EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Public Health Functions

GRANT AGREEMENT FOR AN ACTION

AGREEMENT NUMBER — ECDC/HERA/2021/004 ECD.12218

The European Centre for Disease Prevention and Control (hereinafter referred to as "the Centre" or "the ECDC"), represented for the purposes of signature of this Grant agreement by Director, Andrea Ammon,

on the one part,

and

National Institute of Public Health (NIPH)/ Státni zdravotni ústav (SZU)

Public body

Official registration No: 75●1●33●

Srobarova 49/48, Prague 1●, 1●● ●● Czech Republic

VAT number: CZ75●1●33●

hereinafter referred to as "the beneficiary", represented for the purposes of signature of this Agreement by Director, Barbora Mackova

on the other part,

[redacted]

HAVE AGREED

to the Special Conditions ("the Special Conditions") and the following Annexes:

Annex I Description of the action (Invitation to submit applications – GRANT/2021/PHF/23776, Questions and Answers document, and submitted application dated 12/07/2021)

Annex II General Conditions ("the General Conditions")

Annex III Estimated budget

Annex IV a) Model interim progress report
b) Model final technical report

Annex V Model financial statement

Annex VI Model terms of reference for the certificate on the financial statements: not applicable

Annex VII Model terms of reference for the certificate on the compliance of the cost accounting practices: not applicable.

Annex VIII Model terms of reference for the operational verification report: not applicable

Annex IX Model Request for Payment

which form an integral part of the Agreement.

The provisions in the Special Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex II "General Conditions" take precedence over the other Annexes.

SPECIAL CONDITIONS

Table of Contents

ARTICLE I.1 – SUBJECT MATTER OF THE AGREEMENT

The ECDC has decided to award a grant under the terms and conditions set out in the Special Conditions, the General Conditions and the other Annexes to the Agreement, for the *action* entitled **Enhancing Whole Genome Sequencing (WGS) and/or Reverse Transcription Polymerase Chain Reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic in the European Union and European Economic Area** as described in Annex I.

By signing the Agreement the beneficiary accepts the grant and agrees to implement the action, acting on its/their own responsibility.

ARTICLE I.2 – ENTRY INTO FORCE AND IMPLEMENTATION PERIOD OF THE AGREEMENT

I.2.1 The Agreement enters into force on the date on which the last party signs it.

I.2.2 The *action* runs from 03 September 2021 until 30 September 2022.

ARTICLE 1.3 – MAXIMUM AMOUNT AND FORM OF GRANT

I.3.1 *The maximum amount of the grant* is EUR 3,065,518.

The action is co-financed by the Centre and the beneficiary/ beneficiaries:

- the beneficiary shall contribute to the action by a minimum of 10% of the estimated eligible costs of the action;

- the Centre shall contribute to the action up to a maximum of 90% of the estimated eligible costs of the action.

I.3.2 The grant takes the form of:

(a) reimbursement of up to 90% of the eligible costs of the *action* ("reimbursement of eligible costs"), which are estimated at EUR 3,406,131 and which are:

(i) actually incurred ("reimbursement of actual costs") for the listed categories of costs in Article I.10 for the beneficiary and the affiliated entities.

(ii) reimbursement of unit costs: not applicable

(iii) reimbursement of lump sum costs: not applicable

(iv) reimbursement of flat-rate costs of 7% of the eligible direct costs ("flat-rate cost")

(v) reimbursement of costs declared on the basis of the beneficiary's usual cost accounting practices: not applicable

(b) unit contribution: not applicable

(c) lump sum contribution: not applicable

(d) a flat-rate contribution: not applicable

(e) financing not linked to costs: not applicable.

ARTICLE I.4 – REPORTING, REQUESTS FOR PAYMENTS AND SUPPORTING DOCUMENTS

I.4.1 Reporting periods

Not applicable.

I.4.2 Request for a second pre-financing payment and supporting documents

The beneficiary must submit a request for a second pre-financing payment, under the condition that at least 70% of the first pre-financing payment was consumed.

The request must be accompanied by the following documents:
(a) a progress report on the implementation of the *action* ('interim progress report');
(b) a statement on the amount of the previous pre-financing instalment used to cover costs of the *action* ('statement on the use of the previous pre-financing instalment'). The statement must be drawn up in accordance with Annex V.

I.4.3 Request for interim payment and supporting documents

Not applicable

I.4.4 Request for payment of the balance and supporting documents

The beneficiary must submit a request for payment of the balance within 30 calendar days following the end of the last reporting period.

This request must be accompanied by the following documents:

(a) a final report on implementation of the *action* ('final technical report'), drawn up in accordance with Annex IV, containing:
(i) the information needed to justify the eligible costs declared ;
(ii) information on subcontracting as referred to in Article II.11.1(d);

(b) a "final financial statement"
The final financial statement must include a consolidated statement and a breakdown of the amounts claimed by the beneficiary and if applicable its affiliated entities.

The final financial statement must be drawn up in accordance with the structure of the estimated budget set out in Annex III and in accordance with Annex V and detail the amounts for the applicable forms of grant set out in Article I.3.2 for the last reporting period;

(c) a "summary financial statement"

This statement must include a consolidated financial statement and a breakdown of the amounts declared or requested by the beneficiary and if applicable its affiliated entities, aggregating the financial statements already submitted previously and indicating the revenue, if any, generated by the *action* referred to in Article II.25.3 for the beneficiary and its affiliated entities other than non-profit organisations.

The summary financial statement must be drawn up in accordance with Annex V;

(d) a certificate on the financial statements and underlying accounts ('certificate on the financial statements').

The certificate must certify that the costs declared in the final financial statement by the beneficiary concerned and if applicable its affiliated entities for the categories of costs reimbursed in accordance with Article I.3.2 are real, accurately recorded and eligible in accordance with the Agreement.

In addition, the certificate must certify that all the revenues generated by the *action* referred to in Article II.25.3 have been declared for the beneficiary and if applicable its affiliated entities other than non-profit organisations.

The beneficiary shall submit such a certificate with all the actual costs, including the costs if applicable of its affiliated entities, as referred to in Article I.3.2. This certificate must be produced by an approved external auditor or, in case of public bodies, by a competent and independent public officer.

I.4.5 Information on cumulative expenditure incurred

Not applicable.

I.4.6 Currency for requests for payment and financial statements and conversion into euro

Requests for payment and financial statements must be drafted in euros.

The beneficiary and if applicable its affiliated entities with general accounts in a currency other than the euro must convert costs incurred in another currency into euros at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union* (available at http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html), determined over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, conversion must be made at the average of the monthly accounting rates established by the European Commission and published on its website (https://ec.europa.eu/info/funding-tenders/procedures-guidelines-tenders/information-contractors-and-beneficiaries/exchange-rate-inforeuro_en, determined over the corresponding reporting period.

The beneficiary and if applicable its affiliated entities with general accounts in euros must convert costs incurred in another currency into euros in accordance with their usual accounting practices.

I.4.7 Language of requests for payments, technical reports and financial statements

All requests for payments, technical reports and financial statements must be submitted in English.

ARTICLE I.5 — PAYMENTS AND PAYMENT ARRANGEMENTS

I.5.1 Payments to be made

The Centre must make the following payments to the beneficiary:

- a first pre-financing payment;
- a second pre-financing payment, on the basis of the request for the second pre-financing payment referred to in Article I.4.2;
- one payment of the balance, on the basis of the request for payment of the balance referred to in Article I.4.4.

I.5.2 Pre-financing payments

The aim of the pre-financing is to provide the beneficiary with a float. The pre-financing remains the property of the Centre until it is cleared against interim payments or, if it is not cleared against interim payments, until the payment of the balance.

