

The ADDIS software for evidence based health care policy

current status and future directions

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Introduction

- Aggregate Data Drug Information System (ADDIS)
 - Decision support for health-care policy decisions
 - Explicitly evidence-based
- Presentation outline
 - The past 4 years: ADDIS 1.x
 - Project context & goals
 - Demonstration of ADDIS 1.16.5
 - The next 3 years: ADDIS 2.x
 - Project context & goals
 - Our future plans
 - Demonstration of decision analysis component

Project Escher

- Escher is a national research project of the Dutch Top Institute Pharma that aims to improve drug regulation through science
- 16 PhD students and 4 PostDocs working in 5 universities (RUG/UMCG, UU/UMCU, Erasmus MC) in collaboration with industry (MSD, GSK, Amgen, WINap)



Escher 3.2 Goals

Develop a drug information system:

- Effective knowledge access and management
- Answer drug efficacy and safety questions
 - in an efficient, transparent and accountable way
 - within and across compounds
 - for a broad audience (including regulators)
- Improve consistency in regulatory decision making
- Based on systematic review and meta-analysis

Evidence-based health care policy

Basing policy on evidence is challenging:

- Data acquisition
 - e.g. systematic review
- Evidence synthesis
 - e.g. meta-analysis, disease state models
- Decision aiding / making
 - e.g. benefit-risk or cost-effectiveness analysis

Example: regulatory benefit-risk decision making

Regulatory decision making:

- Based on pivotal evidence from trials
- But not using formal decision modeling

Lack of (the use of) formal methods:

- Hides the reasoning that supports a decision
- Causes lack of transparency / traceability
- Raises doubt about consistency

Causes of informal process:

- Lack of suitable models/tools
- Explicit preferences → potential controversy

ADDIS: Aggregate Data Drug Information System

Decision support system for health care policy:

- Database of clinical trials
- Evidence synthesis (network meta-analysis)
- Decision aiding (multi-criteria benefit-risk analysis)

It is a partial solution:

- Database is assumed available (or delivered by company)
- Gathering the data is still a major hurdle!
- But the ADDIS 1.x system / data model is a first step

ADDIS 1.x demo

- And now for a quick demonstration...

IMI GetReal

- GetReal is a European project of the Innovative Medicines Initiative (IMI) that aims to integrate randomized and observational data to best inform relative effectiveness
- 5 work packages, 13 academic partners, 15 industry partners, ties with regulatory and reimbursement networks
- EUR 16mln funding, 130 person-years of effort over 3 years, primarily senior scientists



Innovative Medicines Initiative



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GetReal WP4

Objectives:

- Joint modeling of randomized and observational data
- Predicting relative effectiveness from randomized data
- Predicting differences in effectiveness between countries

Role of ADDIS:

- Data management for case studies
- Make methods usable by a wider audience

ADDIS in GetReal

IMI GetReal case studies will

- be more complex
- involve more data
- integrate data provided by multiple stakeholders

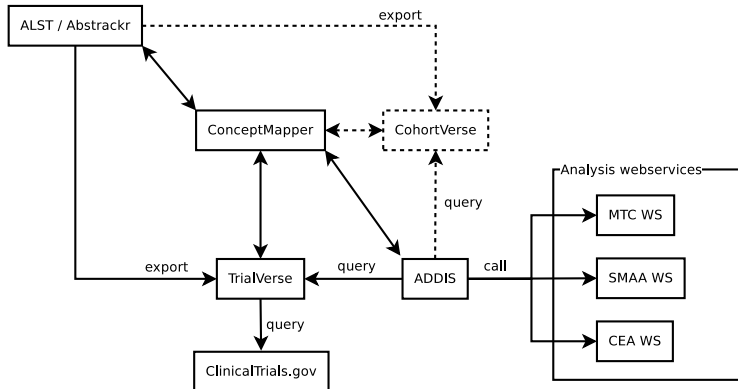
Current ADDIS 1.x architecture ill suited:

- sharing datasets is difficult
- simultaneously editing datasets impossible

ADDIS 2.x plans

- Web-based multi-user system
- Collaborative database building
- Flexible (ad hoc) data integration / harmonization
- Predictive modeling / relative effectiveness

ADDIS 2.x architecture



ADDIS 2.x status

Past year or so (part time, 2 persons):

- Implementation of R packages for analysis functionality
- Implementation of web-service wrapper around R
- Prototyping of other components

Coming 6 months (full time, 2 developers, 1 researcher):

- Analysis feature parity with ADDIS 1.x
- Automated import from many sources (e.g. ClinicalTrials.gov)
- Initial harmonization work

ADDIS 2.x demo

- And now for a quick demonstration...
 - of the first functional ADDIS 2.x component

Discussion

ADDIS 1.x

- Successful prototype of decision support for evidence-based policy decision making
- Generated a lot of interest
- But current architecture not feasible long-term

ADDIS 2.x

- New web-based architecture, collaborative database building
- Eventually we hope to solve the data acquisition problem
 - Drastically reduce need for systematic reviewing
- Many challenges ahead!