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D6.1.1 – System Integration Plan, Initial Integrated Prototype and Evaluation Report

WP6 *Integration and Evaluation*

Task 6.1/6.2 *Platform Integration/Testing and Evaluation*

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1. Executive Summary

This report intends to inform the reader about the 1st prototype's (SW) integration, tests and evaluation results. It also provides information about how to access the 1st prototype and what is the current deployment of the different components in the testing environment that has been set up for this purpose.

Section 3 gives the overview of the initial integrated prototype setup.

Section 4 presents the integration plan and interactions between the different components, (section 4.1) and integration tests and results (section 4.2)

Section 5 presents the evaluation results based on the usability requirements and the evaluation criteria as defined in WP2 (ID2.4.1).

Section 6 presents some "lessons learnt" from the 1st prototype integration, presents screenshots and log files of components during communication with other PONTE components in 3 different scenarios and outlines packaging and lessons learnt which are of value for the 2nd Prototype.

Section 7 presents the conclusions.

2. Introduction

The Initial Integrated Prototype comprises the first PONTE prototype which follows the Initial User Requirements (D2.1.2, M06) and the Initial PONTE Architecture (D3.1.1, M09) with the actual implementation of the components having taken place in WP4 and WP5. The first releases from the latter WPs have been integrated into the Initial Integrated Prototype. The initial integrated prototype focuses on Phase 2 and includes:

- the initial **PONTE authoring tool (PAT)** through which the researcher can design the clinical trial with particular focus on setting the test of hypothesis, navigation through the CTP, inclusion/exclusion criteria, (*ICCS/NTUA*)
- the initial **Semantic Representation Layer (SRL)** which is driven from the "Clinical Trials Data Requirements" (ID4.1.1, PM12) (*CETIC*, *ICCS/NTUA*)
- the initial **Decision Support (DS)** component which provides the predefined queries per section, performs Clinical Trial Protocol (CTP) validation upon user request and builds the risk profile of the patients' selected from the hospital who satisfy the eligibility criteria for the clinical trial (*ICCS/NTUA*)
- the initial **EHR Communication component** which receives the requests for the number of patients satisfying the eligibility criteria during clinical trial design and for selecting the patients who meet these criteria when the recruitment request has been submitted after the approval of the CTP (*ICCS/NTUA*)
- the initial **Ontology Based Search Engine (OBSE)** which receives predefined questions from the PONTE authoring tool (PAT) specific to the Clinical Trial Protocol (CTP) sections and retrieves results from online available documents from PubMed and ClinicalTrials.gov. Furthermore the OBSE can be used for stand-alone queries. (*TUD*)

This prototype is delivered both in terms of developed source code and a report (the current one) which presents the integration plan, the deployment, the evaluation results, the lessons learnt and the future plans.

2.1 Glossary of Acronyms

Acronym	Definition
CTP	Clinical Trial Protocol
D	Deliverable
DS	Decision Support
EC	European Commission
EHR	Electronic Health Record
GUI	Graphical User Interface
OBSE	Ontology Based Search Engine
PAT	PONTE Authoring Tool
SOA	Service Oriented Architecture
SRL	Semantic Layer Representation
SUSAR	Suspected Unexpected Serious Adverse Reaction
UC	Use Case
WP	Work Package

WS	Web Service
XML	Extensible Markup Language

3. PONTE Initial Integrated Prototype Set Up

The different components of the platform are deployed in a testing environment which – for the 1st prototype – consists of three main domains namely TUD, CETIC and ICCS/NTUA. At the current stage the different domains are due to the fact that the technical partners are concurrently developing different components, which are deployed accordingly. In the future, all PONTE components will be deployed under the same domain – the PONTE domain. An exception to that rule is the EHR domain (currently hosted in ICCS/NTUA, *simulating* the Hospital domain as a different "EHR domain") which will remain separated from the PONTE domain; still some PONTE components (namely the Hospital DS which builds the patients' risk profile and the Hospital EHR Request Processor which receives the requests and properly forwards them towards the hospital EHRs) will have to be deployed locally (i.e. in the Hospital's domain) as shown in Figure 1 and Figure 2 for privacy reasons. The test database follows the structure of the CNR EHR database, whereas the test data are based on the THIRST study (as the queries posed relate to the eligibility criteria of the THIRST study) and were validated by NKUA as medical experts.

Overall, the architecture of the system follows the one presented in the PONTE deliverable D3.1.1 "Initial Overall PONTE Architecture - Interface definition and Component Design". Two different approaches that we can follow in order to communicate with the EHRs of each hospital have been identified and respectively implemented for the initial prototype. In both approaches the eligibility criteria specified by the researcher through the PAT are saved in the *EligibilityCriteria.xml*. The difference in these two approaches lies on how the request in made towards the EHRs, in other words the kind of interface that is exposed.

The first one (SPARQL approach) is presented in Figure 1. Within this approach, requests to the EHRs are posed through a SPARQL endpoint. Two types of questions are supported:

i. number of patients (case i),

ii. information (patient ID, diseases, drugs) on the patients selected as satisfying the criteria (case ii)

Due to the fact that an .xml to SPARQL transformation of the criteria is required at the SRL (Semantic Layer Representation) domain, the *EHR Request Handler* Web Service was developed within PONTE.

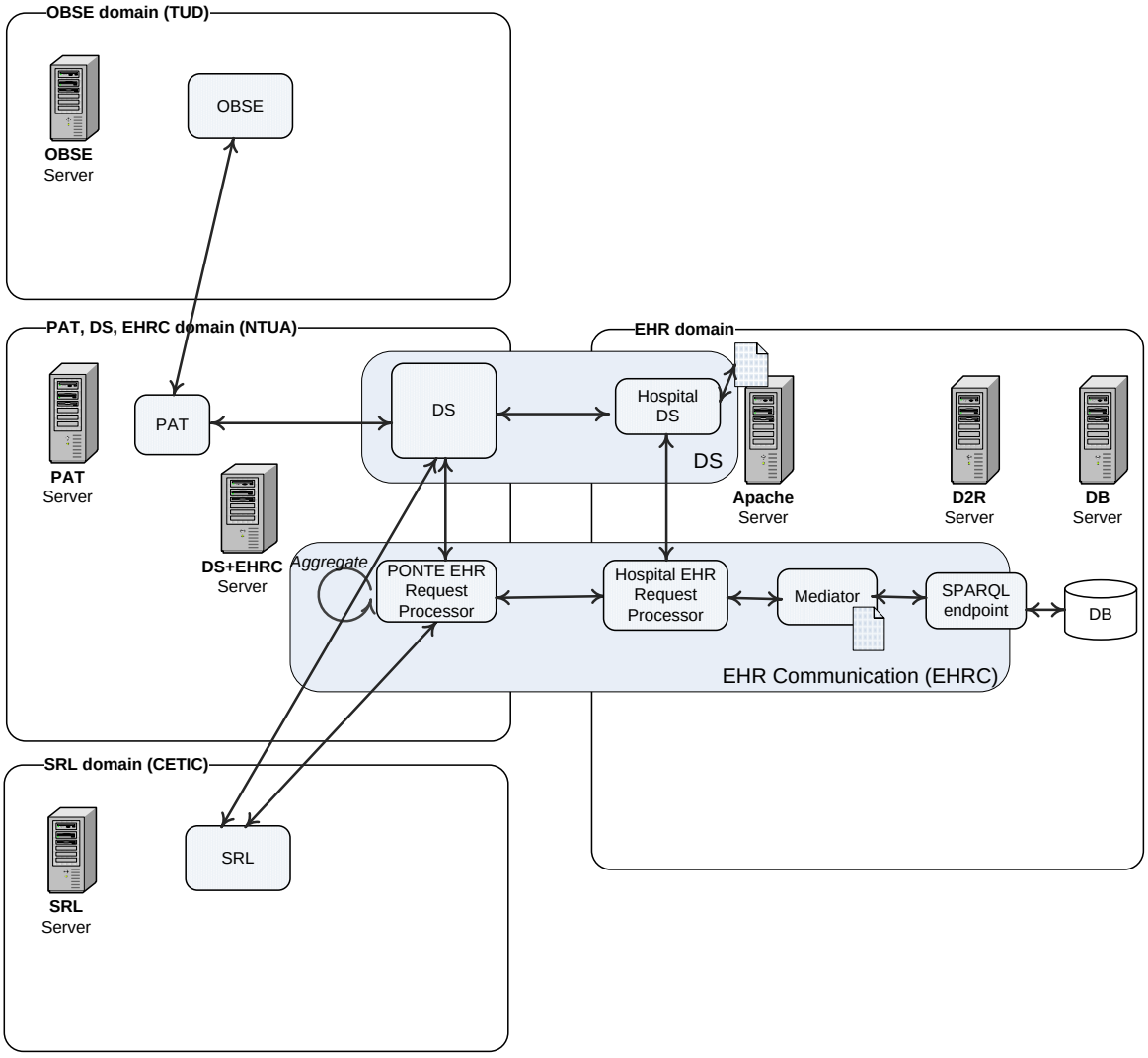


Figure 1 SPARQL approach - Set Up

Figure 2 depicts the second approach (WS-based). In this case the .xml file with the eligibility criteria is sent to the EHR domain (to the Hospital EHR Request Processor) and fed to the Hospital WS (where an xml to SQL transformation takes place). The Hospital WS sends back the response to the Hospital EHR Request Processor and the latter sends it to the Hospital DS (case ii) or to the PONTE EHR Request Processor (case i).

