PHC-15 2014

Clinical Research on Regenerative Medicine

TREGeneration

Repair of tissue and organ damage in refractory chronic graft versus host disease after hematopoietic stem cell transplantation by the infusion of purified allogeneic donor regulatory T lymphocytes

1. **João F. Lacerda**, Hospital Santa Maria / Faculdade de Medicina da Universidade de Lisboa / Instituto de Medicina Molecular (IMM) - *Coordinator*
2. **Matthias Edinger**, Universitaetsklinik, Regensburg (UHREG)
3. **Frédéric Baron**, Laboratory of Cell and Gene Therapy, CHU Sart-Tilman, Liège (CHU S-T)
4. **Mario Arpinati**, Department of Hematology, University Hospital S.Orsola-Malpighi, Bologna (Seràgnoli)
5. **Marie-Laure Yaspo**, Max Planck Society, Max Planck Institute for Molecular Genetics, Berlin (MPIMG)
6. **Hans Lehrach**, Alacris Theranostics GmbH, Berlin (Alacris)
7. **Marta García-Fiñana**, Department of Biostatistics, Faculty of Health & Life Sciences, University of Liverpool, Liverpool (UoL)
8. **Birgit Fuchs**, GABO:mi Gesellschaft für Ablauf-organisation:milliarium mbH & Co. KG (GABO:mi)

TREGeneration
First - Strategy

1. Novel project

2. Strong + Inclusive consortium
   - Do not be afraid to include partners that add value
   - Include scientific SMI
   - Include Management Company

3. Support from your funding officers

4. Dependable writing team (*your team*)

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Second – Write it

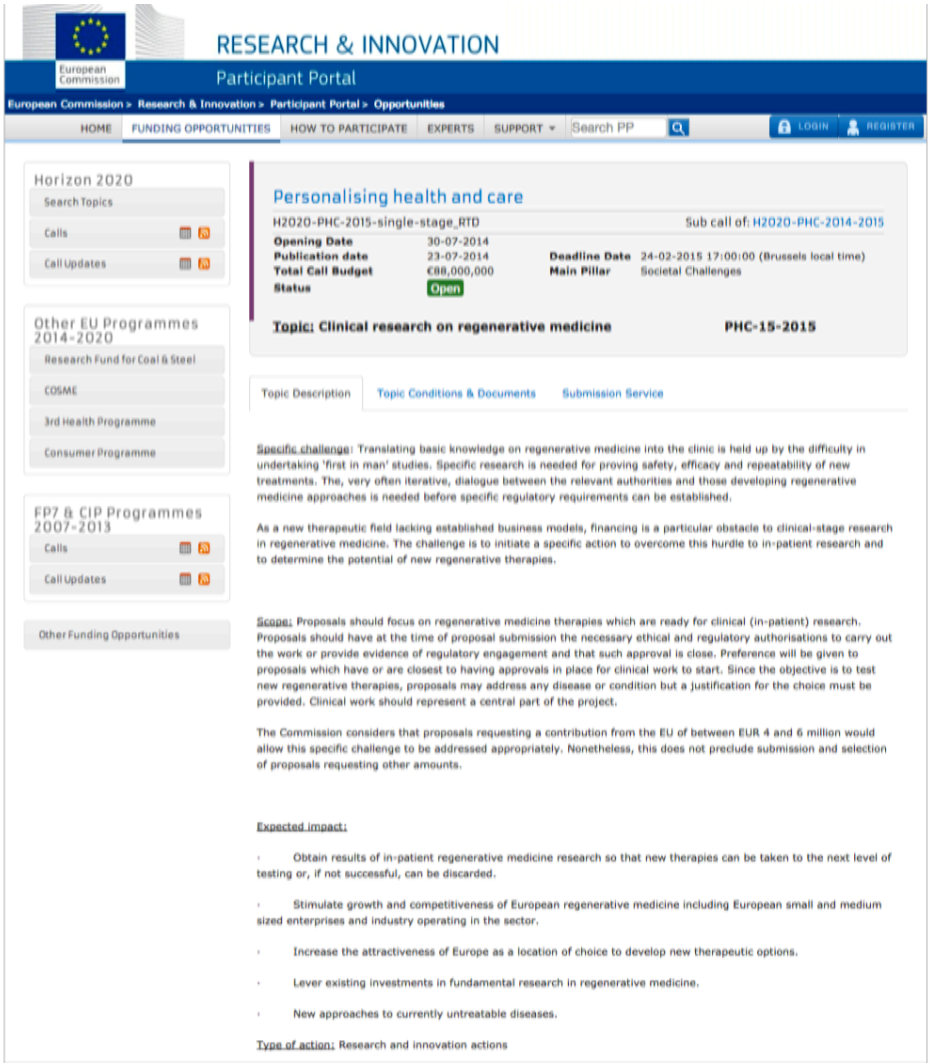
1. Make sure that your project clearly adresses critical requirements of the call:
   - Specific Challenge
   - Scope
   - Expected Impact

