ReMINE

High performances prediction, detection and monitoring platform for patient safety risk management

FP7 Contract: 216134



- Deliverable -

D7.4 ReMINE 3rd Pilot Platform

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1. Executive summary

1.1.Project Overview

The present document constitutes a deliverable of the Work Package (WP) 7 –Demonstration, Task 7.2 - 'System integration, testing and validation (DEM)' of the REMINE FP7 EU co-funded R&D project.

This deliverable describes in detail the final platform prototype. It is important to notice that, as agreed upon by the reviewers and the Commission during ATR2, the first and second prototypes were merged in a single prototype, so in this deliverable are described all the components of the final ReMINE platform (3rd prototype) and a comparison between the 1&2nd Prototype with the 3rd. Moreover is described all the additional work implemented from the last ATR.

The final platform has received a number of improvements and now includes all the functionalities originally foreseen.

NoemaLife, the deliverable responsible, has coordinated the analysis of the platform described in this deliverable; all the technical partners involved in task T7.2 activities and, in general, in WP7 activities have participated and contributed to the completion of the deliverable.

1.2. Task Description

The objective of the task is to define and develop the "Running PILOTs Site" REMINE Platform, integrated with the all components and deployed in the PILOTS site, that will be called the "REMINE Production Prototype (RPP)". The Deliverable D7.4 takes in account the ReMINE Final Platform (RFP) describing the last developments and modifications passing from RPP2 to RFP.



2. Abbreviations

| 2. Addreviations | | | |
|------------------|----------------------------------------------------------------------|--|--|
| Abbreviation | Stands for | | |
| A&E | Accident & Emergency | | |
| ACM | Association of Computing Machinery | | |
| AE | Adverse Event | | |
| API | Application Programming Interface | | |
| ATNA | Audit Trail and Node Authentication | | |
| B2B | Business-to-Business | | |
| BAM | Business Activity Monitoring | | |
| BFO | Basic Formal Ontology | | |
| BPEL | Business Process Execution Language | | |
| BPM | Business Process Management | | |
| BPMI | Business Process Management Initiative | | |
| BPMN | Business Process Modeling Notation | | |
| BRE | Business Rule Engine | | |
| CA | Certification Authority | | |
| CDA | Clinical Document Architecture | | |
| CEN | Committee Européen de Normalisation | | |
| CIA | Confidentiality, Integrity, Authentication | | |
| CTS | Common Terminology Service | | |
| DAL | Data Acquisition Layer | | |
| DB | DataBase | | |
| DBMS | DataBase Management System | | |
| DEMS | Data Events Management System | | |
| DOLCE | Descriptive Ontology for Linguistic and Cognitive Engineering | | |
| DRL | Drools Rule Language | | |
| DSL | Domain Specific Languages | | |
| EHR | Electronic Health Record | | |
| EIS | Entity Identification Service | | |
| ERP | Enterprise Resource Planning | | |
| ESB | Enterprise Service Bus | | |
| ETL | Extract Transform Load | | |
| EU | European Union | | |
| GUI | Graphical User Interface | | |
| H-ERP | Hospital Enterprise Resource Planning | | |
| HIS | Hospital Information System | | |
| HL7 | Health Level 7 | | |
| HSSP | Healthcare Services Specification Project | | |
| HTML | Hyper Text Markup Language | | |
| HTTPS | Hyper Text Protocol Secure | | |
| HW | HardWare | | |
| ICD | International Classification of Diseases and related health problems | | |
| IHE | Integrating the Healthcare Enterprise | | |
| ISO | International Organization for Standardization | | |
| | 1 - 0 | | |

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| JCAHO | Joint Commission on Accreditation of Healthcare Organizations |
|---------|----------------------------------------------------------------------|
| JCAPS | Java Composite Application Platform Suite |
| JDK | Java Development Kit |
| JVM | Java Virtual Machine |
| JSON | Java Script Object Notation |
| KPI | Key Performance Indicators |
| | · |
| LDAP | Lightweight Directory Access Protocol |
| LIS | Laboratory Information System |
| MPI | Master Person Index |
| NIST | National Institute of Standards and Technologies |
| OASIS | Organization for the Advancement of Structured Information Standards |
| ОВО | Open Biomedical Ontologies |
| OMG | Object Management Group |
| OPCS | Office of Population Censuses and Surveys |
| OTD | Object Type Definition |
| OWL | Ontology Web Language |
| PAS | Patient Administration System |
| PKI | Public Key Infrastructure |
| R&D | Research & Development |
| RAPS | Risk(s) Against Patient Safety |
| RBAC | Role-Based Access Control |
| RDP | Remote Desktop Control |
| RHS | Right Hand Side |
| RM | Risk Management |
| RMSE | Root Mean Square Error |
| RLUS | Retrieve Locate Update Service |
| SAML | Security Assertion Markup Language |
| SHEL | Software Hardware Environment Liveware |
| SLA | Service Level Agreement |
| SMS | Short Messaging System |
| SNOMED | Systematized Nomenclature of Medicine |
| SOA | Service Oriented Architecture |
| SOAP | Simple Object Access Protocol |
| SOA4HL7 | Service-oriented Architecture For HL7 |
| SQL | Structured Query Language |
| SSL | Secure Sockets Layer |
| SW | SoftWare |
| TLS | Transport Layer Security |
| UDDI | Universal Description, Discovery and Integration |
| VPN | Virtual Private Network |
| WHO | World Health Organization |
| WP | Work Package |
| WS | Web Services |
| WSDL | Web Services Web Services Description Language |
| WSS | Web Services Security Web Services Security |
| ****** | vvco services security |

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| XACL | XML Access Control Language |
|-------|-------------------------------------------|
| XACML | eXtensible Access Control Markup Language |
| XDS | cross (X) enterprise Document Sharing |
| XML | Extensible Mark-up Language |
| XSD | XML Schema Definition |

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3. 2nd and 3rd Prototype components

In the next table is presented a comparison between 1&2 Prototype and 3rd prototype:

| Components/functionalities | 1&2 Prototype | 3rd Prototype | Improvements |
|-------------------------------------|------------------------------|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| H-ERP Bridge | ✓ (Niguarda, Sacco, TRFT) | ✓ (+SEK) | All messages integration |
| DAL/DEMS | ✓ for Niguarda | ✓ (Sacco and TRFT hospitals) | Integration with all messages coming from H-ERP Bridge/DAL Database connection management Static object instantiation |
| Database | ✓ | | Audit service completion WS-Eventing development on RLUS service to be used in the data mining and knowledge inference module Completion of the metadatabase reasoner in the form of SIMP designer (designer for the semantic signifiers) and the reasoner itself as an executer for these templates inside the RLUS implementation RLUS Wrapper Web Service for the Process Mapper that encapsulates RLUS client business logic |
| KPIs implementation and reporting | ✓ (example KPIs) | ✓ (all KPIs were defined, implemented and reported) | Changes in processes and optimization KPIs according to users Scenarios enhancement |
| Business rules | ✓ (real time rules) | ✓ (real time + predictive) | New real time rules Predictive rules for Sacco hospital (RAPS prediction, detection and control) |
| Forms and contextual data insertion | ✓ (first version) | ✓ (enhanced) | Friendly and intuitive interfaces Changes and enhancements Checking input data in real-time More information available New data required based on medical staff requirements Barcode and RFID use |

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| | | | Automotic in |
|----------------------------------|------------------------------------------------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | Automatic input |
| | | | New forms (Incident report development for SEK) |
| | | | immediate notifications (message boxes) |
| | | | – Translations |
| Risk Calculation | | ✓ (only for Sacco) | calculation of the risk for each patient based on medical conditions and hospital status |
| Automatic planning of activities | | ✓ (only for Sacco) | prediction of the patient status (mainly, the dilatation width) and the resources needed for each patient (staff, devices and rooms) |
| Risk manager interface | √ (first version - different from the interface of tasks and processes of Intalio) | ✓ (integrated with intalio ui-fw - enhanced version) | All ReMINE information is presented in one interface. All components were integrated in a common GUI (processes, tasks, alerting, Business Activity monitoring etc.) The interface automatically enables |
| | | | and disables different components - User friendly - More information available |
| | | | Role -based access control |
| Alerting Management System | ✓ (first version) | ✓ (second version with differentiations from the initial approach) | Monitor the system status and also configure and change the behavior of the entire component. Create new alert instances and can also cancel an existing alert. Escalation Process, which runs in the background controlling the elapsed time for each "open" alert and triggering new messages if no acknowledgment information was received in the configured time. Acknowledgment Process, which comprises of the necessary interface |
| | | | published, and accessible, to the several channel providers. The most relevant interface for this process is the SMS acknowledgment interface, which due to its nature must be accessible from the internet |

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| What if tool | - | ✓ | Enable the risk manager to explore the consequences of various patient characteristics based on the protocol model |
|--------------------|---|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Visualization tool | - | ✓ (research prototype) | The visualization provides charts of the patient's parameters which are mandatory to assess the patient's condition representations of applied treatment plans as well as of plans that are to be applied in the near future, integrating a variety of diverse kinds of information |
| Data mining | - | ✓ (TRFT and Niguarda) | Rules were extracted for TRFT and were validated by users Note: For Niguarda the data mining results indicated that due to the high values in the error indicators, no correlation was detected for predicting the final time of administration |

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4. Pilots Server Specifications

This section will describe in brief the specifications in terms of HW and SW associated with the REMINE pilots. The set-up prescribed here is common for all 4 of the REMINE pilots. Since a precise setup cannot be achieved due to the nature of the different OEM suppliers and hardware manufacturers, small deviations are permitted as long as the changes are checked with the integration leader (Q&R).

The following Hardware specifications apply to the REMINE Pilots' Server:

| Hardware | | | |
|------------------|-----------------------------------------------------------------|--|--|
| Processors | Type Intel: Xeon E7450 | | |
| | Multi-Core processor technology: 6-core | | |
| | 64-bit processor: Yes | | |
| | Processor Qty: 1 | | |
| | Processor number: E7450 | | |
| | Clock speed: 2.4 GHz | | |
| Cache Memory | Installed Size L2 cache – 3x3=9 MB | | |
| | Installed Size L3 cache - 12 MB | | |
| RAM | 8 GB | | |
| Storing capacity | At least 500 GB usable (redundancy level: at least Raid 1 or 5) | | |

It is strongly suggested that the Server is constructed in such a way so as to allow for future expansion capabilities in terms of CPU, RAM and storing capacity.



5. H-ERP Bridge

This section provides information regarding the 'H-ERP Bridge' Module which is responsible for gathering data from Hospital Information Systems, in order to make them available via HL7/XML schemas to the 'Data Acquisition Layer' and subsequently the 'Data Event Management System', responsible for coding, tagging and 'classifying' this data based on the REMINE ontology rules and the 'Data Events' definitions established, while also for thereafter storing them into the REMINE Database.

5.1.Purpose

The 'H-ERP Bridge' ('H-ERP' in following) inputs data directly from the HIS's of the Pilots, including such information as patient historical data, test results, etc, through a number of dedicated/customised interfaces. This module is also responsible for the communication with 'Data Acquisition Layer' (DAL) module via a messaging and queuing system.

5.2.2nd Prototype Functionalities

As previous described the H-ERP bridge is responsible for gathering information from HISs and send them to DAL module in standard way (HL7/XML V2.5) via a dedicated set of customised interfaces specifically deployed for the Pilot's HISs, developed and running on a specific integration middleware

In the second prototype H-ERP bridge developed the whole engine and the main integration adapters for IT pilots (Niguarda and Sacco).

To address effectively this particular requirement in the most 'generic' fashion, the H-ERP has been designed to be capable of handling data from hospital data sources in two different ways as follows:

- <u>Data Mart PUSH:</u> Connection with these data sources must be maintain at all times by the H-ERP in order to:
 - Retrieve all data coming from those sources.
 - Select data of interest.
 - O Queue data into a dedicated message queue.
 - o Transform them for the 'Data Acquisition Layer' (HL7/XML Protocol Transformation).
 - 'Push' them to the 'Data Acquisition Layer'.
- <u>Data Mart PULL:</u> These sources must be available for 'querying' at any time by the H-ERP in order to:
 - o Retrieve the results of specific queries posed by the DAL on the data marts agreed.
 - Perform data queries to the HIS.
 - Retrieve queried data from the HIS.
 - Select data of interest.

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- Queue them into a dedicated message queue.
- o Transform them for the 'Data Acquisition Layer' (HL7/XML Protocol Transformation).
- Push them to the 'Data Acquisition Layer'.



The two different ways are used in the pilots as described in the following:

- Push WebService exposed by Data Acquisition Layer and used by H-ERP Bridge for the "pushing" integration of the HL7 messages. This way is used for pushing messages from the HIS of Niguarda, Sacco and TRFT (3 Push scenarios).
- Pull WebService exposed by the H-ERP Bridge and used by the Data Acquisition Layer for retrieving
 ("pulling") the available type of messages. This way is also used in SEK Hospital for getting clinical
 information from SEK HIS using Effica (The name of SEK HIS) Web Services. Then H-ERP bridge
 process the clinical information gathered from HIS and convert them in standard HL7 messages
 sent via HL7 in push way to DAL.

5.3.3rd Final Prototype Functionalities

For the Final Prototype of the H-ERP Bridge module, the main enhancements are related to the following items:

- NIGUARDA Pilot (IT)
 - Consolidation of the integrations developed for 1st and 2nd prototype.
 - o Bug fixing.
- SACCO Pilot (IT)
 - Consolidation of the integrations developed for 1st and 2nd prototype.
 - Bug fixing
- TRFT Pilot (UK)
 - o Development, test and Go Live of all the integrations required
- SEK Pilot (FIN)
 - o Development, test and Go Live of all the integrations required

5.4.Dependencies

For its role, the H-ERP depends in particular from two main actors:

- 1) The Pilot's HIS's interface with 3rd parties
- 2) The DAL module:

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5.5.Interfaces with other components

As described before for its role, the H-ERP is directly linked with to two main actors:

- 3) The Pilot's HIS: H-ERP depends directly on the associated SW platforms deployed for performing the 'role' of the local Hospital Information System. For the 4 pilots involved in the project H-ERP has been developed in order to manage 4 different type of HIS with 4 different types of integration Adapter:
 - a. NIG: HL7 V2.5 Piped to HL7 V2.5 XML integration adapter



- b. SACCO: DB materialized Views to HL7V2.5 XML integration adapter
- c. TRFT: HL7 V2.4 Piped to HL7 V2.5 XML integration adapter
- d. SEK: Web Services to HL7V2.5 XML integration adapter
- 4) The DAL module: H-ERP is directly connected to the DAL module for 2 activities:
 - a. Sending data via HL7 version 2.5 and XML.
 - b. Receiving specific queries via Web services in order to retrieve specific associated clinical or other data (for SEK Scenario)

5.6.Resources

The H-ERP module places the following two specific resources requirements on the REMINE platform:

- The Enterprise Service Bus JCAPS (Java Composite Application Platform Suite (ORACLE-SUN)) application to standardize and manage all data integrations between Clinical SW platforms.
- A physical Server (HW and O.S.) in order to host the JCAPS application and the Runtime of the integration adapters.

