Call for Clinical Trials in Cancer 2017 (Step 1)

The strategic research area for cancer at Lund University (LU) hereby announces a call for support to plan and execute clinical trials with focus on **translational cancer research**. The call is a 2-step process where in the first step up to 10 projects can be granted with up to 250,000 SEK per project. Step 1 includes a Letter of intent of and a study protocol synopsis (see details below). Step 1 is intended to cover costs for finalizing an approved protocol, fees for ethical and biobank approval, and biostatistical support. Step 2 will be announced separately approximately one year after project start of step 1 and approvals from both biobank and ethical committee are needed in order to fulfil the criteria for submitting a full proposal.

**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 for step 1**
15 September – Call opens
31 October – Deadline to submit application
30 November – External review finished
15 December – Decisions announced

**Project period (12 months):** January 1st – December 31st 2018

**Budget:** Max 2,500,000 SEK (max 250,000 SEK per project; max 10 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
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- The intervention may include systemic therapy with a registered pharmaceutical agent but also a novel indication as well as surgical or radiotherapeutic intervention
- Study designs include prospective cohort studies and randomised controlled trials with a defined clinical and translational end-point

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 synopsis, 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 the BioCARE board based on the overall recommendation by the 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. A report is mandatory when applying for Step 2.

Application format
The application should contain the following documents (max 14 pages), all with the name of the main applicant in the header of each page.

(1) A single cover page with general information as follows:
   a. Project Title
   b. Name of the main applicant, current position and affiliation
   c. Name of the co-applicant(s), current position(s) and affiliation(s)

(2) Letter of Intent (LoI) (max 2 pages; 12 pt) with the following headings:
   a. Background: Describe the rationale of the proposal based on your own research findings or clinical expertise
   b. Project team: Describe the composition of the project team and collaboration pre-clinical and clinical researchers, including young scientists
   c. Approval(s): Describe any approvals needed for starting the clinical trial e.g. Biobank, Ethical Committee, and eventually Medical Product Agency and/or Swedish Radiation Safety Authority approvals
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(3) Supporting documents (max 8 pages; 12 pkt):
   a. Mandatory: Protocol synopsis (max 2 pages, 12 pt) – template provided
   b. Timelines
   c. Optional: Informed Consent Form (ICF), investigator’s brochure (IB) etc
   d. References

(4) Curriculum vitae of main applicant and co-applicant(s) (max 2 pages each; 12 pt)
   – important to add relevant experience and courses related to clinical trials

(5) Budget (max 1 page, 12 pt) including indirect costs with specification of
   personnel costs, running costs, fees for approvals, course fees, travel costs etc.
   Add information about co-funding (source, amount , period)

Submission
Submit your proposal as a single pdf document ordered as above to
pia.berntsson@med.lu.se. Deadline is October 31st.

For more information or questions, please contact
Pia Berntsson pia.berntsson@med.lu.se, Lisa Rydén lisa.ryden@med.lu.se or Mattias
Belting mattias.belting@med.lu.se