

PROJECT STATUS REPORT II

Enclosure 1

Model implementation in Masaryk Memorial Cancer Institute : basic principles

The key aim of this project topic is (A) to demonstrate real evaluation of DI inside hospital and (B) to create model implementation that can be offered in the form of guidelines.

Following list summarizes reached outputs:

- Audit of data sources in MCI. All data sources that could at least potentially contribute to HTA process were examined and critically assessed from the viewpoint of parametric status. This step helped us to correctly localize the HTA and DI evaluation among relatively heterogeneous databases. Available data sources were fractionated into 11 modules with very different operational and information roles (**Fig. 1**).



Figure 1. Defined modules of data sources in model health care facility

- The main aim of this project is to increase accessibility of data on dose intensity of anti-tumor therapy. To reach this, we had to separate time-related clinical records from specialized modules like laboratory examinations etc. This approach logically clustered data modules into four strategic groups (Fig. 2):
 - Main frame for patient's documentation : PD01 and PD02. These components bring basic characteristics of patient, disease and its development. All the other data like examinations, adverse eventsand others can be fully interpreted only within this frame, giving us the information on who is the patient, what is the type and severity of the disease and what is the effectiveness of therapy.

- Supporting components: laboratory data and results of examinations (PD03 – PD05)
- Key components describing the therapy from plan, through potential modifications to final results. PD08 – PD10.
- Reasoning and interpretation of occurred complication, non-standard situations etc: PD06

