Database for the clinical validation of INSIDE

5/4/2018

Meeting INSIDE

Giancarlo Sportelli

Objectives

- Designing and deploying a database management system (DBMS) for collecting, processing and sharing the data collected in the framework of the INSIDE project and with special focus on the longitudinal clinical study planned for 2018 at CNAO

- The DBMS will
  - Provide a software front-end application
  - Provide a back-end server that will support data collection during the treatments, data revision and data sharing
  - Ensure the safety and reliability of the acquired data
  - Allow fine control on access rights to the data

Main tasks

- Define of a data collection protocol (entities + workflow)
- Develop a server architecture
- Develop a database schema (models + constraints)
- Develop a Create/Read/Update/Delete (CRUD) software front-end application
- Develop a back-end server software
- Develop an automated procedure for safeguarding patients privacy and respecting local ethics regulation

Implementation 1/2

- Application refers to Clinical Validation Protocol (shared by Elisa on 28/3/2018)
- Data models shared on 15/1/2018, revised during approx. 1 month (not closed yet)
- Data insertion workflow shared on 12/2/2018, revised during approx. 1 week (not closed yet)
- Available budget approx. 5 k€
- Front-end development plan initially committed to external companies
  - Widen: few interactions, no quotations received
  - 3AS: many (passive) interactions, 9k€ preliminary quotation
  - Net7: few (active) interactions, 20k€ - 25k€ preliminary quotation
- Front-end development needs to be replanned using internal resources

Implementation 2/2

- Back-end resources requested to INFN Pisa (already granted)
- Back-end development and management committed to INFN Pisa Data Center
- Clinical data management and collection will be arranged together with CNAO network admins (Venchi et al., preliminary meeting held on 12/2/2018)
- Need for a detailed project in order to effectively plan for hardware/network resources at CNAO

