

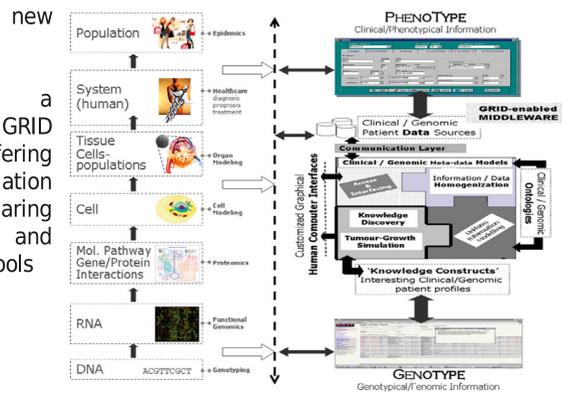
## Cancer clinical trials in the post-genomic era

- New technologies (e.g. microarrays) allows a description of cancer at the whole-genome level
- The amount of information obtained per patient is increasingly large and becoming intractable without advanced statistical methods
- Large (international) cohorts of patients are needed to extract a sometimes weak signal from an enormous amount of noisy data
- Complex interaction patterns between genes are unveiled and disease mechanisms understood
- In-silico models of tumor growth can predict response to chemo- and radiotherapy

## ACGT objectives and GRID approach

The aim of ACGT is to provide medical researchers with optimal means and resources to fight cancer  
The project will focus on this achievement by:

- Defining common standards of data storage
- Developing new ontologies
- Implementing a bio-medical GRID infrastructure offering seamless mediation services for sharing data and data-processing tools



## Data Protection and Security Framework

Legal and ethical aspects are considered at all levels of the technical development of the ACGT infrastructure, from the handling of access rights to patient information to considerations about the meaning of informed consent on data/biological-sample usage in heavily computerized clinical trials. Therefore a technical and legal security framework was set culminating in the "center for data protection" ([www.privacypeople.org](http://www.privacypeople.org))

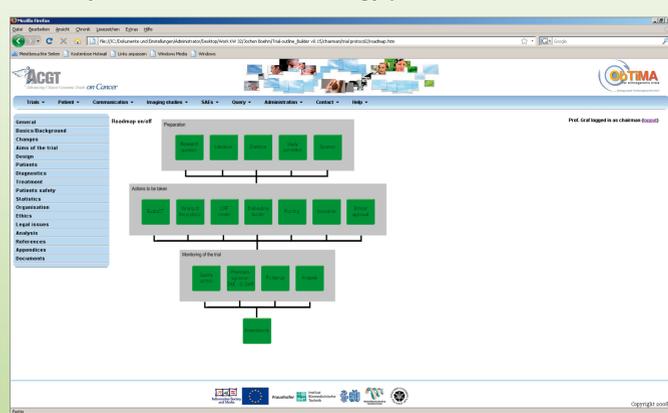


ObTiMA – An Ontology Based Clinical Trial Management System  
for clinicogenomic trials

Ontology based Trial Management for ACGT

### A new approach to harmonize, collect, share and integrate data from clinical studies:

- Study items are created from the cancer ontology during study design
- CRFs in CDISC ODM standard contain ontology information
- Study data base includes ontology paths as standard metadata



### ObTiMA Architecture

Repository

Trial Outline Builder (general view)

graphical schema

patient specific view

Trial Builder

CRF Creator

Patient Data Management System

### Advantages:

- Study items contain standardized metadata
- Data from different clinical trials can be compared through semantic queries
- Data from different trials can be automatically integrated and shared

### ACGT General Information

FP6 - IST - Integrated project (IP)  
Integrated biomedical information for better health

Start date: Feb 1, 2006  
End date: Jan 31, 2010  
Project cost: 16'747'206 €  
EU funding: 11'887'000 €  
Partner institutions: 25

### Knowledge discovery tools

The analytical core of the ACGT infrastructure is built on top of open-source software, both from ACGT partners and from the wider bioinformatics community.

Software components of the ACGT infrastructure are interconnected through web services. Access to physical databases is abstracted through a uniform data access layer. Semantic consistency of the data is ensured by a systematic usage of ontologies. Semantically meaningful data are presented to data analysis tools (in pink on the picture above) by the mediator. End-user interaction with the ACGT infrastructure is made via the portal, which interface is adapted to the needs of the user using the environment (clinicians, data analyst, ...). The physical infrastructure of ACGT is a computation/data GRID, which is required for the storage and statistical processing of high-throughput data.