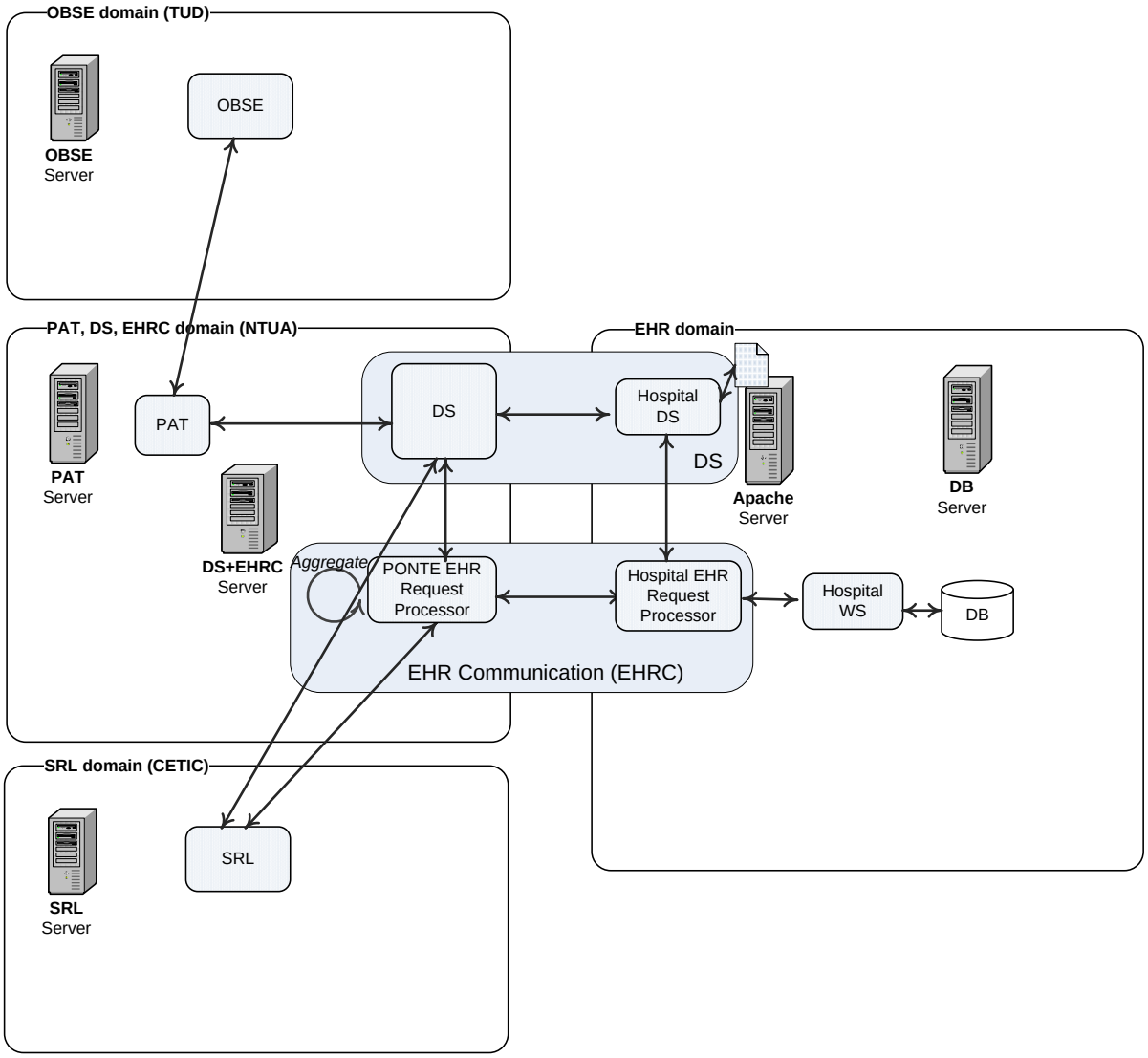


Figure 2 Hospital WS approach - Set Up

Based on both approaches presented above, the deployment of which is presented in these figures, no patient data is transmitted outside the hospital domain. Instead the PONTE sub-component which processes the information retrieved from the EHRs (patient ID, diseases, drug) in order to generate the risk profile per patient (see ID5.2.1) is deployed within the hospital domain (Hospital DS).

During this process, this component communicates with the Decision Support services at the PONTE domain, sending a list of disorders and drugs (but no patient IDs) found in patient data. The Decision Support communicates with the SRL in order to get information about drug interactions and so on, creates a list of remarks per disease and drug (e.g., study drug interacts negatively with drugA) and sends it back to the Hospital DS. The latter – in the Hospital domain - is then responsible for using the provided information and predefined rules to create a safety profile for each patient. Each profile is stored locally, thus patient data privacy and confidentiality are maintained.

Concerning the infrastructure of the first prototype, PAT has been deployed on the PAT server (running 64-bit edition of Windows Server 2008 Enterprise / Apache Tomcat servlet container) and DS and EHR Communication are deployed on the DS+EHRC server running the same configuration. The SRL server hosts the SRL services and the PONTE ontologies. The OBSE is deployed at the OBSE Linux server at TUD with local adapted OBO versions of the PONTE ontologies for document

indexing/entity recognition. A separate machine is hosting the Hospital DS and the Hospital EHR Request Processor (Windows 7/Apache Tomcat), whereas a similar machine is hosting the D2R server. The EHR database (mySQL) is stored at the DB server. The PAT, DS, EHRC , EHRP and SRL components have all been developed using the Java(tm) programming language and assorted open source frameworks and tools (see section 5 for more details)

Our experience when testing and running the initial integrated prototype was that the EHR Communication component – due to the heavy processing it performs – requires to be deployed at a separate server and preferably its components to be deployed separately for performance reasons. Moreover, the Ontology server requires high computational capacity and could be part of our future considerations that cluster or even Cloud could serve as an underlying infrastructure allowing for faster queries to the ontologies.

4. PONTE Platform Integration Plan, Implementation and Testing

4.1 Integration Plan and Implementation

As it has been presented in D3.1.1, PONTE follows a SOA (Service Oriented Architecture) approach with the PONTE components interacting with each other through Web Services (apart from queries to the PONTE ontology which are performed through SPARQL queries posed at the SRL SPARQL endpoint).

The following table summarises the communication between PONTE Components and has been used for monitoring the integration process within PONTE. This table presents the integration of each component with the rest of the PONTE components it communicates with (i.e., it sends a request to and receives a response from), the Use Case(s) (see D2.1.1) it corresponds to, its date in integration plan and current status (Status:: green: ok, orange: only interface-functionality implemented for next iteration, light blue: to be updated in the next iteration).

Semantic Representation Layer (SRL)			
Case	**Request Received includes**	**Response Sent includes**	**Status**
Semantic Representation Layer :: Semantic Mapper			
Find corresponding code for a given one (part of UC10, 11)	XML document with: the code, its classification system and the new one	List with the relative codes found annotated with the terms same, broader term, narrower term, partially overlapping term	12/07/2011
Semantic Representation Layer :: CTP Repository			
Get SPARQL query for the 2 cases (patient selection and available population size) (UC11)	Question_ID, CTP_ID	The SPARQL query	20/07/2011
Get Hospitals for the trial (UC10) *(to be updated)*	CTP_ID	String: Hospital IDs separated by the character ";" .	18/07/2011
Save current CTP version (UC7)	CTP .xml file	CTP_ID	12/07/2011
Get Hospitals for the trial (UC3) (to be updated)	CTP_ID	List of Hospitals	18/07/2011
Semantic Representation Layer :: Ontology Manager			
Get information about drugs/ diseases/ genes (UC11)	SPARQL query	XML document with the SPARQL query results	18/07/2011

Decision Support (DS)			
Case	**Request Received includes**	**Response Sent includes**	**Status**
Decision Support (DS)			
List of Pre-defined Queries in section (UC4)	CTP_ID , Section_ID	List of Pre-defined Queries in section (human readable and machine readable)	03/06/2011
Patient Selection (UC10)	List of drugs, diseases	xml containing detailed information about the drugs and diseases in the request	22/06/2011
Dependencies Validation (enriched UC4)	CTP_ID	List: for each parameter in each section list of parameters it depends on and how	04/07/2011
Decision Support:: Hospital DS			
Risk Profile Building (UC11)	An XML document	Boolean	04/07/2011

Ontology-Based Search Engine			
Case	**Request Received includes**	**Response Sent includes**	**Status**
Ontology Based Search Engine			
Free Search (UC5)	-	-	02/05/2011
"Execute" Predefined Query (UC4)	(machine readable links stored @DS)	ok	03/06/2011