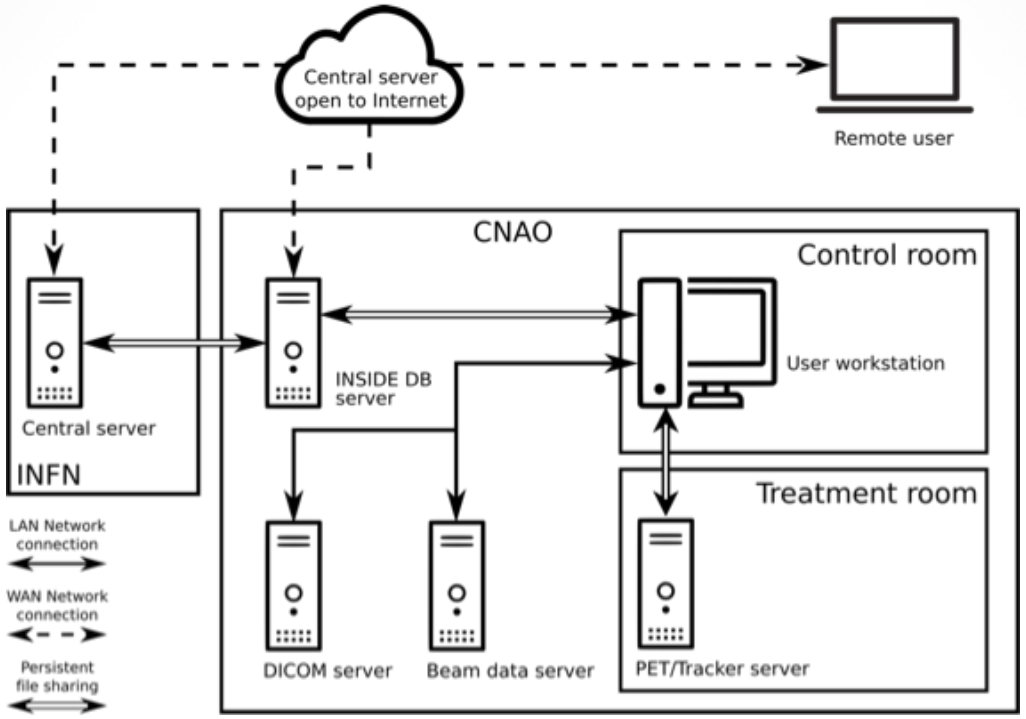
Data collection protocol: entities

- Phantom
  - Serial number (string)
  - Name (string)
  - Shape (string)
  - Composizione (string)
  - Etc.
- Patient
  - 1 or 2 CT/TP/segmentation (DICOM binary file)
  - Text description of the TP
  - Patient reference
  - Etc.
- Exam
  - Target
  - Treatment
  - Measured acquisition
  - Simulated acquisition
  - 3D image with range differences (DICOM binary file)
  - Etc.
- Acquisition system status
  - SW version (string)
  - SW configuration (text file)
  - Etc.
- Treatment
  - Treatment type (monoenergetic, TPS, uniform, free beam)
  - Date and time (timestamp)
  - Dose delivery data (text file/zip with several text files)
  - TPS data (text file/zip with several text files)
  - Etc.
- Calibration
  - Energetic calibration (zip)
  - Temporal calibration (zip)
  - Thresholds calibration (zip)
  - TA calibration mask (zip)
  - Baseline calibration (zip)
- Slow control daily log
  - Temperature monitor (txt)
  - Console (txt)
  - SiPM current
  - LV current
- Acquisition
  - Operators (user type/user name/role)
  - Acquisition type (measured/simulated)
  - Target
  - Target position
  - PET position (string)
  - Tracker position (string)
  - 3D sequential images (at different times).
  - Raw acquisition file (binary)
  - Acquisition log (text file)
  - Etc.
- Data analysis
  - Author (user)
  - Input data (zip)
  - Output data (zip)
  - Executables (zip)
  - Output images
  - Etc.

