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PROJECT STATUS REPORT II.
Enclosure 3

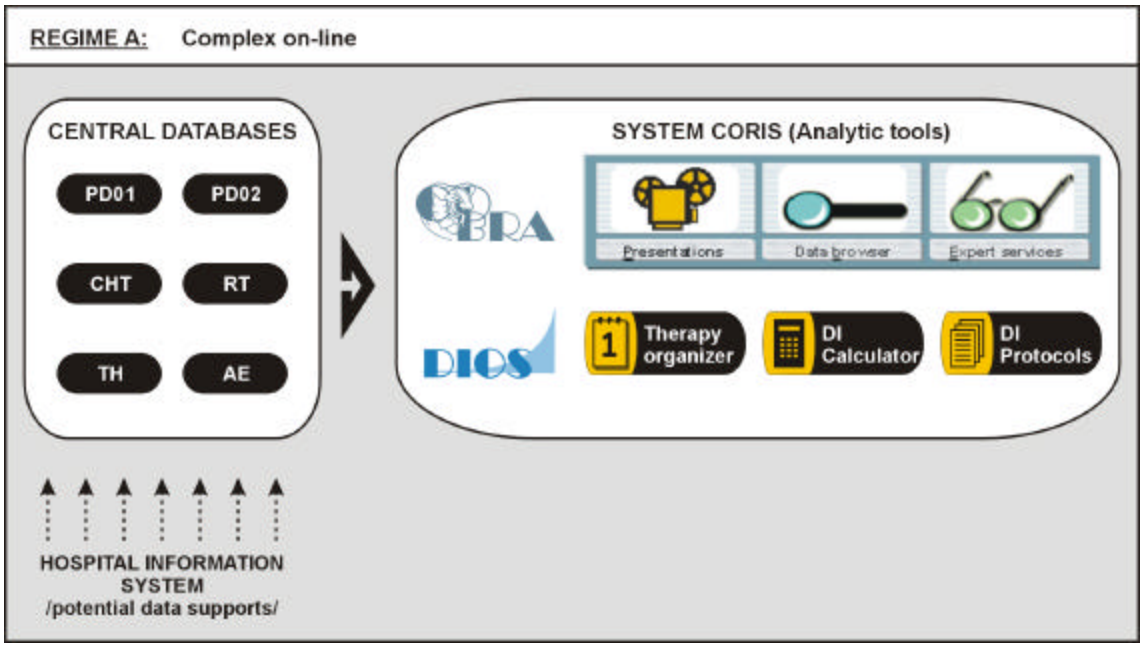
Software solution for health technology assessment and dose intensity monitoring

The aim of the project is basically to develop widely accessible software tools with computational background for HTA monitoring and dose-intensity evaluation. Final proposal works with three variants (regimes) that are proposed for different situations:

- **REGIME A.** On-line solution working with central database out of health care facilities
- **REGIME B.** Local implementation of parametric s tructure and standards into databases directly in health care facility
- **REGIME C.** Local minimal solution, developed for the situation with lack of valid and parametric clinical data.

All three solutions are based on the same principle and the analytical procedures are fully compatible. The difference is in operational conditions and availability of suitable data.