EHR Communication - SPARQL Approach			
Case	**Request Received includes**	**Response Sent includes**	**Status**
EHR Communication :: PONTE EHR Request Processor			
Find Total Eligible Patients (UC4)	CTP_ID	Integer (Total Number of Eligible Patients)	05/07/2011
Find Clinical Characteristics of the Eligible Patients (UC11)	CTP_ID	Boolean (Success/Failure - Overall Response)	05/07/2011
Hospital EHR Request Processor			
Find Total Eligible Patients (UC4)	SELECT SPARQL query (includes the eligibility criteria in the WHERE clause)	Integer (Total Number of Eligible Patients in the Hospital)	05/07/2011
Find Clinical Characteristics of the Eligible Patients (UC11)	SELECT SPARQL query (includes the eligibility criteria in the WHERE clause)	Boolean (Success/Failure)	05/07/2011
EHR Communication :: Mediator			
Execute SPARQL query (for UC4, UC10, UC11)	A SELECT SPARQL query defining the information we would like to retrieve from the EHR datasource (select clause) and the Eligibility Criteria that the patients should fulfill (where clause)	An XML document, with the results received from the execution of the SELECT SPARQL query. *Based on the following xsd:* http://www.w3.org/TR/rdf-sparql-XMLres/	05/07/2011

EHR Communication - WS Approach			
Case	**Request Received includes**	**Response Sent includes**	**Status**
PONTE EHR Request Processor			
Find Total Eligible Patients (UC4)	An XML Document including the CTP_ID, Question_ID (indicating whether it is case i or ii) and the Eligibility Criteria	Integer *(Total Number of Eligible Patients in the Hospital)*	05/07/2011
Find Clinical	An XML Document	Boolean	05/07/2011

EHR Communication - WS Approach			
Case	**Request Received includes**	**Response Sent includes**	**Status**
Characteristics of the Eligible Patients (UC11)	including the CTP_ID, Question_ID (indicating whether it is case i or ii) and the Eligibility Criteria	*(Success/Failure – Overall Response)*	
EHR Communication :: Hospital EHR Request Processor			
Find Total Eligible Patients (UC4)	An XML Document including the CTP_ID, Question_ID (indicating whether it is case i or ii) and the Eligibility Criteria	Integer *(Total Number in Hospital)*	05/07/2011
Find Clinical Characteristics of the Eligible Patients (UC11)	An XML Document including the CTP_ID, Question_ID (indicating whether it is case i or ii) and the Eligibility Criteria	Boolean *(Success/Failure)*	05/07/2011
EHR Communication :: Hospital WS			
Execute SPARQL query	An XML document with the Question_ID (information we would like to receive from the EHR datasource) and the Eligibility Criteria	An XML document with the data found in the EHRs of the hospital and metadata about which criteria were used	05/07/2011

Table 1 PONTE Components Communication cases (Status:: green: ok, orange: only interface-functionality implemented for next iteration, light blue: to be updated in the next iteration)

It should be noted that the security components have been developed but has not been integrated yet.

4.2 Integration Testing

The purpose of integration testing for the Initial Integrated Prototype has been to verify the initial PONTE functional requirements. As a first step, unit testing was performed for each component, during which, the individual components were tested in terms of expected functionality at both class and component level. Following this, the test cases defined within ID2.4.1 “Validation Plan, Evaluation Criteria and Set of Knowledge Sources” were applied. It should be noted that no capability tests took place for this prototype, but are scheduled to take place for the second version of the PONTE integration prototype.

The following table presents the results (status) of the aforementioned tests (*green* indicates success, *orange* indicates partial success with open issues left which are described, *yellow* indicates that this test case is planned for the next prototype):

Test Case ID	Main Components Involved	Status
PONTE_BT_PPS_V_01	All	OK
PONTE_BER_STH_V_01	PAT, SRL	Auto-completion to be provided in the 2nd Prototype
PONTE_BER_STH_I_02	PAT, SRL	Planned for 2nd Prototype/ For now, the user selects values from a list
PONTE_BER_SCH_V_01	PAT, SRL	Planned for 2nd Prototype
PONTE_BER_SCH_I_02	PAT, SRL	Planned for 2nd Prototype
PONTE_BER_SCH_V_03	PAT, SRL	Planned for 2nd Prototype
PONTE_BER_PIS_V_01	PAT, DS, OBSE	OK
PONTE_BER_PIS_V_02	OBSE	OK
PONTE_BER_PIS_V_03	OBSE	Planned for 2nd Prototype
PONTE_BER_PIS_V_04	OBSE	Planned for 2nd Prototype
PONTE_BER_PIS_V_05	OBSE, SRL	*As it is based on the PONTE Ontology, more work on this is expected for the 2nd Prototype.*
PONTE_BER_PIS_I_06	OBSE	Planned for 2nd Prototype
PONTE_BER_PIS_V_07	OBSE	Planned for 2nd Prototype
PONTE_BER_PIS_V_08	OBSE	Planned for 2nd Prototype
PONTE_BER_VCTP_01	PAT	OK
PONTE_BER_SCTPP_V_01	PAT, SRL	OK
PONTE_BER_SCTPP_V_02	PAT, DS	OK
PONTE_BER_SCTPP_V_03	PAT, DS	OK
PONTE_BER_SCTPP_V_04	PAT, DS	OK
PONTE_BER_SCTPP_V_05	PAT, SRL, EHR Communication	OK
PONTE_BER_SCTPP_I_06	PAT, DS	Planned for 2nd Prototype
PONTE_BER_SIV_S_01	PAT, SRL	Versioning needs to be updated

		Expected in 2nd prototype
PONTE_BER_UCTP_V_01	PAT, SRL	Versioning needs to be updated – To be updated in the 2nd Prototype
PONTE_BER_SCTP_V_01	PAT, SRL	CTP status flag needs to be incorporates in the CTP ontology – To be updated in the 2nd Prototype
PONTE_BER_SCTP_I_02	PAT, DS	OK
PONTE_BER_RPS_V_01	PAT, DS, EHR Communication	OK
PONTE_BER_DPA_V_01	PAT, SRL	Planned for 2nd Prototype
PONTE_BER_DPA_I_01	PAT, SRL	Planned for 2nd Prototype
PONTE_BER_AP_I_01	PAT, SRL	Planned for 2nd Prototype
PONTE_BER_AP_I_02	PAT, SRL	Planned for 2nd Prototype
PONTE_BER_L_V_01	Security, PAT	Planned for 2nd Prototype
PONTE_BER_L_I_02	Security, PAT	Planned for 2nd Prototype
PONTE_BER_L_I_03	Security, PAT	Planned for 2nd Prototype

Table 2 PONTE Test Cases results, status and planning

5. Initial PONTE Integrated Prototype Evaluation

Within this first iteration, as it was mentioned before, the main goal was to verify the correct communication of the initial versions of the components. At this point, this initial platform, given its above mentioned goal, while it was being integrated, it was presented to NKUA (the Evaluation process leader) who led the evaluation process based on the criteria described in ID2.4.1 “Validation Plan, Evaluation Criteria and Set of knowledge sources”.

5.1 User Friendliness

In the following table the evaluation results for the user friendliness requirements (included in ID2.4.1) regarding the Initial Integrated Prototype are presented.

Criteria	User friendliness requirement	Evaluation Outcome
Simplicity	To evaluate if the use of the PONTE platform is straightforward or if it requires special skill.	No special skills are required. Navigating through the ontologies seems a little complicated. Training on this will be required.
Readability	To check transparency of data information; the problem is much more important when it comes to cross-border applications.	So far no issues
Design	Was the graphical interface appreciated by the users? It is a secondary but not negligible factor in determining an application’s success.	The GUI seems friendly and easy to use. The same comment on ontologies (as above) applies here.
Reachability of services	This indicator is about the ability to reach the available services and understand them, which is often a challenge with many applications.	The services match the Use Cases of D2.1.1 and are easy to understand in terms of returned results.

Navigability	To measure the user's ability to locate his/her progress within a given navigation path	PONTE offers 3 navigation paths through the CTP. The Successive view seems straightforward. The Dependencies view seems useful, although if too many levels are there, then it seems a little complicated (need more time for getting used to it). The Semantic View seems helpful. Within PONTE CTP view, there are 3 areas for use: - the pre-defined queries area which provides the queries per section a researcher may want to answer: seems straightforward - the preparation area for the researcher to fill in values for parameters attached to the CTP section: seems straightforward - the free-text area for filling in the CTP section information: seems straightforward. Probably need for checking for inconsistencies between preparation area and free-text area, if possible.
Perception of application criticality	Is the user aware of the importance of each step he/she is taking e.g. when updating a CTP parameter?	The importance of changing a CTP parameter is known to the researchers. However, proper messages when changing critical parameters is required (like changing the main CTP parameters; study disorder, investigational drug, target which is foreseen for the next iteration, but also to other ones).
Error message readability	One point which is not always very clear in applications is error diagnostics. If the service is interrupted for any reason, is the user able to recognize the cause of malfunctioning?	The Error Messages need to be simple and easy to understand. Maybe a tip on what to do next would be helpful.
Access speed	A long wait in getting the expected results may discourage the user. The users' expectations in this regard might be very high, especially if the service has been advertised as very beneficial.	Overall, no high real-time operation requirements. The pre-defined queries are presented finely at the respective area of the PAT. Navigation and CTP saving have no delays. Search results are returned in a satisfying time. No performance requirements are posed for the number of patients and the patient selection, although for the first one a fast service would be preferable, if possible.

Table 3 Evaluation of Criteria for measuring User friendliness

5.2 User Satisfaction

In the following table the evaluation results for the user satisfaction requirements (included in ID2.4.1) regarding the Initial Integrated Prototype are presented.

