Recruitment methods

RECRUITMENT

Participants for clinical trials

INTRODUCTION

This material is made by the PACT project (Patient Centered Clinical Trials), which is a public-private partnership project to facilitate easy access to clinical research in Denmark:

- To improve overview of ongoing clinical research.
- To facilitate access to clinical trials by strengthening recruitment.
- To strengthen decentralization of clinical trials to facilitate completion of clinical trials closer to the patients.

This material will be continuously updated.

Please contact Trial Nation for any further questions or clarifications concerning recruitment of participants for clinical trials.

- This material is meant to inspire and help when choosing recruitment methods in connection with clinical intervention trials.
- When using this material, users must still comply with current legislation and any future amendments.
- There are more recruitment methods than those introduced in this material. The methods presented here are validated across the Danish healthcare authorities and currently the most widely used.
- Researchers in collaboration with research support services are responsible for ensuring that methods comply with current legislation.

GENERAL GUIDELINES

Approval from relevant authorities
Before recruitment make sure all necessary approvals from authorities have been obtained.

Collaboration with external partners
Must comply with current legislation, including EU General Data Protection Regulation (GDPR). Written collaboration agreements are required.

Handling and storage of data
Must comply with EU GDPR and local guidelines.
Written collaboration agreements must be made with collaborators concerning research data responsibility.

Recruitment arrangement and material for potential trial participants
The material must clearly state that when responding, potential participants only consent to receive further information.

When drafting the recruitment material, it is important to state clear selection criteria for trial participation.

Recruitment strategies must be thoroughly described in the protocol for applications under EU Clinical Trial Regulation (CTR) in Part II. Further information at the Danish National Center for Ethics website.

The scientific ethics committee system

- The relevant scientific ethics committee must approve all material for potential trial participants in all intervention trials.
- When applying for approval, the overall trial must be described, how trial participants are identified, how to contact participants, and which information will be provided. The material, including photos and illustrations, must be objective.
- When a trial has been approved by the scientific ethics committee, the investigator can receive medical record data from the treating physician/medical team, to recruit the patients complying with in inclusion and exclusion criteria, if this has been described in the application. The investigator cannot approach patients unless permission has been granted from the treating physician or the hospital management.

RECRUITMENT METHODS

The topics listed below, represent the validated and most widely used recruitment methods in Denmark.

Consult your Danish research colleagues if these methods are of interest, to get the best set-up for your particular clinical trial.

- Social media
- Recruitment of patients in active treatment
- Private recruitment platforms
- Local databases for future research purposes
- Distribution or invitation by mail
- Digital mail and information campaigns
- Use of the electronic health record in recruitment
- Recruitment through patient associations
- Collaboration with pharmacies

Social media

- Advertising for a clinical trial on SoMe must always be approved by the scientific ethics committee and refer to a home page with a trial description and where interested participants can type in their own contact details or find contact details for the investigator. This will allow the investigator or the trial team to establish contact.
- It must not be possible to comment on or tag others in posts on social media advertising for clinical trials.
- Organisations may have local guidelines for posts on e.g., SoMe and intranet. When using the public SoMe profile of a department, participants must be able to reply using a secure mail or contact system.
- Several SoMe platforms can target posts for specific users and use algorithms to target posts to specific segments, including specific patient populations, because users of these platforms have consented to giving out this information when they created a profile. The price for this type of advertising varies.
- Advertising on e.g., Facebook can also be shared at other SoMe platforms such as Instagram and LinkedIn.

Recruitment of patients in active treatment

- Many relevant candidates for clinical trials are identified by physicians in connection with admission or outpatient visits. A patient's interest is documented in the medical record, and the trial responsible contacts the patient for further information.
- Only physicians can include trial participants in clinical trials involving medicine.

Private recruitment platforms

- Private recruitment companies offer help to recruit participants through their own databases of potential trial participants who have accepted to be contacted for participation in research. These companies will search databases for potential participants and contact these or advertise on their website or SoMe platforms. Prices for these services vary.

Local databases for future research purposes

- A clinical department can have a local database of patients who have consented to be contacted in connection with future research projects.
- The patients consent to clearly defined data registered in the database, how long the data can be registered in the database and if new data will be registered continuously.

Use of the electronic health record in recruitment

- The electronic health record can be used to identify potential trial participants for current or future trials. This pre-screening can outline if there is an adequate number of eligible candidates for a specific trial. Permission is not required to estimate number of potential trial participants based on relevant inclusion and exclusion criteria (no personal data is retrieved). Permission is needed before identification and contact is made.
- It is important to translate search parameters into adequate codes for accurate results.

Distribution or invitation by mail

- Invitations by mail, digital mail and information campaigns can be used to recruit participants.
- Consult your Danish research colleagues if these methods are of interest, to get the best set-up for your particular clinical trial.

Digital mail and information campaigns

- Invitations by mail, digital mail and information campaigns can be used to recruit participants.
- Consult your Danish research colleagues if these methods are of interest, to get the best set-up for your particular clinical trial.

Recruitment through patient associations

- Patient associations can distribute recruitment material to their members but cannot provide personal information about members to trial responsible or trial staff without member consent.
- Patient associations may be involved in recruitment. The Danish collaborator must be consulted on local rules and guidelines.

Collaboration with pharmacies

- Pharmacies are visited by a broad part of the population – both healthy people and people with specific diseases who may be eligible for clinical trials.
- Pharmacies may be involved in recruitment. The Danish collaborator must be consulted on local rules and guidelines.

Contact

For more information, please contact us at: contact@trialnation.dk

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