The Centre must make a first pre-financing payment of 60% of the maximum amount indicated in Article I.3.1, EUR 1,839,311 to the beneficiary within 30 calendar days from the entry into force of the Agreement, except if Article II.24.1 applies.

The Centre must make a second pre-financing payment of 30% of the maximum amount indicated in Article I.3.1, EUR 919,655 to the beneficiary within 60 calendar days from when the Centre receives the request for second pre-financing payment referred to in Article I.4.2, except if Article II.24.1 or II.24.2 apply.

I.5.3 Interim payment

Not applicable.

I.5.4 Payment of the balance

The payment of the balance reimburses or covers the remaining part of the eligible costs and contributions for the implementation of the *action*.

If the total amount of earlier payments is greater than the final amount of the grant determined in accordance with Article II.25, the payment of the balance takes the form of a recovery as provided for by Article II.26.

If the total amount of earlier payments is lower than the final amount of the grant determined in accordance with Article II.25, the Centre must pay the balance within 60 calendar days from

when it receives the documents referred to in Article I.4.4, except if Article II.24.1 or II.24.2 apply.

Payment is subject to the approval of the request for payment of the balance and of the accompanying documents. Their approval does not imply recognition of the compliance, authenticity, completeness or correctness of their content.

The Centre determines the amount due as the balance by deducting the total amount of pre-financing and interim payments (if any) already made from the final amount of the grant determined in accordance with Article II.25.

The amount to be paid may, however, be offset, without the beneficiary's consent, against any other amount owed by the beneficiary to the Centre or to an executive agency (under the EU or Euratom budget), up to the *maximum amount of the grant*.

I.5.5 Notification of amounts due

The Centre must send a *formal notification* to the beneficiary:

(a) informing it of the amount due; and
(b) specifying whether the notification concerns a further pre-financing payment, an interim payment or the payment of the balance.

For the payment of the balance, the Centre must also specify the final amount of the grant determined in accordance with Article II.25.

I.5.6 Interest on late payment

If the Centre does not pay within the time limits for payment, the beneficiary is entitled to late-payment interest at the rate applied by the European Central Bank for its main refinancing operations in euros ('the reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the time limit for payment expires, as published in the C series of the *Official Journal of the European Union*.

Late-payment interest is not due if a beneficiary is a Member State of the Union (including regional and local government authorities and other public bodies acting in the name of and on behalf of the Member State for the purpose of the Agreement).

If the Centre suspends the time limit for payment as provided for in Article II.24.2 or if it suspends an actual payment as provided for in Article II.24.1, these actions may not be considered as cases of late payment.

Late-payment interest covers the period running from the day following the due date for payment, up to and including the date of actual payment as established in Article I.5.8. The Centre does not consider payable interest when determining the final amount of grant within the meaning of Article II.25.

As an exception to the first subparagraph, if the calculated interest is lower than or equal to EUR 200, it must be paid to the beneficiary only if the latter requests it within two months of receiving late payment.

I.5.7 Currency for payments

The Centre must make payments in euros.

I.5.8 Date of payment

Payments by the Centre are considered to have been carried out on the date when they are debited to its account.

I.5.9 Costs of payment transfers

Costs of the payment transfers are borne as follows:
(a) the Centre bears the costs of transfer charged by its bank;
(b) the beneficiary bears the costs of transfer charged by its bank;
(c) the party causing a repetition of a transfer bears all costs of repeated transfers.

I.5.10 Payments to the beneficiary

The Centre must make payments to the beneficiary.

Payments to the beneficiary discharge the Centre from its payment obligation.

ARTICLE I.6 — BANK ACCOUNT FOR PAYMENTS

All payments must be made to the beneficiary's bank account denominated in euro as indicated below:

Name of bank: [redacted]

Precise denomination of the account holder: [redacted]

IBAN code [redacted]

ARTICLE I.7 — DATA CONTROLLER, COMMUNICATION DETAILS OF THE PARTIES

I.7.1 Data controller

The entity acting as a data controller as provided for in Article II.7 is the Centre.

I.7.2 Communication details of the Centre

Any communication addressed to the Centre shall be sent to the following address:

ECDC
Attn: [redacted]
Gustav III:s boulevard 40
169 73 Solna, Sweden
Email: [redacted]

I.7.3 Communication details of the beneficiary

Any communication from the Centre to the beneficiary must be sent to the following address:

[redacted]
National Institute of Public Health (NIPH) / Státní zdravotní ústav (SZU)
Srobarova 49/48, Prague 10, 100 00 Czech Republic
[redacted]

ARTICLE I.8 — ENTITIES AFFILIATED TO THE BENEFICIARY

The following entities are considered as affiliated entities for the purpose of the Agreement:

- Public Health Institute Ostrava
- Public Health Institute Usti nad Labem
- Faculty of Science, Charles University
- Institute of Molecular Genetics of the Czech Academy of Sciences
- Biology Centre, Czech Academy of Sciences
- Centre for Infectious Animal Diseases in Czech University of Life Science Prague
- The Institute of Molecular and Translational Medicine

ARTICLE I.9 — OBLIGATION TO CONCLUDE AN INTERNAL COOPERATION AGREEMENT

Not applicable.

ARTICLE I.10 — ELIGIBILITY OF COSTS

By way of derogation from Article II.19.2, the direct cost considered as eligible under this Agreement, provided that they satisfy the eligibility conditions set out in Article II.19.1, are the following:

1. points (a), (d), (f) of Article II.19.2
2. point (h) of Article II.19.2 with the following exception : the value added tax (VAT) is considered as an ineligible costs in case the activities described in Annex I are carried out by a non-taxable entity[1]

[1] Activities engaged in as a public authority by the beneficiary where it is a Member State, regional or local government authority or another body governed by public law.

3. the full cost of purchase of equipment subject to the following conditions[2]:
   i) in accordance with the usual purchasing practices of the beneficiary; and
   ii) provided that the contract is awarded to the tender offering best value for money or, as appropriate, to the tender offering the lowest price; and
   iii) avoiding any *conflict of interests*.

4. the costs related to audits.

ARTICLE I.11 — ADDITIONAL PROVISIONS

Article II.12 shall not apply.

SIGNATURES

For the beneficiary

[redacted]

Signature [redacted] Digitálně podepsal [redacted] Datum: 2021.09.06 17:33:31 +02'00'

Done at _____, on _____

In duplicate in English

For the ECDC

Director

[redacted]

Digitally signed by: [redacted] (EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL)
Date: 2021-09-07 14:19:45 UTC

Signature: _____

Done at Solna, on _____

[2] The full cost of purchase of equipment is eligible as this is justified by the nature of the action and the context of the use of the equipment.

ANNEX II — GENERAL CONDITIONS[3]

PART A — LEGAL AND ADMINISTRATIVE PROVISIONS

ARTICLE II.1 - DEFINITIONS

The following definitions apply for the purpose of the Agreement:

'Action': the set of activities or the project for which the grant is awarded, to be implemented by the beneficiary/ beneficiaries as described in Annex I;

'Breach of obligations': failure by the/a beneficiary to fulfil one or more of its contractual obligations;

'Confidential information or document': any information or document (in any format) received by either party from the other or accessed by either party in the context of the implementation of the Agreement that any of the parties has identified in writing as confidential. It does not include information that is publicly available;

'Conflict of interests': a situation where the impartial and objective implementation of the Agreement by the/a beneficiary is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest or any other shared interest with the Centre or any third party related to the subject matter of the Agreement;

'Direct costs': those specific costs which are directly linked to the implementation of the *action* and can therefore be attributed directly to it. They may not include any *indirect costs*;

'Force majeure': any unforeseeable, exceptional situation or event beyond the control of the parties that prevents either of them from fulfilling any of their obligations under the Agreement, which is not attributable to error or negligence on their part or on the part of the subcontractors affiliated entities or third parties in receipt of financial support and which proves to be inevitable despite their exercising due diligence. The following cannot be invoked as *force majeure*: labour disputes, strikes, financial difficulties or any default of a service, defect in equipment or materials or delays in making them available, unless they stem directly from a relevant case of *force majeure*;

'Formal notification': form of communication between the parties made in writing, by mail or electronic mail which provides the sender with compelling evidence that the message was delivered to the specified recipient;

'Fraud': any act or omission relating to the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, the non-disclosure of information in violation of a specific obligation, with the same effect or the misapplication of such funds or assets for purposes other than those for which they were originally granted;

[3] The general conditions are valid for both types of agreement: mono-beneficiary and multi-beneficiaries.

