.6 is used.

Use

The platform can be configured by Admins. Connections are defined one to the openEHR instance and one connections to the Europe schema research database. And one for every country schema .

For each country a query is defined to retrieve country specific data from the openEHR, platform as well as European query (which excludes the Subject ID).

For every query a mapping is generated to a relational database schema.

The ETL processes are scheduled to run every hour, so the statistics database is maximum 1 hour behind on the openEHR database. It does a full refresh.

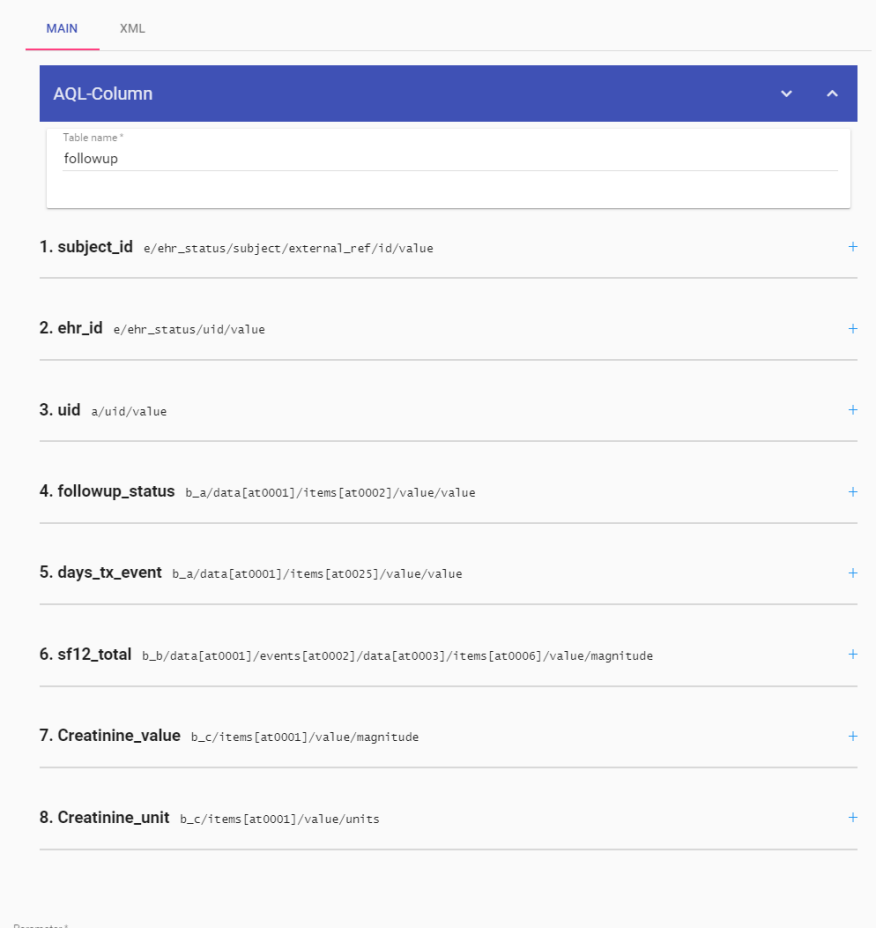


Figure 7AQL to SQL mapping example

Configuration

The AQL queries can be found within the Github repository.

Terminology adapter

Description

The terminology adapter contains all terminologies used within the archetypes. Examples are the HLA nomenclature, ICD-10 etc.

Use

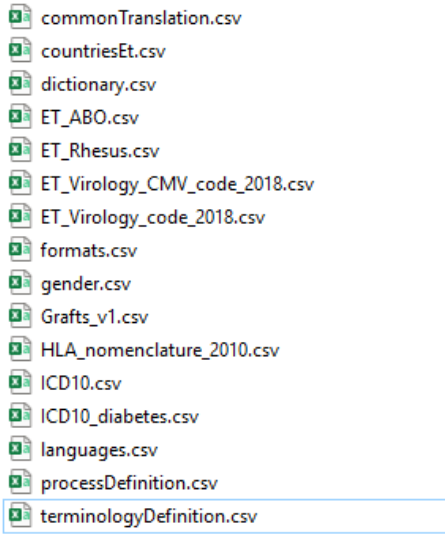
The platform can be configured by Admins. Connections are defined one to the openEHR instance and one connections to the Europe schema research database. And one for every country schema .

