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INTEGRATE

Driving excellence in Integrative Cancer Research through Innovative Biomedical Infrastructures

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1 Publishable summary

Public summary

The collaborative INTEGRATE project aims to support a novel research approach in oncology through the development of innovative biomedical infrastructures enabling multidisciplinary collaboration, management and large-scale sharing of multi-level data, and the development of new methodologies and of predictive multi-scale models in cancer. The INTEGRATE infrastructure will bring together heterogeneous multi-scale biomedical data generated through standard and novel technologies within post-genomic clinical trials and seamlessly link to existing research and clinical infrastructures, such as clinical trial systems, eCRFs, and hospital EHRs, in order to enable a range of innovative applications.

INTEGRATE delivers solutions that support a large and multidisciplinary biomedical community ranging from basic, translational and clinical researchers to the pharmaceutical industry to collaborate, share data and knowledge, and build and share predictive models for response to therapies. Moving away from empirical medicine, towards evidence-based personalized care has the potential to both dramatically improve patient outcome and to reduce costs.

The project also aims to make relevant steps towards semantic interoperability. To be able to reuse previous efforts in data sharing, modeling and knowledge generation, and to access relevant external sources of data and knowledge it is beneficial to adhere whenever possible to widely-accepted standards and ontologies. The use of standards will also support wide scale adoption of our solutions. A first version of our semantic interoperability layer has been implemented based on the HL7 v3 standard and on relevant medical ontologies/terminologies: SNOMED-CT, MEDDra, LOINC. The BRIDG standard has been used to represent the clinical trial information in our environment.

An important objective of this project is to build tools that facilitate efficient the execution of post-genomic multi-centric clinical trials in breast cancer. A range of such tools aim to support recruitment through the automatic evaluation of the eligibility of patients for trials based on matching the characteristics of the patient population required by the trial to the patient data available for instance in the hospital EHR. Other range of tools focus on central review of pathology images and on the INTEGRATE Analysis Platform enabling both statistical and prediction analysis. First versions of these tools have been implemented and are currently being evaluated with clinical users.

The INTEGRATE consortium focuses on sustainability beyond the scope of the research project, building a long lasting translational research infrastructure that will promote scientific collaboration among European cancer research centres, pharmaceutical companies, and biomedical research communities well beyond the FP7 funding period. While the core users of the project outcomes are members of the Breast International Group network, we will also actively promote our approach and solutions in wide user communities and in other disease domains.

INTEGRATE partners

PHILIPS

BIG
BREAST INTERNATIONAL GROUP

FORTH
Institute of Computer Science

CUSTODIX

Institut Jules Bordet Instituut

POLITÉCNICA

EU CONTRACT
FP7 ICT-2010-270253
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PROJECT WEBSITE
www.fp7-integrate.eu/

Recent advances in genomics and other "omics" technologies are revolutionizing biomedical research in general, and research in oncology in particular. Yet, despite the impact of these technologies on the understanding of cancer biology, translation into better patient outcomes has often been disappointing.

It is now largely recognized that achieving the full potential of personalized cancer treatment will require the integration of clinical, genomic and imaging data on a large scale. But many obstacles hinder this integration, such as the lack of standardization.

By tackling the technological obstacles impeding the optimal exploitation and integration of clinical trial data, INTEGRATE will allow faster and better development of predictive models of drug response, biomarkers, and targeted anticancer agents for breast cancer.

Sharing and integration of data from breast cancer clinical trials

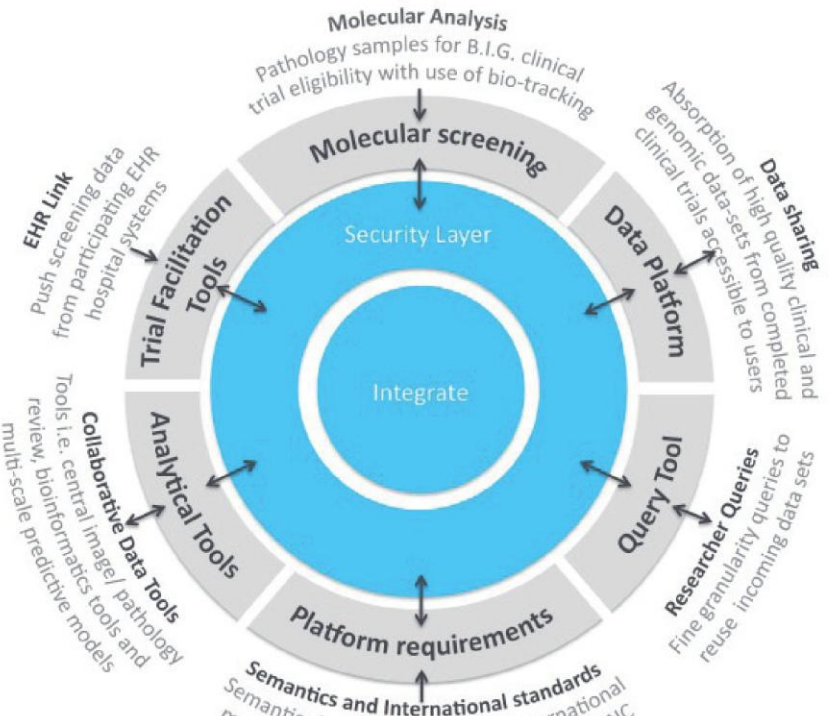
At the centre of INTEGRATE is a shared repository of clinical, genomic and imaging data, originating from multiple clinical trials in breast cancer. By accessing data from multiple trials, researchers will be able to build predictive models, identify biomarkers and answer other research questions faster and with more confidence. Additionally, fine-grained control of access to subsets of the data by different user groups will enable flexible patterns of collaboration.

The "semantic interoperability layer", consisting of the core data set and flexible data and metadata models, will allow the easy integration of data and the implementation of intelligent workflows that incorporate knowledge of breast cancer. By adopting commonly agreed standards for data sharing and medical nomenclature, INTEGRATE will also be able to "talk" to other data sharing platforms and become a data hub integrated in a wider network.

Tools for oncologists and breast cancer researchers

INTEGRATE will provide tools to streamline the screening phase of breast cancer clinical trials. Before a patient is enrolled in a clinical trial, she (or he) must meet a certain number of eligibility criteria such as age, cancer type and stage, or previous or concomitant treatments. INTEGRATE will facilitate this by managing lists of eligibility criteria for registered trials, and by automating electronic data capture and the evaluation of the criteria. It will also provide interfaces to allow linking and extracting of clinical data for eligibility from electronic health records, the acquisition of molecular testing data from central laboratories, and the tracking of biological samples.

INTEGRATE will also provide tools for central review of data across trials, allowing the definition of panels of experts and creating a framework for accessing and annotating data. In this context, it will integrate tools to visualize and annotate digital pathology images.



Finally, tools for statistical and bioinformatics analyses of data will also be incorporated in INTEGRATE, and a collaborative environment will be provided where researchers can share and annotate statistical models built from the data. The modular nature of the architecture will make it possible to easily plug in analytical components on top of the data querying component.