5.7.Data/Messages

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5.7.1. Niguarda (IT)

5.7.1.1. Data

| DATA | ТҮРЕ | SOURCE |
|---------------------------------|---------------|--------|
| Patient demographics (e.g. age) | String | A&E |
| Patient ID | ID | A&E |
| Time of triage | Time | A&E |
| Priority code from triage | Single choice | A&E |
| Full assessment | Time | A&E |
| Doctor ID | ID | A&E |
| ECG execution | Boolean | A&E |
| Blood examinations order (time) | Time | A&E |
| Blood examinations order (list) | Multi-choice | A&E |

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| DATA | ТҮРЕ | SOURCE |
|----------------------------------------------------------------------|----------------------------------------------------------|--------|
| Test tubes sent from the A&E | Time | A&E |
| Test tubes delivered to lab | Time | LIS |
| Blood examinations results available | Time | LIS |
| Exam results | Float | |
| PlateletsGlycaemiaAPPTT | but usually the test results can be also free text | LIS |
| CT scan order | Time | A&E |
| CT scan image availability | Time | RIS |
| Administration of fibrinolitic treatment (time) | Time | A&E |
| Administration of fibrinolitic treatment (location) | Single choice | A&E |
| Discharge from the A&E to the Stroke Unit | Time | A&E |
| Exit of the patient from the clinical pathway | Boolean | A&E |

5.7.1.2. Messages

For Niguarda Pilot scenario and for the last prototype, the H-ERP Bridge is managing those kinds of messages:

- ADT: Admission messages, Assessment, ECG, Treatment, Reassessment messages
- ORM: Radiology Order Message
- OML: Lab. Analysis Order Message
- OUL: Lab. Analysis tests results message

The SW module exported from ReMINE server to the RFP cd are files in ZIP format exported directly from the JCAPS platform related to the integration adapters developed and deployed. These files allow to reimport and to re-create again the same integration adapters in another JCAPS platform.

| Clinical Event | Data Source availability | Sender | Type of Message | Status |
|------------------|-----------------------------|----------------------|---------------------------------------------|-----------------------|
| Triage | Yes | A&E (CBIM-PIESSE) | HL7 - ADT^A04 Register a Patient Message | Developed, Tested, |
| Neuro Assessment | Yes | A&E (CBIM-PIESSE) | HL7 - ADT^A08 Update Patient Information | Deployed, Running |

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| Lab tests Order | Yes | A&E (CBIM-PIESSE) | HL7 - OML^O33 Laboratory Order for Multiple Orders Related to a Single Specimen Message | |
|-----------------------------------------|-----|------------------------------|--------------------------------------------------------------------------------------------|---------------------------------|
| Lab samples CheckIN | Yes | LIS (NoemaLife- DNLab) | HL7 - OML^O21 Laboratory Order | |
| Lab tests Results | Yes | LIS (NoemaLife- DNLab) | HL7 - OUL_R22 Unsolicited Specimen Oriented Observation Message | |
| Radiology tests Order (Head CT Scan) | Yes | A&E (CBIM-PIESSE) | HL7 - ORM-O01 General Order | |
| Image Ready from Radiology dept. | NO | RIS (Agfa - Elefante) | NA | NA |
| ECG Execution | Yes | A&E (CBIM-PIESSE) | HL7 - ADT^A08 Update Patient Information Message | |
| Fibrinolitic Treatment | Yes | A&E (CBIM-PIESSE) | HL7 - ADT^A08 Update Patient Information Message | Developed, |
| A&E ReAssesment | Yes | A&E (CBIM-PIESSE) | HL7 - ADT^A08 Update Patient Information Message | Tested, Deployed, Running |
| A&E Exit from Clinical Pathway | Yes | A&E (CBIM-PIESSE) | HL7 - ADT^A08 Update Patient Information Message | |
| A&E Discharge | Yes | A&E (CBIM-PIESSE) | HL7 - ADT^A03 Discharge/End Visit Message | |

5.7.2. Sacco (IT)

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5.7.2.1. Data

| DATA | TYPE | SOURCE |
|------------------------------------|---------------|-------------|
| Admission | | A&E |
| Patient demographics (e.g. age) | String | ISOLA BELLA |
| Patient ID | ID | ISOLA BELLA |
| Time of triage | Time | ISOLA BELLA |
| Active labour diagnosis check list | | Form |
| Nulliparous vs. Parous | Single choice | |



| DATA | ТҮРЕ | SOURCE |
|---------------------------------------------------------------------------------------------------------------|---------|--------------|
| Contractions ≥ 2 in 10 minutes, regular and painful? | Boolean | |
| Cervical length | % | |
| | | |
| Low risk labour diagnosis check list | | Form |
| Physiological medical and obstetric history | Boolean | |
| Singleton healthy gestation in vertex position | Boolean | |
| Absence of known fetal disease | Boolean | |
| 37-41+6 completed weeks of gestational age confirmed by ultrasound | Boolean | |
| Intact membranes or rupture of the membranes < 24 hours with clear amniotic fluid and negative vaginal tampon | Boolean | |
| Estimate of fetal weight between 2500 and 4000 grams | Boolean | |
| Normally inserted placenta | Boolean | |
| Spontaneous labour | Boolean | |
| | | |
| FHR monitoring registration | | Form/Barcode |
| Start of monitoring | Time | |
| End of monitoring | Time | |
| Patient name | String | |
| Patient ID | ID | |
| Midwife name | String | |
| Midwife ID | ID | |
| Device ID | String | |
| Obstetrician assessment monitoring | | Form |

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| DATA | ТҮРЕ | SOURCE |
|----------------------------------------------------------------------------------------|---------|--------|
| Obstetrician/midwife name | String | |
| Obstetrician/midwife ID | ID | |
| Patient name | String | |
| Patient ID | ID | |
| Time of assessment | Time | |
| Regular tracing | Boolean | |
| Woman general condition | Boolean | |
| Dilatation | Integer | |
| Low risk confirmed | Boolean | |
| | | |
| "Exit" | | Form |
| Patient name | String | |
| Patient ID | ID | |
| Obstetrician name | String | |
| Obstetrician ID | ID | |
| Time of "exit" (delivery, discharge,) | Time | |
| Resources management | | Form |
| Number of working devices assigned to the labour assigned to the Obstetrics Department | Integer | |
| Number of midwifes on duty in the Obstetrics Department (per work shift) | Integer | |
| Number of obstetricians on duty in the Obstetrics Department (per work shift) | Integer | |

5.7.2.2. Messages

For Sacco Pilot scenario and for the last prototype, the H-ERP Bridge is managing 1 kind of message:

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• ADT: Admission messages

The SW module exported from ReMINE server to the RFP cd are files in ZIP format exported directly from the JCAPS platform related to the integration adapters developed and deployed. These files allow to reimport and to re-create again the same integration adapters in another JCAPS platform.

| Clinical Event | Data Source availability | Sender | Type of Message | Status |
|-------------------|--------------------------------|--------------------------------|---------------------------------------------|-----------------------------------------------|
| Patient Admission | Yes | A&E (Praezision-Isolabella) | HL7 - ADT^A04 Register a Patient Message | Developed, Tested, Deployed, Running |

5.7.3. TRFT (UK)

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5.7.3.1. Data

| DATA | ТҮРЕ | SOURCE |
|----------------------------|---------------|----------|
| Use Case 1 | | |
| Patient name | String | PAS/Form |
| Patient address | String | PAS |
| Previous MRSA infections | Boolean | PAS |
| Previous C. diff. flag | Boolean | PAS |
| Previous ESBL flag | Boolean | PAS |
| Patient infection code | Single choice | Form |
| Patient actual ward | String | PAS |
| Patient previous wards | String | PAS |
| Last MRSA test date | Date | LIS |
| Last MRSA test results | String | LIS |
| Last C. diff. test date | Date | LIS |
| Last C. diff. test results | String | LIS |
| Last ESBL test date | Date | LIS |



| DATA | ТҮРЕ | SOURCE |
|------------------------|---------------|----------|
| Last ESBL test results | String | LIS |
| | | |
| Use Case 2 | | |
| Cubicle ID | String | Form |
| Patient name | String | Form |
| Patient infection code | Single choice | Form |
| Cubicle status | Single choice | Form |
| Kind of cleaning | Single choice | Form |
| Assigned staff | String | Form |
| Completed cleaning | Time | Form |
| | | |
| Use Case 3 | | |
| Patient name | String | LIS/Form |
| Patient infection code | Single choice | Form |
| Kind of infection | String | Form |
| MRSA screening order | Date & Time | LIS |
| MRSA screening results | String | LIS |
| | | |
| Use Case 4 | | |
| Patient name | String | PAS/Form |
| Patient infection code | Single choice | Form |
| Patient actual ward | String | PAS |
| Patient previous wards | String | PAS |



| DATA | ТҮРЕ | SOURCE |
|-----------------|------|--------|
| Ward admittance | Date | PAS |
| Ward discharge | Date | PAS |

5.7.3.2. Messages

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For TRFT Pilot scenario and for the last prototype, the H-ERP Bridge is managing 2 kind of messages:

- ADT: Admission and Patient messages
- ORU: Lab. Analysis tests results message

The SW module exported from ReMINE server to the RFP cd are files in ZIP format exported directly from the JCAPS platform related to the integration adapters developed and deployed. These files allow to reimport and to re-create again the same integration adapters in another JCAPS platform.

| Clinical Event | Data Source availability | Sender | Type of Message | Status |
|------------------------|--------------------------------|--------------------|-----------------------------------------------------|----------------------|
| Patient Admission | Yes | PAS (Totalcare) | HL7 - ADT^A01 Admit/Visit notification message | |
| Patient Update | Yes | PAS (Totalcare) | HL7 - ADT^A08 Update Patient Information message | |
| Lab. Tests Results | Yes | LIS (WinPath) | HL7 - ORU^R01 Unsolicited Observation message | |
| Patient Transfer | Yes | PAS (Totalcare) | HL7 - ADT^A02 Transfer Patient Message | Developed, |
| Patient Discharge | Yes | PAS (Totalcare) | HL7 - ADT^A03 Discharge/End Visit message | Tested, Deployed, |
| Patient Registration | Yes | PAS (Totalcare) | HL7 - ADT^A28 Patient Registration | Running |
| Patient Details Update | Yes | PAS (Totalcare) | HL7 - ADT^A31 Patient Update | |
| Patient Merge | Yes | PAS (Totalcare) | HL7 - ADT^A34 Patient Merge | |
| Change Patient ID | Yes | PAS (Totalcare) | HL7 - ADT^A47 Change Patient ID | |



5.7.4. SEK (FIN)

5.7.4.1. Data

| DATA | ТҮРЕ | SOURCE | |
|-------------------------------------------------------------------------------|-------------|--------|--|
| Patient data | | Effica | |
| Patient demographics (e.g. age) | String | | |
| Patient ID | ID | | |
| Diagnosis | String | | |
| Medical history (anamnesis) | String | | |
| Allergies | String | | |
| Medication plan/prescriptions | String | | |
| Ward (room, bed) | String | | |
| Bracelet RFID tag | String | | |
| Cup RFID tag | String | | |
| Drug prescription | | Effica | |
| Prescription issue | Date & Time | | |
| Drug name | String | | |
| Dosage | String | | |
| Route of administration | String | | |
| Patient name | String | | |
| Patient ID | ID | | |
| Time of administration | Time | | |
| Dangerous interactions of the drug with other drugs prescribed to the patient | String | | |

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| DATA | ТҮРЕ | SOURCE |
|-------------------------------------------------------------|--------|-------------------------------------|
| Dangerous interactions of the drug with patient's allergies | String | |
| Drug trolley preparation | | RFID tags – Forms on Netbook/PDA |
| Patient name | String | |
| Patient ID | ID | |
| Time of administration | Time | |
| Drug name | String | |
| Dosage | String | |
| Route of administration | String | |
| Nurse name | String | |
| Nurse ID | ID | |
| Cup RFID tag | String | |
| Drug administration | | RFID tags – Forms on Netbook/PDA |
| Patient name | String | |
| Patient ID | ID | |
| Current time | Time | |
| Drug name | String | |
| Dosage | String | |
| Route of administration | String | |
| Time of administration | Time | |
| Nurse name | String | |
| Nurse ID | ID | |
| Bracelet RFID tag | String | |



| DATA | ТҮРЕ | SOURCE |
|--------------|--------|--------|
| Cup RFID tag | String | |

5.7.4.2. Messages

For SEK Pilot scenario and for the last prototype, the H-ERP Bridge is managing 2 kind of clinical information, retrieved in pull mode from the HIS Effica via two web services exposed by Effica, then mapped in two different standard HL7 messages:

- ADT: Admission messages. Gathered from Effica's Web Service "GetActualWardPlacements".
- RGV: Patient Medications. Gathered from Effica's Web Service "GetPatientMedication".

The SW module exported from ReMINE server to the RFP cd are files in ZIP format exported directly from the JCAPS platform related to the integration adapters developed and deployed. These files allow to reimport and to re-create again the same integration adapters in another JCAPS platform.

| Clinical Event | Data Source availability | Sender | Type of Message | Status |
|----------------------------------------------|--------------------------------|-------------------------|-----------------------------------------------------|-----------------------|
| Patients Admitted | Yes | HIS (Tieto - Effica) | HL7 - ADT^A08 Update Patient Information Message | Developed, Tested, |
| Patient's Medications/ Drug Prescriptions | Yes | HIS (Tieto - Effica) | HL7 - RGV^O15 Pharmacy/Treatment Give Message | Deployed, Running |

5.8.Installation instructions

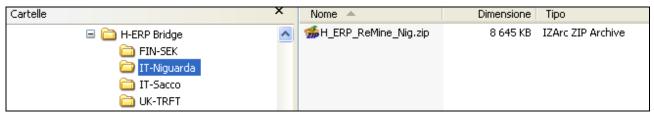
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For the installation of the H-ERP bridge module must be used what described in the official JCAPS configuration and user guides or tutorials.

http://dsc.sun.com/docs/javacaps/topics/index.jsp

http://dsc.sun.com/docs/javacaps/tutorials/screencasts/InstallingCAPS6/launch.html

The Contents of the cd for the H-ERP Bridge module consists of the following 4 zip files:



These files have been exported directly from the JCAPS platform of the H-ERP Bridge and they include all the files related to the integrations developed for the RFP. With those files all the integrations can be imported again from scratch in another JCAPS platform.



6. Data Acquisition Layer

6.1.Purpose

This component is responsible for processing the largely varied data received from the Hospital information System (HIS), before storing them as part of the REMINE DB. This processing mainly includes the transformation of the hospital 'messages' passed on by the 'H-ERP Bridge' component from their HL7 XML form into the CDA/non-CDA used by the REMINE DB. Moreover, this layer will also 'enrich' the associated data with appropriate 'coding' references (i.e. SNOMED, LOINC, ICD9/10).

The DAL component consists one of the core ReMINE components where a semantic transformation of the data coming from pilots HIS, is taking place for further usage by the ReMINE platform.

6.2.2nd Prototype Functionalities

The functionality of the component is described as follows:

- Receive/collect, parse and transform a new HL7 v2.x message from 'H-ERP Bridge' component. There are two different ways that this functionality is offered. The first and simpler way is a "PUSH" scenario where the H-ERP bridge pushes the HL7 v2.x messages through a web service exposed by the DAL component. The second way is a "PULL" scenario. In this case the DAL component after a request for another REMINE component, requests from the H-ERP bridge the appropriate information. The request is made using a web service exposed by the H-ERP bridge for this purpose. Following the "PULL" request made to the H-ERP bridge component, the component sends to the DAL component the appropriate HL7 messages. Following the collection of the messages the DAL component parses the messages, appropriately normalizes them with respect to the selected/applicable coding schemas (e.g. ICD9/10, SNOMED or other) and transforms them in CDA documents (HL7 v3.0).
- Create or Update a CDA document (HL7 v3.0) and store it to the REMINE metadatabase.