REGIME 1. Complex solution for on-line operation



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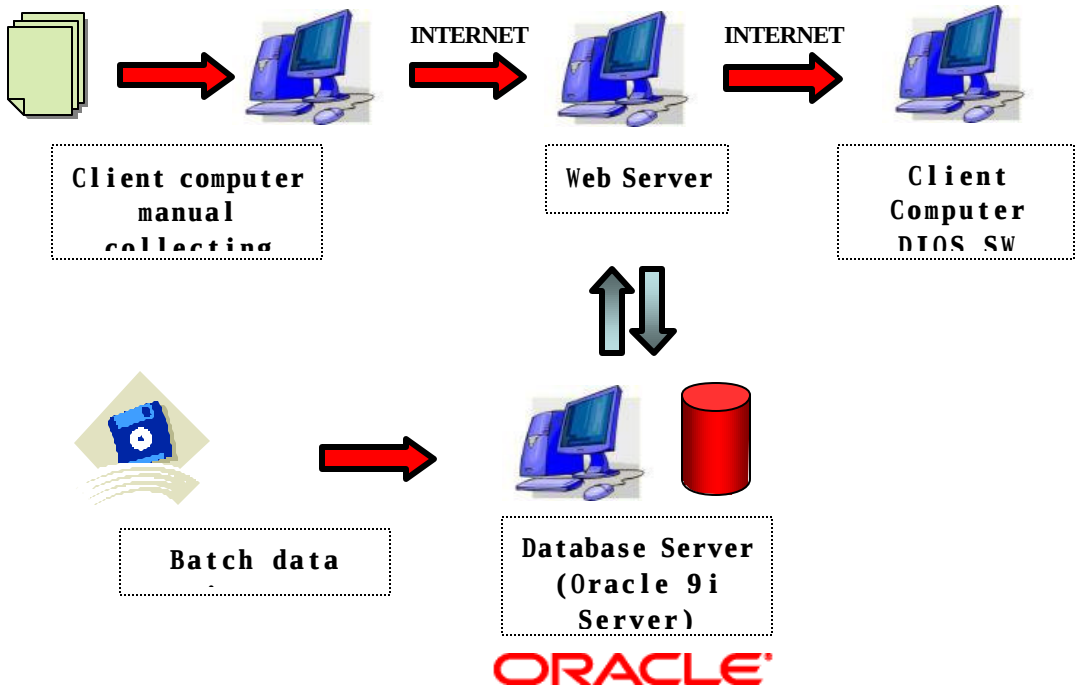
- Standard on-line solution
- Suitable for multicentric arrangement
- Two ways of data collecting
  - manual collecting
  - batch data import



This schema is offered as a solution for a multi-centric clinical data collection. Data can be inserted either manually or by ad-hoc data import. Data is world-wide accessible by Internet. No direct communication with hospital information systems is involved.

Central database:

- Standardized forms for basic clinical data /**PD01**, **PD02** – see enclosure 01/
- Therapeutic records (**CHT**, **RT**)
- Basic reporting on adverse events and complications (**AE**)
- Ability to import basic therapeutic records from reports to health insurance companies (**TH**)

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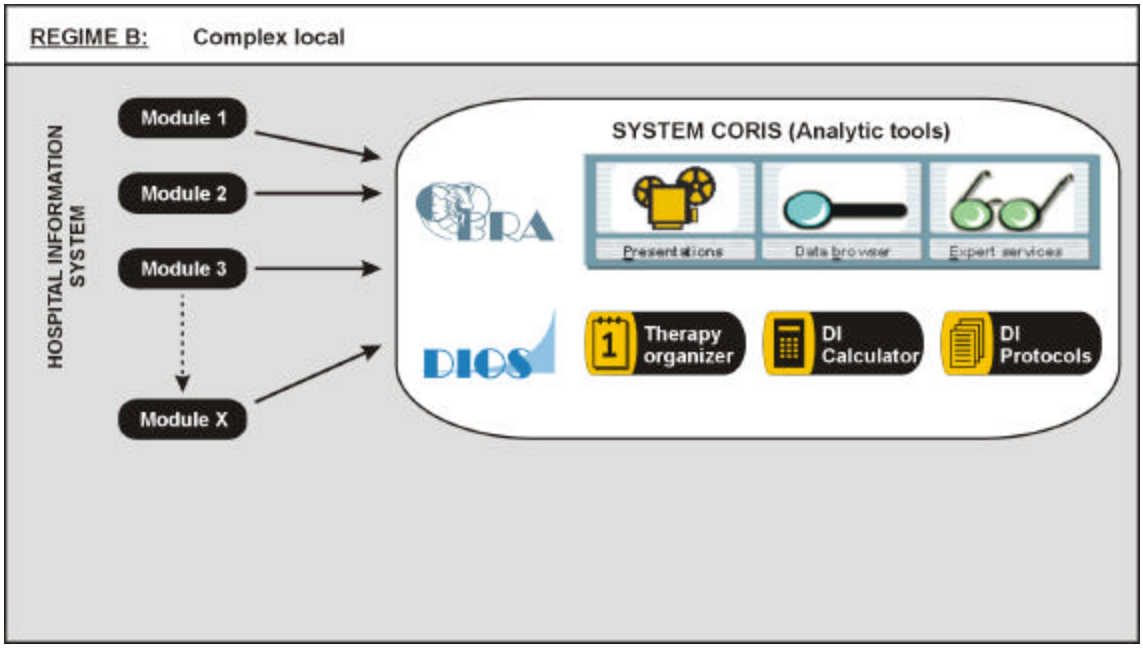
Central database can be locally analysed by expert tools grouped in two complex packages:

- Comprehensive data browsers (system COBRA)
  - Presentations
  - Interactive data browser
  - Analytic tools (automated graphical outputs combining clinical records and DI monitoring)

- DIOS SW
  - Therapy organizer
    - Specialized SW working with minimal data that are available in all health care facilities in Czech Republic (reports on therapeutic steps for health insurance companies) /SW provides retrospective overview of therapeutic procedures and aggregates these clinical records/
  - DI calculator
  - DI protocols
    - These tools require complex data on CHT (RT) regimes, dosage and timing during the therapy and results. They returns numerical calculus of all dose-intensity parameters, their statistical processing and possible benchmarking of individual values.

REGIME 2. Complex solution for implementation inside health care facility



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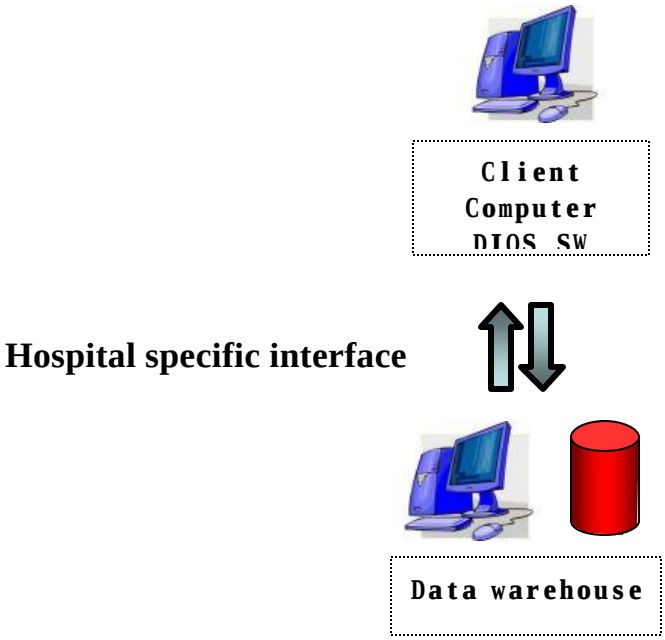
- Specific solution for each individual hospital
- Suitable for hospital with its own data-warehouse
- Creating hospital specific interface is necessary



For a hospital with existing data warehouse it is the most suitable regime. Tools for management and analyses of clinical data are directly linked to hospital data warehouse (structure and functionality of analytic tools is the same as in REGIME 1). The interface must be created for each individual hospital. Data is not accessible out of the hospital.

REGIME 2 is developed and applied in Masaryk Memorial Cancer Institute as model solution (see also enclosure 01).

