Standard requirements for GCP-compliant data management in multinational clinical trials.

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Abstract:
BACKGROUND:
A recent survey has shown that data management in clinical trials performed by academic trial units still faces many difficulties (e.g. heterogeneity of software products, deficits in quality management, limited human and financial resources and the complexity of running a local computer centre). Unfortunately, no specific, practical and open standard for both GCP-compliant data management and the underlying IT-infrastructure is available to improve the situation. For that reason the "Working Group on Data Centres" of the European Clinical Research Infrastructures Network (ECRIN) has developed a standard specifying the requirements for high quality GCP-compliant data management in multinational clinical trials.
METHODS:
International, European and national regulations and guidelines relevant to GCP, data security and IT infrastructures, as well as ECRIN documents produced previously, were evaluated to provide a starting point for the development of standard requirements. The requirements were produced by expert consensus of the ECRIN Working group on Data Centres, using a structured and standardised process. The requirements were divided into two main parts: an IT part covering standards for the underlying IT infrastructure and computer systems in general, and a Data Management (DM) part covering requirements for data management applications in clinical trials.
RESULTS:
The standard developed includes 115 IT requirements, split into 15 separate sections, 107 DM requirements (in 12 sections) and 13 other requirements (2 sections). Sections IT01 to IT05 deal with the basic IT infrastructure while IT06 and IT07 cover validation and local software development. IT08 to IT015 concern the aspects of IT systems that directly support clinical trial management. Sections DM01 to DM03 cover the implementation of a specific clinical data management application, i.e. for a specific trial, whilst DM04 to DM12 address the data management of trials across the unit. Section IN01 is dedicated to international aspects and ST01 to the competence of a trials unit's staff.
CONCLUSIONS:
The standard is intended to provide an open and widely used set of requirements for GCP-compliant data management, particularly in academic trial units. It is the intention that ECRIN will use these requirements as the basis for the certification of ECRIN data centres

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Hivatkozások
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