6.3.3rd Prototype Functionalities

In the 3rd Prototype of the Remine platform the following improvements were added to the main functionality of DAL component already implemented in the 2nd prototype:

- Database connection management for optimizing the memory usage of the component, a database connection pooling mechanism was added
- Static object instantiation for optimizing the use, and reuse, of shared (such as javax.xml.xpath.XPath used to retrieve data from XML, Logger used to log messages) objects
- A monitoring extension module that enables the notification by email when the DAL service has stopped (due to server restarts etc.) in order for the system administrator to take proper actions.

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6.4. Dependencies

The DAL component depends on the 'H-ERP bridge' component in order to acquire data produced from the Hospital Information System. It also depends on the on the RLUS service of the Remine Database component for the persistence storage of the newly created or updated CDA documents.

6.5.Interfaces with other components

For being able to accept incoming data from the 'H-ERP bridge' component, the DAL Component exposes a web service interface that the 'H-ERP bridge' can use to push the data to the component. In case of 'PULL' scenario the component uses a web service exposed by the 'H-ERP bridge' in order to ask for incoming data. The component also utilizes the RLUS web service provided by the Remine Database component.

6.6.Resources

In terms of software prerequisites, DAL component requires the following:

- · SAXXON XSLT and XQUERY processor
- · Apache Tomcat
- · Apache AXIS2 libraries
- · JDOM java library
- · MySQL server
- · JDBC driver library

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6.7.Data/Messages

The following table includes the different messages HL7 v2.0 messages parsed by the component for each pilot.

| PILOT | Message Type |
|----------|--------------|
| NIGUARDA | ADT^A03 |
| | ADT^A04 |
| | ADT^A08 |
| | OML^O21 |
| | OML^O33 |
| | ORM^O01 |
| | OUL^R22 |
| TRFT | ADT^A01 |
| | ADT^A02 |
| | ADT^A03 |
| | ADT^A08 |
| | ADT^A28 |
| | ADT^A31 |
| | ADT^A34 |
| | ADT^A47 |
| | ORU^R01 |
| SEK | ADT^A08 |
| | RGV^O15 |



| | BAR^P12 |
|-------|---------|
| SACCO | ADT^A04 |

An example of a sample ADT^A04 from the Niguarda pilot and its corresponding CDA Document created by the Parser-Transformer module is shown below.

ADT^A04 message

```
<?xml version="1.0" encoding="UTF-8"?>
<ADT_GENERICO xmlns="urn:h17-org:v2xm1" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <MSH>
        <MSH.1>|</MSH.1>
        <MSH.2>^~&amp; |</MSH.2>
        <MSH.3>
           <hd.1>PIESSE</hd.1>
        </msh.3>
        <MSH.4>
           <hd.1>CBIM</hd.1>
        </MSH.4>
        <MSH.5>
            <hd.1>REMINE</hd.1>
        </MSH.5>
        <MSH.6>
            <hd.1>REMINE</hd.1>
        </MSH.6>
        <MSH.7>
            <TS.1>201009011945</TS.1>
        </MSH.7>
        <MSH.9>
            <MSG.1>ADT</MSG.1>
            <MSG.2>A04</MSG.2>
        </MSH.9>
        <MSH.10>355c6908-ffe3-4690-9c77-42deb8e58798</msh.10>
        <MSH.11>
           <PT.1>P</PT.1>
        </msh.11>
        <MSH.12>
            <VID.1>2.5</VID.1>
        </MSH.12>
    </MSH>
    <EVN>
        <EVN.1>A04</EVN.1>
           <TS.1>201009011945</TS.1>
       </EVN.2>
    </EVN>
        <PID.3>
            <CX.1>456456456</CX.1>
            <CX.4>
                <HD.1>PK</HD.1>
            </CX.4>
            <CX.5>FI</CX.5>
            <CX.6>
                <HD.1>BDA</HD.1>
            </CX.6>
            <CX.9>
                <CWE.1>R</CWE.1>
            </cx.9>
        </PID.3>
        <PID.3>
            <Cx.1>321321321</Cx.1>
            <CX.5>SS</CX.5>
        </PID.3>
        <PID.3>
```



```
<CX.1>989898989898</CX.1>
    <CX.5>NI</CX.5>
</PID.3>
<PID.3></PID.3>
<PID.3></PID.3>
<PID.5>
    <XPN.1>
        <FN.1>lastname</FN.1>
    </XPN.1>
    <XPN.2>first name</XPN.2>
</PID.5>
<PID.7>
    <TS.1>19260928</TS.1>
</PID.7>
<PID.8>M</PID.8>
<PID.11>
    <XAD.1>
       <SAD.1>VIA GRAZ ,99</SAD.1>
        <SAD.2></SAD.2>
        <SAD.3></SAD.3>
    </XAD.1>
    <XAD.2></XAD.2>
    <XAD.3></XAD.3>
    <XAD.4>015146</XAD.4>
    <XAD.5></XAD.5>
    <XAD.6></XAD.6>
    <XAD.7>L</XAD.7>
    <XAD.8></XAD.8>
    <XAD.10></XAD.10>
    <XAD.11></XAD.11>
    <XAD.13>
       <TS.1></TS.1>
   </XAD.13>
</PID.11>
<PID.11>
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        <SAD.1>VIA GRAZ ,99</SAD.1>
        <SAD.2></SAD.2>
        <SAD.3></SAD.3>
    </XAD.1>
    <XAD.2></XAD.2>
    <XAD.3></XAD.3>
    <XAD.4>015146</XAD.4>
    <XAD.5></XAD.5>
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    <XAD.7>H</XAD.7>
    <XAD.8></XAD.8>
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    <XAD.13>
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        <SAD.1></SAD.1>
        <SAD.2></SAD.2>
        <SAD.3></SAD.3>
    </XAD.1>
    <XAD.2></XAD.2>
    <XAD.3></XAD.3>
    <XAD.4>071051</XAD.4>
    <XAD.5></XAD.5>
    <XAD.6></XAD.6>
    <XAD.7>N</XAD.7>
    <XAD.8></XAD.8>
    <XAD.10></XAD.10>
    <XAD.11></XAD.11>
    <XAD.13>
        <TS.1></TS.1>
```



```
</XAD.13>
        </PID.11>
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            <XTN.12>8787878787</XTN.12>
        </PID.13>
        <PID.14>
            <XTN.3>PH</XTN.3>
        </PID.14>
        <PID.18>
            <CX.1>6546546545654</CX.1>
        </PID.18>
        <PID.19>456465465</PID.19>
        <PID.23>071051</PID.23>
        <PID.26>
            <CE.2>100</CE.2>
        </PID.26>
        <PID.28>
            <CE.2>100</CE.2>
        </PID.28>
        <PID.33>
            <TS.1>200704020756</TS.1>
        </PID.33>
    </PID>
    <PV1>
        <PV1.2>E</PV1.2>
        <PV1.3>
           <PL.1>300</PL.1>
        </PV1.3>
        <PV1.4>E</PV1.4>
        <PV1.19>
            <CX.1>2010563265</CX.1>
        </PV1.19>
        <PV1.44>
            <TS.1>201009011936</TS.1>
        </PV1.44>
    </PV1>
    <PV2>
        <PV2.3>
            <CE.1>32</CE.1>
            <CE.2>DISTURBI NEUROLOGICI FOCALI E CONVULSIONI - DEFICIT DI FORZA UNO O PIU&apos; ARTI
- INSORTO DA > 4 ORE - cardiopatico noto, diabetico NID. vomito.</CE.2>
        </PV2.3>
        <PV2.25>V</PV2.25>
    </PV2>
</ADT GENERICO>
CDA Document
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<ClinicalDocument xmlns="urn:h17-org:v3" xmlns:xsd="http://www.w3.org/2001/XMLSchema"</pre>
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
        <typeId extension="POCD HD000040" root="2.16.840.1.113883.1.3"/>
       <templateId root="2.16.840.1.113883.3.27.1776"/>
       <id extension="355c6908-ffe3-4690-9c77-42deb8e58798" root="2.16.840.1.113883.3.270.1.1"/>
       <code code="51855-5" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"</pre>
displayName="Clinical note"/>
       <effectiveTime value="201009011945"/>
```

<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"</pre>

<setId extension="456456456" root="2.16.840.1.113883.3.270.1.2"/>

<id extension="456456456" root="2.16.840.1.113883.3.270.1.3"/>

<given>lastname</given>

codeSystemName="Confidentiality" displayName="Normal"/>

<patient>

<name>

<versionNumber value="1"/>

<patientRole>

<recordTarget>



```
<family>first name</family>
                              </name>
                              <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"
codeSystemName="AdministrativeGender" displayName="Male"/>
                              <birthTime value="19260928"/>
                      </patient>
               </patientRole>
       </recordTarget>
       <author>
               <time value="200704020756"/>
               <assignedAuthor>
                      <id extension="PIESSE" root="2.16.840.1.113883.3.270"/>
                       <representedOrganization>
                              <id root="2.16.840.1.113883.3.270"/>
                      </representedOrganization>
               </assignedAuthor>
       </author>
       <custodian>
               <assignedCustodian>
                      <representedCustodianOrganization>
                              <id root="2.16.840.1.113883.3.270"/>
                              <name>CBIM</name>
                       </representedCustodianOrganization>
               </assignedCustodian>
       </custodian>
       <componentOf>
               <encompassingEncounter>
                      <code code="338709012" codeSystem="2.16.840.1.113883.6.96"</pre>
codeSystemName="SNOMED-CT" displayName="Triage">
                              <qualifier>
                                     <name code="388521012" codeSystem="2.16.840.1.113883.6.96"</pre>
codeSystemName="SNOMED-CT" displayName="Priority"/>
                                     <value code="394848005" codeSystem="2.16.840.1.113883.6.69"</pre>
codeSystemName="SNOMED-CT" displayName="Normal priority"/>
                              </qualifier>
                       </code>
                      <effectiveTime value="201009011936"/>
               </encompassingEncounter>
       </componentOf>
       <component>
               <structuredBodv>
                      <component>
                              <section>
                                      <code code="11496-7" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Assessment"/>
                                      <title>Patient visit additional information</title>
                                             <observation classCode="COND" moodCode="EVN">
                                                     <code code="8319008"</pre>
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Principal diagnosis"/>
                                                     <text>DISTURBI NEUROLOGICI FOCALI E CONVULSIONI
- DEFICIT DI FORZA UNO O PIU' ARTI - INSORTO DA > 4 ORE - cardiopatico noto, diabetico NID.
vomito.</text>
                                                     <statusCode code="completed"/>
                                                     <targetSiteCode code="449662019"</pre>
codeSystem="2.16.840.1.113883.6.69" codeSystemName="SNOMED-CT" displayName="Neurological disorder"/>
                                             </observation>
                                      </entry>
                              </section>
                       </component>
               </structuredBody>
       </component>
</ClinicalDocument>
```



6.8.Installation instructions

DAL is consisted of a single file packaged as a Web application archive. To install it to the Apache Tomcat server it is only required that is copied inside the "webapps" folder under the installed Tomcat folder tree structure.

7. Intalio Processes

7.1.Purpose

A business process is a collection of related, structured activities or tasks that produce a specific service or product to accomplish a specific organizational goal. It often can be visualized with a flowchart as a sequence of activities. Business process modeling (BPM) in software engineering is the activity of representing processes of an enterprise, so that the current process may be analyzed and improved. The business processes representing the business logic of the different clinical procedures have been developed under Intalio platform using Business Process Modeling Notation Language (BPMN). The aim of this language is to facilitate communication between IT and line-of-business (LOB).

BPM offers several key advantages to define the business processes of an organization. BPM makes a business process absolutely transparent, greatly improving visibility and efficiency. Bottlenecks can literally be seen, and removed. It can show where the most delays are occurring, and where is each transaction stuck as it passes from one stage to another. Data about each and every transaction is logged and can be retrieved as and when required. Therefore, it is possible to analyze accurately what happened. Referencing is also easier as embedded searches allow for data to be picked up as required for study.

The BPMN is translated to Business Process Execution Language (BPEL), a standard executable language to be processed for a server.

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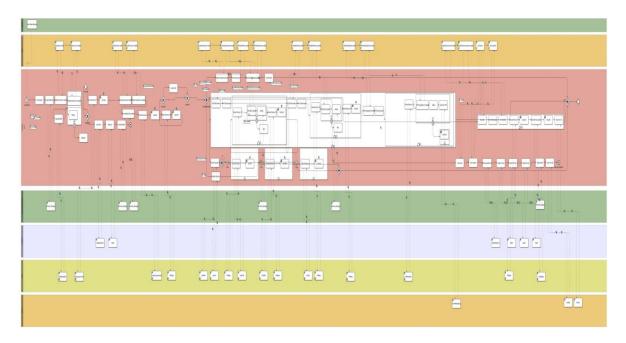


Figure 1. Business Process Example

7.2. 2nd and 3rd Prototype Functionalities Comparison

The 3rd Prototype functionality highly increases the quality of service provided by the platform. As the core of the application an improvement in any subcomponent drives to a modification and consequently an enhancement of the business processes. Moreover the processes have been enriched to improve the functionality and to deal with potential failures. Mainly the enhancements can be listed as follows:

- Scenarios enhancement for a better description of the clinical business procedures
- Fully Integration with the sub-modules of ReMINE
- Processing all messages coming from H-ERP Bridge/DAL
- Improvement of the outcoming data storage (quantity and quality): the information stored in the internal database and the data related to Key Performance Indicators (KPIs)
- Development of RLUS Wrapper Web Service for the Process Mapper that encapsulates RLUS client business logic
- Changes in processes according to enhancements in sub-modules and optimization
- Recovering from some failures due to input data or the unavailable services
- Integration with new business rules to offer more flexibility in the clinical pathways

7.3. Dependencies

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The processes define the clinical pathway and coordinate the remainder modules of the system. We can find dependencies between the business processes and all the single modules of ReMINE. Consequently, the dependencies between the processes and the sub-systems of the platform are really strong. The



malfunction of some modules can produce failures in the whole business process. This tight dependency is intrinsic to Software Oriented Architecture (SOA) systems.

7.4. Interfaces with other components

Processes in BPEL export and import information by using web service interfaces exclusively. That is why the different modules of the system are exposed as a web services. Therefore the interconnections between the ReMINE executable processes (BPEL) and the different subsystems are carried out through SOAP messages for accessing to the desired web services, conforming a SOA system. In this way the different ReMINE processes control the business flow and the orchestration of the different sub-modules. The processes and the rest of the components carry out their communication through Simple Object Access Protocol (SOAP) messages.

The web service interactions are part of business collaborations that may involve multiple synchronous and asynchronous web service interactions. Thus the mechanism of correlation is used to relate the different calls to particular clinical process.

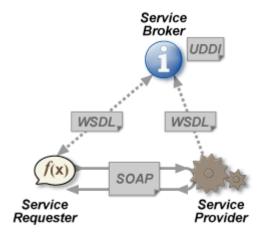


Figure 2. Web Services Architecture

7.5. Resources

The processes are developed under Intalio | BPMS Designer. Intalio Designer is built, at the same time, on the top of Eclipse platform. Once translated to BPEL, they are deployed to a dedicated tomcat server.

Tomcat server is then entailed of receiving external messages coming from DAL/DEMS module and executing the corresponding process to follow the proper clinical pathway. This server is configured and customized to carry out all this labour.

7.6. Data/Messages

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H-ERP Bridge module is responsible for gathering data from hospital clinical sources, so-called Hospital Information System (HIS) in order to make them available via HL7/XML V2.5 schemas to the Data Acquisition Layer (DAL) and subsequently the Data Event Management System (DEMS). The business



processes in BPEL are then exposed as a web services, in order to make them available for the data and events coming from HIS (DAL/DEMS component) which will trigger and interact with the different processes.