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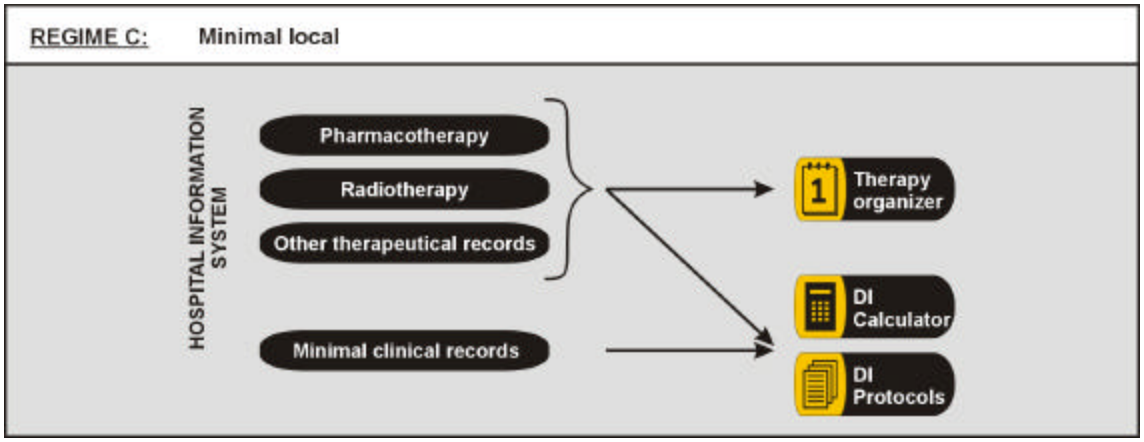
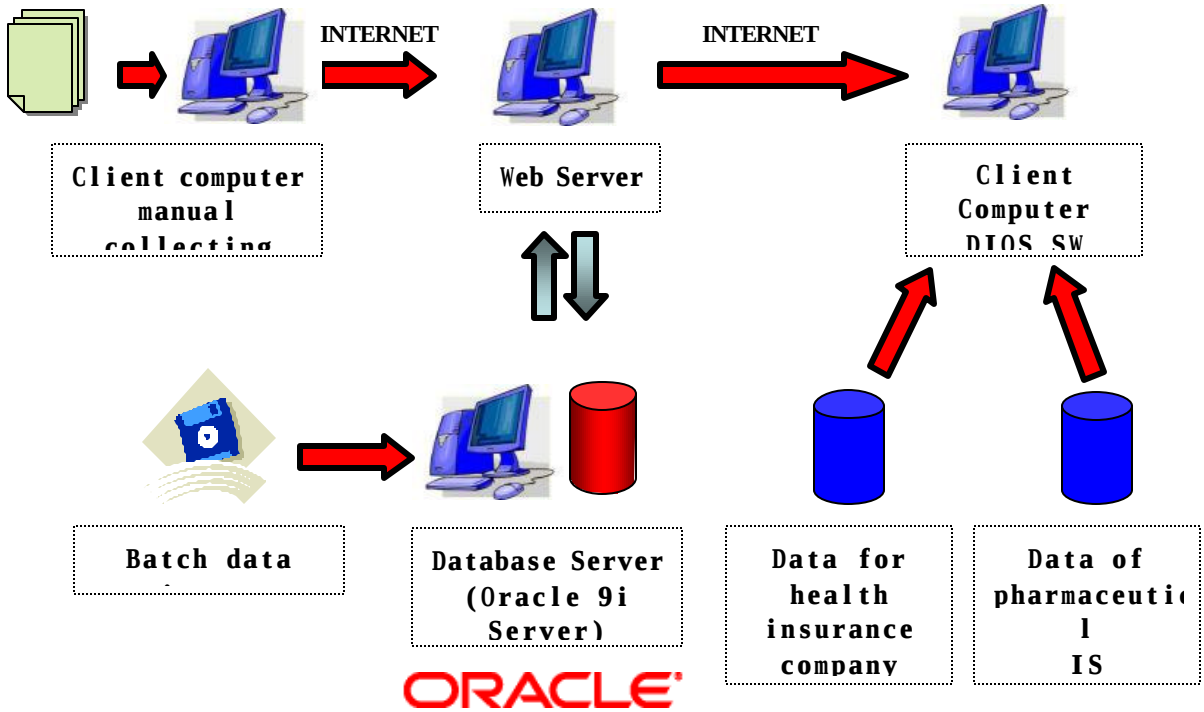
REGIME 3. Minimal solution



- General solution for hospitals where only basic therapeutic data is avaliable
- Suitable for a hospital with its own pharmacy
- Main volume of data is extracted from records for health insurance companies and from pharmaceutical IS



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The regime 3 is basically an extension of the regime 1. Two data sources are appended to very reduced manual data collecting. The first source is data for health insurance companies (HIC). This source contains all acts that were performed and accounted to HIC. Every hospital must collect this data for HIC. Information about administered drugs, including cytostatics, can be extracted from this source. Second source is data from pharmaceutical IS which contains detailed data of administered drugs and this source can supplement the first source. Available structure of data from these sources for individual patients is as follows:

- Patient ID
- Date of administration
- Classification code of drug
- Drug dose
- Price of drug administration

The potential problem is hidden in different drug classification; therefore data from pharmaceutical IS should be preferred, if possible. On the other hand, data for HIC contain more additional information about patient's treatment. The basic structure of non-pharmaceutical data is as follows:

- date of treatment
- type of treatment – special HIC classification
- number of treatments
- price of treatment (in points)

Data from these sources can be supplemented by manual data collection or ad-hoc import process.
Manual data collection is necessary because the sources mentioned above do not contain information about chemotherapy plan and possible adverse effects or events.