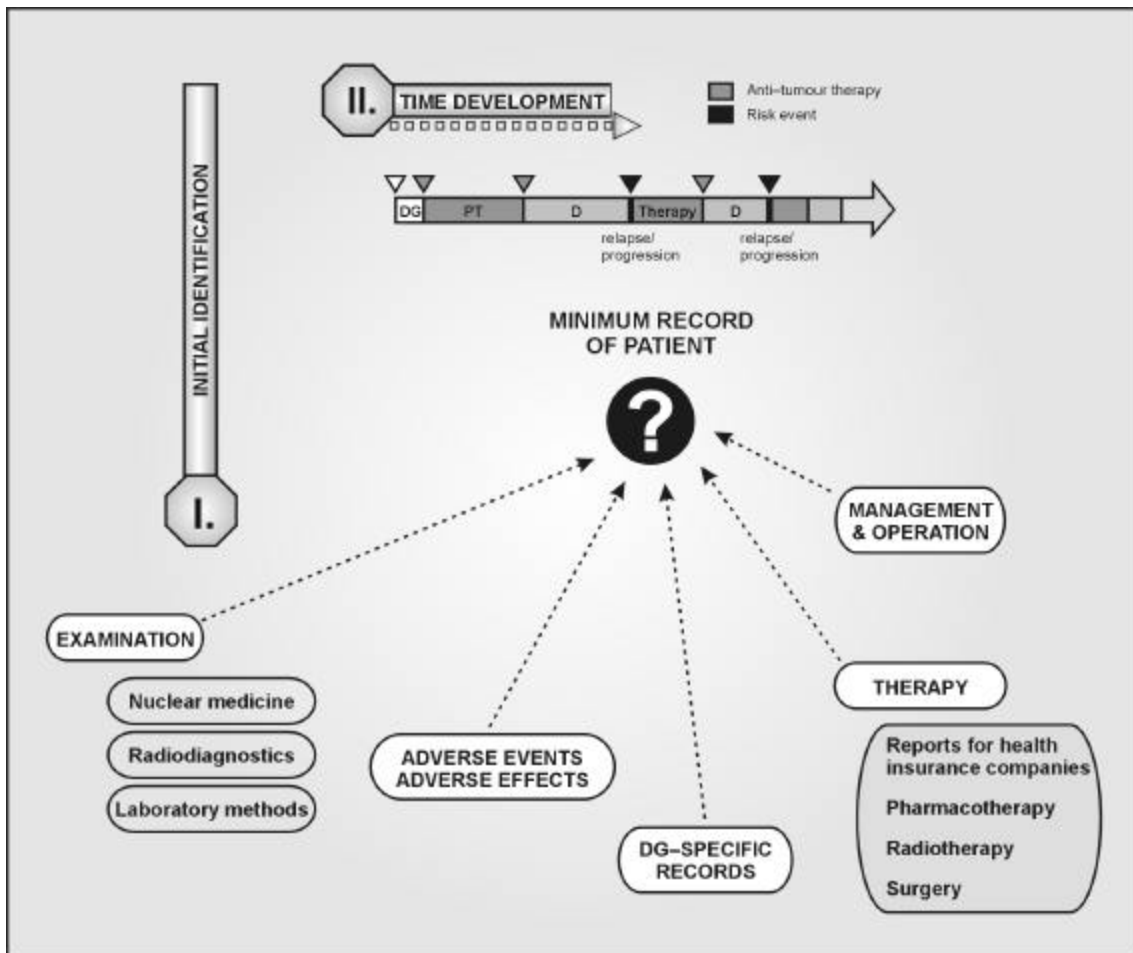


Figure 2. Proposed modules are logically grouped

- Although not directly related to dose intensity data, the most important component in our concept is the basic frame of electronic record: it means PD01 and especially PD02. These components provide data unambiguously indispensable for interpretation of all patterns and changes. PD02 defines therapeutic episodes. (Fig. 3).
- Therapeutic episodes represent discrete time units that can be defined in time and are clearly associated with some therapeutic plan, therapeutic steps and final evaluation.

Therapeutic episodes represent important units also for aims of this project as they can be directly related to dose-intensity measures (Fig. 4).

- Each therapeutic episode should be therapeutically planned and subsequently evaluated for major endpoints. Conceptual therapeutic plans are included in module PDO2 and then automatically related to specialized components that monitor specified therapeutic modality (chemotherapy, radiotherapy, ...). In this structure, dose intensity plays a role of one of the key endpoint and can be directly correlated with the other measures. Time-related clinical records allow reasoning of negative changes or violation of already set plan.

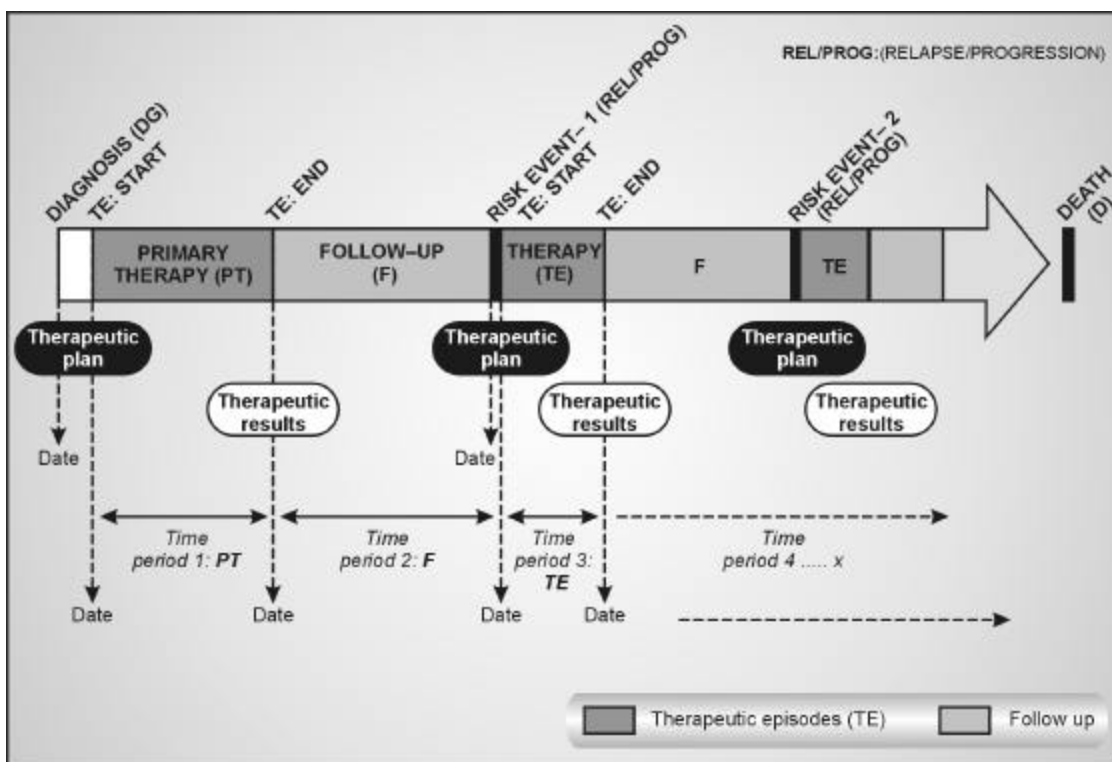


Figure 3. Basic time-related clinical records define therapeutic episodes

- Audit of data sources localized dose-intensity monitoring and evaluation in modules specialized on detailed therapeutic plans (chemotherapy, radiotherapy). All these modules were updated in their functionality in the way, that allows evaluation of therapeutic plans (Fig. 5, 6).