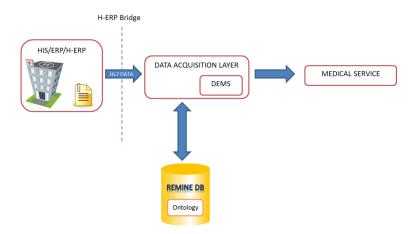


Figure 3. Example of DEMS triggering a process

7.7. Installation instructions

In this section an explanation of how deploy the different business processes (attached in the DVD) in the server is given. First of all, the user should install the tomcat server and thereafter deploy all the processes corresponding to the given scenario.

For installing the tomcat server:

I.Before opening the project in INTALIO, some steps are in order to create and use the database:

- If the scenario use MySql (Sacco)
 - 1. Install MySQL 5.1 if the scenario do not use Derby (http://dev.mysql.com/downloads/mysql/5.1.html)

Important note: mysql credentials must be as follows:

user:"root"
password:"admin"

- 2. Install the connector (http://dev.mysgl.com/downloads/connector/j/5.1.html)
- 3. Create the database: execute the sql scripts of the given scenario
- If the scenario use Derby
 - 1. Create the database: execute the sql scripts of the given scenario
- II.Unzip the intalio-tomcat server. It is found under the folder "DVD_UNIT:\PROCESS MAPPER\INTALIO SERVER"
- III.Customize the server: drag and drop all the folders inside the server tree of the given scenario to the folder of the tomcat server.

Finally it is needed to deploy the whole set of processes:

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- 1. Open Intalio | Designer and import the projects.
- 2. Select all and with right click in the project folders select the option "Clean and build now".
- 3. Deploy the projects in the server.

8. ReMINE Database

Metadatabase services are structured in 2 modules: RLUS (Retrieve Locate and Update Service) and TOS (Taxonomy and Ontology Service). These modules are designed as web services using SQL2008 for data persistence.

RLUS API is the main interface for the database. It is based on HL7 service contracts. RLUS works with two databases: Metadatabase and Data Repository. Having a RLUS entry, its metadata will be in the first database and its content in the second. The content can be binary or simply a reference to where the real data persists thus the name of metadatabase. RLUS is used to provide for the location, retrieval, and update of clinical and non-clinical information. In ReMINE project RLUS represents the API interface layer of the database allowing the management of documents (clinical and non-clinical) with dynamic structure. RLUS can be configured to accept different metadata information for a specific type of information (documents) trough the configuration of slots (metadata information).

The taxonomy and ontology service (TOS) is based on a HL7 CTS1 (Common Terminology Services v1) implementation. The Health Level Seven Version 3 standards are based on a Reference Information Model (RIM) which is flexible and general in structure. Representation of information within this model is dependent on the availability of terminological resources which can be used to populate the properties of the model with appropriate semantic content. Whenever possible, the HL7 Version 3 standard references existing terminological resources instead of attempting to create a new resource within the standard itself.

The metadatabase services represent de core of WP3 modules as seen in the following detailed WP3 architecture diagram:



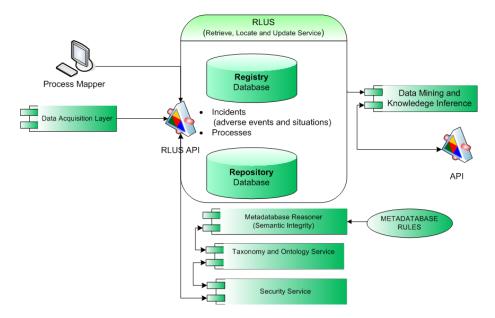


Fig. 1: Detailed WP3 Architecture

8.1.Purpose

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The REMINE metadatabase component manages all the data activities for the REMINE project. It will contain:

- Data that are directly acquired and produced inside the REMINE boundary.
- Data coming from other external data sources.

When possible the REMINE metadata module will always contain the links to where the real data are.

8.2.2nd Prototype Functionalities

Second Revision of the WP3 framework addresses the issues of WP3 within the first prototype of the ReMINE project. As specified in the 2st prototype deployment, WP3 should resume itself to metadatabase foundation, meaning a database service for acquiring, storing and retrieving data without semantic integrity and storage for the taxonomy and ontology. This deliverable addresses more problems than the 1st prototype rises and it explains the metadatabase service in detail (with contracts and database layer, based on RLUS) and a first version of the taxonomy and ontology service (also in detail, based on the CTS version 1 service). It also proposes the security services to secure the communication (authentication and authorization) with these services (based on the described security standards) in the same manner as the other services were described.



8.3.3rd Prototype Functionalities

Third Revision of the WP3 framework represents the last steps that were taken for WP3 framework in the form of WP3 service enhancements:

- Audit service completion: all WP3 services are audit trailed on their main operations
- WS-Eventing development on RLUS service to be used in the data mining and knowledge inference module
- Completion of the metadatabase reasoner in the form of SIMP designer (designer for the semantic signifiers) and the reasoner itself as an executer for these templates inside the RLUS implementation
- RLUS Wrapper Web Service for the Process Mapper that encapsulates RLUS client business logic

8.4.Dependencies

The metadatabase as a concept doesn't necessarily depend on any other component of the ReMINE project, but the other way around. However, RLUS data structure is based on the metadata concept (called slots), allowing it to change easily by matter of configuration to the needs of the metadatabase consumers.

Master Patient Index service works as well with metadata (called traits) adapting to new patient information while TOS has a strict internal data representation and yet allowing it to store various ontologies with different structures.

8.5.Interfaces with other components

Access to the metadatabase is done only trough the existing API of the web services: RLUS for clinical and non clinical documents, MPI for patient management, QED to easily query RLUS data and TOS to manage and query the ontology.

8.6.Resources

The metadata structure of the metadatabase (RLUS tables in a relationship database) is described in detail in the 'Data section'. Access speed is very important for this database. The repository database of RLUS will contain all the binary data, thus size is very important for this database. Required resources depend on the size of the data stored. The server must run a Microsoft SQL 2005 or SQL 2008 instance.

RLUS service will require at least the following resources:

- 1GB RAM
- 100MB hard disk space
- 1GHz CPU
- Microsoft .NET 3.5 Framework SP1



The server that runs the MS-SQL server will comply with Microsoft's hardware requirements for SQL2005 (or SQL2008). Regarding storage space, it is premature to estimate the space that the database will require for the whole REMINE project.

8.7.Data/Messages

RLUS implementation uses the following main database structure:

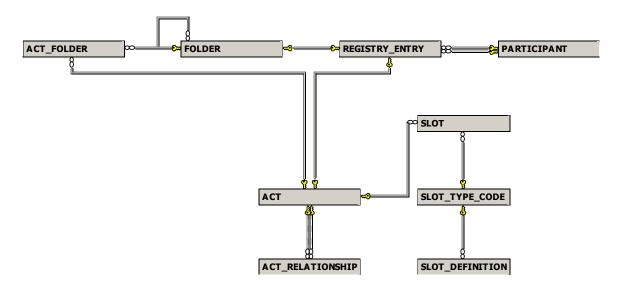


Figure 2: ReMINE RLUS main database tables

The terms in the above figure have as follows:

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REGISTRY_ENTRY – the base abstract table for all RAPS data that will be stored in the metadatabase and contains the main metadata for each RLUS Entry: creation time, description and title of the stored document.

FOLDER – direct implementation of an RLUS Entry, it has a modification time column and also a hierarchical reference to allow a tree implementation of folders.

ACT – An HL7 conformance base table for RAPS data that extends the **REGISTRY_ENTRY** by adding new metadata: a hash code to do a CRC check versus, the binary data in the repository, mime type where it is possible to set the type of the stored type, Uri that points to an external repository, a version number and several identification data.

PARTICIPANT – can only store information regarding a person (patient, physician, etc) and organizations.

SLOT – Tables extending the current metadata; **SLOT_TYPE_CODE** contains the available types for new metadata and **SLOT_VALUE** contains the values for all slots related to a certain **ACT**. However, mapping the slots with a certain derived type from ACT is done with configuration files in RLUS.



TOS Service uses the following database layer:

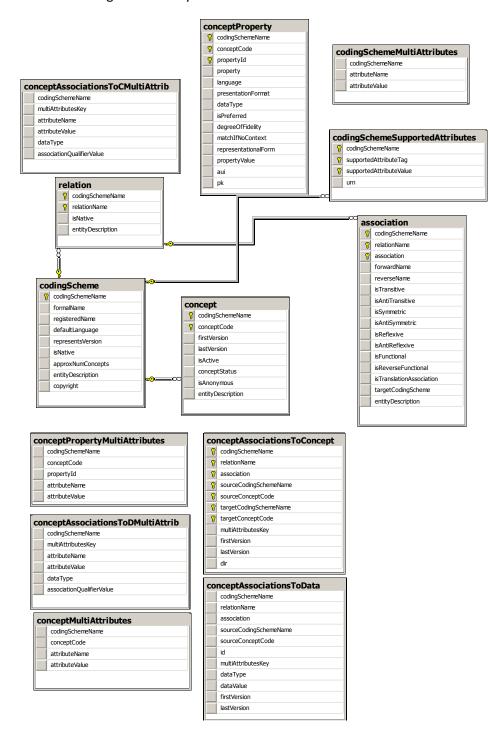


Figure 3: ReMINE TOS main database tables



| Table | Field | Description |
|--------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| codingScheme | approxNumConcepts | An approximation of the number of codes in the coding scheme. This approximation can be used by interface software to determine whether to return complete lists of coding scheme content as a single block or to take alternate action. This field is strictly a "hint" and should never be counted on to have an exact value. |
| | codingSchemeName | This is a short "local name" that is used to reference this specific coding scheme within the context of the containing service. There is no guarantee that the same local name will always be used for the same coding scheme. One service or repository may identify SNOMED-CT as "SCT", and another as "Snomed", etc. The registeredName of the coding scheme should always be used to reference the coding scheme from outside the context of the containing service. SNOMED-CT should always be referenced externally using the official urn, "urn:oid:2.16.840.1.113883.6.96". |
| | defaultLanguage | The local name of the default language used by the coding scheme. This attribute must be a local name in a corresponding supportedLanguage mapping entry. As an example: <codingscheme codingscheme="NCI" defaultlanguage="en"> would correspond to <supportedlanguage urn="urn:oid:2.16.840.1.113883.6.84:en">en</supportedlanguage></codingscheme> |
| | formalName | The official name of the coding scheme as defined by the primary authors. Example: "SNOMED Clinical Terms" |
| | isNative | Used to indicate that this coding scheme is the primary coding scheme for a containing service. The intent of this attribute was to allow "consuming" coding schemes such as the NCI Thesaurus or the UMLS to be identified as the primary scheme supported by a service and that other coding schemes were secondary. |
| | registeredName | The official URN of this coding scheme. Example: <codingscheme codingscheme="NCI" registeredname="urn:oid:2.16.840.1.113883.3.26.1.1"></codingscheme> |



| | | This the identifier that should always be used to reference a coding scheme from external web pages, data base records, etc. |
|---------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | representsVersion | The particular version of the coding scheme that this instance represents. The details of the format and ordering of versions are determined by the authors of the coding scheme. If the versions node is present underneath the codingScheme, this should match one of the codingSchemeVersions in that node. The syntax and semantics of this node are defined by the authors of the coding scheme and no assumptions can be made about collating order, etc. without the codingSchemeVersion reference. |
| | entityDescription | A description of the intent, purpose, use, etc. of the codingScheme (optional). An entity description can contain embedded XML, HTML, etc. as appropriate. |
| | copyright | Licensing and copyright information for the coding scheme. Copyright may contain embedded XML, XHTML, etc. as necessary. Some coding schemes require that the copyright/licensing information be displayed before the coding scheme may be used. It is the responsibility of any application using the LexGrid model to display this information where appropriate if present. |
| concept | conceptCode | A code that represents a specific "meaning" in given situation or context. Every conceptCode must be unique within the context of the containing codingScheme. Currently, all LexGrid concept codes must be derived from the IA5 (or ASCII) character set. While it is technically possible to support case sensitive concept codes (e.g. "m" and "M" identify distinct concepts), database restrictions make this distinction difficult to support. |
| | | When possible, code system curators are strongly encouraged to constrain concept codes to the W3C NCName data type, as it renders them more readily used in XML environments. |
| | | While there is no official size constraint on concept codes, curators are strongly encouraged to keep them relatively small (say < 32 characters) for compatibility use. |
| | conceptStatus | This is the status assigned to the code by the codingScheme curator. If present, this status must be reflected as the local name of a |



| | supportedConceptStatus entry. As an example, if the coding scheme supports "Pending", "Active" and "Retired", there would be three supportedConceptStatus entries: <supportedconceptstatus urn="">Pending</supportedconceptstatus> <supportedconceptstatus urn="">Active</supportedconceptstatus> <supportedconceptstatus urn="">Retired</supportedconceptstatus> urn="">Retired Each codedEntry could then be assigned a status from this list: <concept conceptcode="12345" conceptstatus="Pending"></concept> |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| isActive | This is a boolean value that is derived from a mapping of the conceptStatus field. true (default) - this code will appear in any text search, association traversal or other inquiry false - this code will not appear in search and other queries unless: (a) the code is supplied as an input (lookupConceptCode) - or- (b) the query explicitly states that inactive concepts should be included |
| isAnonymous | If true, this code isn't considered an official part of the codingScheme. Anonymous concepts can appear for the following reasons: (a) Various organizational classifications are implicit in the codingScheme when it is imported (e.g. INTESTINAL INFECTIOUS DISEASES (001-009.99) in ICD-9-CM or secondary classification codes in thesauri) (b) Anonymous constructs in DL type systems, where, for example, the extension of a code is defined as the intersection of all members of class A and the set of all codes that participate in at least one relationship with class B. The set of codes is an |



| | | anonymous construct. |
|-------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | (c) It turns out to be highly useful when a codingScheme always has a "topThing" - a known universal concept that can be used as the root of a subtype hierarchy. By convention, these concepts are given a code of "@" within many LexGrid implementations and are marked as anonymous. |
| | entityDescription | An optional description of the intent and purpose of a codedEntry. Typically, entityDescription contains the "official" representation of the code in the default language and usually, but not always, it matches the preferred representation. |
| | | entityDescription is optional and somewhat redundant. While it improves the readability of the LexGrid content, applications should never depend on it being there and should use the appropriate presentation instead. |
| | | entityDescription doesn't have a language component (although you could cheat and use the xml:lang in an XML rendering), so it assumes the existence of a default language. |
| relation | isNative | "True" means that this relations node is the "native" or default set of associations for the containing coding scheme. At most one relations node should have this value set to "true". If no relations nodes are set to true, software may assume that the codingScheme contains no built-in associations and association queries have to be asked for by name. |
| | entityDescription | A description of the use, purpose, etc. of this set of relations. This field can contain embedded XML, XHTML, etc |
| association | association | The local name of the association. Must be referenced in a corresponding supportedAssociation entry in the codingScheme node. association must be unique within the containing relations collection. |
| | forwardName | A name or designation to be used for the association when reading from source to target. This attribute is required in the LexGrid |