'Grave professional misconduct': a violation of applicable laws or regulations or ethical standards of the profession to which a person or entity belongs, or any wrongful conduct of a person or entity which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence;

'Implementation period': the period of implementation of the activities forming part of the *action*, as specified in Article I.2.2;

'Indirect costs': those costs which are not specific costs directly linked to the implementation of the *action* and which therefore cannot be attributed directly to it. They may not include any costs identifiable or declared as eligible *direct costs*;

'Irregularity': any infringement of a provision of Union law resulting from an act or omission by the/a beneficiary, which has or would have the effect of prejudicing the ECDC or Union's budget;

'Maximum amount of the grant': the maximum ECDC contribution to the *action*, as defined in Article I.3.1;

'Pre-existing material': any materials, document, technology or know-how which exists prior to the/a beneficiary using it for the production of a result in the implementation of the *action*;

'Pre-existing right': any industrial and intellectual property right on *pre-existing material*; it may consist in a right of ownership, a licence right and/or a right of use belonging to the/a beneficiary or any other third parties;

'Related person': any natural or legal person who is a member of the administrative, management or supervisory body of the beneficiary or who has the powers of representation, decision or control with regard to the/a beneficiary;

'Starting date': the date on which the implementation of the *action* starts as provided for in Article I.2.2;

'Subcontract': a procurement contract within the meaning of Article II.10, which covers the implementation by a third party of tasks forming part of the *action* as described in Annex I;

ARTICLE II.2 – GENERAL OBLIGATIONS

II.2.1 For mono-beneficiary – General obligations of the beneficiary

The beneficiary:

(a) is liable for carrying out the *action* in accordance with the Agreement;
(b) must comply with any legal obligations it is bound by under applicable EU, international and national law;
(c) must inform the Centre immediately of any events or circumstances of which the beneficiary is aware, that are likely to affect or delay the implementation of the *action*;
(d) must inform the Centre immediately:
    (i) of any change in its legal, financial, technical, organisational or ownership situation and of any change in its name, address or legal representative;

(ii) of any change in the legal, financial, technical, organisational or ownership situation of its affiliated entities and of any change in their name, address or legal representative;
(iii) of any change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046, including for its affiliated entities.

II.2.2 For multi-beneficiaries – General obligations of the beneficiaries

The beneficiaries:

(a) are jointly and severally liable for carrying out the *action* in accordance with the Agreement. If a beneficiary fails to implement its part of the *action*, the other beneficiaries become responsible for implementing this part (but without increasing the *maximum amount of the grant*);

(b) must comply jointly or individually with any legal obligations they are bound by under applicable EU, international and national law;

(c) must make appropriate internal arrangements to implement the *action* properly. The arrangements must be consistent with the terms of the Agreement. If provided for in the Special Conditions, those arrangements must take the form of an internal cooperation agreement between the beneficiaries.

II.2.3 For multi-beneficiaries – General obligations of each beneficiary

Each beneficiary must:

(a) inform the coordinator immediately of any events or circumstances of which the beneficiary is aware, that are likely to affect or delay the implementation of the *action*;

(b) inform the coordinator immediately:

(i) of any change in its legal, financial, technical, organisational or ownership situation and of any change in its name, address or legal representative;
(ii) of any change in the legal, financial, technical, organisational or ownership situation of its affiliated entities and of any change in their name, address or legal representative;
(iii)of any change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046, including for its affiliated entities;

(c) submit in due time to the coordinator:

(i) the data needed to draw up the reports, financial statements and other documents provided for in the Agreement;

(ii) all the necessary documents required for audits, checks or evaluations as provided for in Article II.27.

(iii) any other information to be provided to the Commission under the Agreement, except if the Agreement requires such information to be submitted directly by the beneficiary.

II.2.4 For multi-beneficiaries - General obligations of the coordinator

The coordinator:

(a) must monitor the implementation of the *action* in order to make sure that the *action* is implemented in accordance with the terms of the Agreement;

(b) is the intermediary for all communications between the beneficiaries and the Centre, except if provided otherwise in the Agreement. In particular, the coordinator:

(i) must immediately inform the Centre:

- of any change in the name, address, legal representative of any of the beneficiaries or of their affiliated entities;

- of any change in the legal, financial, technical, organisational or ownership situation of any of the beneficiaries or of their affiliated entities;

- of any events or circumstances of which the coordinator is aware, that are likely to affect or delay the implementation of the *action*;

- of any change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046, for any of the beneficiaries or their affiliated entities.

(ii) is responsible for supplying the Centre with all documents and information required under the Agreement, except if provided otherwise in the Agreement itself. If information is required from the other beneficiaries, the coordinator is responsible for obtaining and verifying this information before passing it on to the Centre;

(c) must make the appropriate arrangements for providing any financial guarantees required under the Agreement;

(d) must draw up the requests for payment in accordance with the Agreement;

(e) if it is designated as the sole recipient of payments on behalf of all of the beneficiaries, it must ensure that all the appropriate payments are made to the other beneficiaries without unjustified delay;

(f) is responsible for providing all the necessary documents required for checks and audits initiated before the payment of the balance or documents required for evaluation as provided for in Article II.27.

The coordinator may not subcontract any part of its tasks to the other beneficiaries or to any other party.

ARTICLE II.3 – COMMUNICATION BETWEEN PARTIES

II.3.1 Form and means of communication

Any communication relating to the Agreement or to its implementation must:

(a) be made in writing (in paper or electronic form) in the language of the Agreement;
(b) bear the number of the Agreement; and
(c) be made using the communication details identified in Article I.7.

If a party requests written confirmation of an electronic communication within a reasonable time, the sender must provide an original signed paper version of the communication as soon as possible.

II.3.2 Date of communications

Any communication is considered to have been made when the receiving party receives it, unless the Agreement states that communication is considered to have been made on the date when the communication was sent.

Email is considered to have been received by the receiving party on the day of dispatch of that email, provided that it is sent to the email address indicated in Article I.7. The sending party must be able to prove the date of dispatch. If the sending party receives a non-delivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Centre using the postal or courier services is considered to have been received by the Centre on the date on which it is registered by the department identified in Article I.7.2.

Formal notifications are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

ARTICLE II.4 – LIABILITY FOR DAMAGES

II.4.1 The Centre may not be held liable for any damage caused or sustained by the beneficiary/ any of the beneficiaries, including any damage caused to third parties as a consequence of or during the implementation of the *action*.

II.4.2 Except in cases of *force majeure*, the beneficiary/ beneficiaries must compensate the Centre for any damage it sustains as a result of the implementation of the *action* or because the *action* was not implemented in full compliance with the Agreement.

ARTICLE II.5 – CONFLICT OF INTEREST

II.5.1 The beneficiary / beneficiaries must take all necessary measures to prevent any situation of *conflict of interests*.

