SDU
CLINICAL TRIAL UNIT

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University of Southern Denmark

VISION

Through clinical research, the Clinical Trial Unit aims to contribute towards better health and drug safety, and to communicate the results so that they can become common knowledge and achieve broad acceptance.

The Clinical Trial Unit is an independent project unit under the University of Southern Denmark, specialising in phase IV studies. The unit has specialised in running clinical trials in cooperation with general practice and with a focus on post-marketing safety.

The main office is located at J.B. Winsløws Vej 25, in Odense.

We are specialists and handle most tasks in connection with the implementation of clinical trials.

Therefore, it is possible for practising doctors to cooperate with the Clinical Trial Unit regarding participation in clinical trials where they would otherwise be too busy to participate or lack the resources.

As the project unit under the University of Southern Denmark, we want to guarantee that the studies in which the Clinical Trial Unit participates meet all regulatory requirements and legislation concerning Good Clinical Practice.

Therefore, another requirement regarding cooperation with carrying out clinical trials is that the research questions that the studies pose are of general interest and have a scientific purpose.

We also expect to have full access to the study data and the right to publish the results.

WHO WE ARE

The Clinical Trial Unit consists of a day-to-day manager, project doctor, project secretary, project nurse, student assistants, and the head and founder of the Clinical Trial Unit, professor, consultant, MD Jesper Hallas, internationally recognised drug researcher.

As a project unit, we are characterised by our broad competences and subject knowledge. Project nurses have many years of clinical experience from both the primary and secondary sectors. This means that the unit can handle many different areas of specialisation and is in constant development, which is something we highly prioritise.

Furthermore, several members have a master's degree, while others took the specialised training in intensive nursing or diploma courses. Everyone has completed a diploma course in GCP and is a member of Dansk Selskab for Good Clinical Practice.

We are flexible and ready to adapt, and we can always adjust our work procedures to match individual tasks. Implementation and cooperation on previous and current trials has been successful. These trials include phase III, phase IV as well as register trials.

MISSION

The University of Southern Denmark Clinical Trial Unit carries out pragmatic clinical trials as well as register research of the highest international quality. Based on a scientific approach and broad specialist competences, we carry out trials in cooperation with other universities, the drug industry, CRO companies, the Regions as well as general practice.

WE COOPERATE

The Clinical Trial Unit cooperates with other universities internationally. Furthermore, we cooperate with the medical industry, hospitals, CRO companies and general practice.

Over the years, we have established a unique collaboration with over 300 medical practices throughout Denmark. We have created a solid and closely-knit network, which we expect to draw from in connection with future trials.

CTU's day-to-day cooperation relationships:

CTU’s cooperation with general practice

WHAT SETS US APART

What sets the Clinical Trial Unit apart is our flexibility and continuous contact with both trial participants and practising doctors.

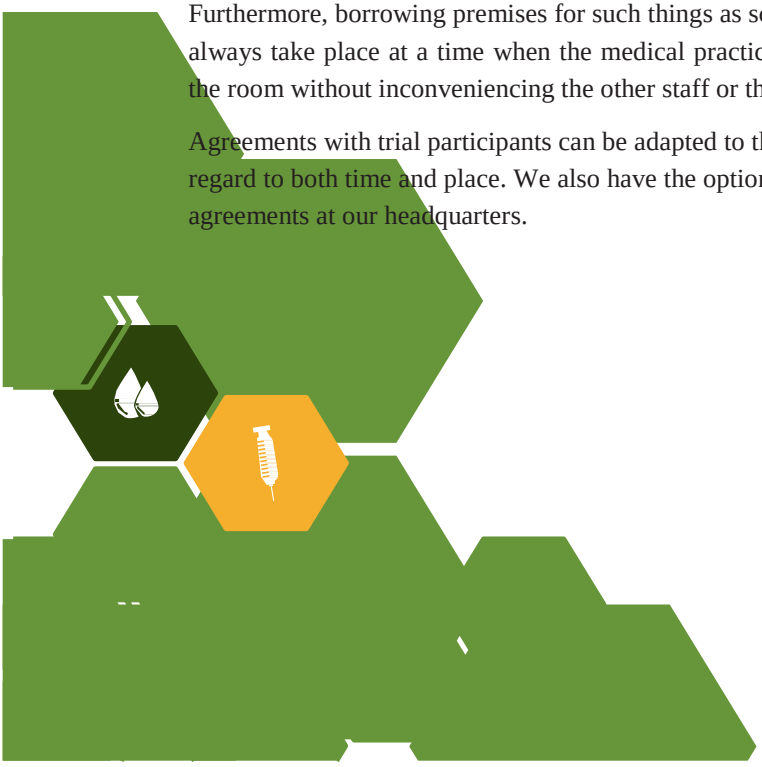
This flexibility and way of working is possible because project nurses are based in different places around the country and have the possibility to adapt the work accordingly.

We are therefore not dependent on bringing the work home. We are very capable of mobilising ourselves in accordance with our work, either to the participant's premises, to a medical practice or to other places.

When running a trial, it is important for us to consider the schedule of practising doctors as much as possible, so that initiation meetings and other meetings are scheduled at the least inconvenient times.