Criteria	User satisfaction requirement	Evaluation Outcome
Improved efficiency	This indicator measures the users' perception of how the provided services have improved efficiency as compared to their previous experience.	So far this process is paper-based, searching for literature is based on the journals search engines, or internet search engines in general and no indication about the size of the available patient population is available. Thus, the provided services seem to speed up the process of CTP design, combine important information and structure the work to be done in a more efficient manner.
Improved quality of work	To indicate how users perceive potential improvements of overall quality of work.	Designing the CTP seems to be done more efficiently through the PONTE platform since the information required is structured, dependencies among CTP parameters are presented allowing for avoiding inconsistencies and searching is much more efficient since the tagging of the different available information and the returned results are closer to the question posed. More expectations are posed on the future iterations concerning the relation of the returned search results to the query posed, the dependencies among the CTP parameters (they should be documented in the next iterations and included in the next platform versions), different templates could be considered for some CTP sections which are straightforward. Getting a list of notes per selected patient about comorbidities and administered treatments, and potential side-effects and negative interactions seems useful because the screening process can also become less lengthy and more focused. The rules based on which this notes per patient are formed need to be further enriched.
User perception of service usefulness	To test whether the user consider the PONTE platform useful	The CTP navigation seems satisfactory. Maybe when entering the section parameters and filling in the free text for this section a check could be made for avoiding different values for same parameters. The search is very useful. Saving the most important results seems important and should be considered for the next iteration. The indication of the size of the available patient population satisfying the eligibility criteria while designing the clinical trial seems very useful. It would be more useful (and should be considered in the next version of the platform) to have an indication per hospital apart from a total number.

Confidence	To check to what extent do users trust such a system.	The prototype follows an accepted, trusted CTP structure and the pre-defined queries as well as the rules for decision support come from the clinicians and partially (as they need to be enriched in the next version) satisfy the researchers. Expectations are posed on the PONTE ontology, especially for searching literature. Considerations need to be made about the data sources used. It is understood that open, publicly available data sources are being used for the purposes of the project, but at least during exploitation commercial validated data sources need to be considered.
Improved transparency	To see if users think that now they may have access to more transparent and better information from provided services.	Searching through literature seems easier and the results reflect the questions more effectively. In the next versions of the platform, the PONTE ontology should be richer in order for more sophisticated queries to be posed and better filtered results to be presented. Presenting the most important concepts underneath each result (and not only filtering through the ontology) would be useful for the clinician to select among them.
Readiness for behavioral changes	To estimate how keen users are to modify their habits as a consequence of using the available services.	The system seems very useful and allows for more efficient design of the clinical trials through improved organisation of the information required and links with literature. Its interface is, in general, not complicated.
Acceptance/ improved relations with the new services	To assess whether users consider that the use of such services will improve their relationship with their colleagues and patient, and to evaluate if there is a cultural change in the user's perception of the new services, which is no longer seen as a simple system but rather as a trusted counterpart.	As soon as multiple users and roles will be allowed to use the platform for accessing the different services, it will allow for better and faster collaboration among researchers. This will be further boosted when the researcher is able to save the search results so that other researchers could also view them and comment upon. Concerning the patients, having the researcher a first overall picture – before the actual screening - about the patients' condition (now based on a simple risk profile) can help speed up the screening process as well as reducing the patient population to be screened.
Potential extension to other application/ system	To assess if the users are comfortable enough with the technology so as to wish its use were extended.	Many expectations are posed on the next versions of the platform and the users are looking forward to testing it. Incorporation of Phase 1 during the next iterations is expected to boost the system's potential and support to the clinicians.

Overall satisfaction	A synthesis of all of the above.	Overall, the initial integrated prototype seems useful, relatively easy to use (with some training required especially for the ontology navigation part and the CTP parameters filling in), with interesting services offered (especially the number of patients satisfying the eligibility criteria, the notes on potential side-effects and comorbidities based on the risk profile produced, the filtered search which is expected to be enhanced through the developed PONTE ontology and the consistency checks throughout the CTP). The above services are expected to be enriched with additional features as the ones mentioned in these tables.

Table 4 Evaluation of Criteria for measuring user satisfaction

6. Lessons Learnt – Considerations for the 2nd prototype

The following table summarises the PONTE components and for each one of them presents:

(a) the Web Services exposed by each component,

(b) the required libraries (either External or Internal (i.e. PONTE libraries)) and

(c) the partner(s) involved in its development.

PONTE Component	Web Service / Web Applications	External Libraries/ Frameworks	PONTE Libraries	Partner who Delivered
EHR Communication	PONTE EHR Request Processor (WS)	CXF, Spring		ICCS/NTUA
	Hospital EHR Request Processor (WS)	CXF, Apache xml beans, Spring		ICCS/NTUA
	Mediator (WS) – *rewrites SPARQL queries*	CXF, Align-API, Jena-Arq, Spring	Mediator.lib	ICCS/NTUA
	SPARQL Endpoint (D2R)	Jena-Arq		ICCS/NTUA
	Hospital WS – *transforms from .xml to Hospital SQL*	JAX-WS, JAXB		ICCS/NTUA
SRL	EHR Request Handler (WS) – *transforms from .xml to SPARQL (currently replacing part of CTP Repository WS)*	CXF, Spring, Apache xml beans	SRL.lib	ICCS/NTUA
	CTP Repository (.xml to SPARQL provided by WS above)			CETIC
	Term Code mapper (dummy implementation – only interface)			CETIC
				CETIC
Decision Support	PatientSafetyProfileInterface (WS). Hospital DS – creates safety profile for each patient	CXF , Spring		ICCS/NTUA
	PredefinedQueriesInterface (WS) used by the PAT to retrieve predefined queries	CXF, Spring, Hibernate		ICCS/NTUA
	CtpInterface (WS) Used by the PAT to perform validation of the CTP parameters	CXF, Spring		ICCS/NTUA
PAT	PONTE Authoring Tool interface	JAX-WS, JAXB		ICCS/NTUA
Ontology Based Search Engine	GoWeb based Search Engine (WA)	Spring, Bing API (will not be needed in 2nd Prototype), SAXON		TUD

PONTE Component	Web Service / Web Applications	External Libraries/ Frameworks	PONTE Libraries	Partner who Delivered
	Indexing (WS)	Lucene		TUD

Table 5 PONTE Web Services/Applications and deployment requirements

The following figures present some system screenshots and log files (in order to show interactions among components which do not go through the user interface) which show the output of different components in selected test scenarios. The first set of figures (Figure 6 to **Error! Reference source not found.**) shows screenshots of the PAT during CTP editing. More specifically, they show how PAT interacts with DS in order to present the set of predefined questions per CTP section (Steps 1 and 2 in the following figure) and allow the user to select among them and view the respective results through the OBSE (Step 3 below).

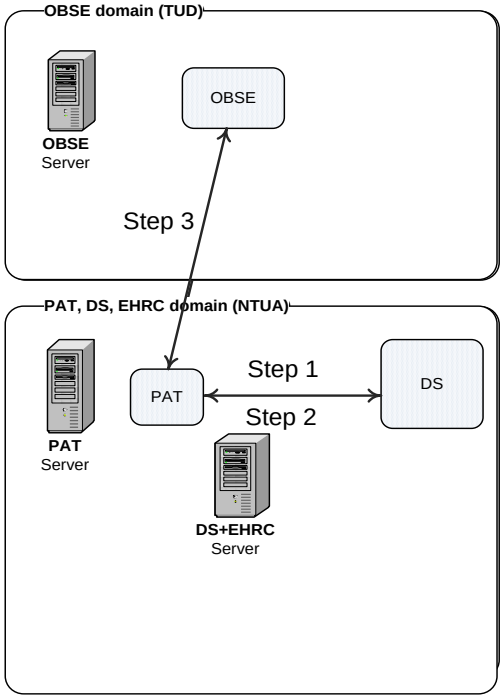


Figure 3 Test Scenario 1

In the next set of figures (to Figure 14) two test scenarios with the interactions among PAT, EHR Communication, DS and SRL in the SPARQL approach are presented. More specifically, they present the cases when the user specifies a set of eligibility criteria for which he requests:

(i) the number of patients (at the hospitals which will participate in the clinical trial) who satisfy the eligibility criteria (*test scenario 2*),

(ii) patient selection based on the eligibility criteria (*test scenario 3*).