A modular, reusable and secure software architecture

The loose coupling between these components through a standards-based, service-oriented architecture will create a platform that can be readily adapted to changing requirements and integrate external components. This approach also ensures that parts of INTEGRATE can be reused in other contexts.

Dr. Lina Pugliano
BIG and BrEAST Research Fellow
July 2012

INTEGRATE impact & dissemination

INTEGRATE is being developed and will be used in the context of the Breast International Group (BIG) research program to support molecular screening and data sharing for its users. Parallel to this, INTEGRATE is also reaching out other ICT initiatives (EURECA, p-medicine, TRANSCEND, Sage Bionetworks, VPH NOE etc.) and end-users groups through meetings, participation in events and through the INTEGRATE Launching Event (September 2013).

INTEGRATE aims to provide

- Optimised integration of multi-level data across oncology clinical trials
- Support for molecular screening for targeted anticancer drugs
- Support for biological sample tracking
- Extraction of relevant clinical data from electronic health records
- Semantic integration with a focus on breast cancer trials
- Robust and reusable software components
- Emphasis on data security and flexible data access control
- Tools for central review of trial data with a focus on pathology data
- Analytical tools and predictive model sharing

The INTEGRATE project is partially funded by the European Commission under the 7th Framework Programme.

2 Project objectives for the reporting period

The general project objectives that were relevant for the reporting period are described below. Next, we summarize the activities that contributed to reaching these objectives.

BUILD INFRASTRUCTURE COMPONENTS AND TOOLS FOR THE STORAGE, SHARING AND MANAGEMENT OF DATA, INFORMATION, KNOWLEDGE AND MODELS

INTEGRATE will build reusable components based on which we will set up a dynamic infrastructure supporting our user community to store, manage and share biomedical data, models, tools, methodologies, and knowledge. The current heterogeneity in healthcare-related research, manifest at the level of methodologies, workflows, data processing, and ICT infrastructures, tools and services, has significant negative impact on medical knowledge discovery, on the validation of clinical research results and on the adoption of the new results in clinical care for more predictive, individualized, effective and safer healthcare. On the ICT side, a main barrier is the lack of interoperability among relevant infrastructures, services and tools, due to the low adoption of common standards and terminologies. INTEGRATE will build solutions based on established standards for storing, annotating and exchanging biomedical data, metadata, models and knowledge. The use of established standards and terminologies also supports the integration with existing infrastructures and the access to external relevant repositories adhering to those standards and terminologies.

BUILD TOOLS TO ENABLE COLLABORATION

We will support the description and execution of shared, multi-disciplinary and multi-site workflows. An important requirement for emergent collaborations is a shared workspace that is accessible to all collaborators. Ideally, this workspace should include all the important transactions that have taken place among scientific workers. In addition to a shared and open workspace, emergent collaboration requires meta-level information that highlights the significance of the transactions that are occurring or have occurred within a group of collaborators. Meta-level information that indicates the significance of transactions within a group can help a group determine which issues it should tackle first and which contributions should be given more weight than others.

ENABLE SEMANTIC INTEROPERABILITY TO EXISTING RESEARCH AND CLINICAL INFRASTRUCTURES

The ability to interface to existing medical research infrastructures is an important objective of INTEGRATE, as it is the basis for reaching a large community of users. Furthermore, to promote the fast adoption of the clinical research results into clinical care, we need to also target standards-based interoperability to existing clinical infrastructures.

From the technology viewpoint, in order to provide an efficient, robust and semantically interoperable solution, one needs to move from plain keyword matching to a combined approach where keywords are mapped to higher level concepts with clearly defined semantics. Such concepts are usually organized in concept hierarchies and include domain specific attributes and relations. Reasoning at this level, rather than at keyword level, is expected to enable us to move from error-prone lexical matching to more robust semantic-aware solutions.

PROTOTYPING AND VALIDATION OF THE INTEGRATE INFRASTRUCTURE COMPONENTS AND TOOLS

The capability of the INTEGRATE environment to achieve the above mentioned objectives will be demonstrated through prototypes implementing realistic clinical scenarios. These scenarios will also allow us to demonstrate the interoperability of our solutions with existing infrastructures.

Objectives for the reporting period

All project workpackages had key objectives for this period. The main directions of work have been:

- The refinement of the user scenarios and the definition of the corresponding use cases. This involved several meetings of clinical users and technical partners and several iterations.
- The availability of clinical data and knowledge necessary for the development of tools. Here the IT department of the IJB provided all necessary clinical data for the development of the semantic interoperability layer and of the demonstrators.
- The first version of the semantic interoperability layer has been implemented.
- New demonstrators implementing the top priority clinical scenarios have been selected and the implementation work has started.
- The demonstrators of year 1 were evaluated with clinical users and were updated based on the received feedback. The effort focused on all three demonstrators: the trial screening prototype, the analysis module, and the digital pathology review tool.
- We worked on the integration of the previous demonstrators with the semantic layer.
- The procedures and scenarios for evaluation had validation of the INTEGRATE environment and tools have been defined.
- The results have been described in several deliverables.
- We have started the planning of the INTEGRATE event which should allow us to disseminate our results in the oncology user community.

All the objectives for the reporting period have been achieved. Further, the document details the achievements per each work package of the project.

Recommendations from previous reviews (if applicable)

A closer collaboration with related projects (P-Medicine, VPH NoE) and a better description of the needs of our clinical users were recommended during the first review. These recommendations were addressed as follows:

- In the updated progress report of year 1, our clinical users extensively described their needs and the rationale behind the prioritization of the selected scenarios and demonstrators. They also focused on describing the process of gathering requirements that involved a large number of clinical users.
- For the evaluation and validation of the project outcomes we have selected several additional clinical sites and we are currently finalizing the details of the

collaboration. They will be introduced during the next project review. The selected new partners are important clinical sites in the EU and beyond.

- We have organized an alignment meeting with the closely-related P-Medicine project and agreed on future close collaboration that includes sharing of tools between the two projects and shared meetings with the user groups of the two projects.
- We have participated with presentations and demonstrators in the VPH NoE event to set up new collaborations.
- We have been accepted to hold a session in a large European cancer conference in 2013. This will enable us to have access to a wider community of clinical users.
- We have organized meetings with several Pharmaceutical companies to collect requirements and feedback on our solutions.

3 Workpackage progress of the period

3.1 WP 1 (IJB)

3.1.1 Objectives (of the reporting period)

The main objectives of WP1 for the 12-18 month period were to elaborate – from the clinical side - on user requirements defined during the first year of the project, as well as collaborating with the technical partners for the iterative implementation of the user needs.
As implementation of software components by the technical partners progressed, the clinical partners had to participate in an iterative process of revision and revalidation of user requirements, in the light of new pilot clinical studies and needs gathered from broader panels of clinical stakeholders.

3.1.2 Status/progress towards objectives WP1 (per Task)

Task 1.1 Identification of the users and their needs
In particular through dissemination activities organized by BIG and academic and commercial stakeholders feedback, a broader panel of clinical and pharmaceutical partners have been consulted in order to validate the relevance of the infrastructural choices made inside Integrate in the wider context of personalized breast cancer trials, beyond the Integrate project itself.