A nomenclature is defined within a CSV file with at least the following columns:

- code, the code for a row within the Nomenclature
- descripition, a description that can be displayed for a specific code
- parent, optional parent of the code if the code has a hierarchy

Configuration

The following terminology are defined (full csv files can be found in Github):



Form builder

Description

Form builder is a drag and drop tool to create forms based on openEHR templates and the better platform

Use

Admin creates or updates a form based on a template. Tags it for use within pathfinder. Uploads the form into your OpenEHR platform. The form will automatically be used in Pathfinder.

Configuration

Form builder runs on tools.marand.si. Find the form description files in our Github. Two forms are created:

- Edith Initial to capture the initial form
- Edith Follow Up to capture the Follow Up form

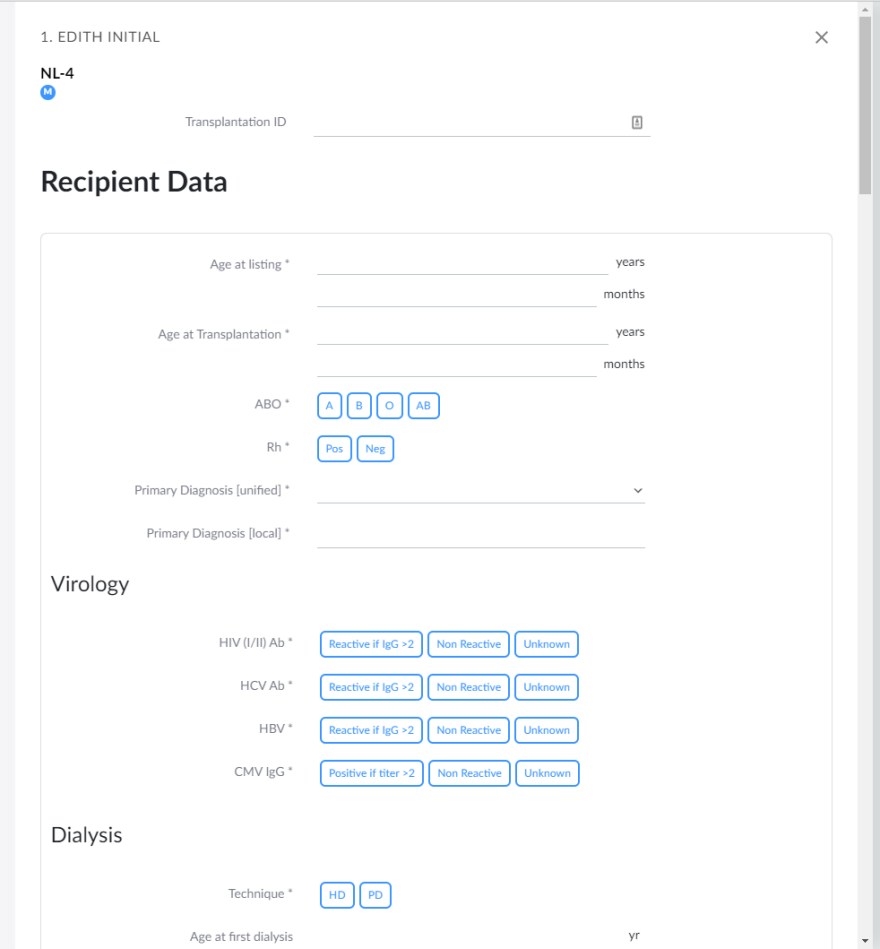


Figure 8 Part of the Edith Initial form

Pathfinder

Description

Better Pathfinder is on openEHR front-end for quickly publishing forms based on openEHR so that endusers can use them. It is focused on data capturing and needs the Better openEHR platform to run on top off.