II.5.2 The beneficiary / beneficiaries must inform the Centre without delay of any situation constituting or likely to lead to a *conflict of interests*. It must take immediately all the necessary steps to rectify this situation.

The Centre may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

ARTICLE II.6 - CONFIDENTIALITY

II.6.1 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*.

II.6.2 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.

II.6.3 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 II.7 – PROCESSING OF PERSONAL DATA

II.7.1 Processing of personal data by the Centre

Any personal data included in the Agreement must be processed by the Centre in accordance with Regulation (EU) No 2018/1725.[4]

Such data must be processed by the data controller identified in Article I.7.1 solely for implementing, managing and monitoring the Agreement or to protect the financial interests of the EU, including checks, audits and investigations in accordance with Article II.27.

Each beneficiary has the right to access, rectify or erase its own personal data and the right to restrict or, where applicable, the right to data portability or the right to object to data processing in accordance with Regulation (EU) No 2018/1725. For this purpose, it must send any queries about the processing of its personal data to the data controller identified in Article I.7.1.

The beneficiary/ beneficiaries may have recourse at any time to the European Data Protection Supervisor.

II.7.2 Processing of personal data by the beneficiary

The beneficiary/ beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiary/ beneficiaries may grant its personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement. The beneficiary/ beneficiaries must ensure that the personnel authorised to process personal data has committed itself to confidentiality or is under appropriate statutory obligation of confidentiality.

[4] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

The beneficiary/ beneficiaries must adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature, scope, context and purposes of processing of the personal data concerned. This is in order to ensure, as appropriate:

(a) the pseudonymisation and encryption of personal data;

(b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;

(c) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;

(d) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing;

(e) measures to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to personal data transmitted, stored or otherwise processed.

ARTICLE II.8 – VISIBILITY OF CENTRE FUNDING

II.8.1 Information on Centre funding and use of the ECDC logo

Unless the Centre requests or agrees otherwise, any communication or publication made by the beneficiary/ beneficiaries jointly or individually 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 Centre; and
(b) display the Centre logo.

When displayed in association with another logo, the ECDC logo must have appropriate prominence.

The obligation to display the ECDC logo does not confer on the beneficiary/ beneficiaries a right of exclusive use. The beneficiary/ beneficiaries may not appropriate the European Union emblem or any similar trademark or logo, either by registration or by any other means.

For the purposes of the first, second and third subparagraphs and under the conditions specified therein, the beneficiary/ beneficiaries may use the ECDC logo without first obtaining permission from the Centre.

II.8.2 Disclaimers excluding Centre responsibility

Any communication or publication that relates to the *action*, made by the beneficiary/ beneficiaries jointly or individually in any form and using any means, must indicate:

(a) that it reflects only the author's view; and
(b) that the Centre is not responsible for any use that may be made of the information it contains.

ARTICLE II.9 – PRE-EXISTING RIGHTS AND OWNERSHIP AND USE OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

II.9.1 Ownership of the results by the beneficiary

The beneficiary/ beneficiaries retain/s ownership of the results of the *action*, including industrial and intellectual property rights, and of the reports and other documents relating to it, unless stipulated otherwise in the Agreement.

II.9.2 Pre-existing rights

If the Centre sends a beneficiary a written request specifying which of the results it intends to use, the beneficiary concerned must:

(a) establish a list specifying all *pre-existing rights* included in those results; and
(b) provide this list to the Centre at the latest with the request for payment of the balance.

The beneficiary/ beneficiaries must ensure that it or its affiliated entities have all the rights to use any *pre-existing rights* during the implementation of the Agreement.

II.9.3 Rights of use of the results and of pre-existing rights by the Centre

The beneficiary/ beneficiaries must grant the Centre the following rights to use the results of the *action*:

(a) for its own purposes and in particular to make available to persons working for the Centre, other Union institutions, agencies and bodies and to Member States' institutions, as well as to copy and reproduce in whole or in part and in an unlimited number of copies;
(b) reproduction: the right to authorise direct or indirect, temporary or permanent reproduction of the results by any means (mechanical, digital or other) and in any form, in whole or in part;
(c) communication to the public: the right to authorise any display performance or communication to the public, by wire or wireless means, including making the results available to the public in such a way that members of the public may access them from a place and at a time individually chosen by them; this right also includes communication and broadcasting by cable or by satellite;
(d) distribution: the right to authorise any form of distribution of results or copies of the results to the public;
(e) adaptation: the right to modify the results;
(f) translation;
(g) the right to store and archive the results in line with the document management rules applicable to the Centre, including digitisation or converting the format for preservation or new use purposes;
(h) where the results are documents, the right to authorise the reuse of the documents in conformity with Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents if that Decision is applicable and if the documents fall within its scope and are not excluded by any of its provisions. For the sake of this provision, the terms 'reuse' and 'document' have the meanings given to them by Decision 2011/833/EU.

The above rights of use may be further specified in the Special Conditions.

Additional rights of use for the Centre may be provided for in the Special Conditions.

The beneficiary/ beneficiaries must ensure that the Centre has the right to use any *pre-existing rights* included in the results of the *action.* The *pre-existing rights* must be used for the same purposes and under the same conditions as applicable to the rights of use of the results of the *action,* unless specified otherwise in the Special Conditions.

Information about the copyright owner must be inserted in cases where the result is divulged by the Centre. The copyright information must read: '© — year — name of the copyright owner. All rights reserved. Licenced to the European Centre for Disease Prevention and Control under conditions.'.

If a beneficiary grants rights of use to the Centre, this does not affect its confidentiality obligations under Article II.6 or the beneficiary's obligation under Article II.2.

ARTICLE II.10 – AWARD OF CONTRACTS NECESSARY FOR THE IMPLENTATION OF THE ACTION

II.10.1 If the implementation of the *action* requires the beneficiary/ beneficiaries 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 beneficiary/ beneficiaries must ensure that the Centre, the European Court of Auditors and the European Anti-Fraud Office (OLAF) can exercise their rights under Article II.27 also towards the beneficiary' contractors.

II.10.2 The beneficiary that is a 'contracting authority' within the meaning of Directive 2014/24/EU[5] or 'contracting entity' within the meaning of Directive 2014/25/EU[6] must comply with the applicable national public procurement rules.

The beneficiary/ beneficiaries 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.

II.10.3 The beneficiary/ beneficiaries remain/s solely responsible for carrying out the *action* and for compliance with the Agreement.

II.10.4. If a beneficiary 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 a beneficiary breaches its obligations under Article II.10.2 the grant may be reduced in accordance with Article II.25.4.

[5] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC

[6] Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC

ARTICLE II.11 – SUBCONTRACTING OF TASKS FORMING PART OF THE ACTION

II.11.1 The beneficiary/ beneficiaries may subcontract tasks forming part of the *action*. If it does so, it must ensure that, in addition to the conditions specified in Article II.10, the following conditions are also complied with:

(a) subcontracting does not cover core tasks of the *action*;

(b) recourse to subcontracting is justified because of the nature of the *action* and what is necessary for its implementation;

(c) the estimated costs of the subcontracting are clearly identifiable in the estimated budget set out in Annex III;

(d) any recourse to subcontracting, if not provided for in Annex I, is communicated by the beneficiary/ coordinator[7] and approved by the Centre. The Centre may grant approval:

(i) before any recourse to subcontracting, if the beneficiary/ coordinator requests an amendment as provided for in Article II.13; or

(ii) after recourse to subcontracting, if the subcontracting:

- is specifically justified in the interim, or final technical report referred to in Articles I.4.3 and I.4.4; and
- does not entail changes to the Agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants;

(e) the beneficiary/ beneficiaries ensure/s that the conditions applicable to it under Article II.8 are also applicable to the subcontractors.