Task 1.2 Definition of user scenarios
User scenarios defined during the first year of the project were not altered in this period. However, clinical partners have helped technical partners interpret them in the course of their implementation. In particular, the molecular screening scenario was further defined by setting up a pilot clinical study entitled “A molecular screening service for future NeoBIG clinical trials - Through the use of INTEGRATE: a data sharing platform for future BIG trials” aiming at testing the interlaboratory reproducibility for different biomarker assays between different departments of pathology located at the Jules Bordet Institute in Brussels, Belgium, the Charite Hospital in Berlin, Germany and the Instituto Europeo di Oncologia in Milan, Italy, IJB, together with BIG, and at evaluating practically the first modules of the Integrate platform.
The protocol of this clinical trial contains several refinements of the Integrate user requirements, in particular as far as scenarios 1 (molecular testing, including biotracking and eligibility criteria matching), 4 and 5 are concerned.

Task 1.3: Legal and regulatory compliance requirements
In order to conduct the aforementioned pilot study, the clinical partners legal teams put in place (i) contractual arrangements with the above mentioned laboratories and recruiting centers, and (ii) a patient information sheet and informed consent. In addition, IJB ensured that the pilot study got approval from the competent ethics committees.

Task 1.4 Definition of the relevant use cases and requirements analysis
As initial software was being developed based on the use cases and scenarios, In particular, the expertise of the clinical partners in the application of genomic

technologies, in cancer-centered electronic Health Records and clinical trial conduct and management has been solicited to ensure the research and clinical relevance of the pilot software for analysis of clinico-genomic data.

3.1.3 Deviations from the DOW and corrective actions

There are no deviations from the DOW.

3.1.4 Planning next period

During the next period, additional refinement of the user requirements will be provided, in an iterative manner. The pilot clinical study for molecular screening will also take place, for which software will be tested and requirements will be thoroughly validated through a survey of clinical partners (inside and outside the consortium).
Results and raw data from the molecular screening pilot trial will be uploaded, stored and assessed using Integrate tools (scenarios 2, 3, 6 and 7) – helping further refine related user requirements.

3.2 WP 2 (Custodix)

3.2.1 Objectives (of the reporting period)

Implement and deploy the demonstrators in line with the specifications that were defined in the initial architecture document of year 1 (in cooperation with WP6 - Pilots, evaluation and validation). Next to this, work needs to be started for the architecture and demonstrators of year 2. Finally the specification and development of the INTEGRATE security services should be further elaborated.

3.2.2 Status/progress towards objectives WP2 (per Task)

Task 2.1 Identification and evaluation of relevant standards

- This task was finished in month 9

Task 2.2 Inventory of re-useable/available relevant solutions and components

- This task was finished in month 9

Task 2.3 Design and implementation of the INTEGRATE reference architecture

- Brainstorm technical meetings were held, defining the scope of the different demonstrators for year 1
- Two demonstrators (‘patient screening demonstrator’ and ‘analytical tools demonstrator’) were implemented and deployed mainly coordinated by WP2, which has dealt with task assignment, load distribution and resources allocation.
- Initial work has started for the next iteration of the architecture and demonstrators for year 2

Task 2.4 Security for dynamic collaborative environments

- Implementation was started of the initial INTEGRATE security services, in the first iteration the STS and identity management framework was developed.
- Integration of the authentication infrastructure in the patient screening demonstrator has been initiated.

- We have started to prepare a scientific paper about the concept of contextual attributes. It will be submitted to HEALTHINF 2013.

Task 2.5: Component integration and interfacing with external systems

- Within this task effort has dedicated during component implementation that component interactions was loosely coupled and interfaces were implemented as agreed (conformance to the architecture). Several telco's have been held for coordination.
- Interfaces have been validated during component integration on the demonstration platform.

3.2.3 Deviations from the DOW and corrective actions

Deliverable D2.5 integration guidelines was merged with D4.3 initial specification of privacy enhancing services and the deadline has been moved to October 2012.

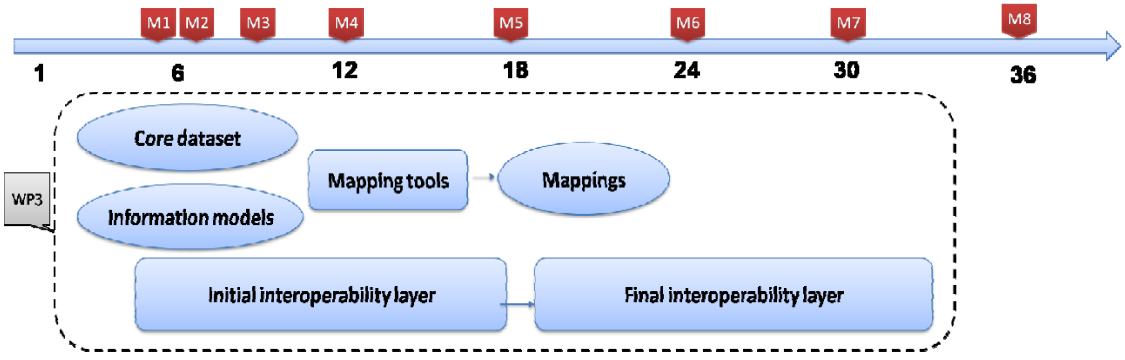
3.2.4 Planning next period

- Continue the next iteration of the architecture, including detailing of the high-level view of the current specified architecture as requested in the first annual review.
- Contribution to the integration guidelines and Initial specification of privacy enhancing services.
- Further specification, integration and deployment of the first iteration of the security services.
- Further integration of the security environment in the demonstrators of year 1 and the upcoming pilot.
- Start of specification and implementation of the cohort selection demonstrator for year 2.

3.3 WP 3 (UPM)

3.3.1 Objectives (of the reporting period)

The main objective in WP 3 is to facilitate communication among the INTEGRATE platform tools through mechanism to homogenize data repositories. From month 12 to month 18, tasks have been mainly focused on the mapping formalism (Task 3.3) and the semantic interoperability layer (Task 3.4), while the core dataset (Task 3.1) and common information models (Task 3.2) have been iteratively refined.



Work Package 3 components and planning

The main mapping formalisms have been identified, that is, links from core dataset concepts to data stored at the common data model. External sources have been also analyzed to be included within the main repository.

3.3.2 Status/progress towards objectives WP 3 (per Task)

Task 3.1 Definition of the semantic core dataset
The core dataset have been refined by identifying a subset of SNOMED and LOINC terms. Concepts that would be included within the INTEGRATE "lingua franca" have been extracted by:

- Automatic analysis of public clinical trials
- Automatic identification within EHRs from data sources
- Manually identified by domain experts

We have included new terms as SNOMED CT extensions for clinical trial eligibility criteria classification, since there is a lack of standardized taxonomy in this field. Deliverable 3.2 (planned to be submitted on month 19) will provide a detailed description of such process. Finally, core dataset vocabularies have been stored using OWL ontology representation language and loaded into a SESAME server to provide semantic reasoning.

