

Chapter 10

Stepwise Semantic Enrichment in Health-Related Public Management by Using Semantic Information Models

Hans-Georg Fill

University of Vienna, Austria & Stanford University, USA

Ilona Reischl

AGES PharmMed, Austria

ABSTRACT

The use of semantic technologies in practical scenarios requires carefully balancing the tradeoff between costs and benefits in order to gain acceptance. In this chapter we report on a project conducted together with the Austrian competent authority in regard to safety in healthcare. It is described how semantic technologies can be combined with conceptual models to support management executives in the distribution of knowledge and the analysis of compliance. The approach is based on a step-wise semantic enrichment of conceptual models with formal semantic schemata in order to support human analyses. It has been implemented on the ADONIS meta modeling platform and applied to a scenario dealing with the management of applications for clinical trials.

INTRODUCTION

Over the past years significant effort and money has been invested into research and industrial projects dealing with semantic technologies by funding organizations such as Darpa, the European

Commission, and Asian funding organizations (Bussler, 2008), (Bertolo, 2005). As a result, a large number of technologies, standards, and research prototypes are today available which permit to easily implement semantic functionalities and apply them to concrete use cases. Thereby, the unique value propositions of semantic technologies in

DOI: 10.4018/978-1-60960-126-3.ch010

order to meet critical real world challenges can be directly assessed cf. (Cardoso, et al., 2007). In the area of information systems, the process to introduce semantic technologies to practical scenarios is governed by the principles of design science. By building and evaluating artifacts in the form of constructs, models, methods, and instantiations (March and Smith, 1995) it can be shown how technologies can be implemented in a working system, thus allowing for the assessment of the suitability of the artifacts for their intended purpose (Hevner et al., 2004). As a consequence, the relevance of the technology for the constituent community, i.e. the practitioners who deal with information systems and their technologies can be estimated (Hevner et al., 2004). With the following elaborations we report on a research project that has been undertaken by the University of Vienna in cooperation with AGES PharmMed as the Austrian Competent Authority in regard to safety in health care. The main objective of the project was to develop IT-based solutions for supporting executives in the area of health-related public management, in particular for the approval of clinical trial applications. The methodology that has been elaborated for this purpose is based on the concept of *semantic information models*. It allows for the combination of visual conceptual models and semantic technologies on the basis of a meta modeling approach and follows a design-oriented research objective. The particular benefit of the approach lies in the facilitation of human analyses of complex visual conceptual models and their alignment to internationally used semantic schemata by using a step-wise approach. The purposes are to support knowledge distribution and compliance management, as well as to establish a basis for performance and resource management in health-related public management. The chapter is structured as follows: The next subchapter will give a brief introduction to the foundations used for our approach and describe the linkages to existing work. Thereafter we will present the details of the approach and how it influenced the

distribution of knowledge in the organization and the assurance of the performance and compliance of the processes. The chapter is concluded with an outlook on future research directions.

BACKGROUND

To provide the foundations for our approach we will briefly give some background information to outline the challenges in the domain of health-related public management, the use of conceptual modeling and meta modeling concepts to represent conceptual visual models and on the currently available semantic technologies in the area of health.

Health-Related Public Management

The development of new medical treatments and products at a high quality and an affordable price is today one of the central challenges in the area of health-related public management. In particular, the research for new drugs involves a large number of resources and imparts considerable risks that have to be taken on by pharmaceutical companies (Sauer and Sauer, 2007). Of every 5,000 molecules tested, about 250 substances enter preclinical testing, 10 enter clinical development and just one will be finally approved by the regulatory authorities and receive the marketing authorization (EFPIA, 2010). For the parties involved in this process it is therefore essential to ensure the efficient use of resources as well as the compliance to legal regulations. On the side of pharmaceutical companies, the findings from basic laboratory research have to be translated into new methods for diagnosis, therapy, and prevention. Despite the large number of tests that can already be conducted during this pre-clinical stage, the crucial data are accumulated during the clinical trial stage, where the substances are applied to humans. Depending on the phase of the clinical trial this involves either healthy volunteers or voluntary patients.

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