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Title: Development of a risk-based trial management and central monitoring concept and visualization of critical assets in a study dashboard to support trial management and central monitoring

Introduction: Identifying the most critical assets of a clinical trial is important to support trial conduct and ensure patient's safety. New risk-based monitoring approaches have been introduced that differentiate between different risk categories of trials based on an initial risk assessment and central monitoring has become more important in the guidance of on-site monitoring.

A continuous evaluation and visualization of critical assets identified by a detailed study specific risk assessment would inform the principal investigator about the study progress, e.g. in terms of recruitment, endpoint assessment, adverse events, as well as on the performance of the study and individual centers in terms of data management and data quality. Information of the trial progress and quality of performance may also guide decisions on where resources, training, monitoring etc. is needed the most. The visualization of performance quality raises the awareness of discrepancies, lack of training or even misconduct and enables early interference in case of low quality performance.

Objective: To develop a generic dashboard that can be adapted for different types of clinical studies and that visualizes the performance quality of most critical assets for trial conduct and trial monitoring.

Methods: The new risk-based trial management and central monitoring concept was developed in a project group of the Department of Clinical Research in Basel. The new concept is based on stakeholder input and a systematic literature search (Klatte K. 2019) and is focused on the identification of trial specific risks that are likely to impact critical assets of the study conduct. Based on study specific risk assessments, we are currently developing a study dashboard for a clinical trial. A study dashboard created by the data science team for the ESTREL study (Subramaniam S.) is the basis for the development of the concept based dashboard. Learning from the experience, we will build a generic dashboard template that can be used for future trials.

In order to evaluate the impact of the new concept and the operating dashboard, there will be a test phase of the study dashboard in 2021. All persons involved with the operation and application of the dashboard will be interviewed after this test phase to assess benefits in terms of study management and conduct and in terms of performance quality.

Results: Having developed a dashboard based on our new concept of risk-based trial management and central monitoring for one clinical trial, we can present the different aspects of the dashboard that were implemented to support the conduct of these trials.

Conclusion: We expect that the study dashboard will support trial conduct, trial management and trial monitoring and improve the guidance of resource use.