



EXPRESSION OF INTEREST

Provision of expert advice on mapping activities related to the regulatory aspects of biologic drug development and its clinical application in Italy and Austria

ICGEB is seeking for a qualified expert advisor interested in working on regulatory requirement on an INTERREG funded research project entitled “PROMOS – Strengthening the bio-medical ecosystem” with partners based in Italy and Austria.

Activities related to the various regulatory aspects of biological drug development and its clinical application in Italy and Austria are expected to be mapped in a 12-month period, with the aim of defining a road map to bring pre-clinical cell-based therapies to clinical phase research.

BACKGROUND

ICGEB operates in an international and multidisciplinary working environment and in the framework of PROMOS Work Package 3 – Regulatory, ICGEB, in collaboration with the Medical University of Innsbruck (Austria), is carrying out research activities aimed at facilitating biologic drug development and its clinical application.

The partners jointly focus on better identifying regulatory barriers and heterogeneity in the area to propose a simplification strategy of the regulatory aspect to foster and enhance a cross-border collaborative environment. As a concrete example, by combining the expertise of multiple project partners, this WP will focus on the use of adipose tissue-derived cells for wound healing therapy.

The specific objectives of this WP are to:

- i) understand the extent to which Intellectual Property Rights and Technology Transfer activities are essential to bring new cell-based therapies on cells to patients with chronic wounds that do not heal;
- (ii) define good practices in the pathway from preclinical to clinical application of cell-based therapy and whether these are different in Italy from Austria;
- (iii) import the missing good practices in either two countries, with the involvement of stakeholders (professionals working with and/or at the relevant regulatory authorities in Italy and Austria).

REQUIRED EXPERIENCE

The consultant will have proven experience in regulatory framework for the development and clinical application of cell-based therapies.

TASKS AND DELIVERABLES

The consultant is expected to delivery in a timely manner the following tasks:

1) By July 2024

Submit a report detailing past and ongoing approaches using adipose tissue-derived cell therapy for wound healing that have reached the clinical phase both in Italy and in Austria, with special focus on:

- a) the criteria to characterize the cell population to be transplanted and
- b) the methods used to monitor and score wound healing.

2) By October 2024

Submit a report on:

- a) the regulatory path to be followed to bring a new adipose tissue-derived cell therapy product to the clinics in Italy and Austria;
- b) the differences in the regulatory paths in Italy and Austria - by October 2024.

3) By April 2025

Submit a final report summarizing conclusions and providing best practice suggestions for sharing among the project partners.

A first draft of each document is expected to be shared with project partners (reference persons: Serena Zacchigna, Giulio Ciucci, Roman Vuerich and Giuseppe Di Mauro from ICGEB, Giovanni Papa from ASUGI/UNITS, Christian Ploner from MUI), one month prior to the deadline for discussion and improvement.

FINANCIAL PROPOSAL

The consultant should submit her/his financial offer with a lump sum for the whole service.

PROPOSAL SUBMISSION

Interested experts are requested to submit their Expression of Interest comprising a cover letter detailing the expert's qualifications, their ability to deliver the above-mentioned activity in the set timeframe, their CV and their financial proposal for evaluation as follows:

Addresses for email submission: claire.poletto@icgeb.org
Email subject: EOI for PROMOS WP3 Consultant
Submission deadline: Friday 19 April 2024

Please include the following full reference in your proposal submission:
EOI for PROMOS WP3 Consultant
Project ITAT-11-023 – PROMOS CUP: F93C23000400005”