2. Do not lose track of topic conditions and documents

3. Be aware about:
   - Who does what (*don't expect others to do your job)*
   - The amount of work ahead

TREGeneration

Second – Write it



RESEARCH & INNOVATION

European Commission

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Other Funding Opportunities

Personalising health and care

H2020-PHC-2015-single-stage_RTD — Sub call of: H2020-PHC-2014-2015

Opening Date	30-07-2014		
Publication date	23-07-2014	**Deadline Date**	24-02-2015 17:00:00 (Brussels local time)
Total Call Budget	€88,000,000	**Main Pillar**	Societal Challenges
Status	Open		

Topic: Clinical research on regenerative medicine **PHC-15-2015**

Topic Description | Topic Conditions & Documents | Submission Service

Specific challenge: Translating basic knowledge on regenerative medicine into the clinic is held up by the difficulty in undertaking 'first in man' studies. Specific research is needed for proving safety, efficacy and repeatability of new treatments. The, very often iterative, dialogue between the relevant authorities and those developing regenerative medicine approaches is needed before specific regulatory requirements can be established.

As a new therapeutic field lacking established business models, financing is a particular obstacle to clinical-stage research in regenerative medicine. The challenge is to initiate a specific action to overcome this hurdle to in-patient research and to determine the potential of new regenerative therapies.

Scope: Proposals should focus on regenerative medicine therapies which are ready for clinical (in-patient) research. Proposals should have at the time of proposal submission the necessary ethical and regulatory authorisations to carry out the work or provide evidence of regulatory engagement and that such approval is close. Preference will be given to proposals which have or are closest to having approvals in place for clinical work to start. Since the objective is to test new regenerative therapies, proposals may address any disease or condition but a justification for the choice must be provided. Clinical work should represent a central part of the project.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Obtain results of in-patient regenerative medicine research so that new therapies can be taken to the next level of testing or, if not successful, can be discarded.
- Stimulate growth and competitiveness of European regenerative medicine including European small and medium sized enterprises and industry operating in the sector.
- Increase the attractiveness of Europe as a location of choice to develop new therapeutic options.
- Lever existing investments in fundamental research in regenerative medicine.
- New approaches to currently untreatable diseases.