Furthermore, borrowing premises for such things as screening visits always take place at a time when the medical practice can provide the room without inconveniencing the other staff or the patients.

Agreements with trial participants can be adapted to their needs, in regard to both time and place. We also have the option of making agreements at our headquarters.



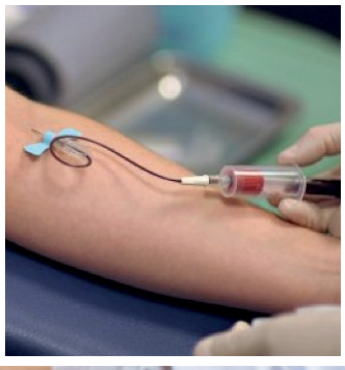
THIS IS WHAT WE EXCEL AT

The project nurses are specialised so as to undertake the most possible tasks when running a clinical trial.

They can carry out both administrative and practical tasks.

Examples of administrative tasks:
Recruitment of medical practices, assisting with various approvals by the authorities, information meetings with practising doctors, identifying suitable trial participants from the central register, assessment of the suitability of trial participants in cooperation with practising doctors, invitations to potential participants and calling them in for screening visits, reporting events, collecting materials for endpoints, updating the Study Site File and status meetings with practising doctors for the purpose of informing the trial participants.

Examples of practical tasks:
Informative conversations with the trial participants, obtaining informed consent at screening visits, randomising the trial participants, follow-up interviews, clinical tests (e.g. BT, dipsticks, ECG, height, weight, taking blood samples), centrifuging blood tests and logistical administration to ensure that the tests reach the specified analysis location, ordering trial medicine, cooperation with the primary sector regarding drug administration, ordering transport for trial participants.



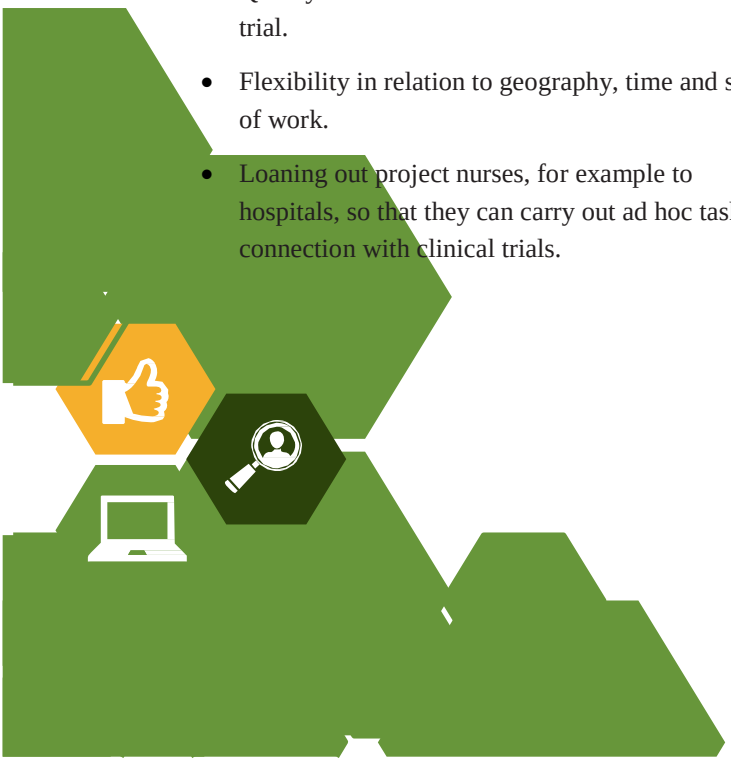
PREVIOUS STUDIES:

- SCOT (phase IV trial), Standard care vs Celecoxib Outcomes Trial. Randomised trial on the cardiovascular safety of using celecoxib compared with conventional NSAID treatment. The trial is carried out as a naturalistic trial in general practice.
- FAST (phase IV trial), Febuxostat vs Allopurinol Streamlined Trial. Randomised study on the risk of developing cardiovascular disease in patients with gout when undergoing treatment with allopurinol and febuxostat. The trial is carried out as a naturalistic trial in general practice.
- Compose (phase III trial), placebo-controlled trial for evaluating the long-term safety of naldemedine for treatment of opioid-induced constipation in patients with non-malignant chronic pain. The trial is carried out in general practice and hospitals.
- Agomelatine (register trial), large multinational trial based on data from health registers for evaluating the safety of using agomelatine, which is a newer drug for treatment of depression.

FOR FUTURE COOPERATION PARTNERS

Among the things we offer are:

- Good, close contact with more than 1/4 of Denmark's medical practices.
- Cooperation on several types of clinical trials.
- Extensive experience with carrying out Phase IV trials and a high professional standard.
- Quality assurance of the scientific questions in the drug testing trials.
- The possibility to use central registers to identify suitable trial participants that can subsequently be invited by their own doctor.
- Quality assurance of the scientific results of the trial.
- Flexibility in relation to geography, time and scope of work.
- Loaning out project nurses, for example to hospitals, so that they can carry out ad hoc tasks in connection with clinical trials.



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