# Designing and implementing (inter)national registries: the Leiden experience with the ProMISe interface

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Abstract:

Over the past years at the Department of Medical Statistics & BioInformatics, section Advanced Data Management, we have developed and used the Project Manager Internet Server (ProMISe) software to enable us to support a large number of (inter)national registries (and clinical trials) with a limited number of people, based on a gradually developed philosophy what the role of IT should be within a biostatistical department where IT is on the one hand considered an integral and essential part of the scientific process but on the other hand is not the primary focus of the biostatisticians involved in studies.

In this workshop I will focus on the implementation of long-term registration projects from a biostatistician's perspective: in my view Generic Data Management software must be …
- Flexible
    * Study coordinator must be able to follow scientific developments and dynamically modify the system in any respect without technical support
    * The software must be able to follow relevant software developments
- Efficient
    * Study coordinators, data managers and research nurses must be able to manage the system in an intuitive way
    * There should be no local copies of software and/or data bases
    * WWW access should be the normal way of data input/output
- Cost-effective
    * The design of a particular project should take little time
    * The structure should automatically balance the requirements for ease-of-data input and ease-of-analysis, both faithful to the protocol
    * All projects must benefit from developments triggered by others

This we have achieved with ProMISe and this is what ProMISe is all about:
- one central core to contain the clinical definitions, the Dictionary of a study
- one central core to contain all data collected
- centralized generation of paper and electronic coding forms as a reflection of the current Dictionary
- structural design that pays attention to the way the data should be checked and analyzed
- one piece of software to run an infinite number of studies in the same way
- an open architecture which allows (and supports) export of Dictionary and Data to any other format or computer program and integration with local data management

Although the approach is not always according to standards in the scientific area of Informatics (e.g. non-normalized data bases) a strict adherence to our philosophy provides clinicians with the possibility of extremely fast development and implementation of (inter)national registries. The price to pay is extreme standardization…. with hopefully enough flexibility to make a balance.