| | model because it is often possible to label associations in a way that is misleading. As an example, an association might be given the local name "part". The assertion, "part(A,B)" is ambiguous here -does it mean that A is a part of B or B is a part of A? The forward name should unambiguously represent the intent of the association in the language of the coding scheme. As an example, if the "part" association is intended to represent the fact that the whole contains the part, the forward name should be something like "hasPart". Similarly, if the association is intended to represent that the part is a part or component of the whole, the forward name should be something akin to "isPartOf". If the association is formally defined as a code in some coding scheme, it is strongly recommended that it have a set of language- |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | specific forwardName and, if applicable, reverseName properties. Without these properties and the associated descriptions it is easy to make errors when determining which code fits the source and which the target slot of a given association |
| isSymmetric and isAntiSymmetric | isSymmetric "true" states that r(A,B) implies r(B,A). False states that it is possible to have r(A,B) without r(B,A). |
| | (a) symmetric associations are always navigable. |
| | (b) the forwardName and reverseName of symmetric associations should always be the same. |
| | (c) The domain and range of symmetric associations must be identical. Associations without the same domain and range are, by default, non-symmetric. |
| | isAntiSymmetric"true" states that r(A,B) and r(B,A) can never both be true. The trivial case of antiSymmetry is the case where the domain and range are mutually exclusive, and it isn't really necessary to state anything about symmetry in this case. The interesting case is where there is partial or complete overlap. The association "hasChild" (referring to people, birth and the like) is antiSymmetric. (Note - think about this. On the class level, it really *is* symmetric), while the association sibling is. |
| isReflexive and isAntiReflexive | isReflexive "true" states that for any member A of the domain of the association r, r(A,A) is true. False states that it is possible that r(A,A) may not be true for all members of the domain and, in fact, it may |



| ŀ | be true for none. |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | isAntiReflexive "true" states that r(A,A) can never be true for any member of the domain of r. |
| | The most common purpose of the reflexive association is to define exactly what is intended by the "subtype" association. One of the questions that has to be asked about a subtype association is whether is "proper" or "improper" in the mathematical sense - is a class considered to be a subtype of itself, according to the authors of the terminology. If it is, isReflexive would be "true" and, if not, isAntiReflexive would be "true". |
| isFunctional and i | isFunctional and isReverseFunctional correspond to the |
| i | FunctionalProperty and InverseFunctionalProperty as defined in the Web Ontology Language (OWL). An association defined with isFunctional true has at most one association target for any given source. An association defined with isInverseFunctional true has a most one source associated with a given target. |
| 5 | This flag indicates that the association represents a "translation" or "mapping" between the containing coding scheme and the coding scheme named in targetCodingScheme. It is used by service software to determine which association is to be used for coding scheme mapping. |
| 1 1 | The reverse name of the association - the text that would be used reading the association from target to source. See: forwardName for a detailed description of the purpose of this attribute. Note the reverse name may not always be applicable - see is Navigable further details. |
| | A description of the association. This field can contain embedded XML, XHTML, etc. |
| 5 | The local name of the codingScheme that, unless otherwise specified, the targetConcept codes are drawn from. Must be a local name in a supportedCodingScheme entry in the codingScheme header. |

For MPI, the database layer follows:



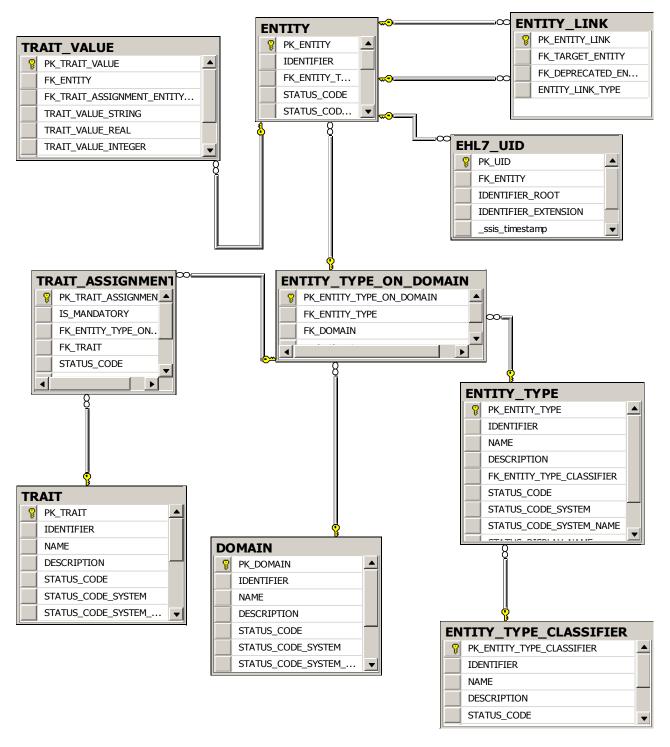


Figure - MPI main database layer

The database tables are somewhat similar with the main MPI classes described earlier in the data contract section.

ENTITY table holds the patient identifier and status code of the entity.

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EHL7_UID table is linked with a entity and it stores and HL7 II (Instance Identifier)



ENTITY_LINK table holds information for linked patients (similar patients).

ENTITY_TYPE table is similar to the EntityType class, holding information of what type of entity we are dealing with. For patient, the type is "HL7-RIM-V3-Person".

ENTITY_TYPE_CLASSIFIER table stores one row: "This classifier identifiers entity types that are specializations of the HL7 RIM V3 'Entity' class".

ENTITY_TYPE_ON_DOMAIN table stores the link between entity types and domains.

DOMAIN table hold information about current domains. The active one is "ReMINE".

TRAIT table contains a list of all traits (similar to an above table stating patient traits).

TRAIT_ASSIGMENT table links a TRAIT with an entity type and domain.

TRAIT_VALUE table contains actual values of traits assigned to an entity (patient)

8.8.Installation instructions

i) Prerequisites installation:

RLUS and TOS require Microsoft .Net Framework 3.5 with Service Pack 1 prior the installation (can be downloaded on the Microsoft web site).

Microsoft SQL 2008 server is required as the Database Management System. A standard setup is suffice, however the following script must be ran on the master database to enable .net common language runtime on SQL:

```
sp_configure 'clr enabled', 1
GO
RECONFIGURE
GO
```

The following directory structure applies to the metadatabase services:

```
+---BD
| \---Backup
+---CLIENT
| \---ManagementConsole
| \---EVS_Import_Export_Console
+---DOCUMENTS
| +---CS&VS
| \---GUIDES
\---SERVICES
+---RLUS
| +---DBRepository
| \---RegistryEntryDefinitions
\---TOS
+---DBRepository
\---Temp
```

ii) Database installation:



The BD folder will contain the SQL server data files once the databases are restored from the BD\Backup files:

- TOS.bak contains the database backup for TOS service
- RLUS.bak contains the database backup for RLUS metadata database
- RLUS_Repository.bak contains the database backup for RLUS Repository database

Using Microsoft SQL Management Studio on the pilot server, databases will be restored using the previous

files:

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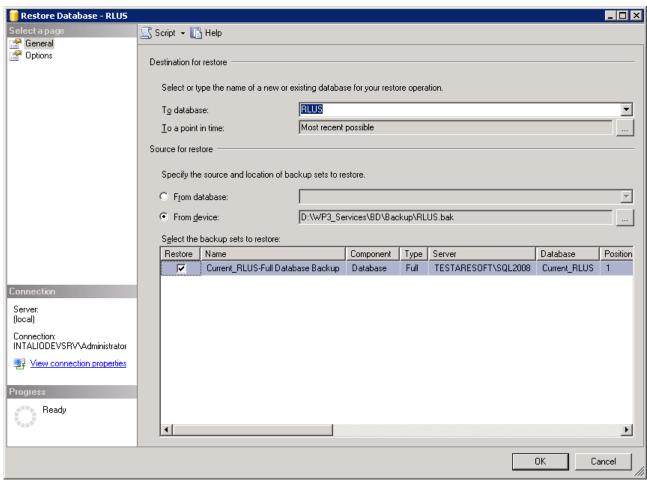


Fig. 4: RLUS Database restoration screen 1

Having selected the RLUS.bak file in the source for the database the admin can select the file name with complete path where the database data will reside (e.g. D:\WP3_Services\BD\RLUS_data.mdf , D:\WP3_Services\BD\RLUS_log.ldf).



The databases name are: RLUS, RLUS_Repository, TOS. If the admin requires another name for any database, he must update de connection string in the services configuration files (described below).

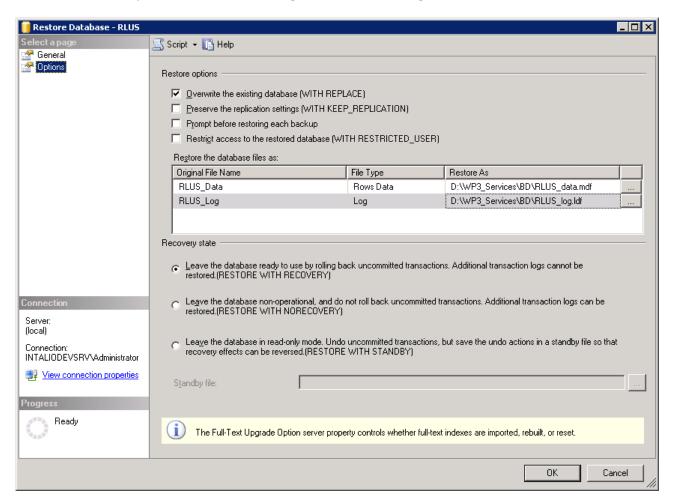


Fig. 5: RLUS Database restoration screen 2

Once all databases have been created (trough restoration) the following SQL server database data file will appear (if used the same name for the file – not mandatory):



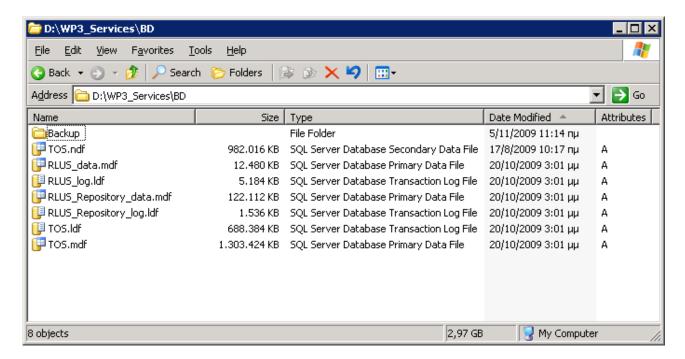


Fig. 6: Metadatabase data files

iii) Services installation:

After the admin will copies the above directory structure with the binaries, further configuration can be done on the services. RLUS and TOS are exposed as web services via http channels and hosted within windows services (each with its own executable):

- For RLUS: ..\RLUS\ RLUS.WinService.Host.exe with configuration file RLUS.WinService.Host.exe.config
- For TOS: ..\TOS\ WinServiceCTS.exe with configuration file WinServiceCTS.exe.config

In the configuration file (WCF – windows communication foundation specific) the service endpoints can be modified (e.g.: http://localhost:10000/RLUSAdministrative) – used if that specific port is already opened:

For RLUS the following lines in the configuration file can be changed and replace the URI with any other valid URI for web services.

```
<add baseAddress="http://localhost:10000/RLUSRuntime" />
<add baseAddress="http://localhost:10000/RLUSAdministrative" />
```

For TOS, the URL for services can be modified in the configuration files:

```
<add key="Xaml.ServiceEndpointURL"
value="http://localhost:10000/Xaml" />
<add key="VocabularyRuntime.ServiceEndpointURL"
value ="http://localhost:10000/CTSVocabularyRuntime"/>
<add key="VocabularyBrowse.ServiceEndpointURL"
```



```
value ="http://localhost:10000/CTSVocabularyBrowse"/>
<add key="MessageRuntime.ServiceEndpointURL"
       value ="http://localhost:10000/CTSMessageRuntime"/>
<add key="MessageBrowse.ServiceEndpointURL"
       value ="http://localhost:10000/CTSMessageBrowse"/>
<add kev="MessageEdit.ServiceEndpointURL"
       value ="http://localhost:10000/CTSMessageEdit"/>
<add kev="VocabularvEdit.ServiceEndpointURL"
       value ="http://localhost:10000/CTSVocabularyEdit"/>
<add key="MappingEdit.ServiceEndpointURL"
       value="http://localhost:10000/CTSMappingEdit"/>
<add key="Import.ServiceEndpointURL"
       value ="http://localhost:10000/CTSImport"/>
<add key="Export.ServiceEndpointURL"
       value="http://localhost:10000/CTSExport"/>
<add key="Mapping.ServiceEndpointURL"
       value="http://localhost:10000/CTSMapping" />
<add key="BulkEdit.ServiceEndpointURL"
       value="http://localhost:10000/CTSEditBulk" />
<add key="SubscriptionAdministration.ServiceEndpointURL"
       value="http://localhost:10000/CTSSubscriptionAdministration"/>
<add key="MessageAdministration.ServiceEndpointURL"
   value="http://localhost:10000/CTSMessageAdministration"/>
```

If the admin has selected different databases names than the ones presented as defaults, each service has a DBRepository folder where the SQL connection string can be found in the connections.xml file. For RLUS there are 3 connection strings (2 to RLUS and 1 to RLUS_Repository database):

Each of the ConnectionStrings node can be modified to match the database the admin restored. For the TOS service there is only one connection to the TOS database: www.wccnnection>

```
<ConnectionID>1</ConnectionID>
```

<ConnectionString>workstation id=localhost;packet size=4096;data source=localhost;persist security info=False;initial catalog=TOS;Integrated Security=SSPI;Connect Timeout=6000</ConnectionString></MyConnection>

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Next the admin has to create the windows services for RLUS and TOS using the "sc create" windows shell command. For example, having a user 'user' with password 'password' belonging to a windows domain 'domain', the batch looks like:

>sc create ReMINE.RLUS binPath= "D:\WP3_Services\RLUS\ RLUS.WinService.Host.exe" start= auto obj= user@domain_password= password

>sc create ReMINE.TOS binPath= "D:\WP3_Services\TOS\ WinServiceCTS.exe " start= auto obj= user@domain password= password

From the "Services" management console the admin can start the services:

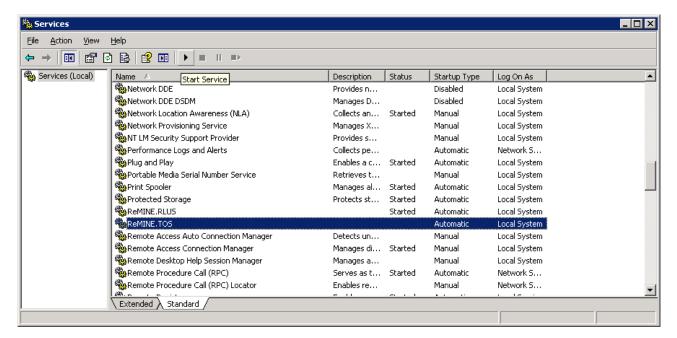


Fig. 7: Metadatabase installed services

Once the services started, the admin can test the WSDL in any browser based on the URL given to each service:



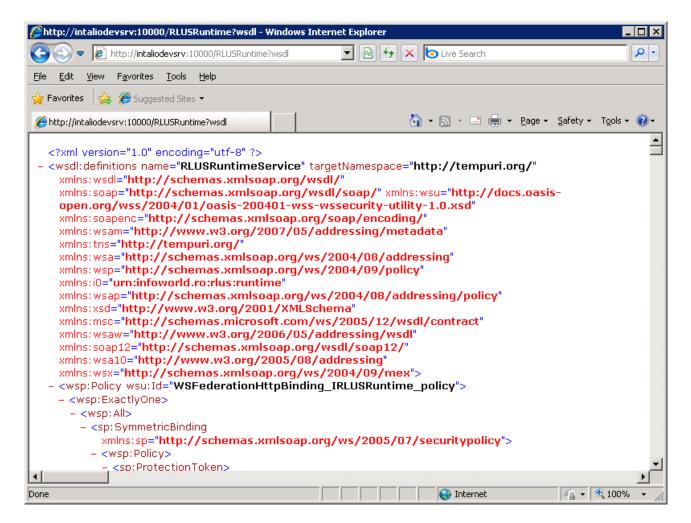


Fig. 8: Accessing RLUS WSDL

In the CLIENT\ManagementConsole\EVS_Import_Export_Console folder there is a setup kit for a management console used to import/export vocabularies in TOS service. The excel files containing the vocabularies and valueSets required for ReMINE found in the implementation guides (DOCUMENTS\Guides) can be found in DOCUMENTS\CS&VS. The admin does not need to import them in TOS, as they are already imported.