Figure 9 to Figure 13 correspond to test scenario 2, whereas Figure 9 and Figure 14 (with the intermediate outputs being similar – not the same as the request now has changed - to the ones presented in Figure 10 to Figure 12) show test scenario 3. In fact, they demonstrate the 1st prototype's approach on issues like:

- how PAT allows the specification of eligibility criteria (Figure 9)
- how PAT communicates the specified eligibility criteria to DS and SRL::*EHR Request Handler* (*Figure 10*) – (Step 1 in *Figure 4* and *Figure 5*)
- the output of the EHR Request Handler – i.e. transformation of the xml message to a SPARQL query over the PONTE ontology (*Figure 11*) – (Step 5 in *Figure 4* and *Figure 5*)
- the output of the Mediator – i.e. the translated SPARQL query received which was based on the eligibility criteria expressed over PONTE ontology into the respective SPARQL query over the Hospital EHR Ontology (*Figure 12*) – (Step 7 in Figure 4 and Figure 5)

- the response received which is forwarded to the PAT (Figure 13) – (Step 10 in Figure 4 and Figure 5)
- the output of the Hospital DS after building the patient risk profile (Figure 14) – (Step 17 in Figure 5)

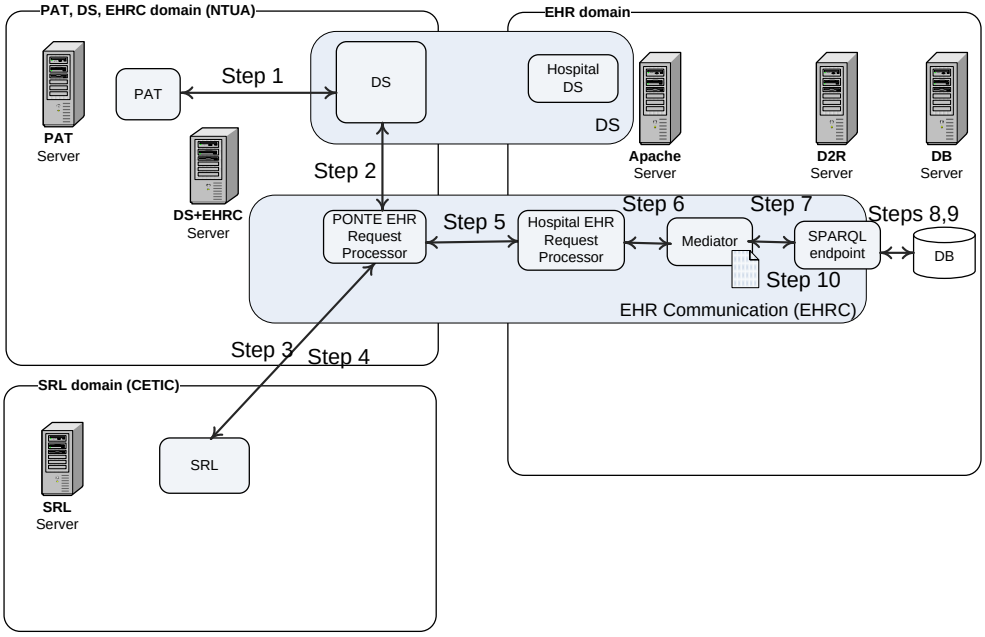


Figure 4 Test Scenario 2

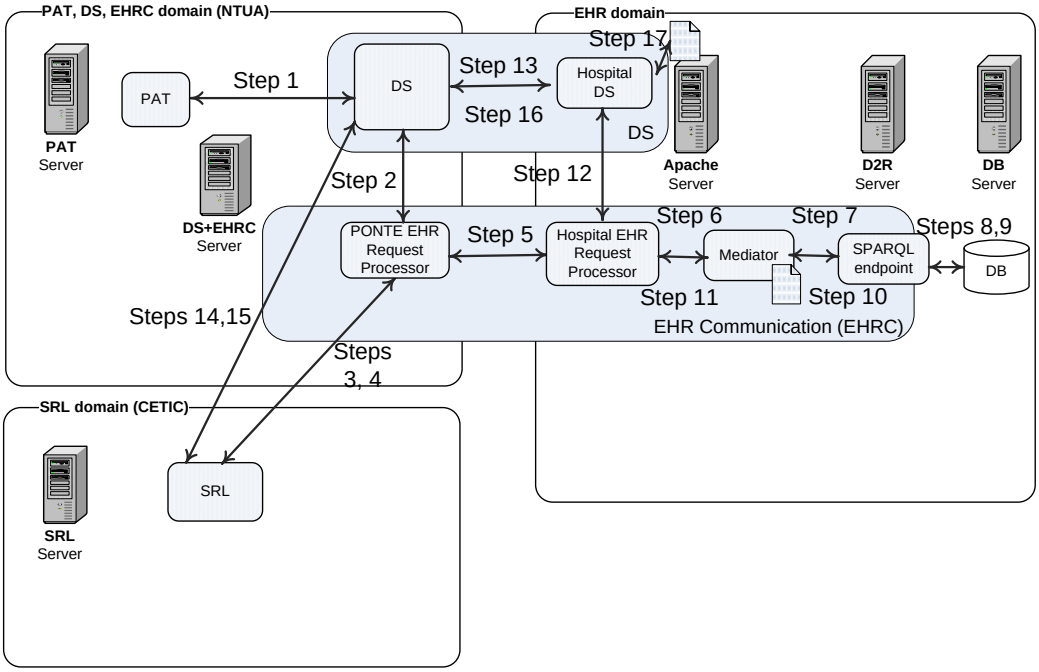
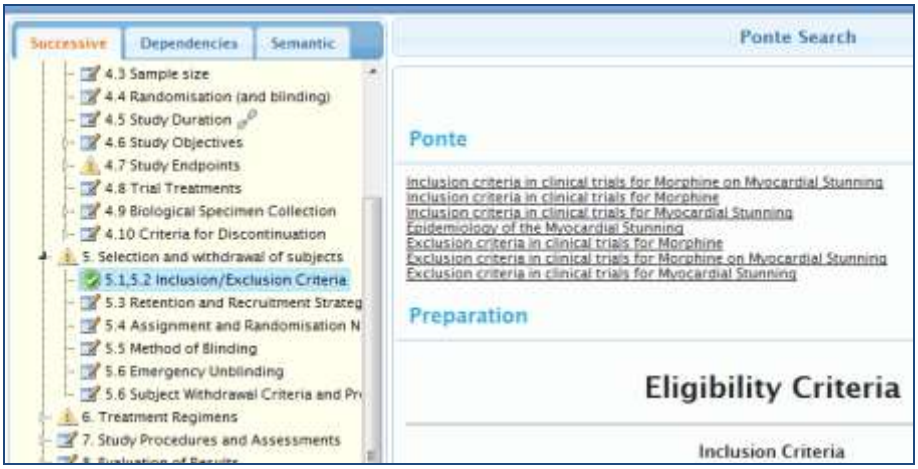
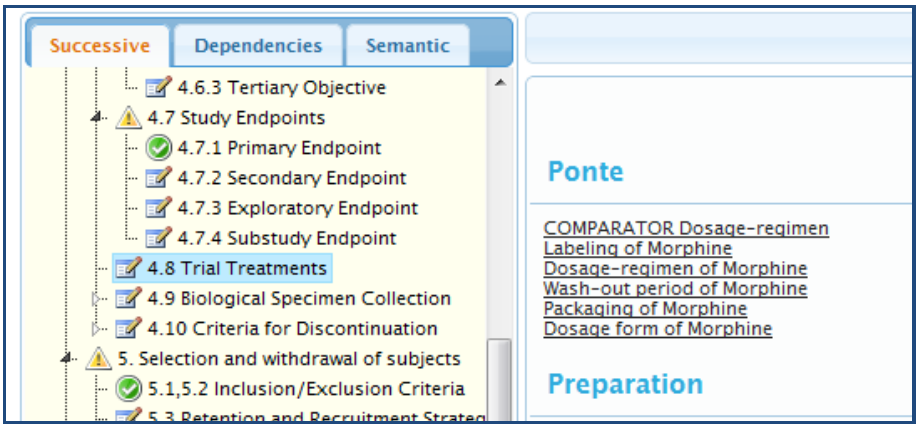
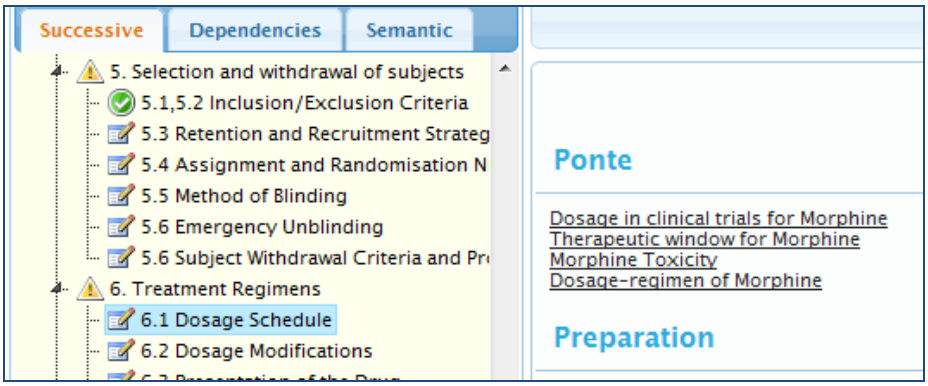


Figure 5 Test Scenario 3

The following figures demonstrate the different “predefined queries” that are available to the user depending on the section s/he navigates to:







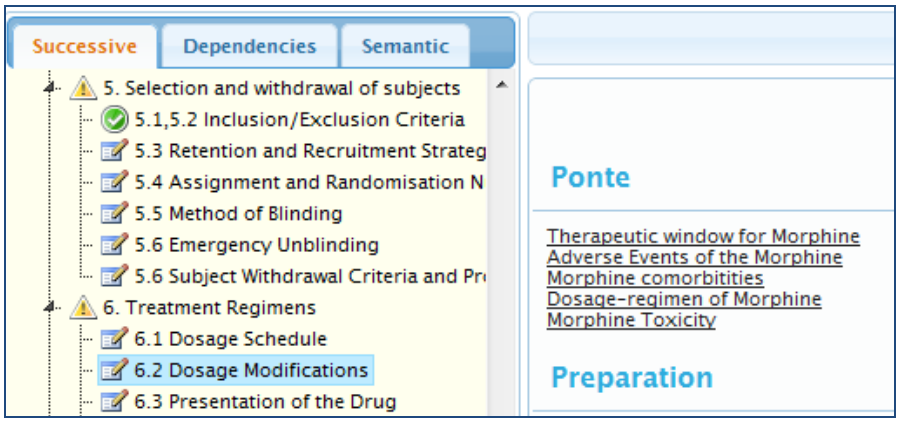


Figure 6 PAT Screenshots: Presentation of the Predefined Queries per section after communication with the DS

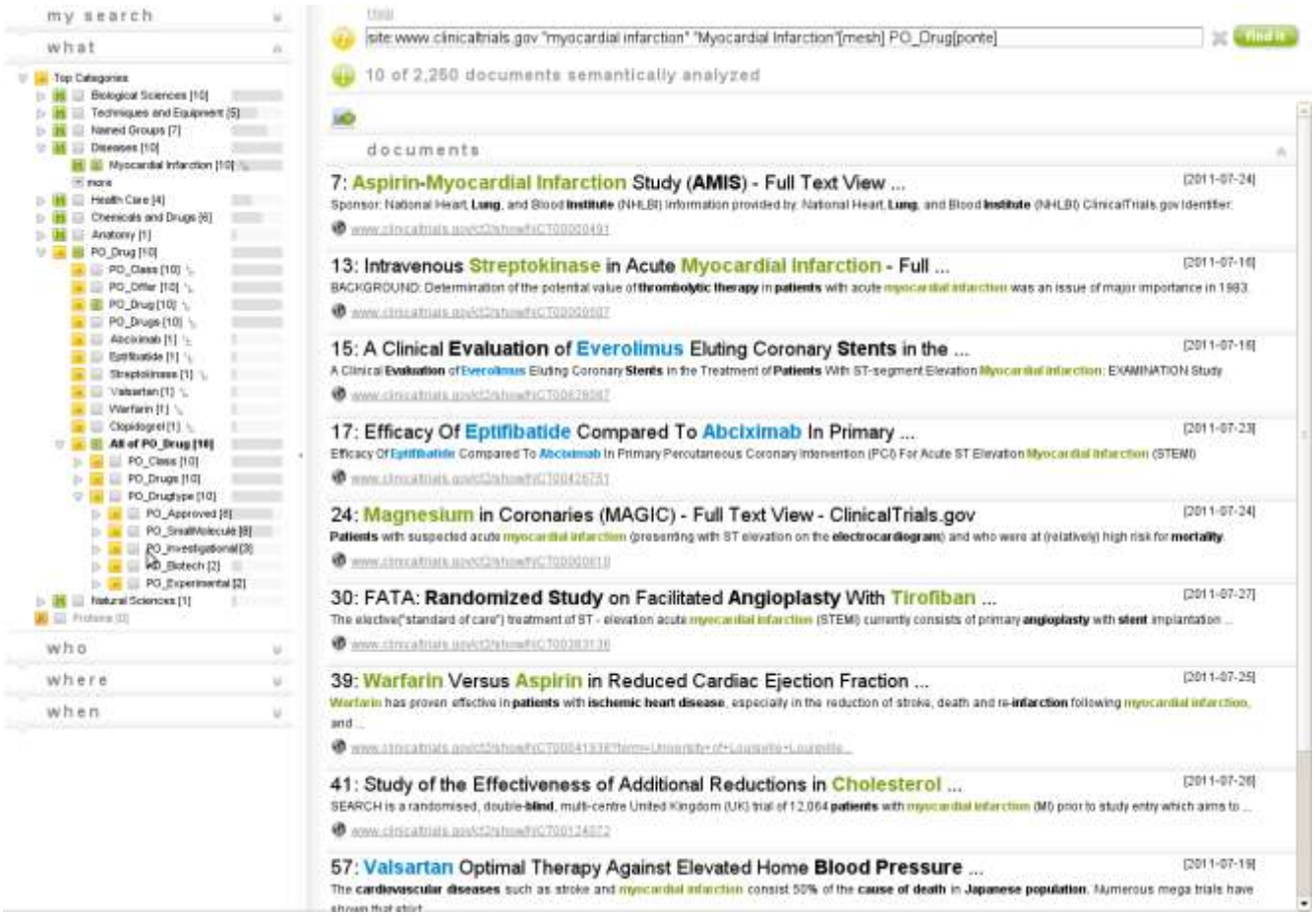


Figure 7 Results for performing an intelligent search based on a predefined query (existing Clinical trials about <DRUG> and <DISORDER>) sent by PAT.

In the upper search bar the query can be seen as created by the PAT. As disorder myocardial infarction was selected and as drug any drug. From the PONTE ontology (PO_Drug, left) drugs can be selected according to their type such as approved, small molecules, or investigational. The disease terms and drugs are highlighted in green, the currently selected investigational drugs in blue.

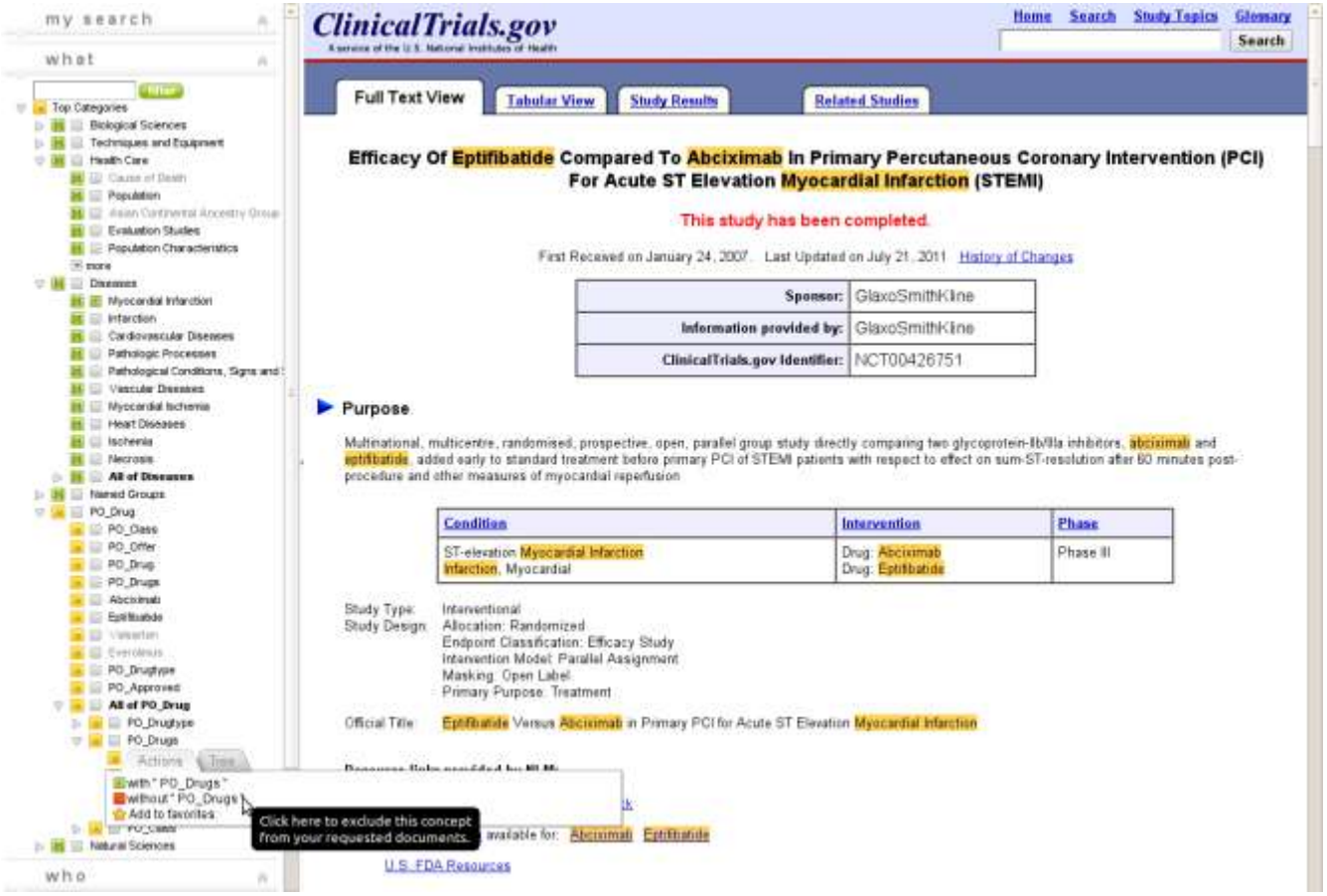


Figure 8 OBSE: Navigating through a query showing inline annotations for a retrieved document from ClinicalTrials.gov. The ontology tree on the left can be used to navigate through the PONTE knowledge base, including or excluding instances and concepts (context menu lower left).

