

## Research Project

### Learning from failure – Understanding the mechanisms of trial discontinuation

#### Third-party funded project

**Project title** Learning from failure – Understanding the mechanisms of trial discontinuation

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**Organisation / Research unit**

Departement Klinische Forschung / Klinische Epidemiologie (Bucher H)

Ethik / Bio- und Medizinethik (Elger)

**Department**

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**Probable end** 30.12.2016

**Status** Completed

One out of four randomized controlled trials (RCTs) is discontinued; insufficient recruitment of participants is the most frequent reason, in particular in investigator-initiated RCTs. Trials initiated by commercial sponsors are less likely to be discontinued suggesting that professional planning and conduct as well as sufficient funding of RCTs help complete recruitment as planned. Currently, the mechanisms and specific root causes of trial discontinuation remain unclear. Evidence-based guidance for trialists and other stakeholders on how to plan and assess recruitment in RCTs is lacking. In most cases, participants and research ethics committees (RECs) are not informed about discontinuation or publication of trial results. Accounts of the work done so far are not disseminated to the scientific community in up to 60% of discontinued RCTs. This entails ethical problems: The patients' and the public's trust in clinical research is undermined, and finite research resources are wasted. It is unknown to what extent trialists are aware of the ethical implications with trial discontinuation and what their attitudes and views are.

We propose three complementary projects that will use both qualitative and quantitative methods to better understand the mechanisms that lead to RCT discontinuation, find ways to meet the associated ethical challenges, and develop guiding principles for involved stakeholders. In Project A we will conduct semi-structured interviews with principal investigators of RCTs discontinued for insufficient recruitment and with key stakeholders of clinical research in Switzerland representing Clinical Trial Units, RECs, the Swiss National Science Foundation (SNSF), the pharmaceutical industry, and Swissmedic. Project B will empirically examine all health-care RCTs funded by the SNSF to explore whether a rigorous selection of trials for funding and monitoring decreases the risk of trial discontinuation including potential effects of full versus partial funding. In Project C we will perform a comprehensive analysis of recruitment patterns from about 500 completed and discontinued RCTs conducted in different countries and settings. It will explore whether insufficient recruitment can reliably be identified at an early stage and determine optimal time points and criteria for the assessment of recruitment progress in RCTs.

Using a mixed methods approach, this study will further our understanding of the complex mechanisms leading to failure in trial recruitment and identify potential lever points for targeted interventions. Following on the successfully completed DISCO study it will continue a line of methodological research that is of high relevance to clinical researchers and trial participants in Switzerland and abroad. At a time in which the legal framework of research involving humans is being revised, the study will provide a most needed empirical base for the elaboration of guidance documents to be used by trialists and other stakeholders.

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Foundations and Associations

**Add publication**

**Add documents**

**Specify cooperation partners**