II.11.2 If the beneficiary/ beneficiaries breach/es obligations under Article II.11.1 (a), (b), (c) or (d), the costs related to the contract concerned are considered ineligible in accordance with Article II.19.2 (f).

If the beneficiary/ beneficiaries breach/es obligation under Article II.11.1 (e) the grant may be reduced in accordance with Article II.25.4.

ARTICLE II.12 – FINANCIAL SUPPORT TO THIRD PARTIES

II.12.1 If, while implementing the *action*, the beneficiary has / beneficiaries have to give financial support to third parties, the beneficiary/ beneficiaries must give such financial support in accordance with the conditions specified in Annex I. Under those conditions, the following information must be stated at least:

(a) the maximum amount of financial support. This amount may not exceed EUR 60 000 for each third party except if achieving the objective of the *action* as specified in Annex I would otherwise be impossible or overly difficult ;

(b) the criteria for determining the exact amount of the financial support;

(c) the different types of activity that may receive financial support, on the basis of a fixed list;

(d) the persons or categories of persons which may receive financial support;

(e) the criteria for giving the financial support.

[7] When reference is made to coordinator, this is applicable for the multi-beneficiaries' agreement.

II.12.2 As an exception to Article II.12.1, if the financial support takes the form of a prize, the beneficiary must give such financial support in accordance with the conditions specified in Annex I. Under those conditions, the following information must at least be stated:

(a) the eligibility and award criteria;
(b) the amount of the prize;
(c) the payment arrangements.

II.12.3 The beneficiary/ beneficiaries must ensure that the conditions applicable to it under Articles II.4, II.5, II.6, II.8, II.9 and II.27 are also applicable to the third parties receiving financial support.

ARTICLE II.13 – AMENDMENTS TO THE AGREEMENT

II.13.1 Any amendment to the Agreement must be made in writing.

II.13.2 An amendment may not have the purpose or the effect of making changes to the Agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants.

II.13.3 Any request for amendment must:

(a) be duly justified;
(b) be accompanied by appropriate supporting documents; and
(c) be sent to the other party in due time before it is due to take effect, and in any case one month before the end of the *implementation period*.

Point (c) does not apply in cases duly substantiated by the party requesting the amendment if the other party agrees.

II.13.4 For a multi-beneficiaries' agreement, a request for amendment on behalf of the beneficiaries must be submitted by the coordinator. If a change of coordinator is requested without its agreement, the request must be submitted by all other beneficiaries and must be accompanied by the opinion of the coordinator or proof that this opinion has been requested in writing.

II.13.5 Amendments enter into force on the date on which the last party signs or on the date of approval of the request for amendment.

Amendments take effect on a date agreed by the parties or, in the absence of such an agreed date, on the date on which the amendment enters into force.

ARTICLE II.14 – ASSIGNMENT OF CLAIMS FOR PAYMENTS TO THIRD PARTIES

II.14.1 The beneficiary/ beneficiaries may not assign any of its claims for payment against the Centre to any third party, except if approved by the Centre on the basis of a reasoned, written request by the beneficiary.

If the Centre does not accept the assignment or the terms of it are not complied with, the assignment has no effect on it.

II.14.2 In no circumstances may an assignment release the beneficiary/ beneficiaries from obligations towards the Centre.

ARTICLE II.15 – FORCE MAJEURE

II.15.1 A party faced with *force majeure* must send a *formal notification* to the other party without delay, stating the nature of the situation or of the event, its likely duration and foreseeable effects.

II.15.2 The parties must take the necessary measures to limit any damage due to *force majeure*. They must do their best to resume the implementation of the *action* as soon as possible.

II.15.3 The party faced with *force majeure* may not be considered in breach of its obligations under the Agreement if it has been prevented from fulfilling them by *force majeure*.

ARTICLE II.16 – SUSPENSION OF THE IMPLEMENTATION OF THE ACTION

II.16.1 Suspension of implementation by the beneficiary

The beneficiary/ coordinator may suspend the implementation of the *action* or any part of it, if exceptional circumstances make such implementation impossible or excessively difficult, in particular in the event of *force majeure*.

The beneficiary/ coordinator must immediately inform the Centre, stating:

(a) the reasons for suspension, including details about the date or period when the exceptional circumstances occurred; and
(b) the expected date of resumption.

Once the circumstances allow the beneficiary/ beneficiaries to resume implementing the *action*, the beneficiary/ beneficiaries must inform the Centre immediately and present a request for amendment of the Agreement as provided for in Article II.16.3. This obligation does not apply if the Agreement is terminated in accordance with Articles II.17.1 or points (b) or (c) of Article II.17.2.1.

II.16.2 Suspension of implementation by the Centre

II.16.2.1 Grounds for suspension

The Centre may suspend the implementation of the *action* or any part thereof:

(a) if the Centre has evidence that a beneficiary has committed *irregularities*, *fraud* or *breach of obligations* in the award procedure or while implementing the Agreement;
(b) if the Centre has evidence that a beneficiary has committed systemic or recurrent *irregularities, fraud* or serious *breach of obligations* in other grants funded by the Centre or the Union or the European Atomic Energy Community ('Euratom') awarded to the beneficiary under similar conditions and the *irregularities, fraud* or *breach of obligations* have a material impact on this grant; or

(c) if the Centre suspects *irregularities, fraud* or *breach of obligations* committed by a beneficiary in the award procedure or while implementing the Agreement and needs to verify whether they have actually occurred.

II.16.2.2 Procedure for suspension

Step 1 Before suspending implementation of the *action*, the Centre must send a *formal notification* to the beneficiary/ coordinator:

(a) informing it of:
  (i) its intention to suspend the implementation;
  (ii) the reasons for suspension;
  (iii) the necessary conditions for resuming the implementation in the cases referred to in points (a) and (b) of Article II.16.2.1; and
(b) inviting it to submit observations within 30 calendar days of receiving the *formal notification*.

Step 2 If the Centre does not receive observations or decides to pursue the procedure despite the observations it has received, it must send a *formal notification* to the beneficiary/ coordinator informing it of:

(a) the suspension of the implementation;
(b) the reasons for suspension; and
(c) the final conditions for resuming the implementation in the cases referred to in points (a) and (b) of Article II.16.2.1; or
(d) the indicative date of completion of the necessary verification in the case referred to in point (c) of Article II.16.2.1.

For mono-beneficiary, the suspension takes effect on the day the *formal notification* is received by the beneficiary or on a later date specified in the *formal notification*.

For multi-beneficiaries, the coordinator must immediately inform the other beneficiaries of the suspension. The suspension takes effect five calendar days after the *formal notification* is received by the coordinator or on a later date specified in the *formal notification*.

Otherwise, the Centre must send a *formal notification* to the beneficiary/ coordinator informing it that it is not continuing the suspension procedure.

II.16.2.3 Resuming implementation

In order to resume the implementation, the beneficiary/ beneficiaries must meet the notified conditions as soon as possible and must inform the Centre of any progress made.

If the conditions for resuming the implementation are met or the necessary verifications are carried out, the Centre must send a *formal notification* to the beneficiary/ coordinator:

(a) informing it that the conditions for lifting the suspension are met; and
(b) requiring it to present a request for amendment of the Agreement as provided for in Article II.16.3. This obligation does not apply if the Agreement is terminated in accordance with Articles II.17.1 or points (b), (f) or (g) of Article II.17.2.1.

II.16.3 Effects of the suspension

If the implementation of the *action* can be resumed and the Agreement has not been terminated, an amendment to the Agreement must be made in accordance with Article II.13 in order to:

(a) set the date on which the *action* is to be resumed;
(b) extend the duration of the *action*; and
(c) make other changes necessary to adapt the *action* to the new situation.