Task 3.2 Definition of the information models of the clinical and research infrastructures
After analyzing a set of common data models candidates from previous projects, a first version of the common data model for the INTEGRATE platform was developed during the past period based on HL7 RIM. As described in D3.1, HL7 RIM provided powerful capabilities of representation for any kind of clinical data and it is widely used to be used together with SNOMED (which INTEGRATE core dataset is mainly based). During the current reporting period, further refinement has been carried out to homogenize data types, one of the main challenges of HL7 RIM models.

Task 3.3 Semantic formalism, mapping tools and mapping implementations
Three different mappings have been identified within the INTEGRATE platform (a detailed description will be available at deliverable 3.4 planned to month 20):

- Links between core dataset concepts and the common data model (also called terminology binding)
- Links among vocabularies composing the core dataset, identifying overlapping among them concepts
- Links between data sources and the INTEGRATE common data model (ETL tools)

The terminology binding will be used mainly to automatically build queries to extract data from the core dataset. Links among ontologies have been analyzed from previous works to identify links among SNOMED, LOINC and MedDra. While Pentaho Kettle open source ETL suite have been used to store information from data sources within the INTEGRATE common data model.

Task 3.4 Design and implementation of the semantic interoperability layer

A first version of the query mechanism has been implemented to retrieve data integrated through the platform. Core dataset concepts are used within SPARQL queries to retrieve through the mapping to the common data model, the required information homogeneously integrated. Reasoning capabilities have been included to improve query building, increase the semantic power of the INTEGRATE platform and improve sustainability when new sources are included.

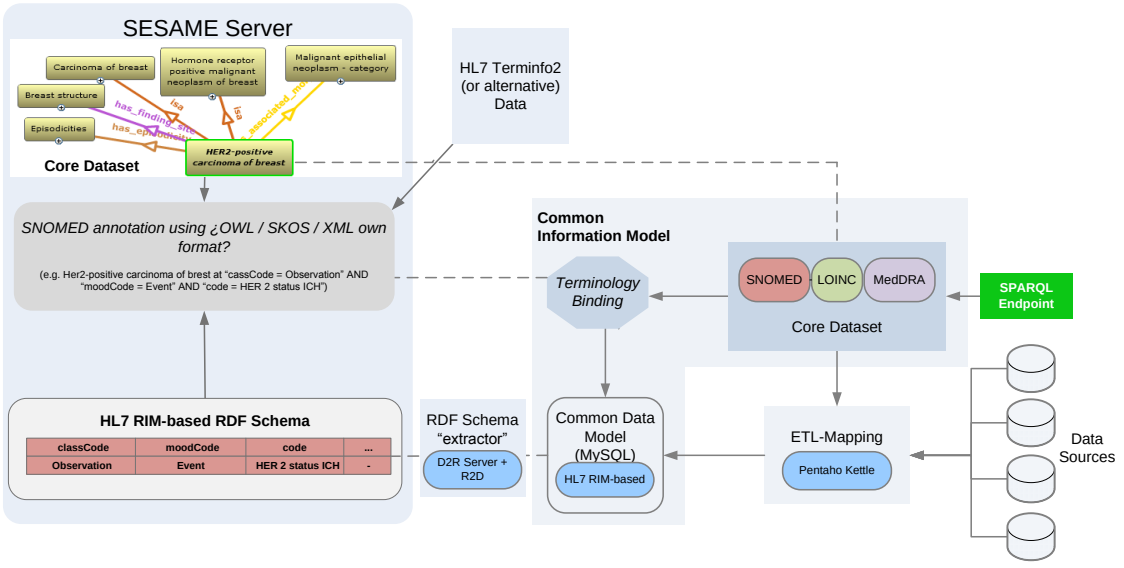
Task 3.5 Standards-based uniform access to external sources
External repositories have been analyzed to enable access, through the same homogeneous mechanism, to complementary data within the INTEGRATE platform. A solution based on uniform interfaces and existing standards is being developed, to enable that INTEGRATE tools and services can access information from external repositories. EHR data sources have been the main external source identified at the moment, exporting data through standard built-in HL7 interfaces. Information encoded using HL7 version 2 and version 3 (XML-based) is then loaded into the common data model using ETL tools and the mapping formalisms. Simple information extraction has been carried out within free text field of data to provide a homogeneous structure. Molecular information from samples has being analyzed to be linked to the common data model.

3.3.3 Deviations from the DOW and corrective actions

There are not significant deviations from the DoW. WP3 have been mainly focused on Task 3.3 and 3.4 during months 12 to 18. Some of the WP4 work load has been moved to the WP3, since previous work on mappings and the semantic interoperability layer is required to provide tools enabling data and knowledge sharing (Task 4.2).

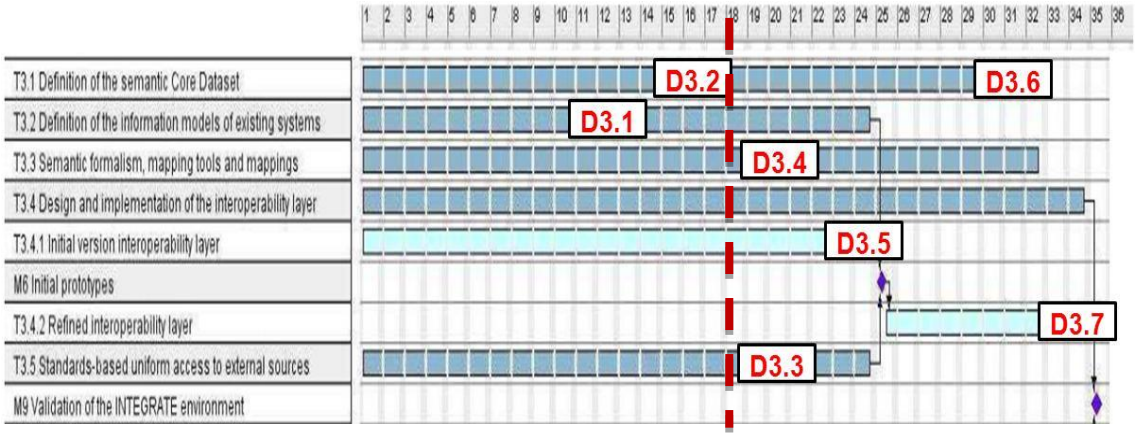
3.3.4 Planning next period

A second version of the semantic interoperability layer has been designed to provide a method to retrieve a set of patients within a cohort selection tool. Although previous developments from the first version will be reused, new components will be required to generate queries based on core dataset concepts (figure below).



Second version of the semantic solution within the INTEGRATE project

Within the next period, the main focus will be centered on implementing a semantic solution covering the cohort selection scenario, in addition to the criteria matcher. Additional reasoning scenarios, including pre and post-coordination concepts, will be implemented to facilitate semantic information retrieval. The common data model and ETL mappings will be adapted to SNOMED CT Normal Forms, and a query builder will be developed to provide the corresponding SPARQL queries to retrieve data related to core dataset concepts.



WP3 task planning according to the DoW

D3.2 about the initial proposal for the core dataset will be submitted on month 19, D3.4 about mappings and D3.3 about access to external sources will be submitted during the next period (month 20).

3.4 WP 4 (FORTH)

After the first review the main action plan set in this reporting period is to implement a first running version of the pathology collaboration environment and do the first testing before the second periodic review.