Type of action: Research and innovation actions

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Second – Write it

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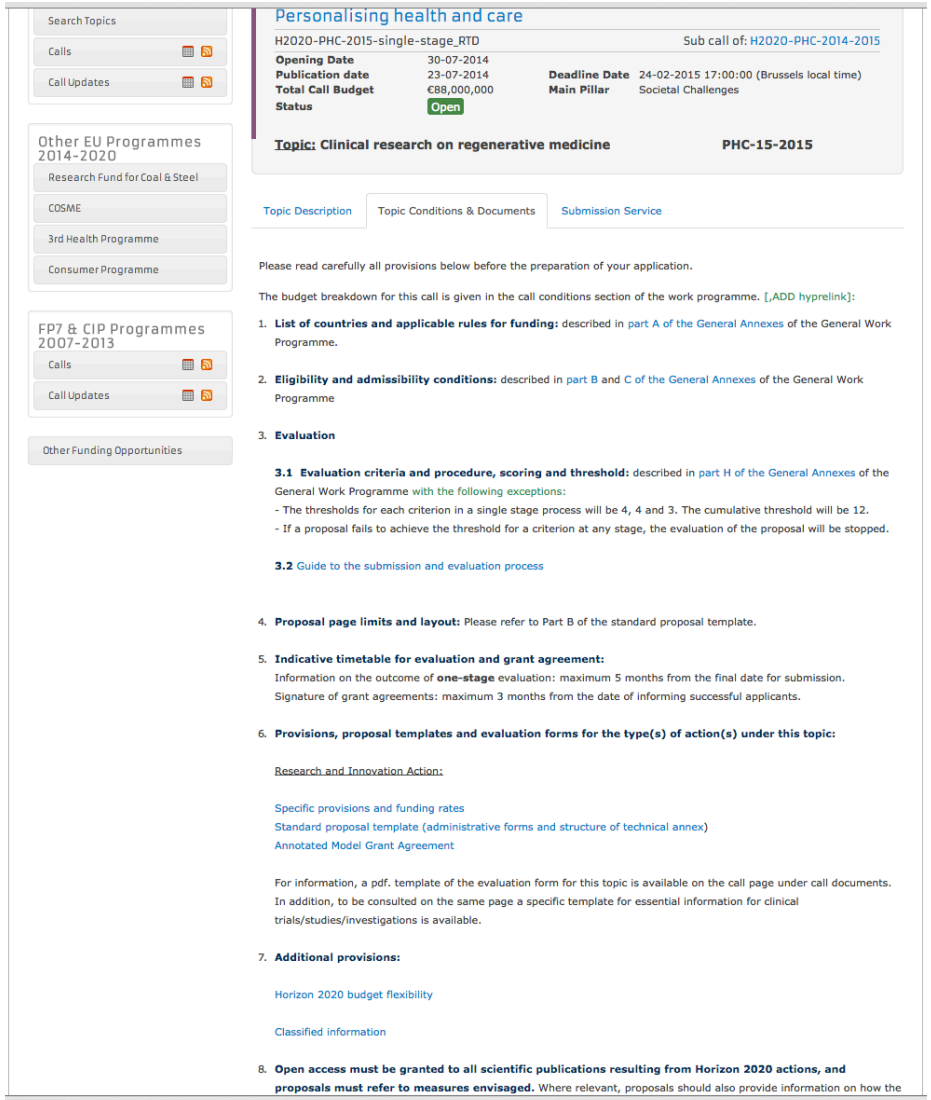

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Topic: Clinical research on regenerative medicine **PHC-15-2015**

Topic Description | Topic Conditions & Documents | Submission Service

Please read carefully all provisions below before the preparation of your application.

The budget breakdown for this call is given in the call conditions section of the work programme. [,ADD hyprelink]:

1. **List of countries and applicable rules for funding:** described in part A of the General Annexes of the General Work Programme.

2. **Eligibility and admissibility conditions:** described in part B and C of the General Annexes of the General Work Programme

3. **Evaluation**

   3.1 Evaluation criteria and procedure, scoring and threshold: described in part H of the General Annexes of the General Work Programme with the following exceptions:
   - The thresholds for each criterion in a single stage process will be 4, 4 and 3. The cumulative threshold will be 12.
   - If a proposal fails to achieve the threshold for a criterion at any stage, the evaluation of the proposal will be stopped.

   3.2 Guide to the submission and evaluation process

4. **Proposal page limits and layout:** Please refer to Part B of the standard proposal template.

