Why do we need ACGT?

Advances in post genomic research have created significant opportunities for offering personalized treatment and better health care services to the population at large. However a number of problems exist. Most critically:

- Researchers have difficulty integrating heterogeneous data from different systems because of a lack of common standards and other technological, medico-legal and ethical issues.
- Today the legal and ethical guidelines for running a clinical trial represent a significant barrier. Nevertheless this barrier serves to ensure the safety of patients enrolled in clinical trials.
- For clinicians it is difficult to set up trials without getting support regarding legal and ethical requirements as well as issues like data management, data processing, data security, data integration, etc..

These problems are still not solved today. The integration of heterogeneous data (molecular genetic data, clinical data and data from Web databases) in clinico-genomic trials is an important point in case especially since it is central to the development of more personalized medicine.

How can ACGT support you?

ACGT will deliver a set of resources to support clinical trial design and research, especially:

**Responsive to this challenge is possible today**

ACGT is an EC co-funded project that develops open-source, semantic and grid-based technologies in support of post genomic clinical trials in cancer research. ACGT focuses on the integration of multilevel biomedical data including clinical data with the ultimate objective to extract new knowledge for developing more individualized treatments for cancer patients addresses clinicians, bio-researchers as well as software developers.

**Trial Management**

- ACGT will provide an Ontology based Clinical Trial Management System for ACGT (ObTiMA), that guides healthcare professionals to set up new trials and protocols and supports creation, storage and reuse of Case Report Forms (CRF’s)

**Data accessibility and security**

- Provide easy access using single password and distribution of credentials
- Provide a general and patient specific view
- Assure patients data security providing tools for automatic encryption and decryption of personal data and images
- Support restricted access to patients data by distributing access rights using roles and rights management

**Patient security**

- Support allocation of patient informed consent respecting the new challenges in the post-genomic area and European directives
- Provide access to personal patient data only for authorised physicians in charge of the patient
- Support reporting of SAEs an SUSARs to regulatory bodies and trial participants

**Usability**

- Use of an end user driven approach with continuous end user evaluation of usability in line with the DIN EN ISO 13407 will assure end user friendly tools

**Data analysis and query**

- Support queries spanning multiple trials as well as seamless integration of heterogeneous data
- Allow the reuse of clinical trial and research data for further research and statistical analysis
- Provide tools for literature mining, knowledge discovery and statistical analysis
- Offer access to a powerful GRID infrastructure for fast and efficient data processing

**Data integration**

- The ACGT Master Ontology and Mediator support the integration of multilevel biomedical data including clinical and imaging data

**InSilico Oncology**

- In Silico Oncology creates multilevel computer models of cancer growth and its response to treatments.
- The “Oncosimulator” tool that is being developed will assist clinicians and other practitioners to better understand disease progression and hopefully design more personalized treatments for patients following its strict clinical validation.

**Legal and ethical issues**

- Multi-level clinical trials have to deal with sensitive personal data. ACGT is fully aware of the legal, technical and ethical implications of the research done in the project. Therefore a technical and legal security framework was set culminating in the “Center for Dataprotection”. The center (www.privacypeople.org) guarantees compliance with the relevant technical and legal requirements and is open for use by any similar project.
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