3.4.1 Objectives (of the reporting period)

For this reporting period of the project, the main effort was to lock the user requirements and their needs regarding the collaboration tools and to tighten the communication with the stakeholders. The result of that effort is a suggested report-form for the central review of pathology images, which is currently being verified by the clinical partners (i.e. pathologists). FORTH has initiated the development of the central review platform for pathology images. The objective for this period has been to set a clear plan for the collaborative environment. Implementation has started according to plan and a rough prototype of a viewer for pathology images have been created.

3.4.2 Achievement/progress made in the past period (per Task)

Task 4.1 Model, data and annotation repositories

Currently WP4 uses local repositories for images and annotations. The bond between the repositories of INTEGRATE will be defined in the coming meeting in Madrid, which is scheduled for October 2012.

Task 4.2 Tools enabling data and knowledge sharing
A first prototype of a viewer for pathology images has been created and it is tested internally, while we add more functionalities and support for image formats.

Task 4.3 Tools enabling collaboration
A pathology report has been compiled by FORTH, and upon its verification, it will be added to the system together with the necessary sharing functionalities.

Task 4.4 Privacy Enhancing Processes and Services
We are investigating the Single Sign On mechanism in order to provide seamless connectivity for the user between the different tools of the project.

3.4.3 Deviations from the DOW and corrective actions
Currently there is no major deviation from the DoW. To esure however that there will be no delays, FORTH needs quick clinical feedback on the requests for well-defined specifications, guides and data for testing.

3.4.4 Planning next period
In the next three to four months we will have ready a first version of the central review platform, with the core functionalities fully implemented in order to be tested by the users, and gather all the necessary feedback for improving and completing the platform. We expect and hope that the sooner the release of the draft platform is, the faster we might get feedback (and thus solve potential issues and discover potentially missing functionality).

3.5 WP 5 (FORTH)

WP5 has largely focused on developing a front end application that will allow the users of the Integrate environment to analyse quickly their data within their secure platform. The prediction tools are being built in the same application.

3.5.1 Objectives (of the reporting period)
Our effort for this reporting period has been mainly focused on the optimization of the existed software that addresses the statistical analysis scenarios, as defined at the Periodic Progress report outcome, for the needs of the INTEGRATE Analysis Platform. Moreover, new functionalities are being added to the platform, for prediction analysis. Finally, a thorough work has been started for extending the connectivity capabilities of the INTEGRATE Analysis Platform and make the interaction between the platform and the INTEGRATE data-warehouse for direct retrieval of the data.

3.5.2 Achievement/progress made in the past period (per Task)

Task 5.1 Definition of clinical scenario (questions) for the INTEGRATE VPH use case

The scenarios as defined and reported in D.5.1 address the research questions that described in D.1.2. These include statistical analysis in clinical, genomic and imaging data, and sophisticated pattern recognition techniques for integrating and selecting the most relevant heterogeneous data that contribute to the prediction of the tumor response to a specific regimen. Therefore, no further work was required during the reporting period except for a refinement in these user needs that took place in the last project plenary meeting in Brussels.

Task 5.2 Definition of genetic and imaging biomarkers and of a modeling methodology

Public available data for breast cancer prognosis and treatment comprising of survival, gene expression, SNP data, and clinical covariates are available through the Synapse Commons Repository and the Sage / DREAM breast cancer prognosis challenge (https://synapse.sagebase.org/Portal.html#BCCOverview:0).

This multi-modal dataset, along with the BIG data from the TOP trial can be used for implementing and assessing the accuracy of our computational models for predictive analysis. This dataset has been already downloaded and is ready to be used to our work.

Task 5.3 Development of predictive models of response to therapy and of the modelling framework

The objectives of task 5.3 are mainly divided into the following actions:

- Optimization of the existed software, addressing the statistical analysis scenarios implemented to the INTEGRATE Analysis Platform, and the platform's infrastructure in general.
    - A multi-user web based environment has been established and now being tested in which several users can login to the platform and run simultaneously various statistical analysis scenarios.
    - Software issues when retrieving the examined variables from the local data-base of the platform are now fixed (i.e. failed in recognizing nominal variables, interactive issues between R and Latex, etc.).
    - On the fly automatically generated HTML report for each scenario is now available, providing a flexible way of assessing and comparing different analysis.
    - A refinement to the overall structure of the generated *.pdf reports has been deployed.
- Development of the predictive analysis tools as defined in D5.1, using the public available dataset from sage base.
    - Start implementing the core software for the predictive analysis tools as reported in D.5.1.
    - A first evaluation of the sage public available dataset using statistical approaches has implemented, assessing the statistical significance of the multi-modal data before entering the predictive analysis framework.
- Technical aspects in providing an integrated framework in which the INTEGRATE Analysis Platform retrieves the examined data directly from the INTEGRATE central data-warehouse.

3.5.3 Deviations from the DOW and corrective actions

No deviations for this reporting period.

3.5.4 Planning next period

The planning of activities for the upcoming period is:

- Finalize the statistical analysis scenarios (software optimization, reporting forms, etc.)
- Proceed with the work for the implementation of the predictive analysis tools.
- Achieve the interaction between the INTEGRATE Analysis Platform and the central data warehouse.

3.6 WP 6 (Philips)

3.6.1 Objectives (of the reporting period)

Considering the user needs as described in WP2 and the corresponding intended pilots, this work package identified specific application objectives to be tested and defined the evaluation criteria. A special focus was to involve the clinical end-user community in the evaluation and validation effort and to choose evaluation and validation sites.

In this period we have formulated evaluation criteria, validation procedures, and feedback report guidelines and the specifications of test (validation) cases and demonstrators.

A crucial objective of WP6 is to coordinate the efforts with the technical staff and the IT departments of the pilot sites, so that the Consortium receives all information required for developing the information models of the existing infrastructures, and all the data necessary for the testing and validation of the INTEGRATE infrastructure components and tools.

Another objective of the WP is to prepare the technical and procedural infrastructure – in compliance with the defined security framework of the project – for the installation of the INTEGRATE software solutions for their extensive evaluation and validation.

3.6.2 Achievement/progress made in the past period (per Task)

Task 6.1 Building the INTEGRATE development and testing environment

For this task, all partners in the project cooperated so that sufficient and suitable clinical data was available for the development of the INTEGRATE tools and semantic interoperability environment. This required close collaboration between the clinical and technical partners to define the needs of the scenarios and the requirements with respect to data and information. The clinical partners provided a wealth of data and information that enabled the development of the functionality. Public data (such as the clinical trial criteria available on the clinicaltrials.gov site and the Sage Bionetworks dataset available at sage.org) were also used in the development of our solutions.

Task 6.2 Formulate evaluation criteria, validation procedures and feedback report guidelines

In this task the procedures for the evaluation and validation activities were established (topic of D6.2). In general evaluation criteria will be continuously adapted to the current state of development of the environment, considering the end-user scenarios and clinical pilots as general guideline. Usability, user-friendliness, speed and robustness will be key criteria in the evaluation process. Quantitative measures of the benefits of the project as a whole were also defined. The validation of the platform will essentially be conducted by the design of and execution of test cases with known results, those will adapted to the specificities of the software issued in each work package.