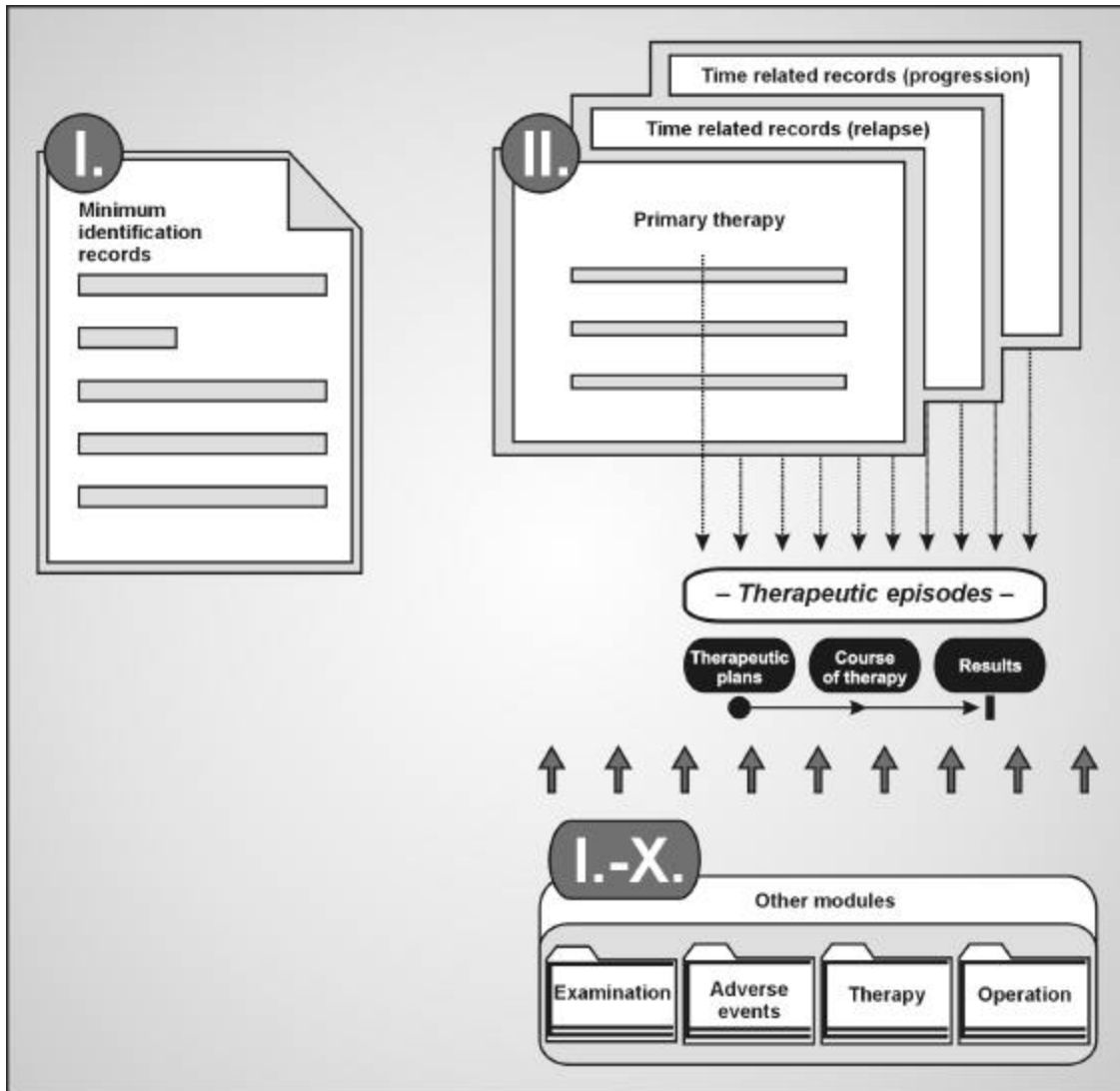


Figure 4. Therapeutic episode is proposed as key unit for the evaluation

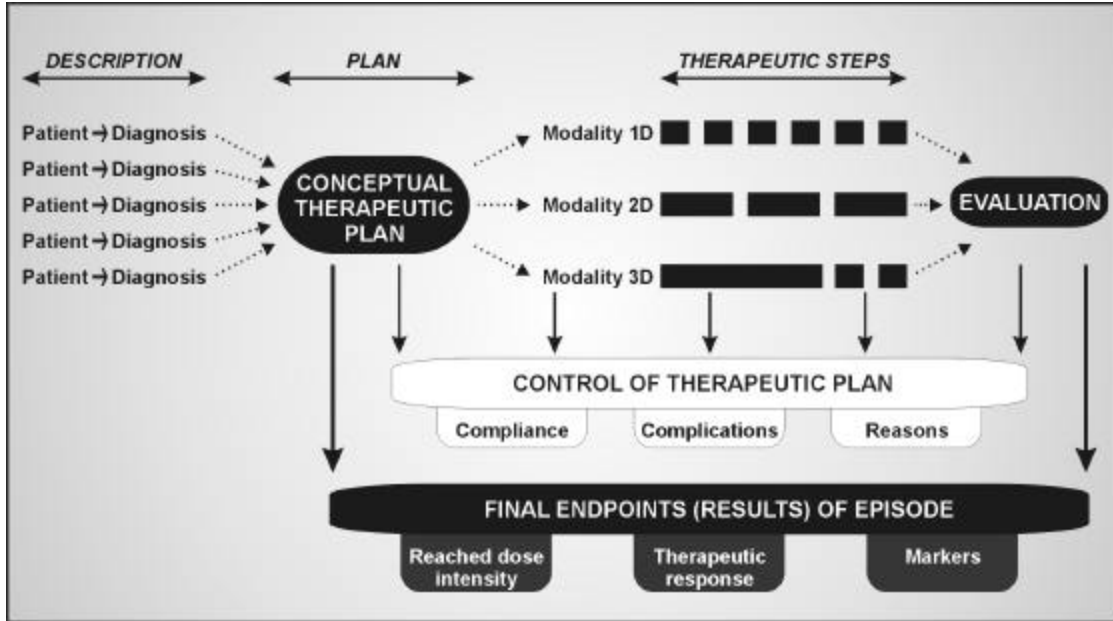