5. **Indicative timetable for evaluation and grant agreement:**
   Information on the outcome of **one-stage** evaluation: maximum 5 months from the final date for submission.
   Signature of grant agreements: maximum 3 months from the date of informing successful applicants.

6. **Provisions, proposal templates and evaluation forms for the type(s) of action(s) under this topic:**

   Research and Innovation Action:

   Specific provisions and funding rates
   Standard proposal template (administrative forms and structure of technical annex)
   Annotated Model Grant Agreement

   For information, a pdf. template of the evaluation form for this topic is available on the call page under call documents. In addition, to be consulted on the same page a specific template for essential information for clinical trials/studies/investigations is available.

7. **Additional provisions:**

   Horizon 2020 budget flexibility

   Classified information

8. **Open access must be granted to all scientific publications resulting from Horizon 2020 actions, and proposals must refer to measures envisaged.** Where relevant, proposals should also provide information on how the

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Second – Write it

4. Proposal has a particular format:
   - Description of the action (DOA) includes work packages (WP), each with specific milestones and deliverables
   - Management has an individual WP
   - Dissemination, communication and outreach are an individual WP
   - Consortium has to be presented emphasizing its expertise in the field

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Outline

1. Part A – Abstract, Partners, Ethics, Budget
   - 33 pages

2. Part B – (Excellence, Impact, Implementation, Members of the consortium, Ethics and Security)
   - 97 pages

3. Annexes
   1. Original ethics documents + translation
   2. Clinical trial forms
   3. Diagnostic and response criteria
   4. Original clinical trial protocols
   5. Preliminary data

Total 335 pages

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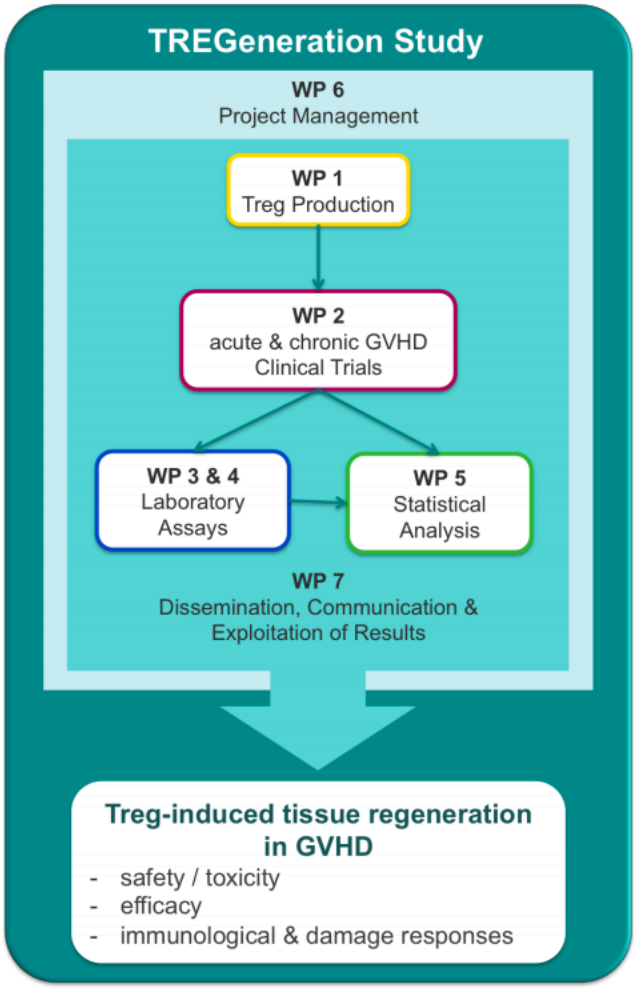
Outline



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Negotiation

1. Involve management company, funding, legal and financial officers of your institution

2. Adequately respond to PO concerns