University of Basel
Department of Clinical Research

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# Information sheet

## Successful recruitment of study participants

*Inadequate recruitment is the most common reason for premature termination of randomised clinical trials (RCTs). This is particularly true for academic trials initiated by sponsor-investigators [1].*

*The reasons for recruitment failure in RCTs are multiple and often interrelated [2,3]. Many causes are considered preventable and therefore should be appropriately considered when planning clinical trials [4].*

### Measures

This table summarises the 10 most common causes of inadequate recruitment [3] and suggests measures to address them in order to reduce the risk of missing recruitment goals.

| 10 most common causes for inadequate recruitment [3] | Measures | Tips & support |
|---|---|---|
| **1. Number of recruitable individuals is overestimated** | • Perform estimation of realistic recruitment numbers based on data from routine clinical practice<br>• Run through the recruitment process in practice | • Info sheet “Estimation of recruitment numbers based on routine data»<br>• Info sheet «Recruitment process in clinical practice» (soon available) |
| **2. Inclusion/exclusion criteria are defined too narrowly** | • Carefully consider all inclusion and exclusion criteria<br>- Are all criteria really necessary?<br>- What impact do the individual criteria have on the number of possible participants?<br>- Define as few exclusion criteria as possible | • Info sheet “Definition of inclusion and exclusion criteria» (soon available) |
| **3. Recruitment is not coordinated well enough with routine procedures in the clinic** | • Adapt the study procedures to the routine procedures in the clinic<br>- Is it clear who is responsible for what, when and where?<br>- Can all responsible persons do their work for the study in addition to routine tasks?<br>- Do the processes work in all centres?<br>- Do the study visits run smoothly from the participants' point of view?<br>- Do participants have additional burdens that could perhaps be avoided? | • Free consultation service on the logistical planning of clinical studies<br>• Free consultation service on the involvement of patients (PPI)<br>• Use of the Outpatient Study Centre (ASZ) |
| **4. Administrative hurdles and time required is too high for the study team or priorities are not clear**<br><br>**Effort for participants is too high** | | |

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| **5. Commitment/collaboration in the study team is lacking** | • Avoid "trial fatigue" through professional project management and careful communication<br>• Openly discuss identification with the study question with all study centres (decision-makers and recruiters) before the start of the study and question the participation of the centre in case of reservations | • Continuous education course «Project Management in Clinical Study Operations»<br>• Free consultation service on how to formulate a research question |
| **6. Identification with the research question is insufficient (equipoise)** | | |
| **7. Initial funding is insufficient** | • Carry out budget planning and control | • Free consultation service on budget planning<br>• Search various funding opportunities |
| **8. Other studies recruit the same patient population or require the same resources** | • Search for ongoing studies at participating study sites | • Assistance in searching study registries (ClinicalTrials.gov or SNCTP study portal)<br>• Free consultation on the recruitment of study sites |
| **9. Study design is too complex to explain and to implement** | • Keep study design as simple as possible<br>- Is the focus on the original research question?<br>- Are all secondary endpoints really necessary?<br>- How complex is the practical implementation of the study?<br>- Can the study be integrated into everyday clinical practice?<br>- Are there sufficient human resources? | • Free consultation service on study methodology and design<br>• Inroductory courses for new study nurses<br>• Use of the Outpatient Study Center (ASZ)<br>• Templates for SOPs, study documents and other documents<br>• Support in the preparation of study information and advertisements |
| **10. Methodological and logistical support is lacking** | | |

For all topics listed above and further questions regarding your research project please contact us at https://contactform.dkfbasel.ch

## References

[1] Prevalence, characteristics, and publication of discontinued randomized trials. Kasenda B, von Elm E, You J, Blümle A, Tomonaga Y, Saccilotto R, Amstutz A, Bengough T, Meerpohl JJ, Stegert M, Tikkinen KA, Neumann I, Carrasco-Labra A, Faulhaber M, Mulla SM, Mertz D, Akl EA, Bassler D, Busse JW, Ferreira-González I, Lamontagne F, Nordmann A, Gloy V, Raatz H, Moja L, Rosenthal R, Ebrahim S, Schandelmaier S, Xin S, Vandvik PO, Johnston BC, Walter MA, Burnand B, Schwenkglenks M, Hemkens LG, Bucher HC, Guyatt GH, Briel M. JAMA. 2014 Mar 12;311(10):1045-51. doi: 10.1001/jama.2014.1361. PMID: 24618966.

[2] Insufficient recruitment and premature discontinuation of clinical trials in Switzerland: qualitative study with trialists and other stakeholders. Briel M, Elger B, von Elm E, Satalkar P. Swiss Med Wkly. 2017 Nov 16;147:w14556. doi: 10.4414/smw.2017.14556. PMID: 29185240.

[3] Exploring reasons for recruitment failure in clinical trials: a qualitative study with clinical trial stakeholders in Switzerland, Germany, and Canada. Briel M, Elger BS, McLennan S, Schandelmaier S, von Elm E, Satalkar P. Trials. 2021 Nov 25;22(1):844. doi: 10.1186/s13063-021-05818-0. PMID: 34823582; PMCID: PMC8613940.

[4] A systematic review of discontinued trials suggested that most reasons for recruitment failure were preventable. Briel M, Olu KK, von Elm E, Kasenda B, Alturki R, Agarwal A, Bhatnagar N, Schandelmaier S. J Clin Epidemiol. 2016 Dec;80:8-15. doi: 10.1016/j.jclinepi.2016.07.016. Epub 2016 Aug 3. PMID: 27498376.