The suspension is lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during the period of suspension that relate to the implementation of the suspended *action* or the suspended part of it may not be reimbursed or covered by the grant.

Suspending implementation of the *action* does not affect the Centre's right to terminate the Agreement or to terminate the participation of a beneficiary in accordance with Article II.17.2, reduce the grant or recover amounts unduly paid in accordance with Articles II.25.4 and II.26.

Neither party may claim damages due to suspension by the other party.

ARTICLE II.17 – TERMINATION OF THE AGREEMENT

II.17.1 Termination of the Agreement by the beneficiary/ beneficiaries

The beneficiary/ beneficiaries may terminate the Agreement.

1. The beneficiary/coordinator must send a *formal notification* of termination to the Centre, stating:

(a) the reasons for termination; and
(b) the date on which the termination takes effect. This date must be set after the *formal notification.*

If the beneficiary/coordinator does not state the reasons for the termination or if the Centre considers that the reasons do not justify termination, the Agreement is considered to have been terminated improperly.

The termination takes effect on the day specified in the *formal notification.*

2. The participation of one or more beneficiaries may be terminated by the coordinator at the request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must send a *formal notification* of termination to the Centre and inform the beneficiary concerned by termination.

If the coordinator's participation is terminated without its agreement, the *formal notification* must be submitted by another beneficiary (acting on behalf of the other beneficiaries).

The *formal notification* must include:

(a) the reasons for termination;
(b) the opinion of the beneficiary concerned by termination (or proof that this opinion has been requested in writing);

(c) the date on which the termination takes effect. This date must be set after the *formal notification*; and
(d) a request for amendment as provided for in Article II.17.4.2(a).

If the coordinator or beneficiary does not state the reasons for the termination or if the Centre considers that the reasons do not justify termination, the participation will be considered to have been terminated improperly. or the participation of one or more beneficiaries

The termination takes effect on the day specified in the *formal notification*.

II.17.2 Termination of the Agreement or the participation of one or more beneficiaries by the Centre

II.17.2.1 Grounds for termination

The Centre may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to affect the implementation of the Agreement substantially or calls into question the decision to award the grant, or a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046, that calls into question the decision to award the grant;

(b) a beneficiary, any *related person* or any natural person who is essential for the award or for the implementation of the Agreement have committed serious *breach of obligations*, including improper implementation of the *action* as described in Annex I;

(c) the implementation of the *action* is prevented or suspended due to *force majeure* or exceptional circumstances and either:
  (i) resumption is impossible; or
  (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or be contrary to the equal treatment of applicants;

(d) a beneficiary or a natural or legal person that assumes unlimited liability for the debts of the beneficiary:
  (i) is declared bankrupt, is subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a Court, has entered into an agreement with creditors, has suspended business activities or is in any analogous situation arising from a similar procedure provided for under the Union or national law;
  (ii) is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the applicable law;

(e) a beneficiary or any *related person* or any natural person who is essential for the award or for the implementation of the Agreement has committed:
  (i) *grave professional misconduct* proven by any means;
  (ii) *fraud*;
  (iii) corruption;
  (iv) conduct related to criminal organisations;
  (v) money laundering;
  (vi) terrorism-related crimes (including terrorism financing);

(vii) child labour or other offences concerning trafficking of human beings;

(f) the Centre has evidence that a beneficiary or any *related person* or any natural person who is essential for the award or for the implementation of the Agreement has committed *irregularities, fraud* or *breach of obligations* in the award procedure or while implementing the Agreement, including if the beneficiary or *related person* or natural person has submitted false information or failed to provide required information;

(g) the Centre has evidence that a beneficiary has committed systemic or recurrent *irregularities*, *fraud* or serious *breach of obligations* in other Union or Euratom grants awarded to it under similar conditions and such *irregularities, fraud* or *breach of obligations* have a material impact on this grant;

(h) a beneficiary or any *related person* or any natural person who is essential for the award or for the implementation of the Agreement has created an entity under a different jurisdiction with the intend to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration or principal place of business;

(i) a beneficiary or any *related person* has been created with the intend referred to in point (h) or

(j) the Centre has sent a beneficiary, in case of multi-beneficiaries through the coordinator, a *formal notification* asking it to end the participation of its affiliated entity because that entity is in a situation provided for in points (d) to (i) and that beneficiary has failed to request an amendment ending the participation of the entity and reallocating its tasks;

(k) for multi-beneficiaries, following the termination of the participation of any one or several beneficiaries, the necessary modifications to the Agreement would call into question the decision awarding the grant or would result in unequal treatment of applicants.

II.17.2.2 Procedure for termination

Step 1- Before terminating the Agreement or participation of one or more beneficiaries, the Centre must send a *formal notification* to the beneficiary for mono-beneficiary, or to the coordinator for multi-beneficiaries:

(a) informing it of:
  (i) its intention to terminate;
  (ii) the reasons for termination; and
(b) requiring it, within 45 calendar days of receiving the *formal notification*:
  (i) to submit observations[8]; and
  (ii) in the case of point (b) of Article II.17.2.1, to inform the Centre of the measures to ensure compliance with the obligations under the Agreement.

Step 2 — If the Centre does not receive observations or decides to pursue the procedure despite the observations it has received, it will send a *formal notification* to the beneficiary informing it of the termination and the date on which it takes effect. In case of multi-

[8] For multi-beneficiaries, the coordinator shall submit observations on behalf of all beneficiaries.

beneficiaries, the formal notification will be sent to the coordinator and the latter must immediately inform the other beneficiaries of the termination.

Otherwise, the Centre must send a *formal notification* to the beneficiary/coordinator informing it that the termination procedure is not continued.

The termination takes effect:

(a) for terminations under points (a), (b) and (d) of Article II.17.2.1: on the day specified in the *formal notification* of termination referred to in the second subparagraph (i.e. in Step 2 above);

(b) for terminations under points (c), (e) to (j) of Article II.17.2.1: on the day after the beneficiary receives the *formal notification* of termination referred to in the second subparagraph (i.e. in Step 2 above).

II.17.3 Effects of termination

1. Effects of terminating the Agreement

Within 60 calendar days from the day on which the termination takes effect, the beneficiary/ coordinator must submit a request for payment of the balance as provided for in Article I.4.4.

If the Centre does not receive the request for payment of the balance by the above deadline, only costs or contributions which are included in an approved technical report and, where relevant, in an approved financial statement, are reimbursed or covered by the grant.

If the Agreement is terminated by the Centre because the beneficiary/ coordinator has breached its obligation to submit the request for payment, the beneficiary/ coordinator may not submit any request for payment after termination. In that case the second subparagraph applies.

The Centre calculates the final grant amount as referred to in Article II.25 and the balance as referred to in Article I.5.4 on the basis of the reports submitted. Only activities undertaken before the date when the termination takes effect or the end date of the *implementation period* as specified in Article I.2.2, whichever is the earliest, must be taken into account. Where the grant takes the form of reimbursement of costs actually incurred as provided for in Article I.3.2(a)(i), only costs incurred before termination takes effect are reimbursed or covered by the grant. Costs relating to contracts due for execution only after termination are not taken into account and are not reimbursed or covered by the grant.

The Centre may reduce the grant in accordance with Article II.25.4 in case of:

(a) improper termination of the Agreement by the beneficiary/ coordinator within the meaning of Article II.17.1; or

(b) termination of the Agreement by the Centre on any of the grounds set out in points (b) to (j) of Article II.17.2.1.

Neither party may claim damages on the grounds that the other party terminated the Agreement.

After termination, the beneficiary's / beneficiaries' obligations continue to apply, in particular those under Articles I.4, II.6, II.8, II.9, II.14, II.27 and any additional provisions on the use of the results, as set out in the Special Conditions.

