

SPECIFIC AND TECHNICAL CONDITIONS FOR

Laboratory services on Whole Exome Sequencing Analysis of paraffin-embedded samples of the FIS project (PI20/00368).

(57 /2020)

I. OBJECT

The present document to contract a laboratory services to provide whole exome sequencing (WES) analysis of the samples collected in the FIS project (PI20/00368; “Genomic characterization of Human Papillomavirus-independent Vulvar Squamous Cell Carcinomas and its precursor lesions”) project in Barcelona, Spain.

All the technical specifications contained in this document are considered to be part of the minimum requirements and do not exclude any other needs for compliance with the purpose of the service contracted.

II. CONTENT OF THE WORK

Unfortunately, there are large knowledge gaps in the natural history of vulvar squamous cell carcinomas (VSCC) and its precursor lesions, particularly important for Human Papillomavirus (HPV)-independent tumors. There is little clarity regarding the molecular pathways involved in HPV-independent carcinogenesis. These tumors represent the majority of VSCC in our setting, and existing data indicates that they are more aggressive than HPV-associated VSCC. In addition, there is a diagnostic problem with the HPV-independent VSCC intraepithelial precursor lesions, due to the absence of reliable biomarkers. Therefore, it is a priority to examine the molecular profile of different premalignant and inflammatory lesions of the vulva, looking for specific biomarkers that could be useful in routine pathological diagnosis. A correct identification and diagnosis of premalignant vulvar lesions would prevent developing invasive carcinomas in a large number of patients. On the other hand, the genomic profiling of invasive carcinomas could help to identify possible therapeutic targets that could be radically different between HPV-associated and HPV-independent tumors. Therefore, an exploratory study of the molecular alterations of VSCC and premalignant HPV-independent lesions is crucial in the current era of precision medicine.

Scope of work

ISGlobal – Barcelona Institute for Global Health is a research centre in international health whose ultimate goal is to help close the gaps in health disparities between and within different regions of the world. For this, we leverage on knowledge generation (research), transmission (training), and application (policy and global development).

One of ISGlobal's clinical research lines is the study of biomarkers of disease and progression in human papillomavirus (HPV)-associated and HPV-independent anogenital cancers and premalignant lesions, including vulvar cancer which represents one of the most understudied malignancies overall. In this context a prospective observational study will be carried out in the Hospital Clínic of Barcelona. The project aims to characterize the molecular landscape of HPV-associated and –independent VSCC and their precursor lesions (differentiated vulvar intraepithelial neoplasia, high-grade squamous intraepithelial lesion, and inflammatory skin lesions).

ISGlobal is looking for a laboratory services mainly focused on Whole Exome Sequencing (WES) of the collected vulvar cancer samples.

The key deliverables are:

1. To provide reliable and timely WES analysis of the paraffin-embedded samples collected throughout the first year of the project.
2. To analyse the WES results using the bioinformatic tools.
3. To assist with the preparation of manuscripts and scientific reports that will include the WES results.

III. PERSON RESPONSIBLE FOR THE CONTRACT (If Applicable)

ISGlobal will appoint a person responsible for relations with the selected laboratory (the "Contract Responsible"), who will coordinate with the staff of the entity and who will channel communications between the two parties.

IV. MANAGEMENT OF WORK AND QUALITY CONTROL

ISGlobal and the selected laboratory will establish by common agreement a calendar of communications that will consist of monthly progress calls. Regardless of these scheduled calls, the Contract Responsible and the project management team may meet at any time if any of the two parties considers it appropriate, depending on the progress of the work hired. At any meeting the responsible person may choose to bring additional participants from ISGlobal if considered convenient. Bi-monthly reports will be provided by the selected laboratory.

V. TECHNICAL REQUIREMENTS OF THE LABORATORY

The laboratory should meet these requirements:

- Long experience with the WES technique in paraffin-embedded cancer samples.
- Availability and experience of work with the Agilent Sure Select v5 kit (the most adequate option for analysis of paraffin-embedded samples and optimal for library design, together with efficient workflow)
- Capacity to provide WES of each paraffin-embedded sample with the genome coverage of at least >150x (implies >18 Gb coverage/sample).

- Capacity of analyzing the results of WES using bioinformatics.

VI. PERIOD OF EXECUTION AND DELIVERY OF THE REPORT

The execution of the work will be carried out through the first 24 months of the project. The current agreement would cover the 24 months.

VII. ESSENTIAL CONTRACTUAL OBLIGATIONS

The following will be considered as essential obligations of the successful bidder:

1. Laboratory analyses coordination:
 - Ensure that all the samples are analysed according to project objectives and timelines.
 - Timely reporting of the cases with insufficient or inadequate quality of DNA to ensure the replacement of these samples with the newly selected ones.
 - Work with the Project Manager and PIs of the study to ensure the completion of the milestones.
2. Interpretation of the WES results
 - Construction of the WES database of the study using advanced bioinformatic tools.
 - Timely assistance with the interpretation of the results.
 - Timely assistance with the elaboration of scientific reports and manuscripts focused on the WES results.

VIII. CONTRACT PERIOD

The duration of the contract will be of 24 months distributed throughout the 12 months of laboratory analysis and 12 months of the results interpretation period.

The estimated start date of the contract is January 18th, 2021.

IX. BUDGET, PRICE AND ESTIMATED VALUE OF THE CONTRACT

The contract budget amounts to the maximum amount of

Euro 100.998€ excluding tax

The award amount will not exceed this budget in any case. The price of the contract, consequently, will be that to which it rises plus the corresponding Value Added Tax, in the case of non-exempt bidders, which must be included in the separate item.

X. ADVERTISING

The present contract will be published by announcement in the Contracting Profile of the entity on the website: www.isglobal.org

XI. PLACE AND DATE OF SUBMISSION OF PROPOSALS

The economic proposals must be submitted by email to the address licitaciones@isglobal.org

The deadline for submitting proposals will end on 27th December 2020.

XII. LEGAL SYSTEM OF THE CONTRACT

The contract is considered a private contract and is subject to private law, ruling by this Schedule, by the contract and documentation attached, and in everything not provided by the applicable civil and commercial legislation.

XIII. EXPENDIENT OF RECRUITMENT, AWARD PROCEDURE OF THE CONTRACT AND DOCUMENTATION TO BE PROVIDED TENDERS

The contracting of the reference services will be awarded by the procedure envisaged in Section IX of the Internal Contracting Instructions of the entity. From the day of publication of the tender notice, interested companies can obtain the necessary documentation to prepare their proposals through the contractor's profile on the website www.isglobal.org.

XIV. PAYMENT METHOD

The organization providing laboratory services will be providing periodically reports on the progress of sample analyses alongside with invoices. Payment will always be made under invoice and 30 days invoice date by bank transfer:

First payment: 20%

Month 6 payment: 30%

Month 12 payment: 30%

Month 18 payment: 10%

Final payment upon completion of work: 10%

Barcelona, December 15th, 2020