

Collaboration Agreement

within

EC G.A. NO. 060701/2021/864481/SUB/ENV.C2 - SUPPORT TO THE MEMBER STATES TO ESTABLISH NATIONAL SYSTEMS, LOCAL COLLECTION POINTS, AND DIGITAL INFRASTRUCTURE FOR MONITORING COVID 19 AND ITS VARIANTS IN WASTE WATERS – ITALY

CUP I85F21004040005

between

Istituto Superiore di Sanità, with registered office in Rome Viale Regina Elena, 299 00161 Italy represented by the President Prof. Silvio Brusaferro (hereinafter: Beneficiary)

and

Regione Siciliana – Assessorato Regionale della Salute – Dipartimento Attività Sanitarie ed Osservatorio Epidemiologico (DASOE) with registered office in Palermo Italy Via Mario Vaccaro, 5 – 90145 represented by the Director Ing. Mario La Rocca (hereinafter: Partner)

Beneficiary and Partner are hereinafter referred jointly as Parties

Whereas:

- Beneficiary and the European Commission Directorate General Environment signed a contract EC G.A. NO. 060701/2021/864481/SUB/ENV.C2 "Support to the Member States to establish systems, local collection points, and digital infrastructure for monitoring COVID 19 and its variants in waste waters Italy "hereinafter referred to as "Grant Agreement", which has been sent in advance to all Regions for acknowledgment.
- In the Grant Agreement provides for sampling to be carried out on all regional territories
- In Italy the health system is organized on a regional basis and regions and autonomous provinces are the competent authorities for the health sector. Therefore, their participation in the project from organization and management, through sampling and sample analysis, to timely data submission is essential to achievement the objectives of the action.
- for the reasons indicated above Beneficiary requests the collaboration of the Partner to carry out the activities as specified in the Annex I of the Grant Agreements.

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It is hereby agreed as follows:

ARTICLE 1 – PURPOSE

The purpose of this Agreement is the collaboration between the Parties to carry out the Projects activities specified in the Annex I of the Grant Agreements and summarized as follow:

1. Transformation of existing research activities into a surveillance system with a focus on SARS-CoV-2 variants by: a) enrolling all of the Italian regions/autonomous provinces (n=21); b) implementing data quality assurance (revision of the national protocol for SARS-CoV-2 quantification in sewage, including quality controls, shared on July 2021 together with reference materials); c) increasing sampling frequency (currently once per week or fortnightly) to twice per week in urban centers ≥150k inhabitants (as per Rec. 2021/472); d) introducing sampling (once per week) in all cities between 50k and 150k inhabitants to provide adequate population/territory coverage; e) implementation of systematic variant analysis through long-read sequencing,

Financial support is granted only and exclusively to implement the above activities.

ARTICLE 2 — ENTRY INTO FORCE AND IMPLEMENTATION PERIOD OF THE AGREEMENT

- 1. The Agreement enters into force on the date on which the last party signs it.
- 2. The action runs from 01/10/2021 to 31/03/2023.
- 3. By way of derogation from Article II.19.1.a, eligible costs are costs incurred during the duration of the operational part of the action as set out in Annex I, which runs as of 01/10/2021 up to and including 31/03/2023.

ARTICLE 3 – FINANCIAL SUPPORT

The financial support allocated for purpose of this Collaboration by the European Commission Directorate General Environment is of Euro 142.634,58 (one hundred forty-two thousand six hundred thirty-four/58).

The contribution is determined based on the distribution criteria defined in the Table of the Decree of the Ministry of Health of 30.10.2021 (GU Serie Generale n.294 del 11-12-2021), which provides the costs for the structuring of the operating network and a variable fee, defined according to the frequency of monitoring, to be allocated taking into account the number of municipalities with more than 150,000 inhabitants and with a number of inhabitants between 50,000 and 150,000, present in the territory

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Activities that may receive financial support are those related to sampling, sample shipping, laboratory analysis, and management of surveillance implementation. These activities will be covered with expenses included under Article II.19 of Annex II of the Agreement, e.g. other eligible costs.

ARTICLE 4 - PAYMENTS AND SUPPORTING DOCUMENTS

The Beneficiary must make the following payments to the Partner:

- one pre-financing of 70% upon signature of this agreement and upon presentation of a request for payment (where the number of CUP **I85F21004040005** will be indicated);
- one payment of the balance, on the basis of the request for payment (where the number of CUP <u>I85F21004040005</u> will be indicated) of the balance referred to in Article I.4.4 of the Grant Agreement.

This request of the balance must be accompanied by the following documents:

- (a) a final report on implementation of the action ('final technical report'), containing: (i) the information needed to justify the eligible costs declared unit cost and lump sums.
- (b) a final financial statement ('final financial statement'). The final financial statement must include a breakdown of the amounts claimed by the Partner for the whole period of the action.

The template for the Final Financial Report will be furnished by Beneficiary (Annex 1).

The Partner must certify that the information provided in the Financial Report is full, reliable and true. The Partner must also certify that the costs incurred can be considered eligible in accordance with the Agreement and that the request for payment is substantiated by adequate supporting documents that can be produced in the context of the checks or audits described in Article II.27 of the Grant Agreement.