9. Data mining and Knowledge Extraction

9.1.Purpose

The REMINE Data Mining Module is dedicated to the extraction of useful patterns from heterogeneous clinical and other HIS (and beyond) data with the aid of semantic modeling. It is part of the core of the system's decision support process, analyzing the enriched/semantically structured data stored in the REMINE DB (gathered from the complex patients' clinical profiles, history and/or other information available in the HIS) to discover patterns in the data which could help the Risk Manager to optimize the associated risk management processes and policies. The output of the module, the discovered patterns in the data is fed to the decision support logical reasoner, the Knowledge Inference System sub-module) for their further elaboration.

The module's primary functionality is to extract the most similar patient's profiles from the integrated and normalized complex clinical data stored in the REMINE Repository. This is done in two steps: firstly the numerical and categorical data will be mined, and later the results will be fed to the semantic component (Knowledge Inference System) describing the risk assessments connected with specific medical symptoms.

9.2.2nd Prototype Implementation

Deliverable D3.7 – First revision of the data mining and knowledge extraction module addresses the development process of both the data mining component, responsible for obtaining a descriptive model of clinical data, and of the knowledge extraction module, which realizes the detection of risky situations based on the clinical data model.

By using data mining scenarios, this deliverable models the situations in which data collected over time can be of effective help in real-time risk identification and mitigation. The data mining and the knowledge inference processes are presented by the application ontology, summarizing the data requirements and the inter-relation between the two processes. The mining process is presented into details, outlining how the data is saved into RLUS (with respect to semantic and syntactic integration issues), data acquisition from RLUS into the general mining database, pre-processing steps including selection, cleaning, transformations and loading into a scenario-specific data warehouse. The technologies chosen and the implementation itself of the mining project are well documented and explained.

As regarding the tightly-related Knowledge Inference System, an Application Programming Interface is proposed, comprising the service, data and fault contracts. The first prototype also details the Risk Manager Interface that receives alerts from the Application Programming Interface and eventually delivers the alerts to the clinicians.

9.3.3rd Prototype Implementation

Third revision of the data mining and knowledge extraction module addresses the implementation of data mining component and the modelling of the selected mining scenarios, as also the development of the



Knowledge Inference System and of the Risk Manager Interface, which consists in the risk manager interface for the alerts produced by the Knowledge Inference System.

Deliverable D3.8 documents the development of the TRFT data mining scenarios, which aims at providing expressive modelling of the historical data of patient administration and related MRSA infection control activities. The laboratory results which confirms MRSA infections together with patient hospital and ward admission are employed for identifying patterns that help predicting future risky situations for the patients. The resulting mining models were used as the rule base for the Knowledge Inference System.

The Knowledge Inference System was implemented by relying on the well-defined foundation of business rule engines. The deliverable specifies how the mining models are reused in this knowledge-based inference engine for producing reliable risk pattern detection in new, real-time incoming data. The Risk Manager Interface was also developed to deliver easy to use visual alerting capabilities to the risk manager user.

9.4.Dependencies

The data mining module depends only on the ReMINE Database from where the training and validating subsets are selected. The CDAService ensures this process. There are two data mining tools used in ReMINE Project, thus creating a dependency on these tools:

- SQL Server Analysis Services
- WEKA

9.5.Interfaces with other components

The Data Mining module provides knowledge representation models for the Knowledge Inference System presented in the following chapter. The knowledge inference system directly accesses the data mining results to see if any new data knowledge is available.

9.6.Resources

Data mining is a computationally and storage intensive operation because it exhaustively searches for recurring patterns in large datasets. Because mining is not an online operation, it works in periodic batches; the use of a dedicated server is not required. The current pilot server specs satisfy the need for this module.

9.7.Data/Messages

The methodology used for data mining is Cross Industry Standard Process for Data Mining (CRISP-DM). This is a data mining process model that describes commonly used approaches that expert data miners use to tackle problems.

Data is sourced into the ReMINE Platform from HIS by using the H-ERP Bridge passes through the Data Acquisition Layer and is stored into the RLUS database. However, the data from HIS must endure some transformations to become conformant to the CDA standards enforced by the RLUS repository. Every data mining scenario must define its own data requirements with respect to the HIS data contract and the CDA document specifications.



As data becomes available in the RLUS, it must be extracted from the RLUS repository, processed and stored into a general Data Mining database, which is done periodically by CDAService.

NOTE for Niguarda Pilot:

In order to evaluate and to decide if a data mining process could be developed for the Niguarda hospital, a data set of data records from the period 1/9/2010 - 10/2/2011. Using the stored HL7 v2 messages from this time period a data set was created in order to execute preliminary tests.

The original data of patients regarding the scenario of this pilot hospital consists of the following records:

| Message Type | Message Count | Unique Patients |
|--------------|---------------|-----------------|
| ADT^A03 | 439 | 192 |
| ADT^A04 | 238 | 218 |
| ADT^A08 | 1694 | 216 |
| OML^021 | 751 | 179 |
| OML^033 | 214 | 176 |
| ORM^001 | 288 | 171 |
| OUL^R22 | 1478 | 187 |

From the above data, a data set was extracted where each dataset's record consists of the data regarding one patient. The attributes describing each patient are listed in the following table:

| DATA | TYPE |
|------------------------------------------|---------|
| Patient unique identifier | String |
| Patient Age | Integer |
| Full assessment | Time |
| ECG execution | Time |
| Exam order | Time |
| Sample delivered to lab | Time |
| Exam result availability | Time |
| Administration of fibrinolitic treatment | Time |
| Assessment by neurology consultant | Time |

All the time attributes was transformed to integer values depicting the difference in minutes of the time point from the patient's start of the triage. The final data set consisted from 202 patient records. From these patients, 39 where finally administered the fibrinolitic treatment while the remaining 163 did not. For this data mining analysis process the WEKA (Waikato Environment for Knowledge Analysis) framework was used. Using the tools provided by WEKA several data mining algorithms where tested. More specifically, the primary goal of the tests was to detect if any correlation exists between the patient's attributes and the final result of the time of the administration of the fibrinolitic treatment. Unfortunately the number of patients belonging to that case (39 patients) was insufficient to detect any correlations between the other attributes and the time of administration. In addition, cluster analysis was carried out using the simple K- Means algorithm but also the more sophisticated Self – Organized Maps algorithm. This analysis again didn't reveal any well separated concentrations (clusters) of data that could be used for the detection of outlier cases.



10. Guideline Execution Engine

Notes to the reader:

- ▲ The Guideline Execution Engine is described in D4.6, Version 2. This section takes a view on the same topic from a different angle.
- △ This section focuses on the What-If Tool. The execution of the MRSA Guideline to obtain daily colour coding at TRFT is described elsewhere.

10.1. Purpose

The purpose of the What-If Tool is to interactively explore the consequences of different input combinations for treatment under the modeled guideline. It has two different uses:

- A The risk manager or other staff exploring risk situations related to that part of the care which is described by the modeled guideline, may gain insights in the consequences of certain constellations, i.e., combinations of patient conditions, which may relate to risks against patient safety.
- ▲ The domain experts can compare their expectations of the guideline execution with the output of executing its model. Differences are commonly seen after initial modeling. In particular the interpretation of missing data is rarely specified in guidelines and must be discussed on a per-case basis.

10.2. 2nd Prototype Functionalities

The What-If Tool was not scheduled to be part of the second prototype.

10.3. 3rd Prototype Functionalities

At the 3rd review, the What-If Tool was not available. It was completed September 2011 when D4.6 was submitted which fully describes its functionalities.

10.4. Dependencies

The What-If Tool does not depend on other parts of the Remine system. It depends on the availability of a web server and the Asbru Interpreter as described below.

10.5. Interfaces with other components

The What-If Tool was implemented as a stand-alone prototype and does not interface with other parts of the Remine system.

10.6. Resources

The What-If Tool is implemented as a set of CGI scripts. It therefore runs on a web server. This web server must have the programming language Perl installed, which is standard on Linux-style systems.



The What-If Tool uses the Asbru Interpreter, which is enclosed with the What-If Tool.

10.7. Data/Messages

Data is only passed between the different forms forming the tool. It is temporally stored locally when starting the Asbru Interpreter, but not meant for reuse.

Messages are not exchanged with the rest of the system.

10.8. Installation instructions

Copy the content of folder WHAT_IF_TOOL on the DVD to a newly created folder which is configured to contain CGI scripts as described in the documentation of the web server in question.

Insure that the files with extension .cgi have execute permission set for everyone (world).

Append start.cgi to the URL of the folder containing the What-If Tool. E.g., if the folder is accessed as

http://www.ifs.tuwien.ac.at/cgiseyfang/remine/

then the What-If Tool is started at URL

http://www.ifs.tuwien.ac.at/cgiseyfang/remine/start.cgi.

11. Visualisation tool (Research Prototype Component -not integrated with ReMINE platform)

Note to the reader: The Visualisation tool is described in D4.8. This section takes a view on the same topic from a different angle – we added cross references to reduce redundancy.

11.1. Purpose

The purpose of the visualisation tool is to show patient data together with plans that were executed. These plans represent care actions as modeled using Asbru.

11.2. 2nd Prototype Functionalities

The intermediate state of work was described in an internal deliverable at M24. The actual implementation was scheduled to be completed in M33.

11.3. 3rd Prototype Functionalities

The final functionalities of the Visualisation Tool are described in Sections 8 and 9 of D4.8. They were implemented before end of October 2010.

11.4. Dependencies

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The Visualisation Tool does not depend on other parts of the Remine system.

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11.5. Interfaces with other components

The Visualisation Tool was implemented as a stand-alone research prototype and does not interface with other parts of the Remine system.

11.6. Resources

The Visualisation Tools is implemented as a JAR file. It requires the Java Runtime Engine, which is included in standard Windows and Linux installations.

11.7. Data/Messages

Data is not exchanged with other parts of the Remine system.

Local storage of data is described in Section 11 of D4.8.

11.8. Installation Instructions

Copy the content of folder CARECRUISER on the DVD to a new folder "carecruiser".

In a DOS window, change to folder carecruiser and there, type:

carecruiser.jar examples\remineData\guidelines\BirthAsbruWithIntentions.xml

Alternatively, use another XML file that you created before.

We provide synthesised patient data for the BirthAsbruWithIntentions.xml guideline.

If you want to add (real or other synthesised) patient data to view in combination with one of the guidelines, you need to edit

carecruiser\examples\remineData\guidelines\BirthAsbruWithIntentions.config

(or another guideline (+.config)) with a text editor of your choice.

In the first line of this file you need to add the name of the file with the additional patient data.

Please put the file with the patient data (a .txt file) into the directory

carecruiser\examples\remineData\patients.

Revision: V0.12 Draft



12. User Interface

12.1. Purpose

Revision: V0.12 Draft

The User Interface (GUI) allows the interaction between the system and the users (clinical staff and administrators). Through the interface the user is able to insert data into the application, modify policies (BRs), configure the system and check the different information and reports that ReMINE provides.

The framework looks different for each user depending on their roles. The interface automatically enables and disables different components and features to ensure proper use of permissions for the different kind of users. Although there is a unique workspace, the Graphical User Interface (GUI) can be divided in two broad parts: Medical Process Interface (MPI) and Risk Manager Interface (RMI).

The Medical Process Interface (MPI) is intended for the clinical staff and it differs from one scenario to another. Mainly the MPI use to be comprised of a tab for the patient admission; a different one for the different clinical tasks to carry out for each patient; one more for the possibility of launching different medical processes; and finally a tab for notifying the RAPS, showing all the alerts triggered for each patient.

There are special tabs for each pilot as in the case of Sacco scenario that presents a tab to provide the patient risk level and a tab displaying a scheduler with the monitoring activity.

The Risk Manager Interface (RMI) is used for the administrator and manager users. This interface is the same in the four different scenarios. It contains three tabs. The first one, Alert Management System (AMS) tab, for managing all the settings and information related to Alert Management System. The second one, Business Activity Monitoring (BAM) tab, provides the report created in run-time based on the information obtained from the database. The Reports are created according to the Key Performance Indicators (KPIs) defined for each scenario and building be means of different charts. These KPIs provide information about the status of processes; medical information regarding the patients; and detailed statistics of the alerts managed by the system. Finally, BPMS tab, allows the Risk Manager user to check the current situation of the system regarding the execution and the performance of the processes (e.g. lifecycle status, process flow, failures, etc.). Moreover, in case the user has the proper rights and permissions, the console allows performing the following actions: start, stop, deploy and undeploy processes.



Figure 4. Graphical User Interface of Sacco scenario (MPI and RMI tabs)

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12.2. 2nd and 3rd Prototype Functionalities Comparison

The 3rd Prototype functionality highly increases the user experience. The interaction between the interface and the users is more friendly and predictable. High efforts for increasing the performance and the visual aspect of the application have been carried out. The results are a faster and nice user interface and consequently a higher acceptance and reliability in ReMINE application. In addition the interface functionality has been enriched and increased. Mainly the enhancements can be listed as follow:

- All ReMINE information is presented in one interface. All components were integrated in a common GUI (processes, tasks, alerting, Business Activity monitoring etc.)
- The interface automatically enables and disables different components based on user roles and privileges
- Friendly and intuitive interfaces
- More information available for the users
- Forms enhancement and optimization:
 - New forms
 - New data required based on medical staff requirements
 - Barcode and RFID use
 - Automatic input
 - Checking input data in real-time for avoiding failures
 - o Immediate notifications for data input mistakes (message boxes)
 - Translations
- Risk level patient chart showing the risk for each patient based on medical conditions and hospital status
- Calendar with prediction of monitorings and virtual future protocol violationsprediction of the patient status (mainly, the dilatation width) and the resources needed for each patient (staff, devices and rooms)
- Role -based access control to the application interface by using Light Directory Active Protocol (LDAP).
- Reports enhancement KPIs according to users

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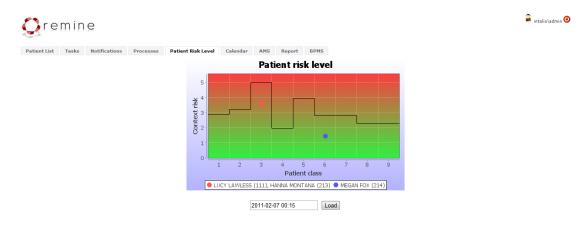


Figure 5. Patient Risk Level tab

12.3. Dependencies

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The GUI is directly interconnected with the processes, the internal database modules and with the security layer for the whole platform. The GUI is able launch different processes and also to interact with the process trough dedicated forms. On the other hand the connection between the GUI and the database allows showing relevant information to the end-user, among them reports and performance statics.

Due to the environment within the project is developed and the information managed, the security implemented for the data handled by the system and the communications is a critical task. The data collected in the hospital for each patient should be confidential and private, hence the security to protect a potential modification or illegal access to the information or any violation of the patient privacy was one of the main goals of the project. Also the communications among all the subsystems and the different access points to the scenarios have to be secured, as they can present several security problems. As the architecture of the system is service-oriented (SOA) the security over the communications presents an important issue.

The REMINE pilot server is placed within the confines of the local HIS Firewall. The local HIS Firewall and the use of specific user access list (with the associated credentials) are the main security measures for avoiding any malicious access to the platform. Also the access to the different parts is restricted depending on the user roles.