Figure 5. Basic design of planning in therapeutic protocols

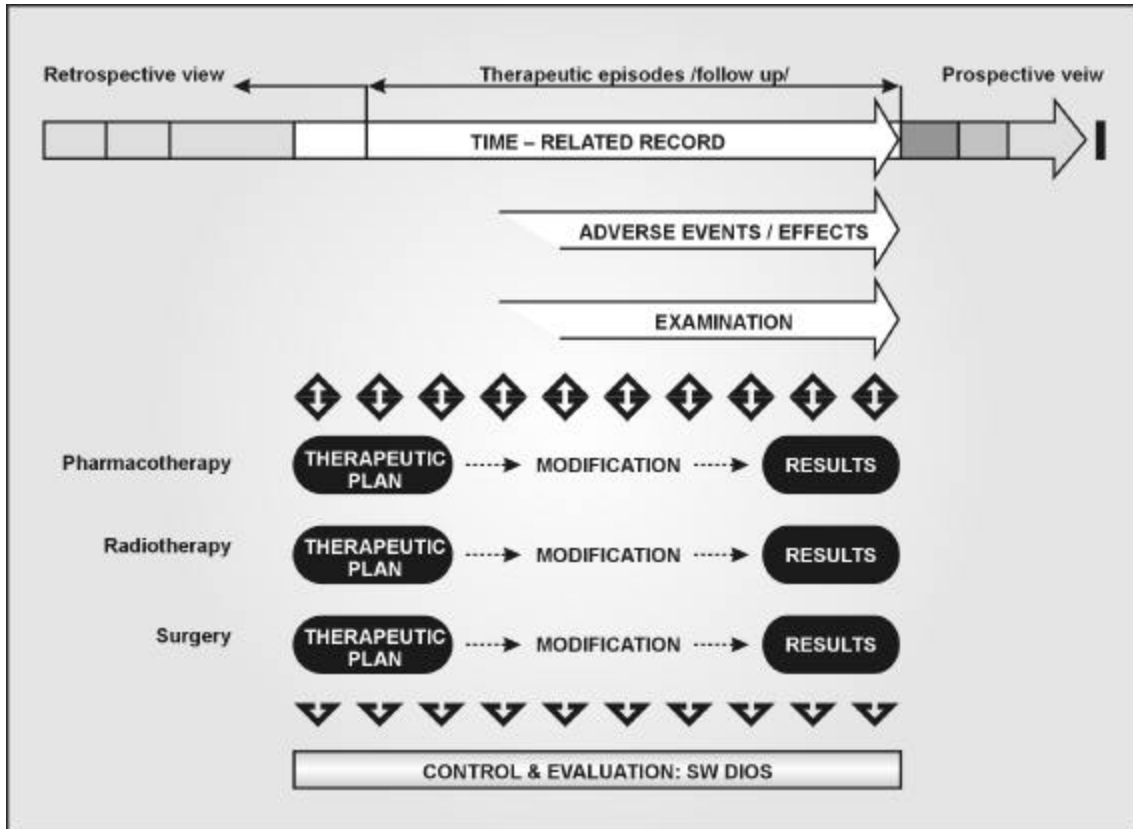


Figure 6. Detailed therapeutic plans must be effectively monitored