Data collection protocol: workflow

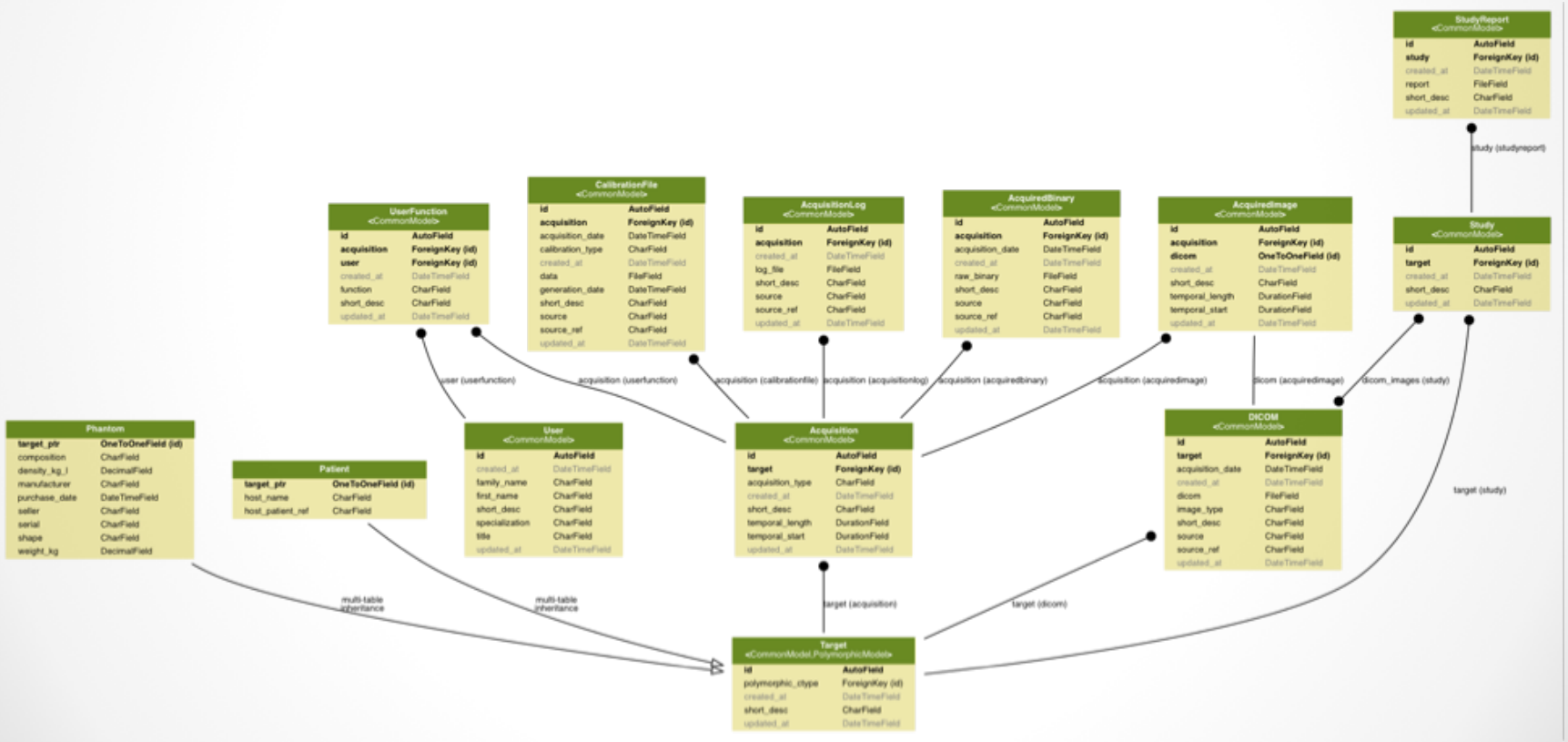
- Data taking can be divided into the following sequential stages:
  - [STAGE 1] Creation of the **data draft**
  - [STAGE 2] Status data retrieval before the treatment
  - [STAGE 3] Acquisition data retrieval after the treatment
  - [STAGE 4] Clinical data retrieval
  - [STAGE 5] Data draft **revision and submission**