The security is implemented under a role based interface and managed by means of LDAP, taking in account the possibilities of Intalio server security. In other words, the different users of the system need to authenticate and obtain rights and permissions for the different resources and task. It is controlled by the security system, denying unauthorized access depending on the roles of the users assigned by the manager of the system.

The ReMINE login makes use of RBAC. Role-based access control (RBAC) is an approach to restricting system access to authorized users. The permissions to perform certain operations are assigned to specific



roles. The users are assigned particular roles, and through those role assignments acquire the permissions to perform particular system functions and components.

The users of the system will have their own credentials to log in the interface with one or more roles assigned in order to allow accessing to the resources with an according level of permission. Every resource which is out of the scope of the user role will be hidden to him, offering different interfaces depending on the users. Then every resource has his own role/s associated for controlling the access from the users.

To gain access to Sacco web-portal the user has to authenticate in order to be able to interact with the platform.



Figure 6: - Login screen



Figure 7: - Example of users for Sacco scenario



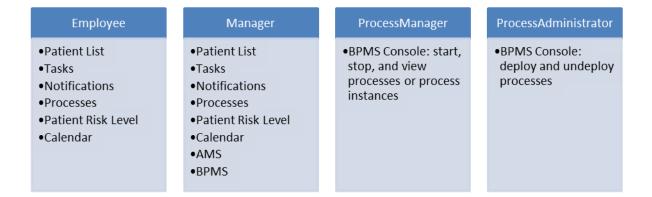


Figure 8: - Example of roles for Sacco scenario

12.4. Interfaces with other components

The GUI has interfaces with processes and with the internal database.

The communication with the processes is carried out with SOAP messages. The processes are exposed as a web services, therefore for triggering new processes, the interface send dedicated SOAP messages to the corresponding end-point. Also the communication between processes and clinical staff is carried out through forms, by an interchange of SOAP messages with all the information of the given forms.

The interface with the internal database is carried out through dedicated database connectors in order to initiate communication with the storage source and to be able to query the internal database to extract the desired information.

12.5. Resources

The GUI consists on a web application and has been developed by means of Java Server Page. Also technologies and standards as HTML, JavaScript, Java or AJAX have been used to develop the application.

On the other hand, the forms to allow the clinical staff interacting with the processes at any point, has been developed under Intalio | Designer tool.

All the web application is running under dedicated tomcat server. To access to the application the user just need to type in the browser the correct URL of the resource they are trying to access.

12.6. Data/Messages

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The data and messages related to the GUI, as defined above, are those present in the communication between GUI and processes or internal database. The former one refers simply to SOAP messages with some information of the patient and application status or information that the clinical staff has introduced in the dedicated forms. The latter refers to the data interchanged between the database with all the clinical information and application status, like key performance indicators (KPIs), business activity monitoring (BAM), alert managing system (AMS) reports, etc.

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12.7. Installation instructions

This module does not need a particular procedure for its installation. By following the installation instructions explained in section 7.7 for the installation of the server is enough. The GUI has been preinstalled as a web application in the dedicated tomcat server, so it is no needed to take further actions.

13. Alerting System

12.8. Purpose

The alerting system intends to enrich Remine with the ability to send Alerts through different channels, namely: SMS, Email. As an administrative tool, the Alert system also provides a connector that stores an "alert" into the database allowing a log to be stored. The system is composed of three main entities: alert, along with the intended delivery channels, and alert instance. An alert might have one, or more, delivery channels configured, which will be used, by the alerting system, when the alert is triggered when an alert is created. Currently, the alerting system supports three different channels:

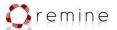
- 1. Log message into database, used mainly for administrative purposes and where the alert will not require to be acknowledged.
- 2. SMS, where an alert message will be delivered to the mobile phone configured in the recipients profile. The acknowledgment of these alerts will be received through the same channel, meaning that the recipient shall reply to the system with an SMS.
- 3. Email, where an alert message will be delivered to the email configured in the recipients profile. In this case the recipient will acknowledge the alert by following the instructions in the email and accessing the provided URL.

In send email and/or SMS actions, there must be defined one or more recipients, belonging to hospital staff.

The system was entirely implemented in Java and is divided into two deploys, one to be deployed in a Tomcat webapp folder, and the other on Axis2 services folder, these components and how to configure and setup them will be described in a section below.

The main interface is a web application, named RemAlerting, which combines two servlets, RemAlerting and SMSResponse. RemAlerting servlet contains the Risk Manager Interface, while the SMSResponse contains a web form that is used by the contracted SMS hosting Service to notify the Remine alerting system of any SMS Acknowledgment.

Finally, the Axis2 service, named RemineNotifierWS, exposes a web service, available to the other Remine modules, and that allows them to initiate and cancel alerts.



13.2. 2nd Prototype Functionalities

The Alert server on the second Prototype had a stable interface with the remaining modules and presented to the system the basic functionalities to send an Alert to the configured recipients. In a brief description, on this release the system presented the following functionalities:

- Alert Sending through Email and SMS
- Alert escalation, by sending a new alert to the next recipient on the alerts recipients list.
- Risk Manager Interface to manage Alert configurations and Alert Recipients information.

13.3. 3rd Prototype Functionalities

The Alert Module was slightly improved on the third Remine Prototype, the major functionalities of the system were already in place, but the users requests have showed the need to change the system a bit. So, the third instalment included a few bug fixes and the following new functionalities:

- Alert sending to a database log, mainly used has a possible log file.
- Programmatically Cancel, or Stop, Alerts. This new functionality allowed the "client" modules to forcibly cancel an alert through the Alerts Web Methods. This also forced a change on second instalment interface.

13.4. Dependencies

The alerting system requires the existence of an email server, along with an email account to be able to send alerts through this channel. Additionally, it also requires a SMS hosting account in order to be able to send and receive acknowledgements through this channel. These information must be configured in the "application.properties" section (detailed instructions on how to find and configure each module are presented in detail under section 13.6).

13.5. Interfaces with other components

The alerting system is mainly used by Intalio in order to alert hospital staff by SMS and/or Email, and the chosen interface was a web service, making it a decoupled module. The decoupling allows other modules to use of the alerting system, and will also allow to scale the system performance horizontally since it can be installed in a different machine from the rest of the application and accessed remotely.

The web service provides two methods to be used by the other modules:

- startAlert: which triggers an alert and execute his actions.
- stopAlert: cancel the execution of pending actions.



It also provides an HTTP Form that should be used by SMS host service to notify alerting system of reply messages. This simplified, and more limited, interface was required, since the chosen SMS provided were not able to use a Web Service interface.

13.6. Resources

Alerting System uses properties files to store its configuration and enable the system administrator to easily change and configure the entire module by editing a text files. The RemAlerting application allows the configuration of database, while the RemineNotifierWS allows the configuration of SMS hosting service and Email provider.

The RemAlerting application contains an application.properties file under "WebContent/WEB-INF/classes/" folder. The table below presents the properties used in this file.

| Propriety | Description | Example |
|-------------|----------------------------------------|-------------------------------------|
| db.url | The connection string to database | jdbc:mysql://neomark.link.pt/remine |
| db.user | The username to get access to database | remine |
| db.password | The password to get access to database | PasswordToBeChanged |

Table 1 – RemAlerting application properties

The RemineNotifierWS deploy contains a similar application.properties file under "resources/META-INF/" folder, and contains the follow properties:

| Propriety | Description | Example |
|-----------------------------|-----------------------------------------------------------------------------------|----------------------------------------------------|
| smsservice.address | The endpoint address to SMS hosting web service | http://ws.smshosting.it/smsWS/se rvices/smsService |
| smsservice.user | The username to log-in into SMS hosting service | Remine |
| smsservice.password | The password to log-in into SMS hosting service | passwordToBeChanged |
| smsservice.originator | The SMS hosting service phone number, used to acknowledge the Alerts sent by SMS. | 00393470000000 |
| smsservice.hostemailaddress | The address to where SMS provider will forward any SMS reply. | 192.168.10.1 |
| smsservice.hostemailport | The port on the previous address that | 80 |



| | the SMS provider will try to reach. | |
|--------------------------|------------------------------------------------|------------------------------|
| smsservice.reply_message | Fixed text to explain the reply | Please reply with the follow |
| | mechanism in the SMS message | message |
| smsservice.key | The keyword that the recipient shall use | Remine |
| | in the reply to an alert. | |
| mail.subject | The email subject | [ALERT] Remine Message Alert |
| mail.mail | The email from where emails are sent | AlertSystem@remine.eu |
| mail.smtp.host | The SMTP server name or ip | mail.remine.eu |
| mail.smtp.port | The port where SMTP server is listening | 25 |
| mail.smtp.user | The username to log-in into SMTP server | Remine |
| mail.smtp.pwd | The password to log-in into SMTP server | passwordToBeChanged |
| mail.smtp.ssl | Specify if connection is secured using SSL | True |
| mail.smtp.auth | Specify if SMTP server requires authentication | True |

Table 2 – RemineNotifierWS application properties

13.7. Data/Messages

The follow image (Illustration 1) presents the Alerting system model, which is currently persisted in a MySQL database, but could easily be changed to other database engine.



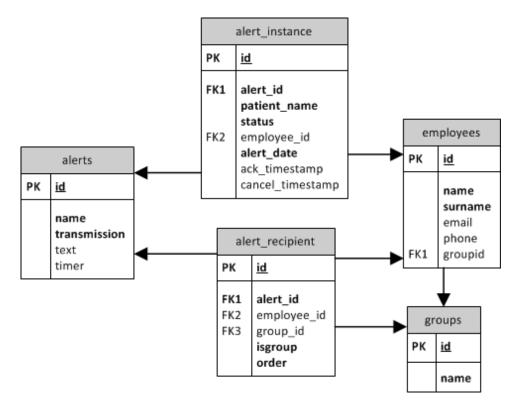


Illustration 1 – Alerting System Model

The alerting system receives messages from other Remine modules, over the published interface named RemineNotifierWS, and also from SMS hosting Service, over SMSResponse Servlet. The Illustration 2 presents a diagram with the input and output messages for the Alerting System.

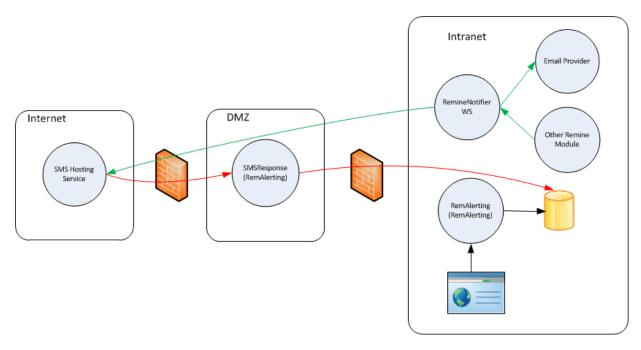


Illustration 2 – Alerting System messages flow

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The alerting system receives requests to start and stop alerts and send notifications to hospital staff from Email provider and a SMS Hosting Service, in case of an SMS reply message the system is notified from SMSResponse servlet.

The RemineNotifierWS interface can be seen in Table 3.

| Method | Method's Arguments | Explanation |
|------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| startAlert | | Create an alert's instance, which result in the execution of the actions associated to the alert |
| | (String) name | The name of the alert that should be sent. |
| | (String) reason | The reason to send the alert, this will make part of the text send by SMS, Email or write into the database. |
| | [Return Value] int | The method returns the ID for the alert created, which can then be used to cancel/stop it. If an error occurs, then the method returns the value -1. |
| stopAlert | | Cancel the execution of an alert instance. |
| | (int) alertId | The alert's instance identifier that wants to cancel. |
| | [Return Value] boolean | The return value is true case everything goes right, and false otherwise |

Table 3 - RemineNotifierWS interface

The SMSResponse Servlet is a single http form, with the follow interface:

| Parameter | Description |
|-----------|----------------------------------------|
| testo | The SMS text |
| Number | The phone number that sent the message |

Table 4 – SMSResponse interface

13.8. Installation instructions

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The alert system is divided into two packages 'deploy', RemAlerting and RemineNotifierWS. The RemAlerting package holds two servlets, RemAlerting and SMSResponse. The servlet RemAlerting contains the implementation of the Risk Manage Web Interface while SMSResponse is a web form that functions as the interface that allows the SMS hosting service to notify the alerting system of replies coming from

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hospital staff. The RemineNotifierWS package holds a web service that provides an interface to other Remine modules initiate and cancel alerts.

The alert system must be accessible to the SMS Provider that it's in the internet, outside the security zone of the application, so as a security precaution, the system architecture will deploy the servlet SMSResponse in the DMZ and the remaining application on the intranet, inaccessible by the outside.

The following image presents a suggested architecture, however some of the system functions may all be aggregated in the same machine instead of being divided as shown in the illustration (eg: email server, database server and web server may all reside in a single machine). It's also possible to reduce physical architecture complexity by using a reverse proxy, and so in that case the reverse proxy would take the responsibility of filtering all internet requests and redirect those to the internal server where the SMSResponse servelet would be installed.

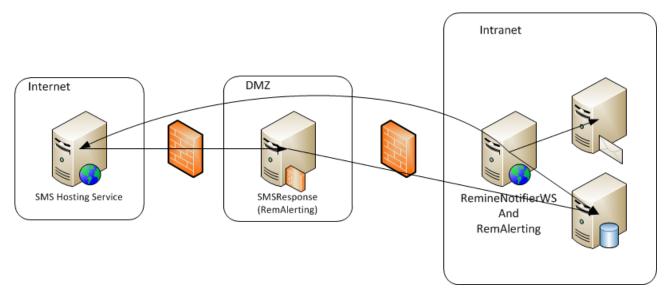


Illustration 3 – Alerting system physical architecture

The Alert system module, requires, and assumes, that the following software and service are already installed:

- Apache HTTP Server
- Tomcat
- Apache Axis2/Java version
- MySQL Server
- Email Server

The system administrator should also have the follow information to correctly configure the application:

- MySQL Database connection string
- MySQL user login



- SMS Hosting Service endpoint
- SMS Hosting Service user login
- Email Server Ip/Name
- Email Server Port
- Email Provider user login (if required)

NOTE: We assume that the MySQL has a database with the schema presented in Illustration 1.

Next we present the steps to install RemineNotifierWS:

- 1. Open RemineNotifierWS.aar file with a compression program like 7zip or WinRar;
- 2. Go to META-INF folder;
- 3. Open **application.properties** file with a text editor;
- 4. Fill the file with the help of **Table 2** that you can find in this document (page 70);
- 5. Save the application.properties file and close RemineNotifierWS.aar file;
- Copy the resulting RemineNotifierWS.aar file to %TOMCAT-INSTALLATION-FOLDER%\webapps\axis2\WEB-INF\services directory;
- 7. Restart Tomcat;
- 8. Open a browser and go to http://httpserver/axis2/services/listServices, you should see RemineNotifierWS in the available services's list.

Step-by-step installation of RemAlerting (intranet and DMZ):

- 1. Go to RemAlerting\WebContent\WEB-INF\classes folder;
- 2. Open application.properties file with a text editor;
- 3. Fill the file with the help of **Table 1** that you can find in this document (page 69);
- 4. Copy RemAlerting folder to **%TOMCAT-INSTALLATION-FOLDER%\webapps** directory;
- 5. Restart Tomcat;
- 6. (Only needed for a DMZ installation) Disable RemAlerting servlet
 - 6.1. Go to RemAlerting\WebContent\WEB-INF\ folder
 - 6.2. Open web.xml and comment the follow block:

```
<servlet-mapping>
```

<servlet-name>remalerting</servlet-name>

<url-pattern>*.html</url-pattern>

</servlet-mapping>

- 6.3. Test application
 - 6.3.1.(Intranet) Open a browser and go to http://httpserver/RemAlerting you should see the alerting system back office.
 - 6.3.2.(**DMZ**) Open a browser and go to http://httpserver/RemAlerting/SMSResponse it should give you a java error
 - 6.3.3.(**DMZ**) Open a browser and go to http://httpserver/RemAlerting it should give you an HTTP 404 message



14. Rules Engine

14.1. Purpose

This sub-model provides recommendations or solutions for driving the flow of a particular situation in order to control and influence the behavior of the business within the healthcare service. The business rules aims to establish the guidelines, defining policies and medical protocols, requirements and conditional statements.

