



PHC-15 2014

Clinical Research on Regenerative Medicine

***TRE*Generation**

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

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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 addresses 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

The screenshot displays the European Commission Research & Innovation Participant Portal. The main content area features a funding opportunity titled "Personalising health and care" (H2020-PHC-2015-single-stage_RTD). The opportunity is open, with a total call budget of €8,000,000 and a deadline of 24-02-2015 17:00:00 (Brussels local time). The topic is "Clinical research on regenerative medicine" under the PHC-15-2015 pillar.

Personalising health and care
H2020-PHC-2015-single-stage_RTD Sub call of: H2020-PHC-2014-2015

Opening Date	30-07-2014	Deadline Date	24-02-2015 17:00:00 (Brussels local time)
Publication date	23-07-2014	Main Pillar	Societal Challenges
Total Call Budget	€8,000,000		
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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Second – Write it

Search Topics

Calls  

Call Updates  

Other EU Programmes 2014-2020



Research Fund for Coal & Steel



COSME

3rd Health Programme

Consumer Programme

FP7 & CIP Programmes 2007-2013

Calls  

Call Updates  

Other Funding Opportunities

Personalising health and care

H2020-PHC-2015-single-stage_RT D Sub call of: [H2020-PHC-2014-2015](#)

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

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 hyperlink](#)]:

- List of countries and applicable rules for funding:** described in [part A of the General Annexes](#) of the General Work Programme.
- Eligibility and admissibility conditions:** described in [part B and C of the General Annexes](#) of the General Work Programme.
- Evaluation**
 - 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](#)
- Proposal page limits and layout:** Please refer to Part B of the standard proposal template.
- 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.
- 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.
- Additional provisions:**

[Horizon 2020 budget flexibility](#)

[Classified information](#)
- 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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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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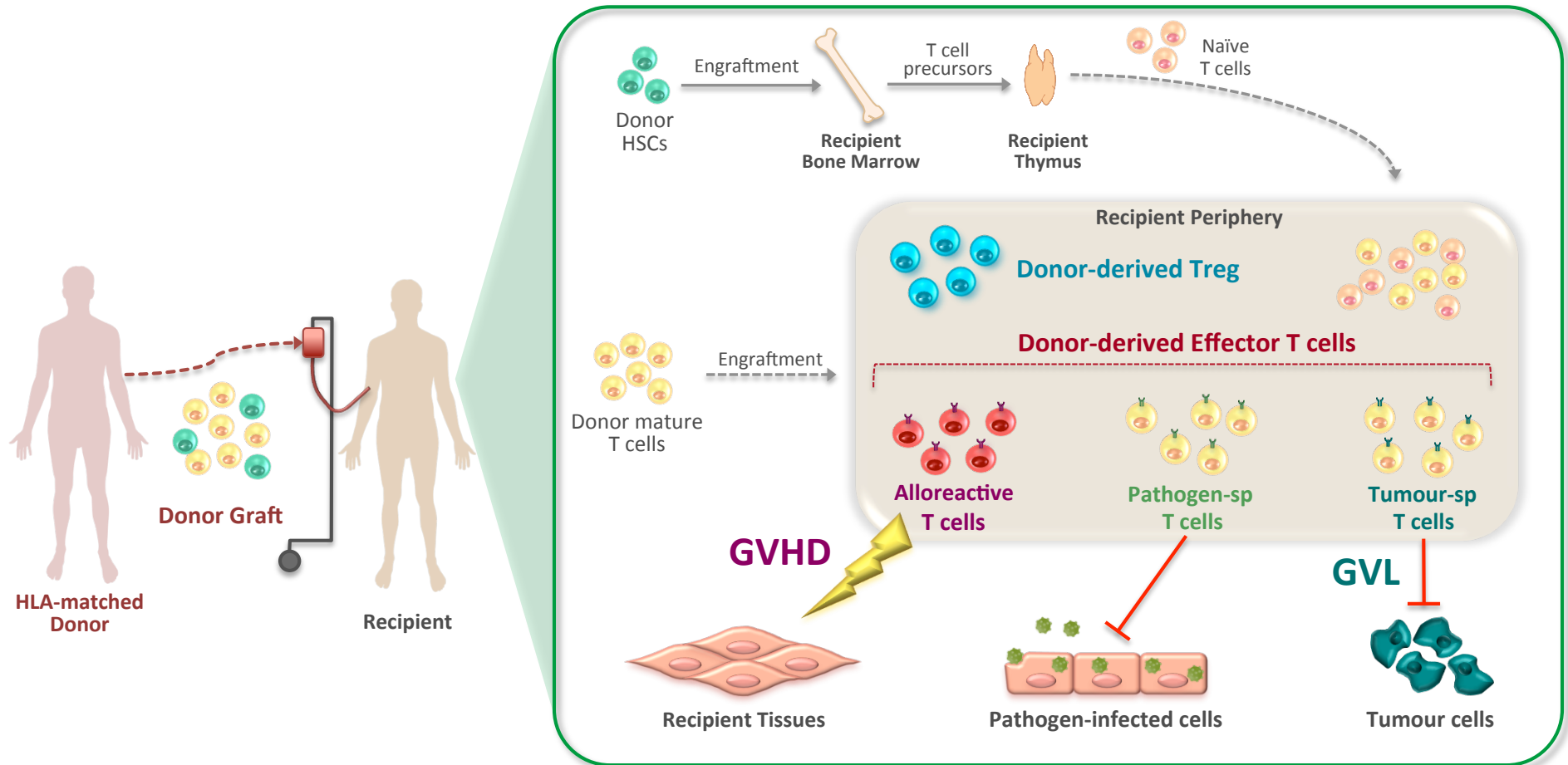
Negotiation

1. Involve management company, funding, legal and financial officers of your institution
2. Adequately respond to PO concerns



Project Overview

Graft versus Host Disease (GVHD)



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1. Series of 5 parallel independent Phase I/II clinical trials exploring the effect of donor Treg in:
 - acute GVHD (1 trial)
 - chronic GVHD (4 + 1 trials)
2. Treg purification, immunologic QC and prospective monitoring post-infusion performed at each center
3. Evaluation of tissue regeneration markers performed at IMM for the consortium

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4. Tracking of infused Treg by NGS performed at Max-Planck + Alacris for the consortium
5. Each clinical trial + local tests can be analyzed and published independently
6. University of Liverpool will gather both clinical and laboratory data for global statistical analysis

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Outline

