Current Status and Future Perspectives of Drug Information Systems

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Extended Abstract

We consider the current status and future perspectives of Drug Information Systems (DISs) from an IS point of view. The information lifecycle of a drug starts already during the drug discovery phase and continues far into the future in prescription- and adverse-effect databases. The drug lifecycle consists of the disjunct phases of discovery, development, approval, and marketing.

Each phase is supported by various types of DISs. We distinguish the following types of DISs: *compound databases* (containing the physico-chemical structural data for the computational drug discovery methods), *(pre-)clinical trial databases* (containing the - raw or aggregate - data of (pre-) clinical trials), *SmPC databases* (containing Summary of Product Characteristics, the source of information visible to non-professionals through drug labelling and package inserts), *ADR databases* (containing data on Adverse Drug Reactions), and *CPOE systems* (Computerized Physician Order Entry systems, automating the human error-prone parts of the process of the prescribing physician, especially with regard to drug prescription).

In this paper, we describe the past literature and existing technology of Drug Information Systems. We develop a mapping of DISs to the phased drug lifecycle, taking into account the system information contents. The mapping shows that currently there is a lack of DISs providing efficacy- and safety-data in a suitable format. This lack severely hinders the possibility of physicians, researchers, as well as regulatory authorities and the pharmaceutical industry, to make quantitative analyses of efficacy and safety over a wide range of drugs.

Drug development, testing and administration are information-intensive areas with varying computing needs. These range from storing a single drug's labeling information to complex algorithms for analyzing quantitative structure-activity relationships in the drug discovery process. We use the term Drug Information System (DIS) for any system that stores data related to *some* phase(s) of the drug

lifecycle, and that processes it into user relevant information. DISs have various uses in, for example, recording clinical trial results, disseminating findings of adverse drug reactions, and operational support in a hospital environment. Although the amount of clinical health research is growing rapidly, the supporting operational systems have only recently received comparable effort in research.

The past few years have seen a rise in the amount of research in DISs, but the majority of health information systems literature seems to concentrate on DISs as a tool to improve drug prescription processes and focus on health care safety in a clinical environment. However, in order to support clinical pharmacological decision making and to access and aggregate information from the complete drug lifecycle, it is crucial to have an overview of existing DISs.

A clear overview of existing DISs enables processes dealing with information gaps between discovery, development, regulatory approval, and pharmacovigilance stages. The main motivation to fill these gaps is the need for a reform of the regulatory process recently brought into discussion by regulatory bodies, academia, and industry. In order to improve management of drug information, we need an overview of DISs nowadays available and contributing to the drug lifecycle. More structured information will lead to improved transparency in the decision making process of regulatory authorities. There exists evidence that even published clinical trial results have had statistical evidence interpreted incorrectly in order to appear positive. Transparency of the process could help to find such incorrect analyses as the original studies would be linked with the aggregated results, and finally, with the marketing authorization decisions that (in principle) take into account all relevant clinical data.

This survey considers the existing literature and DISs from a perspective that is, up to our best knowledge, new in the area. We review the existing technology and DISs from a functional point of view, providing an overview of the current state of the technology. Although we briefly present drug discovery systems, we concentrate on clinical data from drug development. The review is followed by a mapping of the existing systems to the various phases of the drug lifecycle. This mapping should be taken as a starting point for information integration across DISs. The mapping allows finding possible integration points between DISs of different phases, which can eventually lead to information re-use, to improved communication, and following this, to shortened drug development cycles.

The meta-analytical approach as applied in the Cochrane Library seems to be the most appropriate starting point for building the next generation DISs for regulatory uses. The future systems should store all required measurements in a numerical format with strict semantics. For aggregate clinical trial results, we are currently working on building such a system (see http://www.drugis.org).

- This study was performed in the context of the Escher project of the Dutch Top Institute Pharma.
- The full paper appeared in the proceedings of ECIS 2010 (Pretoria), see http://web.up.ac.za/ecis/ECIS2010PR/ECIS2010/Content/Papers/0004.R1.pdf.