

# INTEGRATE



## Driving excellence in Integrative Cancer Research through Innovative Biomedical Infrastructures

Synergy between clinical research and the VPH community will speed up the development and validation of multiscale predictive models in breast cancer - an area in which modelling significantly lags behind due to high variability in molecular/genetic and tissue level characteristics –, improve patient outcomes and reduce costs. **INTEGRATE** will enable this through a dynamic environment, collaboration tools and secure access to comprehensive datasets.

### Objectives of the project

Large efforts dedicated to biomedical research generated many exciting discoveries world-wide, but have not brought so far the desired breakthrough benefits in the clinic, in dramatically improving the patient outcomes. Fragmented efforts, lack of common methodologies and research frameworks, and lack of sufficient and high quality data result in improper validation and make reproducibility of research results a difficult task. The same fragmentation is apparent at the level of infrastructures, systems and tools used in basic and clinical research and in clinical care.

INTEGRATE aims to build 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, with the end goal of improving patient outcome. Our 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.

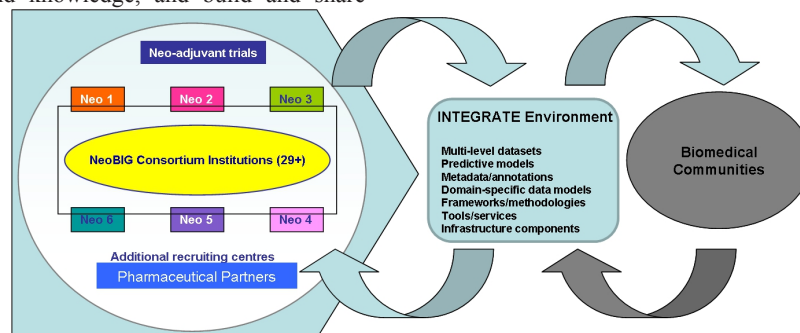
Our main objectives are to:

- Build infrastructure components and tools for the storage, sharing and management of data, information, knowledge and models
- Build tools to enable collaboration
- Support the clinical researchers to build predictive models and a modelling methodology and framework
- Enable semantic interoperability to existing research and clinical infrastructures.

### Project Description

A unique quality of the INTEGRATE approach is the full commitment of the Breast International Group (BIG), as a partner in the project, to contribute patient data and the extensive basic, translational and clinical research expertise of their network to build solutions based on challenging but realistic use cases.

Our vision is to drive research excellence in oncology through a unique accessible biomedical infrastructure integrating diverse mega-datasets, building predictive bionetworks and offering advanced tools to guide the development of effective human therapeutics and diagnostics. These comprehensive datasets will also become available to the biomedical research community through the INTEGRATE infrastructure.



Essential steps in our approach for achieving interoperability improvement include the definition of sound information models describing the clinical research systems, building on existing research results when possible. Electronic health records too need

to be properly modelled; to that end we will adopt the appropriate state-of-the-art representation formalisms such as HL7 CDA, the OpenEHR Reference Model, ISO/EN 13606, etc.

The semantics of the clinical terms will be captured by standard terminology systems, and the scalability of the solution will be achieved by modularization, e.g. instead of aiming at inclusion of the complete SNOMED-CT terminology (more than 300.000 concepts) we will identify a core subset that covers the chosen clinical domain and the datasets in our repositories. Such core data set shall be validated both by clinical and knowledge engineering experts to assure proper coverage and soundness.

### CASE STUDY

INTEGRATE will enable the clinical researcher to seamlessly access breast-cancer multi-scale data and develop breast cancer predictive model methodologies related to specific clinical questions for optimizing therapy, identifying high-risk patients, etc. The researcher will be able to retrieve temporal (e.g. before and after therapy), multi-level (e.g. from microarray to MRI/PET), data from specific population groups (e.g. postmenopausal women), with specific characteristics (e.g. that have received specific therapy regime) and then extract/develop predictive biomarkers/models (e.g. combination of imaging/genetic biomarkers) that could answer questions such as “can these models/biomarkers help predict the specific therapy outcome for a patient to avoid unnecessary/costly treatment?”

As this semantic dataset will be mapped to concepts from existing standardized vocabularies (e.g. well established and widely used clinical terminologies such as SNOMED CT), we will foster scalable semantic interoperability not only among the clinical infrastructures within the project, but also towards other healthcare and research organizations adhering to the adopted standards.

We will first deploy our prototypes at the sites of the INTEGRATE clinical partners, i.e. members in the BIG network, and we will validate them in concrete scenarios. In a second stage, we will promote and validate our solutions with external user groups that expressed interest in INTEGRATE, and we will include them in the evaluation and validation of the INTEGRATE environment.

## Expected Results & Impacts & Preliminary results

### Societal & economic benefits expected

The partnership within INTEGRATE with the Breast International Group enables us to bring the VPH community closer to the world of clinical research, and provide a path towards clinical validation of VPH models. Clinical trials are a formal, well regulated and statistically rigorous process and represent the way in which research results are validated and can be introduced into clinical practice.

INTEGRATE will build infrastructure components enabling the sharing into a large biomedical community of comprehensive datasets and knowledge generated within clinical trials. Access to these has the potential to fuel new research in the biomedical community, which is currently hampered by the lack of sufficient and high quality datasets.

The INTEGRATE project will also support BIG to promote in the clinical community new methodologies and define standards concerning the collection, processing, annotation and sharing of data in clinical research and improve the reproducibility of results of clinical trials.

Providing the necessary infrastructure, tools and services to the clinical research community will enable them to reduce costs by more efficiently setting up and carrying out clinical trials; better reuse of data, knowledge and tools; reduced duplication of efforts; easier access to all relevant information out of external sources; and more insightful generation of new research hypotheses. In the end this means quicker validation of new discoveries in clinical trials and transfer of new results into clinical care to become part of new treatments and improve patient outcomes.

### INTEGRATE

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**Project co-ordinator:**

Philips Electronics Nederland BV

**Contact person:**

Anca Bucur

Tel: +31 40 2749699

Email: [anca.bucur@philips.com](mailto:anca.bucur@philips.com)

Website: [fp7-integrate.eu](http://fp7-integrate.eu)

**Partners:**

- Philips Electronics Nederland BV (Netherlands)
- Breast International Group (Belgium)
- Foundation for research and technology Hellas (Greece)
- Custodix (Belgium)
- Institut Jules Bordet (Belgium)
- Universidad Politecnica de Madrid (Spain)

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### KEYWORDS

Biomedical informatics, Personalised health, Semantic integration of health data, Semantic interoperability, Modelling of physiological processes, Infrastructures, Electronic health records