Server architecture

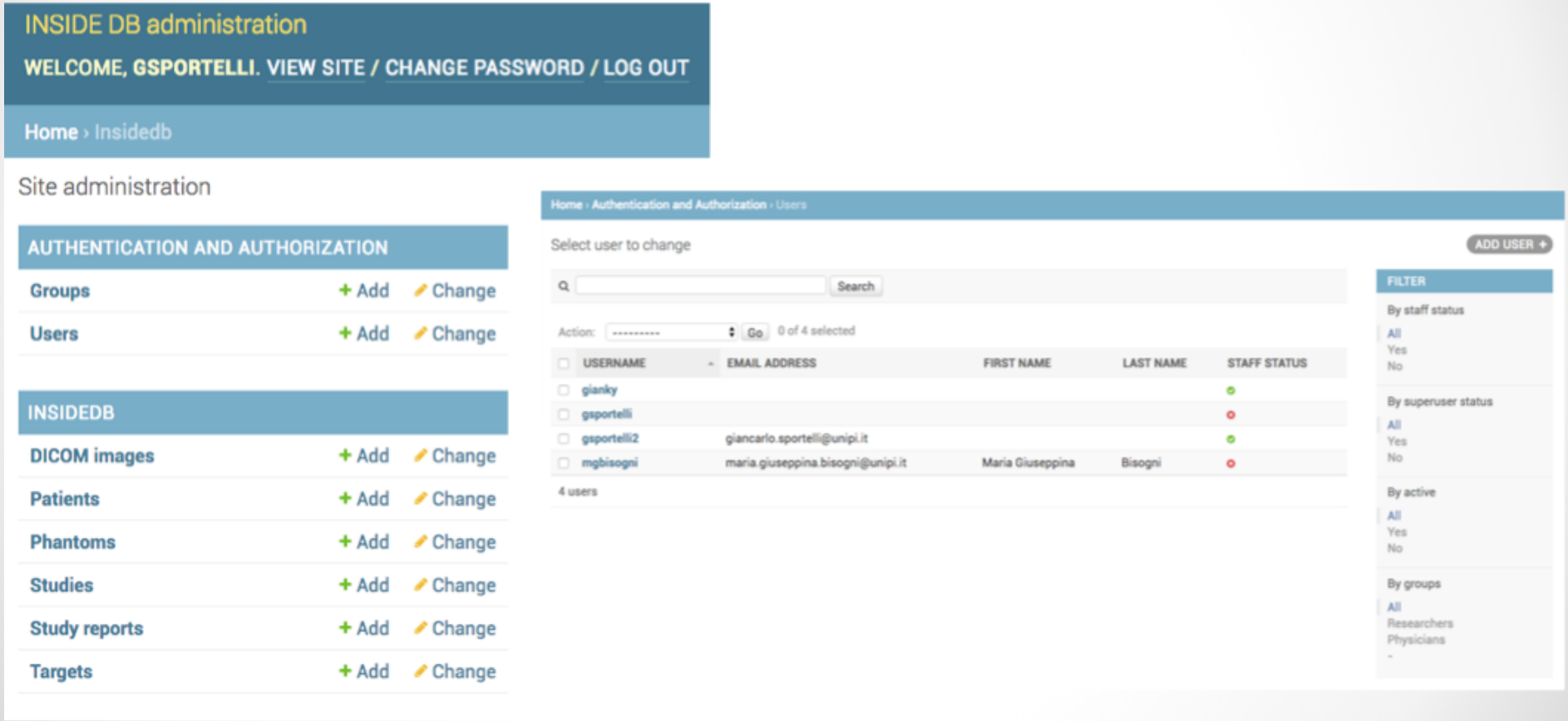


Name	Operating system	Place	Subnet	CPU	RAM	Disk
Central server	Linux	INFN	?	high-end	16 GB	2 TB
INSIDE DB server	Linux	CNAO	?	mid-end	8 GB	10 GB
DICOM server	N/A	CNAO	N/A	N/A	N/A	N/A
Beam data server	N/A	CNAO	N/A	N/A	N/A	N/A
User workstation	Any (Mac?)	CNAO	?	mid-end	8 GB	10 GB
PET/Tracker server	Windows	CNAO	?	high-end	?	?
Remote user	Any	Any	N/A	Any	8 GB	10 GB

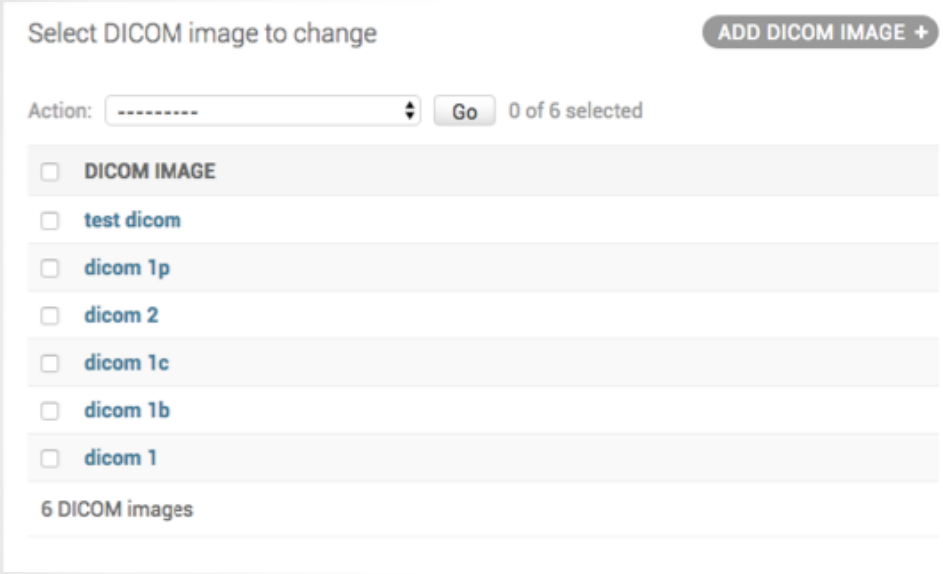
Database SQL schema (models and constraints)