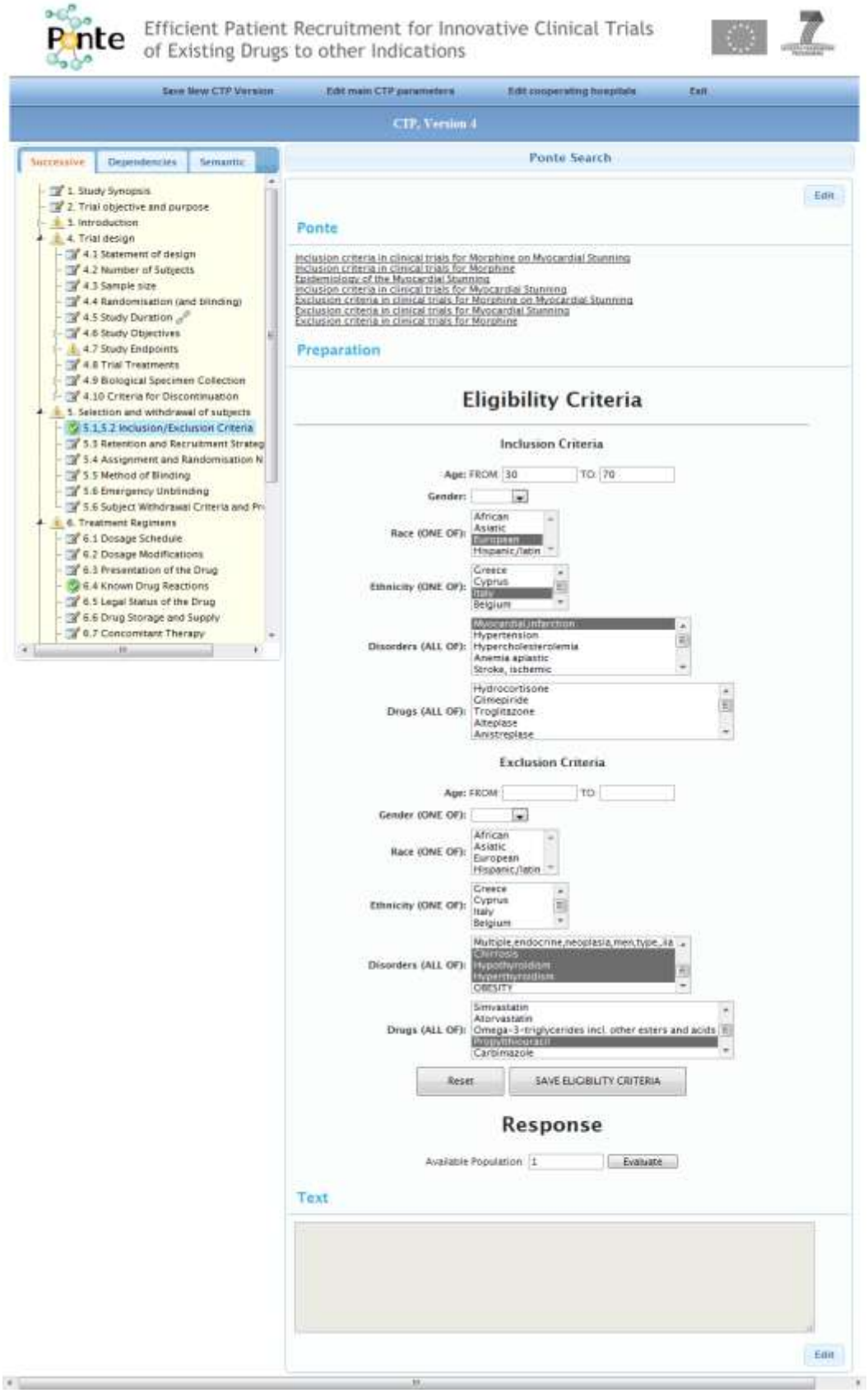


Figure 9 PAT Screenshot: Setting the Eligibility Criteria (values taken from THIRST study)

```
# XML MESSAGE (Generated by PAT)
# ================================================================================

<EhrRequest xmlns="http://www.ntua.org/ponte/criteria">
    <Question xmlns="">ELIGIBLE-PATIENTS-NUMBER</Question>
    <EligibilityCriteria xmlns="">
        <InclusionCriteria>
            <AgeCriterion ID="InAgeCriterion+CTP-ID">
                <HasAgeRestriction>
                    <InRange>
                        <DownLimit>30</DownLimit>
                        <UpLimit>70</UpLimit>
                    </InRange>
                </HasAgeRestriction>
            </AgeCriterion>
            <EthnicityCriterion ID="InEthnicityCriterion+CTP-ID">
                <HasEthnicityRestriction>
                    <InSet>
                        <Value>
                            <Code codeValue="Italy" codeSystem="CNR"/>
                        </Value>
                    </InSet>
                </HasEthnicityRestriction>
            </EthnicityCriterion>
            <RaceCriterion ID="InRaceCriterion+CTP-ID">
                <HasRaceRestriction>
                    <InSet>
                        <Value>
                            <Code codeValue="European" codeSystem="CNR"/>
                        </Value>
                    </InSet>
                </HasRaceRestriction>
            </RaceCriterion>
```

Figure 10 XML Message generated by PAT

```
<DisorderCriterion ID="InDisorderCriterion+CTP-ID">
                <DisorderCodeRestriction>
                    <AllOfSet>
                        <Value>
                            <Code codeValue="410.0" codeSystem="ICD9"/>
                        </Value>
                    </AllOfSet>
                </DisorderCodeRestriction>
            </DisorderCriterion>
        </InclusionCriteria>
        <ExclusionCriteria>
            <DisorderCriterion ID="ExDisorderCriterion+CTP-ID">
                <DisorderCodeRestriction>
                    <AllOfSet>
                        <Value>
                            <Code codeValue="571" codeSystem="ICD9"/>
                        </Value>
                        <Value>
                            <Code codeValue="244" codeSystem="ICD9"/>
                        </Value>
                        <Value>
                            <Code codeValue="242.9" codeSystem="ICD9"/>
                        </Value>
                    </AllOfSet>
                </DisorderCodeRestriction>
            </DisorderCriterion>
            <DrugTherapyCriterion ID="ExDrugTherapyCriterion+CTP-ID">
                <DrugCodeRestriction>
                    <AllOfSet>
                        <Value>
                            <Code codeValue="H03BA02" codeSystem="ATC"/>
                        </Value>
                    </AllOfSet>
                </DrugCodeRestriction>
            </DrugTherapyCriterion>
        </ExclusionCriteria>
    </EligibilityCriteria>
</EhrRequest>
```

Figure 10 (Continued) XML Message generated by PAT

```
# PONTE SPARQL QUERY (Generated by XML to SPARQL transformer)
# ================================================================================

PREFIX rdf: <http://www.w3.org/1999/02/22-rdf-syntax-ns#>
PREFIX xsd: <http://www.w3.org/2001/XMLSchema#>
PREFIX ehr: <http://www.semanticweb.org/ontologies/2011/5/PonteEhrOntology.owl#>

SELECT ( COUNT(DISTINCT ?patient) AS ?TotalEligiblePatients )
WHERE {
   # ******* Inclusion Criteria *******
      ?patient      rdf:type                  ehr:Patient          .
      ?patient      ehr:has_Age               ?age1                .
      ?patient      ehr:has_Ethnicity         ?ethnicity2          .
      ?ethnicity2   rdf:type                  ehr:CNR_Ethnicity    .
      ?ethnicity2   ehr:has_Code              ?ethnicitycode2      .
      ?patient      ehr:has_Race              ?race3               .
      ?race3        rdf:type                  ehr:CNR_Race         .
      ?race3        ehr:has_Code              ?racecode3           .
      ?patient      ehr:has_Disorder          ?disorder4           .
      ?disorder4    rdf:type                  ehr:Disorder         .
      ?disorder4    ehr:has_Disorder_Term     ?disorderterm4       .
      ?disorderterm4 rdf:type                 ehr:ICD_9_Disorder_Term .
      ?disorderterm4 ehr:has_Code             ?icdcode4            .
            FILTER ( ?age1 >= 30 && ?age1 <= 70 )
            FILTER ( REGEX(?ethnicitycode2, "Italy", "i") )
            FILTER ( REGEX(?racecode3, "European", "i") )
            FILTER ( REGEX(?icdcode4, "410.0", "i") )
```

Figure 11 PONTE SPARQL Query (Generated by EHR Request Handler from XML message in Figure 10)

```
    # ******* Exclusion Criteria *******
        OPTIONAL {
                ?patient            ehr:has_Disorder     ?disorder5                .
                ?disorder5          rdf:type             ehr:Disorder        .
                ?disorder5          ehr:has_Disorder_Term      ?disorderterm5       .
                ?disorderterm5      rdf:type             ehr:ICD_9_Disorder_Term .
                ?disorderterm5      ehr:has_Code ?icdcode5 .
                        FILTER (
                                REGEX(?icdcode5, "571", "i") ||
                                REGEX(?icdcode5, "244", "i") ||
                                REGEX(?icdcode5, "242.9", "i") )
        } . FILTER ( ! BOUND(?icdcode5) )
        OPTIONAL {
                ?patient            ehr:receives_Therapy       ?therapy6            .
                ?therapy6           rdf:type                   ehr:Drug_Therapy     .
                ?therapy6           ehr:has_Drug         ?drug6               .
                ?drug6              ehr:has_Drug_Term    ?drugterm6           .
                ?drugterm6          rdf:type                   ehr:ATC_Drug_Term .
                ?drugterm6          ehr:has_Code         ?atccode6            .
                        FILTER (( REGEX(?atccode6, "H03BA02", "i") ))
        } . FILTER ( ! BOUND(?atccode6) )
}
```