Task 6.3 Coordinate specifications of test scenarios and of demonstrators
The test scenarios and the demonstrators to be implemented until de end of the project were elaborated together with the clinical users to reflect priorities and relevance. This is also the topic of deliverable 6.3. Demonstrators for the second review of the project were selected.

3.6.3 Deviations from the DOW and corrective actions
No deviations from DoW during reporting period. D6.3 has been delayed but has been finalized in October 2012. The procedures and scenarios for validation were available in time, in July 2012.

3.6.4 Planning next period

In the next period the WP will support the implementation of the evaluation and validation procedures in the selected scenarios together with the clinical sites. New clinical sites from the network of the Breast International Group are being selected and they will join the INTEGRATE team in the last year of the project. The WP will support the project team in the development of the second year's demonstrators that will be shown during the second review and further validated with the clinical sites.

3.7 WP7 knowledge management (BIG)

3.7.1 Objectives (of the reporting period)
One of the main objectives of this reporting period was to add a project newsletter to the set of dissemination tools made available to the INTEGRATE partners. The second objective was to reach out prospective user groups and to other similar data-sharing/molecular screening initiatives. Finally, ongoing attention should be given to the perspective of long term sustainability of the project.

3.7.2 Status/progress towards objectives WP7 (per Task)

Task 7.1: Dissemination
Dissemination of information happened through the following activities:

Project Newsletters
Building on the dissemination tools which have been put it place in the first year of the project, the first INTEGRATE newsletter was issued in early April 2012, circulated within the partner institutions and posted on the project website (Month 14). At the time

of writing this report, the second issue of the newsletter was being finalized with the aim of publishing it by the end of August (Month 20).

The INTEGRATE newsletters describe aspects of the research performed in INTEGRATE, inform readers about challenges encountered and progress made towards overcoming them, and refer to relevant project deliverables. Each newsletter is edited by two of the six different INTEGRATE partners. This gives readers the opportunity to get to know them and their activities within INTEGRATE better. The table of content is similar from one issue to another.

The first INTEGRATE newsletter included contributions from Philips and BIG. The "Focus Article" gave an overview of the project, its goals and approach. The "Feature Article" described molecular screening in the context of clinical research. The "Viewpoint" section featured an interview with Prof. David Cameron, UK, who has been involved in several data sharing initiatives. In this article he shared his views on the benefits of data sharing for breast cancer, and also some of the accompanying barriers and fears.

The content of the soon-to-be-published second issue of the INTEGRATE newsletter, was mainly generated by FORTH and Custodix, highlighting their contributions to the project i.e. the first two INTEGRATE prototypes which constitute the subject of the "Focus Article" of this issue. This issue also includes an article on p-medicine, another EU funded FP7 project in the eHealth area, with which INTEGRATE consortium partners have set up a close collaboration. The "Viewpoint" section features an interview with Nikolaus Forgó, Professor of Legal Informatics and IT-Law and Co-director of the Institute for Legal Informatics at the University of Hannover, Germany. He answers questions about important data protection issues in the context of INTEGRATE and shares his views on the best approaches to data sharing in cancer research in general. Finally, the "Life in INTEGRATE" and "Events" sections inform the reader on the latest developments and upcoming activities of the INTEGRATE Consortium.

These newsletters have been / will be posted on the INTEGRATE website (www.fp7-integrate.eu) and on BIG website (http://www.breastinternationalgroup.org/). INTEGRATE partners have been invited to circulate them within their own networks.

Project Meetings
During this period, the following meeting contributed to the internal sharing of knowledge and project management:

- Consortium meetings: Ghent, February 7th and 8th, 2012, and Brussels, June 26th and 27th, 2012.
- Telephone conferences are organized, on a regular basis to deal with the day-to-day coordination of the project

Project public website
The INTEGRATE public website (D7.2) is updated on a regular basis by BIG, as partner responsible for the website content.

Publications and abstracts

During this reporting period, a paper was published by UPM in the BMC Medical Informatics and Decision Making[1]

International Meetings

BIG, as clinical partner of INTEGRATE, contributes to dissemination by sharing information on the project within its collaborative network[2]. This occurs throughout the year through the bi-annual BIG scientific meetings or through BIG's own channels of communication such as the BIG newsletter or the BIG website. In this context, BIG was invited as representative of the INTEGRATE Consortium to make a presentation at meeting organized by the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG)[3]. This experience was very fruitful as the meeting was attended by surgical, medical and radiation oncologists as well as supportive care specialists, oncology nurses, patient advocates and data specialists from Australia. Several International keynote speakers with expertise in molecular screening and biomarker development presented scientific research data and strategies for future research advancement. The INTEGRATE project objectives, design and timelines were presented at the end of a scientific session on biomarker development and molecular screening. The presentation was well received by delegates and raised international awareness and interest for the INTEGRATE project which could potentially lead to scientific collaborations for data sharing and molecular screening with researchers of the ANZBCTG.

The INTEGRATE Consortium also actively participated in the 3rd VPH NoE (Virtual Physiological Human Network of Excellence) study group that took place in Barcelona, Spain, from 7 to 11 May 2012. INTEGRATE participated in the session on cancer, co-organized by Professor Norbert Graf (University Hospital of Saarland), and Professor Georgios Stamatakos (National Technical University of Athens). The session brought together top clinical, knowledge management and technology experts who discussed key issues in oncology research and care, addressed the potentially significant role of VPH modelling, shared tools and agreed on future collaborations. It was a great opportunity for the INTEGRATE Consortium to present the INTEGRATE project and make contact with other European researchers active in the VPH area in oncology. This event also gave the opportunity to demonstrate the first INTEGRATE prototype and to gather feedback from clinical users and from other tool developers.

Task 7.2: Exploitation

Task 7.2.1 Adoption of the INTEGRATE solutions

The current thinking of the INTEGRATE partners is developed in the INTEGRATE Initial Exploitation Plan. One of the objectives of this plan is to build on the existing BIG experience and network to enable the implementation of the INTEGRATE solutions beyond the consortium borders. The meeting with ANZBCTG collaborators demonstrates the efforts invested in the promotion of the INTEGRATE solutions within BIG.

[1] Perez-Rey D, Jimenez-Castellanos A, Garcia-Remesal M, Crespo J, Maojo V. CDAPubMed: A browser extension to retrieve EHR-based biomedical literature. BMC Medical Informatics and Decision Making 2012, 12:29. 5 April 2012 http://www.biomedcentral.com/1472-6947/12/29/abstract

[2] The BIG Headquarters is responsible for the coordination of a network of 50 groups based in Europe, Canada, Latin America, Asia and Australasia. These research entities are tied to several thousand specialised hospitals and research centres worldwide.

[3] http://www.anzbctg.org

The INTEGRATE molecular screening scenario which is anchored in the workflow of BIG clinical trials, is also very likely to find applications in the BIG clinical trials setting. It is a solution that could be adopted for other types of cancer as well.

Other markets will also be explored by the INTEGRATE partners such as the bio-pharmaceutical industry companies or other cancer networks.

