

TENDER FOR CONTRACTING a translators' agency for the Horizon 2020 funded project "Study of the efficacy and safety of a novel treatment (SPIOMET) for Polycystic Ovary Syndrome (PCOS) in adolescent girls and young women (SPIOMET4HEALTH).

899671

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### 1. INTRODUCTION TO THE PROJECT

The requested services are part of the SPIOMET4HEALTH project, funded by the H2020 EU Research and Innovation Programme under the Grant Agreement No. 899671.

SPIOMET4HEALTH is a collaborative project led by the Fundació Sant Joan de Déu (FSJD), aiming to provide a novel treatment for adolescent girls and young adult women with PCOS. PCOS negatively affects the health and quality of life of approximately 110 million women around the world who suffer from this syndrome, as well as their offspring. This study is a pioneering opportunity to deal with the syndrome from its root, rather than merely relieving its symptoms.

The project was launched on April 2021, with a duration of 60 months.

SPIOMET4HEALTH is committed to meeting the needs of adolescent girls and young adult women suffering PCOS thanks to the collaboration of 17 international partners, a consortium in which seven tertiary hospitals from four European Member States and 2 associated countries are included.

SPIOMET4HEALTH proposes a treatment combining three medications, which have already proven to be effective in the past, in a single tablet: SPIOMET. The use of this tablet together with lifestyle measures, could normalise ovulation and hormones, and thus revert the alterations associated to PCOS.

### 2. CONTRACTING SERVICE

SPIOMET4HEALTH is a clinical trial that involves 17 partners from 9 countries, Spain, Belgium, Germany, Austria, Denmark, Norway, Italy, Ireland and Turkey. Together, they will test the effects of SPIOMET components on top of lifestyle measures. The clinical trial will be developed by 7 countries: Spain, Germany, Austria, Denmark, Norway, Italy and Turkey, and therefore, all the material generated for ethical committees, regulatory agencies and patients should be translated from the master files, in English, into the local languages. No timeline information to translate all the documents will be available as documents will

be sent to translate as soon as they have been reviewed by the FSJD and the Clinical Research Organization (CRO) or issued by the specific committees and agencies. Therefore, different batches of documents will be sent separately.

The services provided by the supplier contracted by FSJD linked to this tender will be those listed below:

- translations for and issued by ethical committees and regulatory agencies including:
  - regulatory master documents (in English), like clinical study protocol summary, IMP labels, etc., into Spanish, German, Danish, Norwegian, Italian and Turkish;
  - documents from local language into English;
  - material for patients, like questionnaires, informed consents, patient diary, etc., into Spanish, German, Danish, Norwegian, Italian and Turkish;
- translation certificates: one per document;
- any other required translation.

### 3. REQUIREMENTS

#### 3.1. Requirements about the supplier

- The supplier should be a company with more than 10 years of experience
- Supported by a network of native speakers in the target language
- Specialized translators in, at least, the 7 required languages (English, Spanish, German, Danish, Norwegian, Italian and Turkish)
- Bilingual proofreading reviewer
- Experienced translators and senior project managers
- Experience in Clinical Trials
- Experience working with the European Commission
- ISO-certified quality: EN ISO 9000 and EN ISO 17100
- Security procedures to guarantee confidentiality (ISO 27001 certification)

#### 3.2. Requirements regarding the proposal of service

Design the technical proposal to perform the translations, including:

- Definition of technical requirements of the master files
- Workflow of translation
- Team involved
- Workflow of queries
- Best quality offer per word in the target languages
- Repetitions discount

### 4. WORKING METHODOLOGY

The selected provider will work under the coordination of FSJD, who is coordinating the SPIOMET4HEALTH project.

## 5. BUDGET

Quality of the technical proposals submitted and the related budget will be considered in the assessment phase to choose the provider.

## 6. SUBMISSION OF PROPOSALS AND EVALUATION

### 6.1. Deadline for the submission of the proposals:

The deadline to submit proposals is **September 1<sup>st</sup>, 2021, at 12 pm CET**.

### 6.2. Documentation to be submitted:

#### 6.2.1. Documentation about the supplier

- Curriculum with the expertise of the company
- Composition of the team
- Resume of the staff involved in the activities

#### 6.2.2. Documentation about the project

- Technical proposal of tasks detailed in the section 3.2
- Financial proposal

### 6.3. Criteria of evaluation:

The SPIOMET4HEALTH coordination team will assess the different proposals submitted. The expertise and the proposal of activities will be evaluated separately:

- Technical evaluation: 20 points maximum
- Financial evaluation: 20 points maximum
- Requirements about contractor 60 points maximum

The maximum score for every aspect will be:

SCORE	
Technical proposal	Max 20 points
Translation' workflow	6
Team	8
Queries' workflow	6
Financial proposal	Max 20 Points
Repetitions discount	6
Offer per word	14
Requirements about contractor	Max 60 points
Experience of the company	10
Native speakers	10
Specialized translators	10

Proofreading review	10
Experience in clinical trials	5
Experience working with the European Commission	5
ISO quality certification (EN ISO 9000 and EN ISO 17100)	10
ISO 27001 certification	10
<b>TOTAL</b>	<b>100</b>

Only proposals which achieve at least 15 points (technical) + 15 points (financial) + 45 points (requirements) for a total of 75 points will be considered as candidate to perform the activities of this contract. The best technical quality proposal with the fairest budget will be selected.

For any additional information and reception of offers related to this tender, the contact persons and emails are:

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