2. For multi-beneficiaries, effects of terminating the participation of one or more beneficiaries

(a) The coordinator must submit a request for amendment including:

(i) a proposal to reallocate the tasks of the beneficiary or beneficiaries concerned by the termination; and
(ii) if necessary, the addition of one or more new beneficiaries to succeed the beneficiary or beneficiaries concerned in all their rights and obligations under the Agreement.

If the Centre terminates the participation of a beneficiary, the coordinator must submit the request for amendment within 60 calendar days from the day on which the termination takes effect.

If the coordinator terminates the participation of a beneficiary, the request for amendment must be included in the *formal notification* of termination referred to in Article II.17.2.

If termination takes effect after the end of the *implementation period*, no request for amendment must be provided unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Centre, the Agreement may be terminated in accordance with Article II.17.2.1 (k). The request for amendment may be rejected if it calls into question the decision awarding the grant or is contrary to the equal treatment of applicants.

(b) The beneficiary concerned by termination must submit to the coordinator:

(i) a technical report; and
(ii) where applicable, a financial statement covering the period from the end of the last reporting period to the date when termination takes effect.

The coordinator must include this information in the payment request for the next reporting period.

Only activities undertaken before the date when the termination takes effect must be taken into account. Where the grant takes the form of reimbursement of costs actually incurred as provided for in Article I.3.2(a)(i), only costs incurred by the beneficiary concerned before termination takes effect are reimbursed or covered by the grant. Costs relating to contracts due for execution only after termination are not reimbursed or covered by the grant.

The Centre may reduce the grant in accordance with Article II.25.4. in case of:

(a) improper termination of the participation of a beneficiary by the coordinator within the meaning of Article II.17.2 or
(b) termination of the participation of a beneficiary by the Centre on any of the grounds set out in points (c), (f), (g), (h) or (i) of Article II.17.3.1.

Neither party may claim damages on the grounds that the other party terminated the participation of a beneficiary.

After termination, the concerned beneficiary's obligations continue to apply, in particular those under Articles I.4, II.6, II.8, II.9, II.14, II.27 and any additional provisions on the use of the results, as set out in the Special Conditions.

ARTICLE II.18 – APPLICABLE LAW, SETTLEMENT OF DISPUTES AND ENFORCEABLE DECISIONS

II.18.1 The Agreement is governed by the applicable Union law, complemented, where necessary, by the law of Sweden.

II.18.2 In accordance with Article 272 TFEU, the General Court or, on appeal, the Court of Justice of the European Union, has sole jurisdiction to hear any dispute between the Union and any beneficiary concerning the interpretation, application or validity of the Agreement, if such dispute cannot be settled amicably.

II.18.3 In accordance with Article 299 TFEU, for the purposes of recovery within the meaning of Article II.26, the Centre may adopt an enforceable decision to impose pecuniary obligations on persons other than States.

An *action* may be brought against such decision before the General Court of the European Union in accordance with Article 263 TFEU.

PART B — FINANCIAL PROVISIONS

ARTICLE II.19 – ELIGIBLE COSTS

II.19.1 Conditions for the eligibility of costs

Eligible costs of the *action* are costs actually incurred by the beneficiary and which meet the following criteria:

(a) they are incurred within the *implementation period*, with the exception of costs relating to the request for payment of the balance and the corresponding supporting documents referred to in Article I.4.4;

(b) they are indicated in the estimated budget. The estimated budget is set out in Annex III;

(c) they are incurred in connection with the *action* as described in Annex I and are necessary for its implementation;

(d) they are identifiable and verifiable, in particular they are recorded in the beneficiary's accounting records and determined according to the applicable accounting standards of the country where the beneficiary is established and according to the beneficiary's usual cost accounting practices;

(e) they comply with the requirements of applicable tax and social legislation; and

(f) they are reasonable, justified and comply with the principle of sound financial management, in particular regarding economy and efficiency.

II.19.2 Eligible direct costs

To be eligible, the *direct costs* of the *action* must comply with the eligibility conditions set out in Article II.19.1.

In particular, the following categories of costs are eligible *direct costs*, provided that they satisfy the eligibility conditions set out in Article II.19.1 as well as the following conditions:

(a) the costs of personnel working under an employment contract with the beneficiary or an equivalent appointing act and assigned to the *action*, provided that these costs are in line with the beneficiary's usual policy on remuneration.

Those costs include actual salaries plus social security contributions and other statutory costs included in the remuneration. They may also comprise additional remunerations, including payments on the basis of supplementary contracts regardless of the nature of those contracts, provided that they are paid in a consistent manner whenever the same kind of work or expertise is required, independently from the source of funding used.

The costs of natural persons working under a contract with the beneficiary other than an employment contract or who are seconded to the beneficiary by a third party against payment may also be included under such personnel costs, provided that the following conditions are fulfilled:

(i) the person works under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed);
(ii) the result of the work belongs to the beneficiary (unless exceptionally agreed otherwise); and
(iii) the costs are not significantly different from the costs of staff performing similar tasks under an employment contract with the beneficiary;

(b) costs of travel and related subsistence allowances, provided that these costs are in line with the beneficiary's usual practices on travel;

(c) the depreciation costs of equipment or other assets (new or second-hand) as recorded in the beneficiary's accounting statements, provided that the asset:
(i) is written off in accordance with the international accounting standards and the beneficiary's usual accounting practices; and
(ii) has been purchased in accordance with Article II.10.1 if the purchase occurred within the *implementation period*;

The costs of renting or leasing equipment or other assets are also eligible, provided that these costs do not exceed the depreciation costs of similar equipment or assets and are exclusive of any finance fee;

Only the portion of the equipment's depreciation, rental or lease costs corresponding to the *implementation period* and the rate of actual use for the purposes of the *action* may be taken into account when determining the eligible costs. By way of exception, the full cost of purchase of equipment may be eligible under the Special Conditions, if this is justified by the nature of the *action* and the context of the use of the equipment or assets;

(d) costs of consumables and supplies, provided that they:
(i) are purchased in accordance with Article II.10.1; and
(ii) are directly assigned to the *action*;

(e) costs arising directly from requirements imposed by the Agreement (dissemination of information, specific evaluation of the *action*, audits, translations, reproduction), including the costs of requested financial guarantees, provided that the corresponding services are purchased in accordance with Article II.10.1;

(f) costs entailed by *subcontracts* within the meaning of Article II.11, provided that the conditions laid down in Article II.11.1 (a), (b), (c) and (d) are met;

(g) costs of financial support to third parties within the meaning of Article II.12, provided that the conditions laid down in that Article are met;

(h) duties, taxes and charges paid by the beneficiary, notably value added tax (VAT), provided that they are included in eligible *direct costs*, and unless specified otherwise in the Agreement.

II.19.3 Eligible indirect costs

To be eligible, *indirect costs* of the *action* must represent a fair apportionment of the overall overheads of the beneficiary and must comply with the conditions of eligibility set out in Article II.19.1.

Eligible *indirect costs* must be declared on the basis of a flat rate of 7 % of the total eligible *direct costs* unless otherwise specified in Article I.3.2.

II.19.4 Ineligible costs

In addition to any other costs which do not fulfil the conditions set out in Article II.19.1, the following costs may not be considered eligible:

(a) return on capital and dividends paid by the beneficiary;
(b) debt and debt service charges;
(c) provisions for losses or debts;
(d) interest owed;
(e) doubtful debts;
(f) exchange losses;
(g) costs of transfers from the Centre charged by the bank of the beneficiary;
(h) costs declared by the beneficiary under another *action* receiving a grant financed from the Centre budget or the Union budget. Such grants include grants awarded by a Member State and financed from the Union budget and grants awarded by bodies other than the Centre for the purpose of implementing the Union budget. In particular, if the beneficiary receives an operating grant financed by the EU or Euratom budget, it may not declare *indirect costs* for the period(s) covered by the operating grant, unless it can demonstrate that the operating grant does not cover any costs of the *action*;
(i) contributions in kind from third parties;
(j) excessive or reckless expenditure;
(k) deductible VAT.