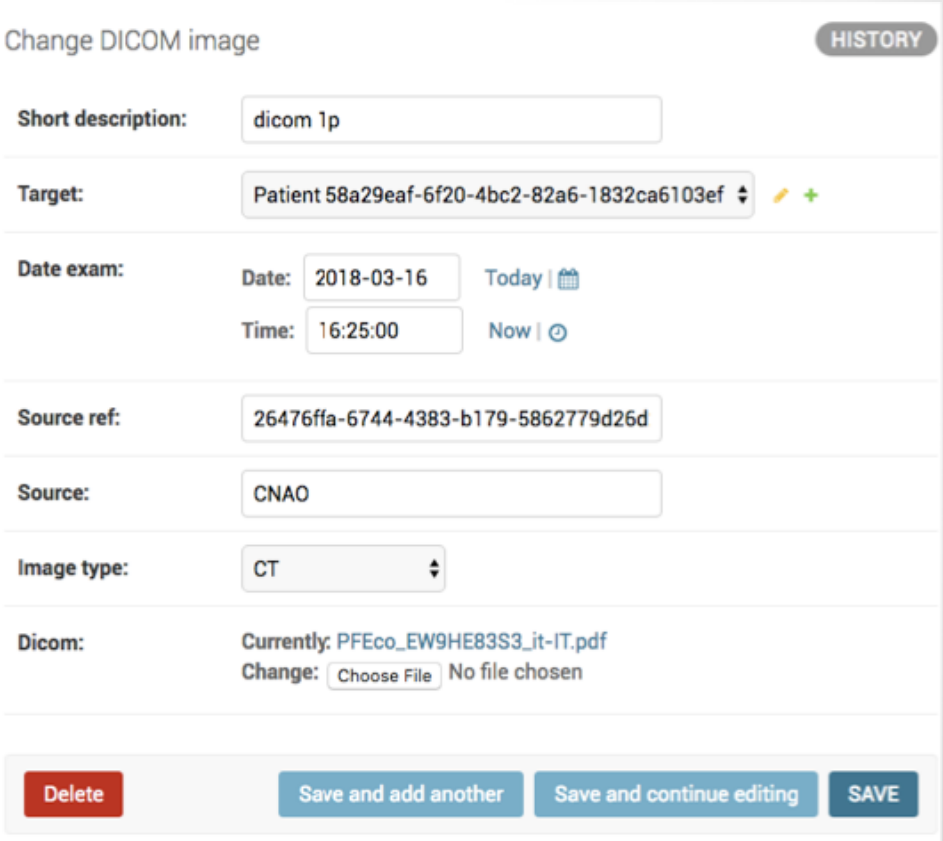


CRUD front-end application 1/2



CRUD front-end application 2/2





Privacy and access control

- Probably not yet available at the beginning of the study
- Access will be restricted to trained personnel from the INSIDE collaboration
- Privacy issues will be handled on a per case basis

Schedule

- December 2017: survey SW development companies (done)
- January 2018: definition of development specification and company collaboration kick-start (specification almost complete, no suitable offers received)
- March 2018: production of the first software prototype (to be done with internal resources, early demo by May 2018, new deadline June 2018)
- April 2018: software test and validation (to be done with internal resources + additional resources, new deadline to be decided)