Results: We adopt a standards-based approach in the development of our semantic interoperability layer. The semantics of the clinical terms will be captured by standard terminology systems such as SNOMED CT, ICD, LOINC, and scalability will be achieved by modularization, identifying a core dataset which covers the chosen clinical domain and our data. The core dataset will be validated by clinical and knowledge engineering experts to assure proper coverage and soundness.
Relevant clinical scenarios have been identified and formalized in technical use cases, and are used as basis for our requirements analysis. We have defined an open, service-oriented architecture which provides the technical blueprint for the implementation of the INTEGRATE framework (www.fp7-integrate.eu).
Conclusions: The huge potential of the current biomedical research in oncology cannot be fully exploited in the absence of a coordinated and systematic approach. Our infrastructure will enable the sharing within a large biomedical community of comprehensive datasets and knowledge generated by clinical trials. The project will support BIG in promoting in the clinical community new methodologies and standards concerning the collection, processing and sharing of data. This will improve the reproducibility of high resolution translational research embedded in clinical trials and facilitate future research.
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2162 POSTER

Implementation of an Open Source FDA and GCP Compliant Electronic Case Report Form (eCRF) System in an Oncology Department − an Option?

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Introduction: The data monitoring, regulatory procedures and data management in investigational trials are still having trouble to fulfill the national legislation. Investigators are forced to use inadequate tools in their trials − there is no audit trails in an excel worksheet.
Internet-based connectivity offer resources to improve the quality and efficiency of data management operations.
At Herlev University Hospital and Rigshospitalet, Departments of Oncology, we have implemented an Open Source FDA and GCP compliant Electronic Case Report Form (eCRF) system − OpenClinica. The system covers all the data management processes.
Materials and Methods: Several both commercial and Open Source eCFR systems were investigated to ensure if they fulfilled governmental legislation and GCP demands. Secondly a set of minimum requirements were established concerning system functionality and security. It was decided to implement OpenClinica based on above considerations and the following criteria: economy, department policy, resources, IT infrastructure and availability.
An implementation plan was created including (main tasks only): Testing as part of FDA and GCP compliance
- IQ − Installation Qualification
- OQ − Operational Qualification
- PQ − Performance Qualification
- Site Standard Operational Procedure (SSOP), not yet finished.

Results: At the Departments of oncology, three studies have been up using OpenClinica, as summarized below.
- Project I. Enrolled 51/51 finished (Normal complexity)
- Project II. Enrolled 589/800 (Complex)
- Project III. Enrolled 2/500 (Very complex)

The complexity refers to treatment schedule and amount of different eCRFs. The final aim is to use OpenClinica for all investigator initiated studies in the department.
Discussion: At a time when clinical resources and financial budgets are tight, we have to find new ways to solve problems with inadequate data management tools. One option might be to turn to the many Open Source programs available today.
To succeed in implementing an Open Source FDA and GCP compliant eCRF system one needs:
- Allocation of adequate resources in the form of skilled dedicated staff covering the whole data management process including research nurses, physicians, secretaries and IT personnel.
- Funding − The system is free BUT the implementation is NOT.
- A well defined time implementation plan.
- Preferably some person(s) with experience from similar projects

2163 POSTER

Integrating Web-based Real-time Analysis System With Clinical Research Database Facilitates Interim Analysis

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Background: Interim analysis is usually used for assessing patients' performance on clinical trials and modification or early termination of the trial if there is large difference between treatment groups. However, performing interim analysis requires separate data collection and processing at certain predetermined points. The study aim was to decrease time and effort needed for collecting, validating, cleaning and analysing data.
Materials and Methods: In our novel technique, we have developed a clinical research system that entitles performing real-time data collection for our patients and feeding the database with updates at each visit. Data were validated automatically at data-entry step and challenged against different algorithms. Real-time statistical analysis results including survival analysis are updated in numerical and graphical presentations without the need for stopping the trial or data collection. The whole trial results are updated collectively based on each individual visit. This instant statistics interface is made available for independent researchers and auditors.
Results: With automated web-based solution, data-entry validation, cleaning and simultaneous analysis time and effort decreased significantly. Moreover, interim analysis became available at any point in the trial so allowed the researcher to examine the trial concurrently. This can help the researchers to modify the trial at any time earlier or later than a predetermined point. Its web-based property made the results available remotely for central reviewing and auditing.
Conclusion: Integrating online statistical analysis with clinical research systems improved data-entry process, and study monitoring, hence it improved the interim analysis and decision making.

2164 POSTER

Central Multi-disciplinary Consultation and Decision Making on Treatment of Patients With Complex Tumours

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Objective: Centralization of the decision making on treatment of patients with complex tumours in order to achieve proper treatment and care for every oncological patient in north east region of The Netherlands, by multi site and multi-disciplinary oncology meetings with expert consultants.
Background: The comprehensive cancer of The Netherlands (CCCN) aims to achieve proper treatment and care for every oncology patient within the country. To reach this aim, the CCCN can call upon the consulting services of 400 medical experts from university medical centers. One of the tasks of these experts is advising medical specialists in general hospitals, thus ensuring the availability of high-quality specialised cancer care throughout the Netherlands.
Methods: Through expert consultation and centralised decision making in tumour boards, patients can rely on being treated at the highest quality level, according to the latest findings, regardless of the hospital. In recent years the CCCN initiated general tumour boards to be replaced by tumour-specific multi site and multi disciplinary meetings. Sometimes with 4 to 6 hospitals simultaneously, accompanied by one or more consultants from the expert center. To enable these meetings video conference is used.
Video conferencing involves specific demands on the organization of oncology meetings. The CCCN supports hospitals in buying, installing and using the hardware. The CCCN supports secured webbased patient information sharing among participants. The CCCN provides virtual meeting rooms, using videoconferencing standards and internet, in which all kinds of diagnostic images can be presented in real to all participating locations. Hospitals are provided with training of members and chairmen. A guideline is developed for the organisation of multi site oncology meetings per videoconferencing, including a format for patient presentation.
Results: All hospitals in the CCCN-region have facilities for video conferencing. In addition, all radiotherapy centers and pathology laboratories use video conferencing to participate in the tumour boards, which easily and secure take place in a virtual meeting room. It's possible to share data during videoconferencing: on one screen the participants of the other locations are projected, on the other screen the patient presentation and images such as CT scans. Even tele-pathology through high definition coupe scanners can be used in tumour boards. Several multi site tumour specific tumour boards are implemented. For instance for ovarian cancer and urologic tumours on a weekly basis, so that all patients are being discussed with experts before the start of their treatment.