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CURRENT STATUS and FUTURE PERSPECTIVES of DRUG INFORMATION SYSTEMS

(from an IS point of view)

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Context of our work

- We work within a large pharmaceutical research project (Escher, 17 PhD students, few PostDocs) about regulatory barriers,

  as the only IT-subproject

- We have to design and build an Expert System/Knowledge Management System to support regulatory assessors of new drugs in their decision making,

  but in a new/better (more informed) way (i.e. to best of all available knowledge)

Use of the term Drug Information System

We use the term Drug Information System (DIS) to describe the systems that store data *related to some phase(s) of the drug lifecycle,* and that process it into user relevant information

The problem

- There is a lack of DISs providing efficacy- and safety data about drugs in a suitable format, e.g. for drug (dis)approval
- This lack severely hinders the possibility to make quantitative analyses of efficacy and safety over a wide range of
  - drug studies (of the same drug)
  - drugs (for the same illness)

Our purpose

- Marketing authorization decisions should (in principle) take into account all relevant clinical data, to be traced back to the original studies
- We want to point out information gaps in the drug development process
- Find possible integration points between DISs of different phases, which can eventually lead to information re-use, better communication, and, finally, to streamline and shorten drug development cycles

Our methods

- A clear overview of existing DISs enables us to pinpoint information gaps in the drug life cycle
- We describe the past literature and existing technology of Drug Information Systems from a functional (IS) point of view

  (which is new in the area)

Drug life cycle (main phases)

- Discovery (incubation/before birth)
- Development (becoming mature)
  - Pre-clinical
  - Clinical
- Approval (declared adult)
- Marketing (adult life)

Kind of clinical trials

(per life cycle phase)

- Discovery (incubation)
- Development (becoming mature)
  - **Pre-clinical trials**
  - **Clinical trials (Phases I-III)**
- Approval (declared adult)
- Marketing (adult life)
  - **Phase IV clinical trials**

DIS types

compound DBs

contain the physico-chemical structural data

for the computational drug discovery methods

(pre-)clinical trial DBs

contain the (raw or aggregate) data of (pre-)clinical trials

SmPC DBs

contain SmPC's (Summary of Product Characteristics), the source of information visible to non-professionals (through drug labelling and package inserts)

DIS types

ADR DBs

contain data on adverse drug reactions (ADRs)

CPOE systems

Computerized Physician Order Entry (CPOE) systems automate the human error-prone parts of the process of the prescribing physician, especially with regard to drug prescription

DIS types vs. life cycle phases (cf. Figure 1)

	Discovery	Development Pre-clin.	Development Clin.	Approval	Marketing
Compound DBs	+				
(pre-)clinical trial DBs		+	+		+
SmPC DBs		+	+	+	+
ADR DBs					+
CPOE systems			+	+	+

DIS types and their content form (cf. Table 1)

	Quantitative data?	**Aggregated and/or Raw data?**
Compound DBs	Y	R
(pre-)clinical trial DBs except Janus	N Y	A R+A
SmPC DBs	N	A
ADR DBs	N	A
CPOE systems	N	A

Reviewed DISs (cf. Table 1)

	Name	**Start year of data**
Compound DBs	Cambridge Structural Database NCI DIS 3D database	1970 1994
(pre-)clinical trial databases	Janus Cochrane ClinicalTrials.gov EudraCT ClinicalStudyResults.org	- 1988 2000 2004 2004
CT/SmPC DB	NCI Drug Dictionary	1980’s

Reviewed DISs (cf. Table 1)

	Name	**Start year of data**
CT/SmPC DB	NCI Drug Dictionary	1980's
Other SmPC DBs	DailyMed EMEA EPAR Lung Association of Saskatchewan lung disease drug repository	1993 2004 2006
ADR DBs	MedEffect Canada EMEA ADR AERS (FDA)	N/A 2001 2004
CPOE systems	Various	Various

Concluding remarks

- There are several information gaps in the drug development process

  The gaps originate from systems that have been designed to support only some steps (rather than to comprehensively support all steps) of the complete drug lifecycle

- There is an actual need to fill the gap of quantitative data found by this survey

- The results of this survey can be taken as a starting point for information integration across DISs

Concluding remarks

- The best way seems to make them interoperable instead of aiming for a single integrated enterprise system
- Future systems should store all required measurements in a numerical format with strict semantics
- We are working on a more elaborate (survey like) paper
- For aggregate clinical trial results, we are currently building such a system, for approval purposes
  (see http://www.drugis.org, open source software)

Thank you for your attention