Use

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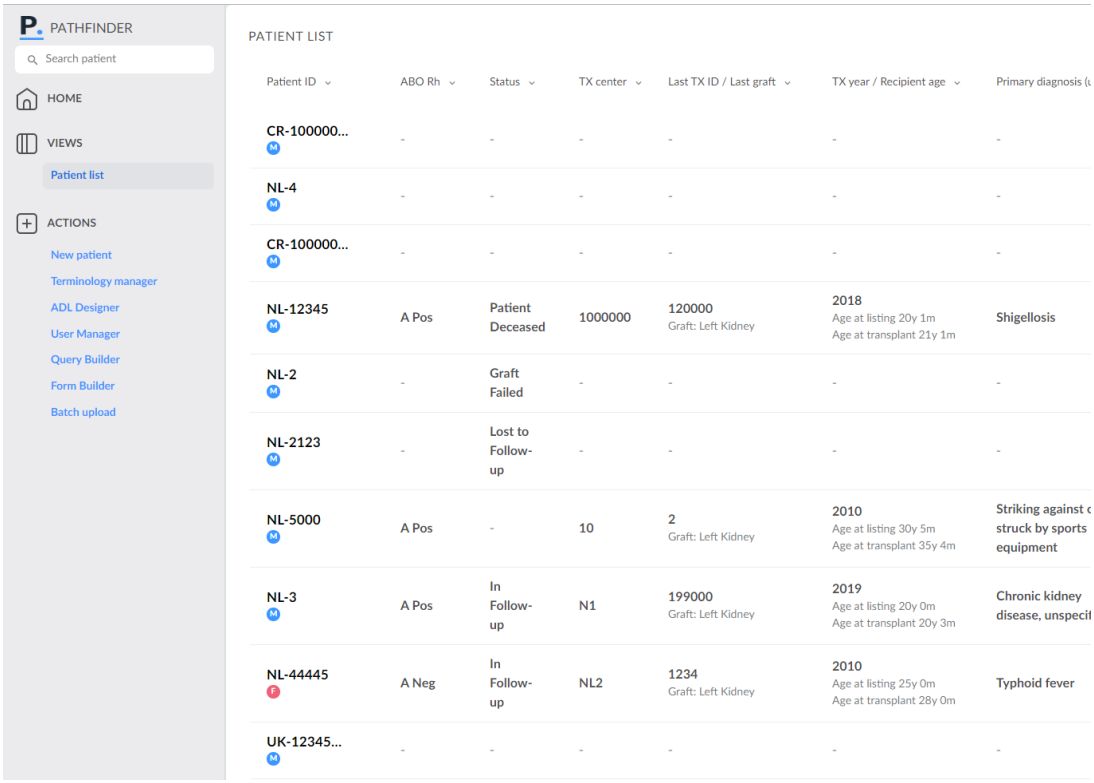


Figure 9 Pathfinder - Patient list

The following function can be used be End User within PathFinder.

Patient list

A list of all patients (visible for you user), you can select patients from here.

Search patient

Find a patient by patient ID.

New Patient

Register a new patient ID. Patient ID should start with countrycode and followed by a pseudonymised patient ID (Like NL-12345) generated by the NCA .

