

## Metadata-based analysis to improve clinical trial exchange

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### Abstract

*There are various, important information sources devoted to the diffusion of clinical trials, but they fail to achieve a complete coverage of clinical research. The demand for a mandatory public registration of clinical trials is emerging from different institutions, which are making efforts to develop common metadata schemas to both increase information exchange and make this information publicly available. The paper describes a metadata analysis of the various solutions of CT data representations adopted by important stakeholders such as national Health authorities, database information providers and standardisation organisations.*

### 1. Introduction

Progress in medical research depends largely on the results of clinical trials (CT). In controlled conditions, and following methodologically sound procedures, CTs test specific clinical and therapeutical hypotheses on a sample of a pre-defined number of patients. CTs are mainly planned and funded by pharmaceuticals firms with an interest in testing new drugs or treatments, or by government agencies that back medical research.

Each state has its own regulatory mechanisms for clinical trials along with a corresponding policy for the diffusion of information on CTs. The 1964 Helsinki declaration, successively modified in 2004 [1], established the basic ethical principles that guide medical research when human subjects are involved. Among these principles, the declaration included that of the right to correct information. Regrettably, despite the existence of numerous databases that supply information on CTs, there is no comprehensive source of information on ongoing and concluded clinical studies and even when national registries are maintained, they are often accessible only to a limited number of bodies and regulatory agencies.

The internationalisation of the pharmaceuticals industry on the one hand, and of medical research on the other, today raise a series of issues, ranging from the need to disseminate information on clinical trials, so as not to duplicate costly research and to verify the results, to cutting experimentation time in order to increase medical knowledge to benefit public health. The drive to fulfil these objectives involves many stakeholders such as international bodies, medical and patients' associations, the pharmaceuticals industry, governmental research bodies and ICT and information specialists. The latter ones need to apply the appropriate technology to support the automation of the complex CT process as well as to develop systems for diffusing information both to potential patients and health professionals.

In the light of this, it is increasingly important to develop interoperable systems based on meta-data that can be easily exchanged among the different components of the CT process, simultaneously enabling diffusion of data on clinical trials also to external users. This explains the urgent demand from numerous stakeholders for CT registration to be made obligatory and for public access to such information. This is not only to fill an information gap, but also to lay the foundations for the development of a common language for information exchange.

This paper presents part of an analysis included in a larger project, which has a twofold aim:

- a) the development of a comprehensive CT model which makes it possible to identify suitable tools to automate the entire process;
- b) ICT support to increase interoperability between organisations, platforms and applications.

To reach the first goal we have modelled the interaction between the CT sub-processes [2], we have identified the roles and information needs of the stakeholders directly participating in the process (coordinating centre, investigators, statisticians, etc.) as well as the information needs of the stakeholders *outside* the process (National Health authorities, systematic reviewers, physicians, patients looking for alternative care treatments).

The second objective, described in this paper, requires a preliminary analysis of the various solutions of CT data representations adopted by important stakeholders such as national Health authorities, information providers and standardisation organisations, which are currently making efforts to develop a common