Common definition for categories of clinical research: a prerequisite for a survey on regulatory requirements by the European Clinical Research Infrastructures Network (ECRIN)

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Abstract:
BACKGROUND:
Thorough knowledge of the regulatory requirements is a challenging prerequisite for conducting multinational clinical studies in Europe given their complexity and heterogeneity in regulation and perception across the EU member states.
METHODS:
In order to summarise the current situation in relation to the wide spectrum of clinical research, the European Clinical Research Infrastructures Network (ECRIN) developed a multinational survey in ten European countries. However a lack of common classification framework for major categories of clinical research was identified, and therefore reaching an agreement on a common classification was the initial step in the development of the survey.
RESULTS:
The ECRIN transnational working group on regulation, composed of experts in the field of clinical research from ten European countries, defined seven major categories of clinical research that seem relevant from both the regulatory and the scientific points of view, and correspond to congruent definitions in all countries: clinical trials on medicinal products; clinical trials on medical devices; other therapeutic trials (including surgery trials, transplantation trials, transfusion trials, trials with cell therapy, etc.); diagnostic studies; clinical research on nutrition; other interventional clinical research (including trials in complementary and alternative medicine, trials with collection of blood or tissue samples, physiology studies, etc.); and epidemiology studies. Our classification was essential to develop a survey focused on protocol submission to ethics committees and competent authorities, procedures for amendments, requirements for sponsor and insurance, and adverse event reporting following five main phases: drafting, consensus, data collection, validation, and finalising.
CONCLUSION:
The list of clinical research categories as used for the survey could serve as a contribution to the, much needed, task of harmonisation and simplification of the regulatory requirements for clinical research in Europe.

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