Task 7.2.2 Ensuring project sustainability
In the previously period, consultations with representatives of similar initiatives, representatives of the Pharmaceutical Industry and other stakeholders were organised. These consultations and subsequent analysis have led to the production of an initial exploitation plan. There were no additional activities related to this task during the past 6 months but effort will be invested on this subject the coming months

Task 7.2.3 Educational activities
There are no educational activities to report for this reporting period.

Task 7.3 Standardisation
As reported in the previous section 1.7.2, INTEGRATE has participated in the VPH NoE (Virtual Physiological Human Network of Excellence) study group meeting which contributes to the definition of standards in the VPH area.

Task 7.4 Intellectual Property
There are no Intellectual Property related activities to report for this reporting period.

3.7.3 Deviations from the DOW and corrective actions

Task 7.1: Dissemination
There was a shift in the production timeline of the newsletter as first issue of the first newsletter (D7.4) - initially due in Month 12 - was delivered in Month 14 and the second issue (D7.6) will be issued in Month 20 instead of Month 18.

Task 7.2: Exploitation
BIG and Custodix (i.e. the main partners involved in the writing of the initial exploitation plan) delivered the Initial Exploitation Plan (D7.4) as planned in Month 14 (cf. Request for extension sent in December 2011). BIG has not carried any exploitation orientated activity from Month 14 till Month 18 as its efforts were focused on the initiation of the molecular screening prototype. As already reported the molecular screening scenario is being developed within BIG and INTEGRATE, which will offer sustainability opportunities. Refinements to the Initial Exploitation Plan will therefore be necessary to reflect this new reality.

3.7.4 Planning next period

As mentioned above, efforts will be made to adapt the current INTEGRATE Initial Exploitation Plan to the evolution of the project. INTEGRATE will also strive to meet the end-users communities. With this view, BIG will spend the next months getting ready to organize the INTEGRATE Launching Event to be held at the 17th ECCO - 38th ESMO - 32nd ESTRO European Cancer Congress in September 2013 in Amsterdam. Parallel to this, BIG will continue its dissemination activities (e.g. website,

INTEGRATE newsletter, publication in journals, scientific meetings etc.) aimed toward all stakeholders.

4 Achievements per individual partner

Beside of the general WP information, given by the WP leader, we need some additional information per individual partner. Just a short summary (bullet points)

Partner 1 Philips

In this reporting period Philips contributed to a range of activities in the project

- Attended technical, review and consortium meetings
- Contribution to the elaboration of the solution for the semantic interoperability layer of the project.
- Contributed to the demonstrators for the first review meeting
- Build the interactive UI of the patient screening demonstrator, the trial metadata repository and contributed to the development of the matching scripts.
- Lead the elaboration of deliverables D3.2 and 2.5 and contributed to several other deliverables.
- Contributed to the content of the newsletter.
- Discussed an provided input for the scope of the INTEGRATE demonstrators in year 2
- Contributed to and reviewed D7.3 initial dissemination plan and D7.4 Initial exploitation plan
- Lead the writing of a scientific paper about the selection of the core dataset based on widely-used medical ontologies (accepted in BIBE 2012)

Partner 2 BIG

With respect to the definition of user requirements, BIG made the following contributions:

- support the technical partners in the interpretation of the user requirements as initial software components are implemented.
- refine the user requirements, the contractual, legal and regulatory requirements in the context of clinical studies that it develops.
- engage a broader panel of stakeholders (academic groups and pharmaceutical companies) to define, refine, and adapt the INTEGRATE user scenarios with their needs.

In this context, BIG has setup, in collaboration with IJB, a pilot clinical study that will be used to thoroughly validate user requirements, initial software implementations, and the logistical, legal, and regulatory components of the INTEGRATE solution.

With respect to data models and interoperability, BIG re-defined the histopathological classification of breast cancer to be used as part of the semantic core dataset, on the basis of World Health Organization classification.

For predictive modeling and simulation, VPH scenarios were further elaborated, in collaboration with FORTH. In particular, BIG validated the clinical relevance of these scenarios and helped identify software components (e.g. Bioconductor packages) to implement the predictive modeling scenarios.

For WP7, knowledge management, the following things were achieved:

- publication of the first issue of the project newsletter.

- redaction of the second issue of the project newsletter.
- updating, on a regular basis, of the project website.
- presentation of the project at international meetings.
- redaction of an initial exploitation plan.

Partner 3 FORTH

After the first review the main action plan set in this reporting period is to implement a first running version of the pathology collaboration environment and do the first testing before the second periodic review. WP5 has largely focused on developing a front end application that will allow the users of the Integrate environment to analyse quickly their data within their secure platform. The prediction tools are being built in the same application.

In summary the main achievements are:

- FORTH has interacted with all the stakeholders and implementation of the collaborator environment has started with the goal to be completed by the second review. Security components have been discussed with CUSTODIX.

- FORTH has successfully demonstrated the first version of the analytical tools and models in the first year review.

- The analytical tools platform has been refined and a new version has been released for evaluation from the clinicians/bioinformaticians. The analytical tools platform will be linked to the integrate environment in collaboration with UPM allowing the user to perform queries from the central database.

Partner 4 Custodix

- Attended technical, review and consortium meetings
- Contribution in discussions about semantic approaches, data sources and common and local information models
- Discussed the scope of the demonstrators for the first review meeting
- Worked out the technical specification of the patient screening application
- Collaborated to the implementation and deployment of the screening application
- Wrote sections in the INTEGRATE newsletter
- Discussed an provided input for the scope of the INTEGRATE demonstrators in year 2
- Contributed and reviewed D7.3 initial dissemination plan and D7.4 Initial exploitation plan
- Lead the writing of a scientificpaper about contextual attributes (to be submitted to HEALTHINF 2013)
- Started with implementation of the INTEGRATE security services (authentication)
- Organised several meetings with representatives of pharmaceutical companies to gather feedback on the patient screening

Partner 5 IJB

- In order to provide data ontologically aligned to the choices of the Integrate platform (i.e. snomed terminology), Multidisciplinary Oncology Consults (MOC) semantics have been adapted, extending the Core Data Set to adjuvant and metastatic settings, as well as other topologies that Breast Cancer. This aims at providing usable data for the next stages of the pilot projects, including eligibility criteria checking in the Molecular Screening Use Case.
- The semantics of the internal IJB database of clinical trials has been redesigned for reuse in interoperable settings, both for the standardized storage of protocol (and eligibility criteria) and for clinical trial metadata (target organ, trial phase, clinical setting, treatment types including but not limited to chemotherapy, formalized representation of the study theoretical calendar …)
- The proposed definition of the Integrate Core Data Set has been revised and broadened in light of this work on MOC semantics and clinical trial metadata. Moreover, in collaboration with the Eureca project team, the IJB Integrate team started a prospective methodological assessment on clinical data to be extracted using Natural Language Processing, which will further enrich the Integrate Core Dataset as the Eureca Core Data Set definition progresses
- Tools and methodologies have been refined for Data Extraction from the IJB eHR, e.g. the LOINC to SNOMED conversion for laboratory data.
- IJB's Breast Cancer Translational Research Unit, together with BIG, helped set up a real-life pilot clinical trial "*A molecular screening service for future NeoBIG clinical trials - Through the use of INTEGRATE: a data sharing platform for future BIG trials"* aiming at testing the first modules of the Integrate platform and interlaboratory reproducibility for biomarkers in four European cancer centers – for which a full protocol has been written.