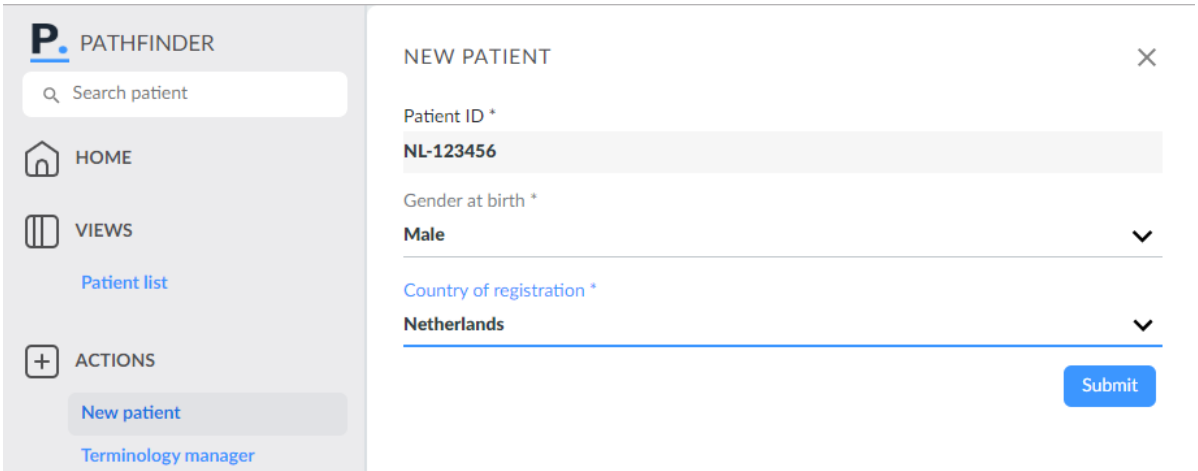


Figure 10 Register new patient

Batch Upload

Upload a csv file (format can be found on Github) containing multiple Initial or Follow Up records . Before uploading the csv file select the correct template from which the upload file was generated: “Edith Follow Up” or “Edit Initial”.

Patient view

Contains patient record, forms.

Patient record

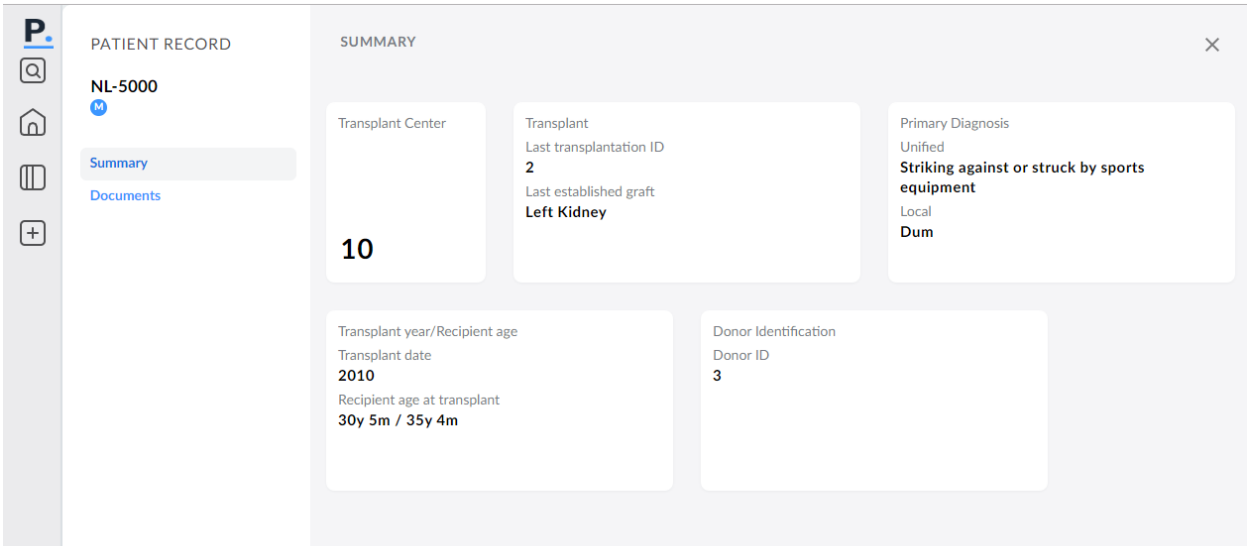


Figure 11Patient record with summary

The patient record contains a summary off the latest values for a patient. Also you can access all Initial and Follow-up form under the documents section. Within the documents session you can also edit the documents if they contain false information.

Forms

By opening one of the two follow-up forms: "Edith Initial" or "Edith Follow-up" you can enter the respective form for this patient.