ReMINE is a rule-based application, which allow to the clinical responsible of the scenario to drive the scenario and the clinical pathway based on the medical protocols and their own policy.



Figure 9: Architecture of a rule-based application system.

14.2. 2nd Prototype Functionalities

The 2nd Prototype had a reduced set of business rules (BRs) integrated. Thus it had less flexibility to control the clinical pathway. In addition less notification messages and alerts due to protocol violation were managed and sent to the clinical staff.

14.3. 3rd Prototype Functionalities

The 3rd Prototype has added a new set of business rules, improving and optimizing the clinical pathway. Furthermore the module for managing predictive business rules has been developed. As the reader may know by previous deliverables, the BRs can be divided in two groups (just for Sacco scenario):

- Real Time Business Rules: support real time management of a contingent risky situation for a specific patient, thus their effect on patient safety is immediate.
- Predictive Business Rules: detect a potential future risky situation for a (group of)
 patient(s), thus their effect on patient safety is in the future. In other words, RAPS
 prediction, detection and control.



The new set of real time BRs added advanced features as BRs with time constrains for triggering alerts when the elapsed time in a medical procedure reach an undesirable threshold.

On the other hand for the functionality of predictive BRs, it has been needed to develop a dedicated BR engine running under Java environment, with classes rather than a web service, as the built-in for the real-time BRs.

14.4. Dependencies

These BRs engines are running under the dedicated tomcat server, both of them (for Sacco scenario) as independent modules. Whether as a web service, like the real time BR engine, or a java routine, like the predictive BR engine (for Sacco). They are interacting with the processes in order to drive the flow of a particular scenario.

14.5. Interfaces with other components

As commented above this module is split in two parts for Sacco scenario, real time and predictive BR engines, so the explanation will be splitted as well.

The former is exposed as an axis2 web service, thus the communication between processes and real time BR engine is carried out through this interface by means of SOAP messages. In this way, the communication and the relation between processes and real time BR engine is highly important and strong.

The latter consists on a java routine that is being executed in a fixed interval of time and on demand (when it is required by the system) for predicting, detecting and advising of potential future risk situations. Therefore the interface with the processes is less tangible in this case. Mainly the communication between these two modules is through the database.

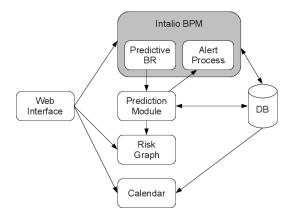


Figure 10. Predictive BR Engine Interface Scheme

14.6. Resources

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Intalio BRE (based on the Drools Open Source project), built-in on the top of Intalio Designer allows the definition of complex business rules that can be invoked by processes at any decision points, or used for the dynamic binding to services and generation of context-sensitive user interfaces. Using a rules engine in combination with a process modeling tool dramatically simplifies the design of complex business processes

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that require many variations across multiple dimensions, such changes in policies or circumstances in the pilots. In other words real time BRs are developed under Intalio|Designer and developed in the server at the same time as the process development. In this development, the business rules engine is exposed as an axis2 web service in the dedicated tomcat server to be accessed by the ReMINE processes.

The predictive BRs (Sacco scenario) are developed in Java code. The routine is running in the dedicated tomcat server and exposed as java classes.

14.7. Data/Messages

The data and messages interchange between real time BR engine service and the processes are carried out through SOAP messages, as the former one is exposed as axis2 web service to handle the communications between these two modules. The SOAP request is sent from the processes, attaching the required information, according to the BR consult. The BR engine by looking up in the BR table, sends the response to the processes with the corresponding results.

Basically the structure of the business rule system consist of two inputs (facts and rules) that are applied to the business rules engine in order to produce the results required. The rules are the policy stated in BR tables and defined by the clinical staff. The facts are sent by the processes depending on the status of the clinical procedure. The output or results are the information returned by the BR engine service. More specifically, the three parts of the BR system are:

- Facts: medical information
- Rules: guidelines based on clinical protocols, defining:
 - Clinical pathway
 - Protocol constrains
 - Time constrains
- Results:
 - Process flow, i.e. clinical pathway
 - Messages and alerts when violation of protocol occurs
 - Messages and alerts when violation of protocol have been foreseen by the system
 - Current and future patient risks and predictions

On the other hand, the predictive BR engine (developed for Sacco scenario) is exposed as java classes, thus the calls to this engine are through the developed java routine. The information of the patients and contextual information of the hospital is extracted from the internal database where the processes have stored all the required information for such module.

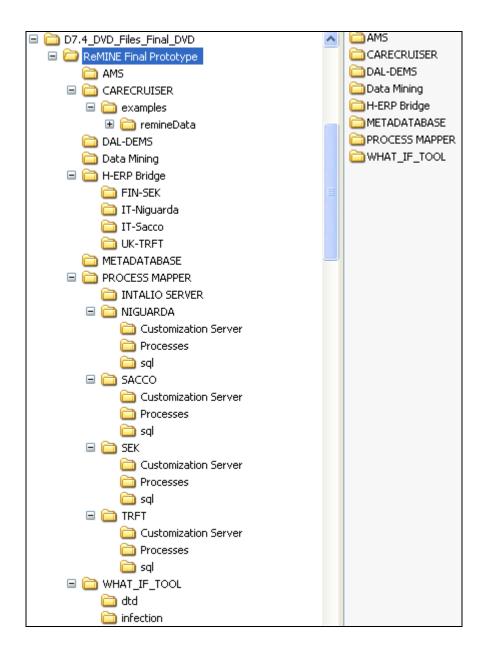
14.8. Installation instructions

This module does not need a particular procedure for its installation. By following the installation instructions explained in section 7.7 for the installation of the processes is enough. The real time BR engine is automatically deployed into the server as axis2 services just by deploying the different processes. Also the predictive BR engine has been pre-installed in the dedicated tomcat server for Sacco scenario, so it is no needed to take further actions.



15. DVD Structure

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16. Annex

16.1. SLA

No modifications in the RFP. What has been described in D7.3 is still up to date.

16.2. Pilots Remote Access (added the other 2 pilots SEK and TRFT)

16.2.1. Niguarda Hospital

Architectural description

The VPN Service available at Niguarda is based on two different technologies: VPN IPSec and VPN SSL.

- VPN IPSec is a VPN which links together two networks through a tunnel over the Internet. This kind of protocol requires that the client machine, which accesses the local network from the outside, has a VPN client installed in order to enable the use of an IP address dedicated to remote connection. In order to access a VPN IPSec network, it is mandatory to manually specify an IP address and the settings related to a digital certificate. Moreover, it may not be possible to set a VPN connection due to the features of the network where the client is placed. For these reasons, it is preferred to provide the service by using the VPN SSL technology, in order to make easier, safer and more functional the connection for external users.
- VPN SSL does not require to install applications or to set particular features on the client machine. The SSL protocol (Secure Socket Layer) is used to grant protection over communication between the Web server and the client PC at application level. Since most web browsers support SSL, this protocol turns out to be simple to be implemented even on a wide number of PCs. Network security for VPN SSL moves from network and operating system level to application level, by applying common network protocols applied over the Internet, without having to implement any relevant modification on the client system. User authentication is prevalently based on token SMS, which requires to enter domain username and password followed by the access code received with a sms sent on user's personal mobile phone. It is even possible to ask for a token hardware to be used as an alternative to the sms code.

Based on the previous descriptions, it has been chosen to prefer VPN SSL, while VPN IPSec has been left just to marginal features. By now, VPN IPSec access is available just to authorized users from a proper service page, after VPN SSL authentication.

VPN SSL of Azienda Ospedaliera Niguarda Ca' Granda is based on a private application realized by Juniper, whose use is allowed to 350 simultaneous users.

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VPN Access and authentication

The user opens one of the compatible Web browsers, Internet Explorer ver. 6 and 7 or Opera ver. 9.26, and access the home page at the following address: http://accessoweb.ospedaleniguarda.it/Example, where "Example" will be substituted by the name of the authentication profile set for the external user.

Then he fills in the first authentication field by typing Domain username and password, which are the same already present in Active Directory (Figure 11).



Figure 11 - Domain authentication

After the first authentication, a new form has to be filled in with the code received through SMS (Figure 12).



Figure 12 - SMS code authentication

If a token hardware has been required, the second form will ask to insert the PIN code shown in the Token display (Figure 13).

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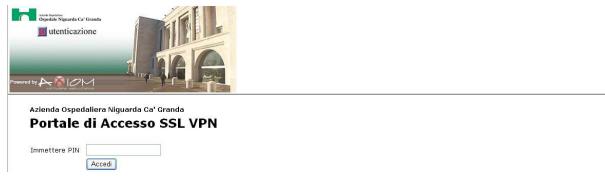


Figure 13 - Token PIN code authentication

After authentication, the following screen will be presented (Figure 14), where the client application session can be activated by clicking on the "Start" button. By selecting "Sign out" the session is terminated.

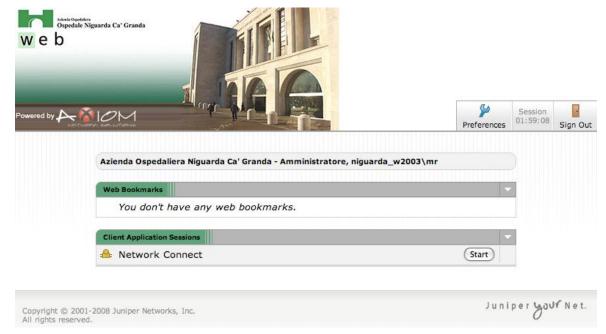


Figure 14 – Client Application Session launching form

Once the access is completed, just authorized areas are shown to the user after the service is self configured on the client PC.

Service accessibility requires a previous authorization, requested through paper modules.

The whole process of authentication and access to VPN service is shown in Figure 15.

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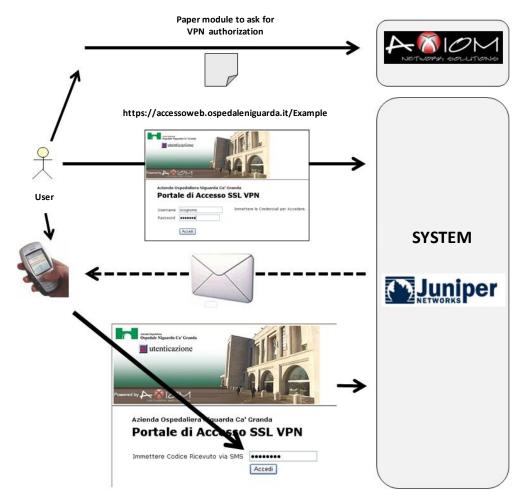


Figure 15 – Authentication and access procedure to VPN service

16.2.2. Sacco Hospital

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Remote access to Sacco Hospital VPN is based on Netasq IPSec .

Client installation and Ospedale Sacco VPN LAN access instructions:

Install the netasq IPSec client, downloadable from http://vpn.netasq.com/, using the serial number provided by Ospedale Sacco

After successful installation, open the VPN client from desktop icon. The online activation process will starts. To accomplish this step is necessary to use the s/n as mentioned before while having an active online internet connection.

After successful online activation, opening client will appear the following mask

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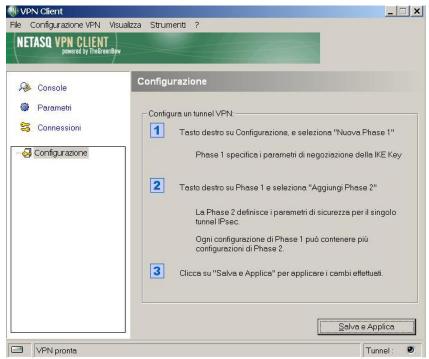


Figure 16 - Sacco - VPN service configuration - 1

Drag your client.tgb configuration file provided by Ospedale Sacco on the word "configuration" in the white section on the left side of the mask. When imported the configuration press the button "save and apply". At this point the screen will appear as follows:



Figure 17 – Sacco - VPN service configuration - 2



Close the configuration panel. You can now open the vpn tunnel towards Ospedale Sacco pressing the right mouse key on the tray bar icon and selecting "open tunnel lan_sacco"



The IPSec tunnel is open and the connection to the Ospedale Sacco LAN is now active.

The communication from IPSec VPN client to lan sacco need the following port and protocols to be opened and active both sides: **500 UDP**, **protocol ESP**, **4500 UDP**

After successfully opening tunnel it's possible to test communication pinging the address: 10.1.10.254

16.2.3. TRFT Hospital (UK)

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The user opens the Web browsers and access the home page at the following address: https://secure.therotherhamft.nhs.uk/dana-na/auth/url_0/welcome.cgi.

Then he fills in the first authentication field by typing the company username (e.g. TP-NOEMALIFE, TP-INDRA,....) and password made by the Domain password + a PIN sent by sms.

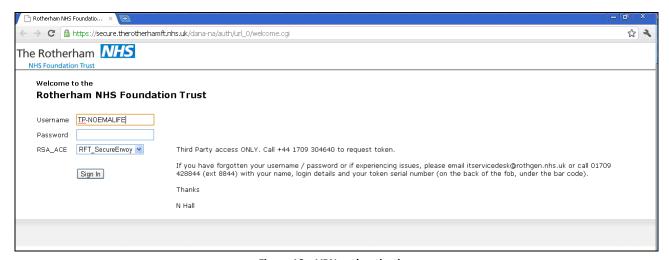


Figure 18 – VPN authentication

After the authentication, a new form pops up where the only server available for the user is the ReMINE server. The link starts a Remote desktop control session. In the same time a new password is sent via sms



for the next access.

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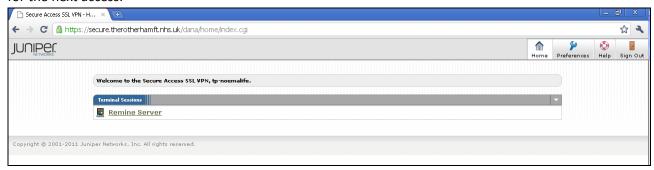


Figure 19 - Server Selection

16.2.4. Kauhajoki Hospital (FIN)

The Access to the ReMINE server hosted in Kauhajoki Hospital is based on a simple authentication via RDP (Remote Desktop Control) because the IP of the ReMINE server is public on Internet.

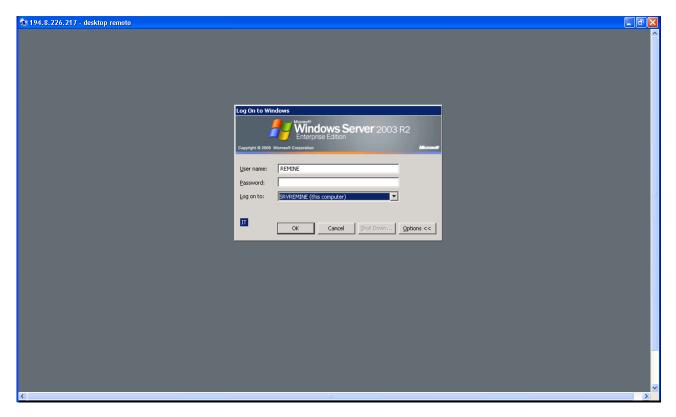


Figure 20 – Server authentication