Figure 11 (Continued) PONTE SPARQL Query (Generated by EHR Request Handler from XML message in Figure 10)

```
# CNR SPARQL QUERY (Generated by Mediator)
# ================================================================================

PREFIX  rdfs: <http://www.w3.org/2000/01/rdf-schema#>
PREFIX  xsd:  <http://www.w3.org/2001/XMLSchema#>
PREFIX  rdf:  <http://www.w3.org/1999/02/22-rdf-syntax-ns#>
PREFIX  vocab: <http://localhost:2020/vocab/resource/>

SELECT  ( count(distinct ?patient) AS ?TotalEligiblePatients )
WHERE
  { { { ?patient           rdf:type                              vocab:t_clinchar .
        ?patient           vocab:t_clinchar_t_clinchar_age ?age1           .
        ?patient           vocab:t_clinchar_d_country_cod  ?ethnicity2     .
        ?ethnicity2        rdf:type                              vocab:d_country  .
        ?ethnicity2        vocab:d_country_d_country_name  ?ethnicitycode2  .
        ?patient           vocab:t_clinchar_d_ethnic_cod   ?race3          .
        ?race3             rdf:type                              vocab:d_ethnic     .
        ?race3             vocab:d_ethnic_d_ethnic_desc        ?racecode3   .
        ?disorder4  vocab:t_diag_t_clinchar_key         ?patient          .
        ?disorder4  rdf:type                            vocab:t_diag      .
        ?disorder4  vocab:t_diag_t_icd9_cod      ?disorderterm4     .
        ?disorderterm4     rdf:type                             vocab:t_icd9       .
        ?disorderterm4     vocab:t_icd9_t_icd9_cod      ?icdcode4
        OPTIONAL {
             ?disorder5          vocab:t_diag_t_clinchar_key      ?patient      .
            ?disorder5           rdf:type                         vocab:t_diag .
            ?disorder5           vocab:t_diag_t_icd9_cod    ?disorderterm5 .
            ?disorderterm5       rdf:type                         vocab:t_icd9 .
            ?disorderterm5       vocab:t_icd9_t_icd9_cod    ?icdcode5
             FILTER ( (  regex(?icdcode5, "571", "i")        ||
                                 regex(?icdcode5, "244", "i") ) ||
                                  regex(?icdcode5, "242.9", "i") )
          }
      }
```

Figure 12 CNR SPARQL Query (Generated by EHR Communication::Mediator) from PONTE SPARQL Query presented in Figure 11

```
OPTIONAL {
              ?drug6              vocab:t_drugt_t_clinchar_key      ?patient      .
              ?drug6              vocab:t_drugt_t_atc_cod    ?drugterm6    .
              ?drugterm6          rdf:type                          vocab:t_atc .
              ?drugterm6          vocab:t_atc_t_atc_cod             ?atccode6
                    FILTER regex(?atccode6, "H03BA02", "i")
        }
    }
    FILTER ( ( ?age1 >= 30 ) && ( ?age1 <= 70 ) )
    FILTER regex(?ethnicitycode2, "Italy", "i")
    FILTER regex(?racecode3, "European", "i")
    FILTER regex(?icdcode4, "410.0", "i")
    FILTER ( ! bound(?icdcode5) )
    FILTER ( ! bound(?atccode6) )
  }
```

Figure 12 (Continued) CNR SPARQL Query (Generated by EHR Communication::Mediator) from PONTE SPARQL Query presented in Figure 11

```
# SELECT RESPONSE - XML MESSAGE (Response from SPARQL endpoint)
# ================================================================================


<?xml version="1.0"?>
<sparql xmlns="http://www.w3.org/2005/sparql-results#">
    <head>
        <variable name="TotalEligiblePatients"/>
    </head>
    <results>
        <result>
            <binding name="TotalEligiblePatients">
                <literal
datatype="http://www.w3.org/2001/XMLSchema#integer">10</literal>
            </binding>
        </result>
    </results>
</sparql>
```

Figure 13 Response to PAT

```
<?xml version="1.0" encoding="UTF-8" standalone="true"?>
- <ns2:PatientProfile xmlns:ns2="http://www.ntua.org/ponte/patprof">
  - <patientProf patientId="http://localhost:2020/resource/t_clinchar/171">
      <Drug>Etanercept</Drug>
      <Drug>L-Cysteine</Drug>
      <Disease>Myocardial_infarction</Disease>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Spirapril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Captopril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Quinapril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Perindopril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Lisinopril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Moexipril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Enalapril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Benazepril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Trandolapril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Fosinopril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Ramipril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
    </patientProf>
  - <patientProf patientId="http://localhost:2020/resource/t_clinchar/176">
      <Drug>Carbimazole</Drug>
      <Drug>Methimazole</Drug>
      <Drug>Fosinopril</Drug>
      <Drug>Etanercept</Drug>
      <Drug>Sunitinib</Drug>
      <Disease>Hyperthyroidism</Disease>
      <Disease>Myocardial_infarction</Disease>
      <Disease>Multiple endocrine neoplasia IIA, 171400</Disease>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Spirapril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Captopril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Quinapril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Perindopril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Lisinopril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Moexipril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Enalapril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Benazepril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Trandolapril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Fosinopril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Patient suffers from Myocardial_infarction which could be treated with Ramipril and in combination with the CTPdrug: Triamterene causes Increased risk of hyperkaliemia</SafetyWarning>
      <SafetyWarning>Triamterene in combination with Fosinopril cause Increased risk of hyperkaliemia</SafetyWarning>
    </patientProf>
</ns2:PatientProfile>
```

Figure 14 Decision Support Output in Patient Selection Process

Based on the experience from the integration efforts within this first iteration of the PONTE project implementation and integration, the following will be taken into great consideration (lessons learnt) for the next prototypes to be delivered:

- Strong dependencies from the PONTE Ontology by many PONTE components (EHR Communication, Decision Support and Ontology-based Search Engine) may be posing delays in the development and testing of these components. For this reason, greater effort will be made within WP4 in order to speed up the development process. Close communication with the clinical experts will be established in order to allow for a valid and rich ontology which satisfies the PONTE purposes.
- In the SPARQL approach, the transformation from xml to SPARQL proved to be a difficult task. More effort will be required towards this direction and alternatives (e.g., SPIN[1]) need to be checked.
- Concerning the EHR Communication components, given their heavy processing and the resulting great computational requirements it is considered that the deployment of these components been made at separate servers for better performance.
- Concerning the Hospital-DS component, in order to create safety profiles for the eligible patients, it needs access to a great amount of data – ontology concepts, linked data, detailed information about drugs and diseases. This is currently done via sending queries to a variety of SPARQL endpoints. The amount of queries is big, even for a single patient with a minimal number of indications. While developing the system we came upon the following challenges and solutions:
    - The query processing and response time is critical to the overall application run time. The server hosting the SPARQL endpoint has increased need for processing power. While initially some endpoint used in the system where hosted by 3rd parties, reliability problems led us to host them in our own servers.
    - Queries are exchanged over the web (http request) so again network infrastructure is critical for the server hosting the SPARQL endpoint, as it needs to handle a big number of requests coming in a short period of time.
- Concerning the Semantic Mapper component (although currently only the interface is available), it is expected that, given the current interface (1 request per code), during the mapping process (especially in the case of transforming the results from the hospitals into PONTE terms and coding systems/vocabularies/classifications), a great number of requests will be sent from EHR Communication to this component in a short period of time. Especially in the case of a great number of hospitals being connected to the PONTE platform, the computational demand and network bandwidth for the machine hosting this component will increase tremendously, if the requests are sent at the same time period (which cannot be avoided easily). Hence, in the next iteration PONTE should investigate different options (different instances of the component at the PONTE domain, local mapping file at the side of the hospitals, etc).
- Better prioritisation of component development will be made in the next iterations in order to avoid any integration delays.
- Import/export functionality of the search engine will have to be improved to allow a seamless integration with the PAT and especially with the Linked Data approach while running as a web application.

[1] *http://www.w3.org/Submission/2011/SUBM-spin-overview-20110222/*

7. Conclusions

This report accompanies the Initial Integrated Prototype of the PONTE project which covers Phase 2. Its implementation was based on the initial user requirements analysis and the initial PONTE architecture which were delivered on PM06 and PM09 respectively. This prototype integrates the components which were developed within WP4 and WP5 by the three technical partners of the PONTE Consortium; CETIC, ICCS/NTUA and TUD. This document presented the integrated plan followed during the integration process, the test cases that were used during the testing process, the deployment cases as well as the outcome of the first evaluation process with particular focus on usability and functionalities provided. The dependencies of the developed PONTE components from external libraries were presented as well as the available web services. Finally, screenshots and content from the log files of the components within 3 different test scenarios were presented in order to show the communication among these components. Based on the integration efforts and the evaluation process, a set of issues that need to be taken into consideration for the next iteration (lessons learnt) was presented.