RISK-BASED MONITORING APPROACH IN ACADEMIC CLINICAL RESEARCH

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BACKGROUND: Academic clinical research requires optimization of limited resources. Monitoring intensity may be adapted to a standardized risk-based approach.

OBJECTIVE: To design a risk-assessment method and a risk-based monitoring strategy for academic clinical research, in compliance with Good Clinical Practice.

METHODS: Risk-based approach principle, and study characteristics were assessed by academic clinical research professionals through a Delphi consensus method, with questionnaires, and a final meeting. Risk-assessment validity was evaluated on operational protocols. A risk-assessment method was proposed, and a risk-adapted monitoring standard operating procedure (SOP) was designed.

RESULTS: Fifty-one professionals from 11 European countries answered the questionnaires. The risk-based approach was accepted (100%). Two primary risks (for participant, and results validity) and 3 secondary risks (for organisation, governance, and target population and public health) were defined, and considered as relevant for assessment. Among 36 study characteristics proposed, 19 were selected for relevance. Twenty-four trial protocols were assessed for risk and characteristics by 15 volunteer professionals. Reproducibility was bad, due to a large inter-assessor variability. So a committee was set-up, and trained to assess risk in 3 levels. The SOP requires the design of a trial-specific monitoring plan, where key-data for monitoring are defined. The number of on-site monitoring visits required on a protocol-specific basis depends on risk level, complexity of trial, and rate of subject enrolment.

CONCLUSION: We defined a risk-assessment method, and a risk-adapted monitoring strategy, with a large delimited extent. This approach aims at optimizing resources among academic clinical research. It will be used, and assessed along with ECRIN activities.