Partner 6 UPM

- Collaboration on user requirements extension
- Collaboration to provide architectural principles and design
- Analysis of core dataset concepts from EHR data
- Implementation of a HL7-based Common Data Model for INTEGRATE
- Implementation of ETL tools to load data sources into the Common Data Model
- Implementation of the reasoning mechanism of the semantic interoperability layer

5 Project management

5.1 Consortium management tasks and achievements

The project has proceeded according to plan. The focus of the WP in the reporting period was to support the activities of the WPs so that the necessary work is carried out efficiently and the project objectives are reached. The project website was regularly updated with the new results. The work in the project was coordinated using the project wiki.

5.2 Changes in the consortium

There were no changes in the consortium in this reporting period

5.3 Cooperation

- The cooperation within the project was excellent, with the partners in the consortium contributing to the work according to the plan and acting as being part of a single coherent team.
- We have reached out to other projects in the area, participating in the event of the VPH NoE with presentations and demonstrations. Additionally, as recommended during the review meeting we have organized an alignment meeting with the P_Medicine project. Together we have agreed on close collaboration and sharing of results. A common event will be planned.
- The project and the first demonstrators were also presented in the consortium meeting of the FP7 EURECA project and further close collaboration was agreed. Clinical partners in EURECA expressed interest to participate in the validation of the tools developed in INTEGRATE.
- We have discussed with several partners of the Breast International Group their participation to the validation of our results in year 3. Several partners will be selected and the amendment for budget allocation will be completed before the second INTEGRATE review.
- We have started the planning of the INTEGRATE event part of a large European oncology event in 2013,

5.4 Meetings

Date	Event	Venue/host	Country
01/02/2012	Technical telco	Sint-Martens Latem/Custodix	Belgium
03/02/2012	Monthly telco	Sint-Martens Latem /Custodix	Belgium
06/02/2012	Technical meeting	Sint-Martens Latem/Custodix	Belgium
07-08/02/2012	Consortium meeting	Ghent/Custodix	Belgium
16/02/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium

01/03/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium
02/03/2012	Monthly telco	Sint-Martens Latem/Custodix	Belgium
06/03/2012	Teleconference BIG-IJB-Philips	BIG	Belgium
08/03/2012	BIG-IJB INTEGRATE Meeting	IJB	Belgium
21/03/2012	BIG Scientific Meeting	EBCC8	Austria
10/04/2012	WP6 meeting	Eindhoven/Philips	Netherlands
19/04/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium
26/04/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium
02-03/05/2012	Pre-review meeting	Brussels/UPM	Belgium
04/05/2012	Review meeting	Brussels/EC	Belgium
10/05/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium
24/05/2012	BIG Meeting with Dr. M. Piccart	BIG	Belgium
24/05/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium
07/06/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium
07/06/2012	Teleconference BIG-FORTH Custodix- Philips	BIG	Belgium
14/06/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium
07-09/05/2012	WoHIT 2012	Copenhagen/Wo HIT	Denmark
24/05/2012	Technical meeting	Sint-Martens Latem/Custodix	Belgium
29/05/2012	Meeting Jansens	Sint-Martens Latem/Custodix	Belgium
31/05/2012	Meeting Merck	Sint-Martens Latem/Custodix	Belgium
01/06/2012	Monthly telco	Sint-Martens Latem/Custodix	Belgium
26-27/06/2012	INTEGRATE Consortium Meeting	IJB	Belgium
05/07/2012	BIG Meeting with Dr. M. Piccart	BIG	Belgium
06/07/2012	Technical meeting	Eindhoven/Philips	Netherlands
19/07/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium
09/08/2012	BIG-IJB INTEGRATE Meeting	BIG	Belgium

6 Deliverables

Deliverable no.	Deliverable name	Lead Partner Acronym	Work Package	Due Date (DoW) Project Month	Delivery Actual Date	Due date Month
2012						
7.4	Initial exploitation plan	BIG	7	12	14	January
7.5	Project newsletter	BIG	7	14	14	March
6.2	Evaluation and validation procedures for the INTEGRATE environment	UPM	6	15	16	April
3.2	Initial proposal for the Core Dataset	Philips	3	16	19	May
2.5	Integration guidelines	Philips	2	18	21	July
4.3	Initial specification of Privacy Enhancing Services	Custodix	4	18	21	July
6.3	Specifications of the evaluation and validation scenarios for the different components	Forth	6	18	21	July
7.6	Project newsletter	BIG	7	18	19	July
8.5	Interim Project Report	Philips	8	19	21	August

6.1 List of milestones

Milestone no.	Milestone name	WP no.	Due date (DoW)	Actual date	Lead partner
MS5	Availabilty of the evaluation and validation procedures and scenarios	7	M 18	M20	Philips

7 Use and dissemination

7.1 Dissemination activities

Planned/actual Dates	Type	Type of audience	Countries addressed	Size of audience	Partner responsible /involved
May 2012	VPH NoE event	Scientific	EU	200-300	Philips, FORTH
June 2012	EURECA consortium meeting	Scientific	EU	60	All partners
June 2012	INTEGRATE – P-Medicine joint meeting	Scientific	EU	30	All partners

8 Manpower overview

Actually Spent 6-Monthly Human Resource Allocation

Partner	WP1		WP2		WP3		WP4		WP5		WP6		WP7		WP8		*Total*	
	planned	spent	Planned	spent	Planned	spent	Planned	spent	planned	spent	planned	spent	Planned	spent	Planned	spent	planned	spent
Philips	0.6	1.6	1.6	2.6	1.7	2.7	1.9	1.9	0.6	1.5	0.9	1.9	0.3	2.3	1.0	1.5	8.6	*16.0*
BIG	1.5	0.91	1.1	0	0.1	0.72	0.9	0.85	1.0	1.0	0.8	0.55	0.9	4.37	0.12	0.48	6.42	*8.88*
FORTH	0.6	0.6	2	3	0.5	3	2.3	9.21	2.7	9.5	0.8	3	0.2	0.7	0.25	0.75	9.35	*29.76*
Custodix	0.5	0.06	3.5	3.51	0.5	0.3	1.7	1.83	0.2	0	0.7	4.6	0.1	1.18	0.08	0.35	7.28	*11.82*
IJB	2.3	2.5	0	0	0.6	0	0	0	1.2	1.0	0.9	1.8	0.3	0.5	0.12	0.25	5.42	*6.05*
UPM	0.5	0.83	1.5	2.54	2.3	1.20	1.2	1.00	0.2	0.21	0.8	0.80	0.2	0.23	0.12	0.14	6.82	*9.25*
Total WP	*12*	*6.5*	*19.4*	*11.65*	*11.4*	*7.92*	*16.0*	*14.79*	*11.8*	*13.21*	*9.8*	*12.65*	*4.0*	*9.28*	*3.3*	*3.47*	*87.8*	*81.76*

(actual man months are rounded 6-monthly best estimates; final accurate man-hours are given in the cost claims)