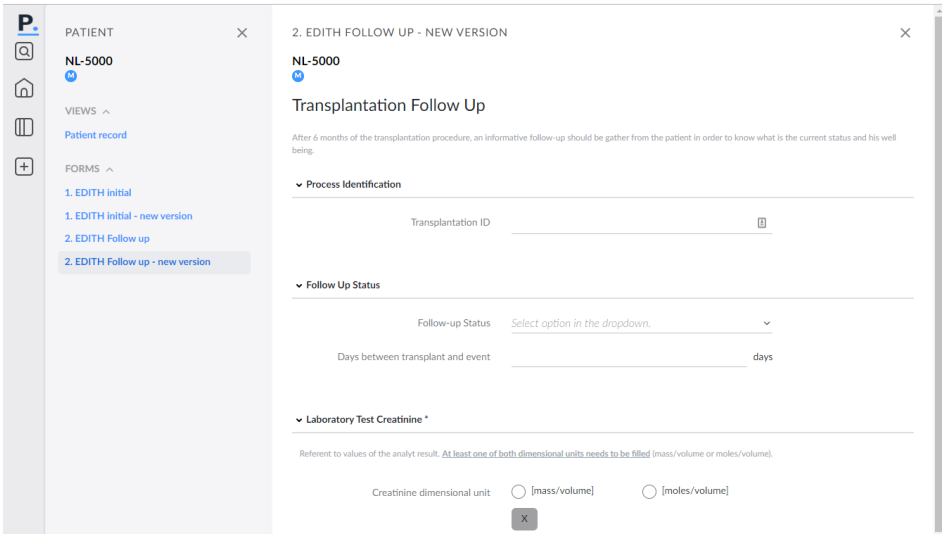


Figure 12Follow-up form

Configuration

In the Github repository the forms and import formats can be found. A manual is available in the Github repository

Statistics (Metabase)

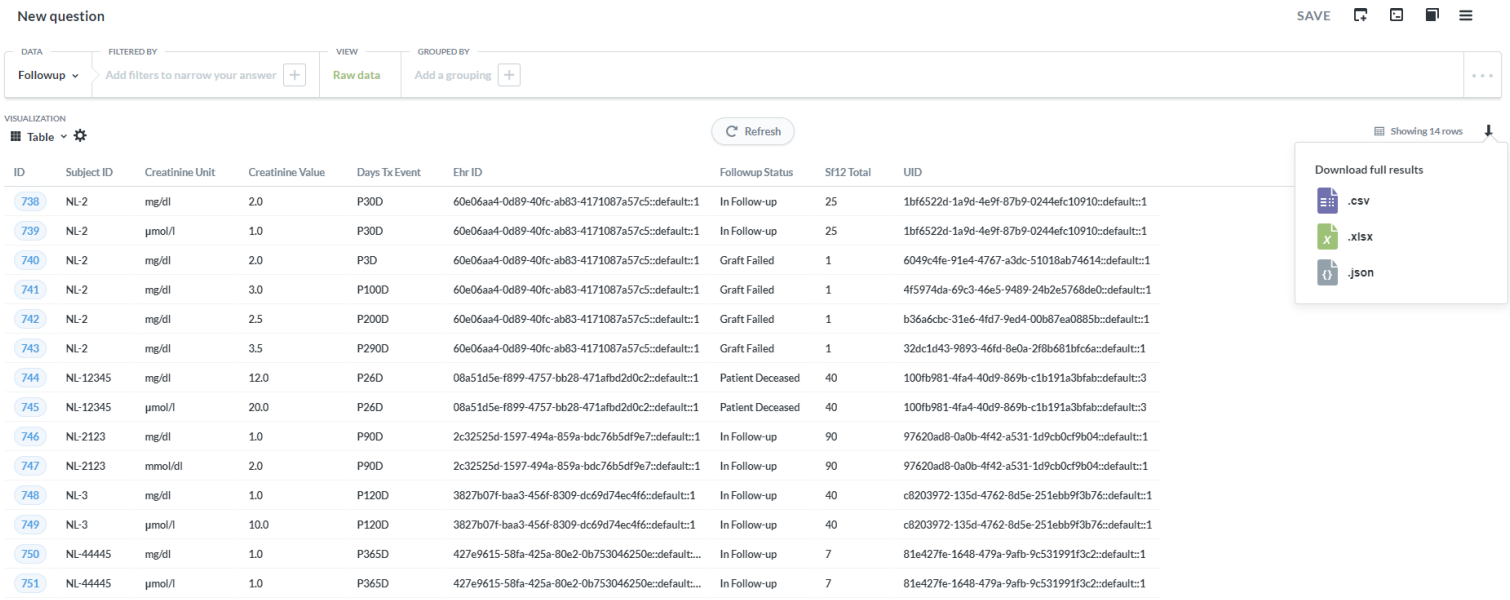
Description

Metabase is an opensource statistics program running on a docker instance in our configuration. It uses the postgress research database as its source database.

