Revising the ECRIN standard requirements for information technology and data management in clinical trials

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Abstract:

The pilot phase of the ECRIN (European Clinical Research Infrastructure Network) certification programme for European data centres, in late 2011, led to a substantial revision of the original ECRIN standards, completed by June 2012. The pilot phase, the conclusions drawn from it and the revised set of standards are described. Issues concerning the further development of standards and related material are discussed, as are the methods available to best support that development. A strategy is outlined based on short-lived specific task groups, established as necessary by a steering group drawn from ECRIN-ERIC. A final section discusses possible future developments.

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