ARTICLE 5 - COST ELIGIBILITY

To be eligible, the direct cost of the action must comply with the eligibility conditions set out in the Grant Agreement Article II.19, Article II.20, is applied to this Collaboration Agreement.

ARTICLE 6 - INELIGIBILITY OF COSTS OF STAFF OF NATIONAL ADMINISTRATIONS

By way of derogation from Article II.19.2 (a), salary costs of the personnel of national administrations are eligible only to the extent that they relate to the cost of activities, which the relevant public authority would not carry out if the project concerned was not undertaken.

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ARTICLE 7 - RIGHT AND OBLIGATIONS

Beneficiary and the Partner undertake to take part in the efficient implementation of the Project, and cooperate, perform and fulfil, promptly and on time, all of its obligations under the Grant Agreement, according to the activities and the involvement of each Party.

ARTICLE 8 – RIGHTS AND OBLIGATIONS – REPORTING

Regarding rights and obligations related to submission of the technical report(s) Grant Agreement Articles I.4 applies.

In particular, the Partner must submit to Beneficiary their contribution to the technical reports in time to allow Beneficiary compliance with the deadlines set out in I.4 of the Grant Agreement.

ARTICLE 9 - RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

Regarding rights and obligations related to implementing the action, Grant Agreement (Annex 1 and Annex 2) Articles II.10 is applied and has the following duties:

- If the implementation of the action requires the Partner to procure goods, works or services, it may award the contract in accordance with their usual purchasing practices provided that the contract is awarded to the tender offering best value for money or, as appropriate, to the tender offering the lowest price. In doing so, it must avoid any conflict of interests.
- The Partner must ensure that the Commission, the European Court of Auditors and the European Anti-Fraud Office (OLAF) can exercise their rights under Article II.27 also towards the beneficiary' partners.
- The Partner that is a 'contracting authority' within the meaning of Directive 2014/24/EU2 or 'contracting entity' within the meaning of Directive 2014/25/EU3 must comply with the applicable national public procurement rules.
- The Partner must ensure that the conditions applicable to it under Articles II.4, II.5, II.6 and II.9 are also applicable to the contractors.
- The Partner remains solely responsible for carrying out the action and for compliance with the Agreement. Article II.10.4.
- If the Partner breaches its obligations under Article II.10.1 the costs related to the contract concerned are considered ineligible in accordance with Article II.19.2 (c), (d) and (e).
- If the beneficiary breaches its obligations under Article II.10.2 the grant may be reduced in accordance with Article II.25.4.

ARTICLE 10 - PRE-EXISTING RIGHTS AND OWNERSHIP AND USE OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

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The conditions set out in the Grant Agreement, (Article II.9), Sections related to Intellectual Property Rights are applied.

In addition:

- The Partner has identified and agreed on the **Background** rights for the Action and have also, where relevant, informed Beneficiary on Access Rights to specific Background subject to legal restrictions or limits. Each Partners:
 - (a) establish a list specifying all pre-existing rights included in those results; and
 - (b) provide this list to the Beneficiary at the latest with the request for payment of the balance.
- The beneficiary must ensure that it or its Partners have all the rights to use any preexisting rights during the implementation of the Agreement.
- The Results developed during the Action could be shared between Beneficiary and the Partner.
- Unless otherwise agreed, the Partner shall be entitled to use its jointly owned Results for non-commercial research activities and educational purposes on a royalty-free basis, by written request to the Beneficiary. Any kind of commercial exploitation of the Results by Partner has to be agreed with Beneficiary.

ARTICLE 11 - CONFIDENTIALITY

- 1. During implementation of the action and for five years after the payment of the balance, the parties must treat with confidentiality any confidential information and documents.
- 2. The parties may only use confidential information and documents for a reason other than to fulfil their obligations under the Agreement if they have first obtained the prior written agreement of the other party.
- 3. The confidentiality obligations do not apply if:
- (a) the disclosing party agrees to release the other party from those obligations;
- (b) the confidential information or documents become public through other means than a breach of the confidentiality obligations;
- (c) the disclosure of the confidential information or documents is required by law.

ARTICLE 12 - VISIBILITY OF UNION FUNDING

Unless the Commission requests or agrees otherwise, any communication or publication made by the beneficiary that relates to the action, including at conferences, seminars or in any information or promotional materials (such as brochures, leaflets, posters, presentations, in electronic form, etc.), must:

- (a) indicate that the action has received funding from the Union; and
- (b) display the European Union emblem.

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ARTICLE 12 - APPLICABLE LAW AND SETTLEMENT OF DISPUTES

The Agreement is governed by the applicable EU and Italian law. If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court of Rome shall have exclusive jurisdiction

This Agreement is compos	sed of:	
Annex 1 Model Fina	ncial Statement	
For		
PER ISTITUTO SUPER	IORE DI SANITA'	
Prof. Silvio Brusaferro President Legal Representative		
Date:		
For		
REGIONE SICILIANA Assessorato Regionale del Attività Sanitarie ed Osser		
Ing. Mario La Rocca Director Legal Representative		
Date:		
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