Use

All NCA's will get access to their own dataset as well as the full dataset anonymized. They can run some statistics on within metabase, but the main purpose is to be able to download the data in a flat and readable format.

Downloads are available in csv, xlsx and json format. Columns are configurable.



ID	Subject ID	Creatinine Unit	Creatinine Value	Days Tx Event	Ehr ID	Followup Status	Sf12 Total	UID
738	NL-2	mg/dl	2.0	P30D	60e06aa4-0d89-40fc-ab83-4171087a57c5::default::1	In Follow-up	25	1bf6522d-1a9d-4e9f-87b9-0244efc10910::default::1
739	NL-2	µmol/l	1.0	P30D	60e06aa4-0d89-40fc-ab83-4171087a57c5::default::1	In Follow-up	25	1bf6522d-1a9d-4e9f-87b9-0244efc10910::default::1
740	NL-2	mg/dl	2.0	P3D	60e06aa4-0d89-40fc-ab83-4171087a57c5::default::1	Graft Failed	1	6049c4fe-91e4-4767-a3dc-51018ab74614::default::1
741	NL-2	mg/dl	3.0	P100D	60e06aa4-0d89-40fc-ab83-4171087a57c5::default::1	Graft Failed	1	4f5974da-69c3-46e5-9489-24b2e5768de0::default::1
742	NL-2	mg/dl	2.5	P200D	60e06aa4-0d89-40fc-ab83-4171087a57c5::default::1	Graft Failed	1	b36a6cbc-31e6-4fd7-9ed4-00b87ea0885b::default::1
743	NL-2	mg/dl	3.5	P290D	60e06aa4-0d89-40fc-ab83-4171087a57c5::default::1	Graft Failed	1	32dc1d43-9893-46fd-8e0a-2f8b681bfc6a::default::1
744	NL-12345	mg/dl	12.0	P26D	08a51d5e-f899-4757-bb28-471afbd2d0c2::default::1	Patient Deceased	40	100fb981-4fa4-40d9-869b-c1b191a3bfab::default::3
745	NL-12345	µmol/l	20.0	P26D	08a51d5e-f899-4757-bb28-471afbd2d0c2::default::1	Patient Deceased	40	100fb981-4fa4-40d9-869b-c1b191a3bfab::default::3
746	NL-2123	mg/dl	1.0	P90D	2c32525d-1597-494a-859a-bdc76b5df9e7::default::1	In Follow-up	90	97620ad8-0a0b-4f42-a531-1d9cb0cf9b04::default::1
747	NL-2123	mmol/dl	2.0	P90D	2c32525d-1597-494a-859a-bdc76b5df9e7::default::1	In Follow-up	90	97620ad8-0a0b-4f42-a531-1d9cb0cf9b04::default::1
748	NL-3	mg/dl	1.0	P120D	3827b07f-baa3-456f-8309-dc69d74ec4f6::default::1	In Follow-up	40	c8203972-135d-4762-8d5e-251ebb9f3b76::default::1
749	NL-3	µmol/l	10.0	P120D	3827b07f-baa3-456f-8309-dc69d74ec4f6::default::1	In Follow-up	40	c8203972-135d-4762-8d5e-251ebb9f3b76::default::1
750	NL-44445	mg/dl	1.0	P365D	427e9615-58fa-425a-80e2-0b753046250e::default:...	In Follow-up	7	81e427fe-1648-479a-9afb-9c531991f3c2::default::1
751	NL-44445	µmol/l	1.0	P365D	427e9615-58fa-425a-80e2-0b753046250e::default:...	In Follow-up	7	81e427fe-1648-479a-9afb-9c531991f3c2::default::1

Figure 13 Metabase download

Configuration

Within Metabase we have created a security group for every NCA which contain all users from the NCA. Also a security group was created for users at the EU level. Every national dataset (includes pseudonymized id's from patients and donors) is setup as a database within Metabase, also a European database is created (which does not contain the pseudonymized id's). Permissions are set in such a way that only NCA's can access the national dataset.