Call for Clinical Trials in Cancer 2018 (Step 2)

The strategic research area for cancer at Lund University (LU) hereby announces a call for support to execute clinical trials with focus on **translational cancer research**. The call is a 2-step process where in the first step up to 9 projects were granted with 250,000 SEK per project in 2017. Step 1 was intended to cover costs for finalizing an approved protocol, fees for ethical and biobank approval, and biostatistical support. In step 2 you will need approval from ethical committee in order to fulfil the criteria for submitting a full proposal. You can apply directly to step 2 if you fulfil all criteria listed below (not mandatory to have approved application in step 1 to apply in step 2).

**Purpose**
The strategic aims of this call are to:
(1) Support initiation of clinical studies based on basic research findings that truly bridge preclinical and clinical disciplines in the cancer field
(2) Engage both young pre-clinical and clinical researchers at the level of PhD studies and postdoctoral level
(3) Promote interactions between pre-clinical and clinical researchers

**Important dates**
9 November 2018 – Call opens
7 January 2019 – Deadline to submit application
30 January 2019 – External review finished
4 February 2019 – Decisions announced

**Project start**: 4 February 2019

**Total budget**: Max 5,000,000 SEK (max 2 projects)

**Eligibility criteria**
- Only one application per main applicant is allowed
- Both pre-clinical and clinical researchers should be part of the project team
- Young researcher at the level of PhD studies and postdoctoral level should be part of the project team
- A clinical trial has the purpose of enabling prevention, diagnostics, or interventional treatment of a malignant disease
- The intervention may include systemic therapy with a registered pharmaceutical agent but also a novel indication as well as surgical or radiotherapeutic intervention
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- Study designs include PROSPECTIVE cohort studies and randomised controlled trials with a defined clinical and translational end-point
- Ethical approval (scanned documents mandatory)
- Project plan including protocol synopsis with objectives and endpoints determined and statistical power or sample size calculations provided (use provided template)

Evaluation
Evaluation among eligible applicants will be done by at least 2 external reviewers based on 4 basic criteria:
(1) Novelty and originality: Grading 7-1
(2) Scientific quality of the proposed research: Grading 7-1.
(3) Merits of the applicant: Grading 7-1
(4) Feasibility: Grading 3-1

Overall grade: Grading 7-1
Projects with an excellent plan, including well defined protocol (and approvals in place), for clinical correlation or implementation of basic research findings are prioritized.

Ranking and Decision Process
External reviewers will rank the project applications individually according to the grading. Under-represented gender of applicant should be prioritised at final ranking of candidates with equal scores.

The final decision is made by BioCARE board based on the overall recommendation from the external reviewers.

Follow-up
A project report, including both scientific and budget aspects should be submitted at the end of the project based on provided templates.

Application format
The application should contain the following documents (max 30 pages in total; 12 pt), all with the name of the main applicant in the header of each page (use provided template with the following headings):

(1) A single cover page with general information as follows:
   a. Project Title
   b. Project team: Describe the composition of the project team and collaboration pre-clinical and clinical researchers, including young scientists
      i. Name of the main applicant, current position and affiliation
      ii. Name of the co-applicant(s), current position (s) and affiliation (s)

(2) Project plan (max 8 pages a-f including the cover page; pages in Appendix g (estimate 13-20 pages) are depending on number of CVs, granted approvals (mandatory Ethics approval plus Informed Consent Form) and if any reporting for step 1 is provided; 12 pt)
a. Background: Describe the rationale of the proposal based on your own research findings or clinical expertise and include references (max one page)

b. Timelines for your project before initiation of trial and planned initiation date (max one page) (timelines for actual trial should be included in the study protocol synopsis)

c. List approval(s) (one page) together with their status and provide scanned copies as appendix with serial numbers with date and duration for approved permits/approvals) e.g. Ethical Committee (mandatory approval needed and mandatory to provide scanned copy of approved permit specific for the trial together with Informed Consent Form (ICF usually 2-5 pages). Other approvals could be such as biobank approval, Medical Product Agency and/or Swedish Radiation Safety Authority approvals.

d. List one page with other documents needed for starting the clinical trial together with their status. Other documents needed could be Investigators Brochure for example.

e. Budget (max 1 page) including indirect costs (INDI) with specification of personnel costs, running costs, patient visits etc. Add information about co-funding (source, amount, period). You should divide the budget into a) pre-trial costs and b) actual trial costs, if possible

f. Study Protocol Synopsis (max 2 pages)

g. Appendix (no specific page limit)
   i. Curriculum vitae of main applicant and co-applicant(s) (max 2 pages per applicant) – important to add relevant experience and courses related to clinical trials
   ii. Scanned copies of approvals (no specific page limit) – ethics committee approval (1-2 page) mandatory together with approved Informed Consent Form (2-5 pages) – which should be specific for the trial.

Additional only for applicants with granted application in Call for Clinical Trial in Cancer 2017 - step 1

   iii. Report for step 1 – progress report for the whole 12-month period step 1 including written 6-month project report (max 2 pages) and economic report (max 1 page). Use provided template for reporting.

Submission
Submit your proposal as a single pdf document (max 1 MB) ordered as above to pia.berntsson@med.lu.se. Deadline is January 7th 2019.

For more information or questions, please contact
Pia Berntsson pia.berntsson@med.lu.se

You can find more trial-related information on websites listed below:
Etikprövningsnämnden i Lund (EPN)
https://www.epn.se/lund/om-naemnden/
Medical Products Agency (MPA)
https://lakemedelsverket.se/malgrupp/Foretag/Lakemedel/Kliniska-provningar/
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Regulatory advice at MPA
https://lakemedelsverket.se/malgrupp/Foretag/Lakemedel/Regulatorisk-radgivning/
Biobank
http://biobanksverige.se/forskning/
Swedish Radiation Safety Authority
https://www.stralsakerhetsmyndigheten.se/omraden/forskning/
ICH GCP ICH E6 (R2) Good clinical practice

Kliniska Studier Sverige - Forum Söder (support functions for clinical trials - regional node)
https://sodrasjukvarsregionen.se/kliniskastudier/
Courses in GCP 9-10 April 2019 & 15-16 October 2019