

Publication

Exploring reasons for recruitment failure in clinical trials: a qualitative study with clinical trial stakeholders in Switzerland, Germany, and Canada

JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

ID 4657873

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Year 2022

Title Exploring reasons for recruitment failure in clinical trials: a qualitative study with clinical trial stakeholders in Switzerland, Germany, and Canada

Journal Trials

Volume 22

Number 1

Pages / Article-Number 844

Mesh terms Ethics Committees, Research; Germany; Humans; Patient Selection; Qualitative Research; Switzerland

Background: Poor participant recruitment is the most frequent reason for premature discontinuation of randomized clinical trials (RCTs), particularly if they are investigator-initiated. The aims of this qualitative study were to investigate (1) the views of clinical trial stakeholders from three different countries regarding reasons for recruitment failure in RCTs and (2) how these compare and contrast with the causes identified in a previous systematic review of RCT publications. Methods: From August 2015 to November 2016, we conducted 49 semi-structured interviews with a purposive sample of clinical trial stakeholders. This included investigators based in Germany (n = 9), Switzerland (n = 6) and Canada (n = 1) with personal experience of a discontinued RCT and 33 other stakeholders (e.g., representatives of ethics committees, clinical trial units, pharmaceutical industry) in Switzerland. Individual semi-structured qualitative interviews were conducted and analyzed using thematic analysis. Results: Interviewees identified a total of 29 different reasons for recruitment failure. Overoptimistic recruitment estimates, too narrow eligibility criteria, lack of engagement of recruiters/trial team, lack of competence/training/ experience of recruiters, insufficient initial funding, and high burden for trial participants were mentioned most frequently. The interview findings largely confirm the previous systematic review on published reasons for recruitment failure. However, eight new reasons for recruitment failure were identified in the interviews, which led to the checklist of reasons for recruitment failure being revised and a new category describing research environment-related factors being added

Publisher BMC

ISSN/ISBN 1745-6215

edoc-URL <https://edoc.unibas.ch/92283/>

Full Text on edoc Available;

Digital Object Identifier DOI 10.1186/s13063-021-05818-0

PubMed ID <http://www.ncbi.nlm.nih.gov/pubmed/34823582>

ISI-Number WOS:000722604100005

Document type (ISI) Journal Article