ARTICLE II.20 – IDENTIFIABILITY AND VERIFIABILITY OF THE AMOUNTS DECLARED

II.20.1 Declaring costs and contributions

The/ each beneficiary must declare as eligible costs or as a requested contribution:

(a) for actual costs: the costs it actually incurred for the *action*;

(b) for unit costs or unit contributions: the amount obtained by multiplying the amount per unit specified in Article I.3.2(a)(ii) or (b) by the actual number of units used or produced;

(c) for lump sum costs or lump sum contributions: the global amount specified in Article I.3.2(a)(iii) or (c), if the corresponding tasks or part of the *action* as described in Annex I have been implemented properly;

(d) for flat-rate costs or flat-rate contributions: the amount obtained by applying the flat rate specified in Article I.3.2(a)(iv) or (d);

(e) for financing not linked to costs: the global amount specified in Article I.3.2(e), if the corresponding results or conditions as described in Annex I have been properly achieved or fulfilled;

(f) for unit costs declared on the basis of the beneficiary's usual cost accounting practices: the amount obtained by multiplying the amount per unit calculated in accordance with the beneficiary's usual cost accounting practices by the actual number of units used or produced;

(g) for lump sum costs declared on the basis of the beneficiary's usual cost accounting practices: the global amount calculated in accordance with its usual cost accounting practices, if the corresponding tasks or part of the *action* have been implemented properly;

(h) for flat-rate costs declared on the basis of the beneficiary's usual cost accounting practices: the amount obtained by applying the flat rate calculated in accordance with the beneficiary's usual cost accounting practices.

For the forms of grant referred to in points (b), (c), (d), (f), (g) and (h), the amounts declared must comply with the conditions specified in points (a) and (b) of Article II.19.1.

II.20.2 Records and other documentation to support the costs and contributions declared

The/ each beneficiary must provide the following if requested to do so in the context of the checks or audits described in Article II.27:

(a) for actual costs: adequate supporting documents to prove the costs declared, such as contracts, invoices and accounting records.
In addition, the beneficiary's usual accounting and internal control procedures must permit direct reconciliation of the amounts declared with the amounts recorded in its accounting statements and with the amounts indicated in the supporting documents;

(b) for unit costs or unit contributions: adequate supporting documents to prove the number of units declared.
The beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, such as accounting statements, to prove the amount declared per unit;

(c) for lump sum costs or lump sum contributions: adequate supporting documents to prove that the *action* has been properly implemented.
The beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, such as accounting statements, to prove the amount declared as a lump sum;

(d) for flat-rate costs or flat-rate contributions: adequate supporting documents to prove the eligible costs or requested contribution to which the flat rate applies.
The beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, such as accounting statements, for the flat rate applied;

(e) for financing not linked to costs: adequate supporting documents to prove that the *action* has been properly implemented;
The beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, such as accounting statements, to prove the amount declared as a financing not linked to costs;

(f) for unit costs declared on the basis of the beneficiary's usual cost accounting practices: adequate supporting documents to prove the number of units declared;

(g) for lump sum costs declared on the basis of the beneficiary's usual cost accounting practices: adequate supporting documents to prove that the *action* has been properly implemented;

(h) for flat-rate costs declared on the basis of the beneficiary's usual cost accounting practices: adequate supporting documents to prove the eligible costs to which the flat rate applies.

II.20.3 Conditions to determine the compliance of cost accounting practices

II.20.3.1 In the case of points (f), (g) and (h) of Article II.20.2, the beneficiary does not need to identify the actual eligible costs covered, but it must ensure that the cost accounting practices used for the purpose of declaring eligible costs are in compliance with the following conditions:
(a) the cost accounting practices used constitute its usual cost accounting practices and are applied in a consistent manner, based on objective criteria independent from the source of funding;
(b) the costs declared can be directly reconciled with the amounts recorded in its general accounts; and
(c) the categories of costs used for the purpose of determining the costs declared are exclusive of any ineligible cost or costs covered by other forms of grant as provided for in Article I.3.2.

II.20.3.2 If the Special Conditions so provide, the beneficiary may submit to the Centre a request asking it to assess the compliance of its usual cost accounting practices. If required by the Special Conditions, the request must be accompanied by a certificate on the compliance of the cost accounting practices ('certificate on the compliance of the cost accounting practices').

The certificate on the compliance of the cost accounting practices must be:
(a) produced by an approved auditor or, if the beneficiary is a public body, by a competent and independent public officer; and
(b) drawn up in accordance with Annex VII.

The certificate must certify that the beneficiary's cost accounting practices used for the purpose of declaring eligible costs comply with the conditions laid down in Article II.20.3.1 and with the additional conditions that may be laid down in the Special Conditions.

II.20.3.3 If the Centre has confirmed that the beneficiary's usual cost accounting practices are in compliance, costs declared in application of these practices may not be challenged *ex post*, if:

(a) the practices actually used comply with those approved by the Centre; and

(b) the beneficiary did not conceal any information for the purpose of the approval of its cost accounting practices.

ARTICLE II.21 – ELIGIBILITY OF COSTS OF ENTITIES AFFILIATED TO THE BENEFICIARY

If the Special Conditions contain a provision on entities affiliated to the beneficiary, costs incurred by such an entity are eligible, if:

(a) they satisfy the same conditions under Articles II.19 and II.20 as apply to the beneficiary; and

(b) the beneficiary ensures that the conditions applicable to it under Articles II.4, II.5, II.6, II.8, II.10, II.11 and II.27 are also applicable to the entity.

ARTICLE II.22 – BUDGET TRANSFERS

The beneficiary/ beneficiaries is/are allowed to adjust the estimated budget set out in Annex III by transfers between the different budget categories, if the *action* is implemented as described in Annex I. This adjustment does not require an amendment of the Agreement as provided for in Article II.13.

However, the beneficiary/ beneficiaries may not add costs relating to *subcontracts* not provided for in Annex 1, unless such additional *subcontracts* are approved by the Centre in accordance with Article II.11.1(d).

For multi-beneficiaries, as an exception to the first subparagraph, if beneficiaries want to change the value of the contribution to which each of them is entitled, as referred to in point (c) of the third subparagraph of II.26.3, the coordinator must request an amendment as provided for in Article II.13.

The first three subparagraphs do not apply to amounts which, as provided for in Article I.3.2(a)(iii) or (c), take the form of lump sums or which, as provided for in Article I.3.2(e), take the form of financing not linked to cost.

ARTICLE II.23 – NON-COMPLIANCE WITH THE REPORTING OBLIGATIONS

The Centre may terminate the Agreement as provided for in Article II.17.2.1(b) and may reduce the grant as provided for in Article II.25.4 if the beneficiary/ coordinator:

(a) did not submit a request for interim payment or payment of the balance accompanied by the documents referred to in Articles I.4.3 or I.4.4 within 60 calendar days following the end of the corresponding reporting period; and
(b) still fails to submit such a request within further 60 calendar days following a written reminder sent by the Centre.

ARTICLE II.24 – SUSPENSION OF PAYMENTS AND TIME LINE FOR PAYMENT

II.24.1 Suspension of payments

II.24.1.1 Grounds for suspension

The Centre may, at any time during the implementation of the Agreement, suspend the pre-financing payments, interim payments, for multi-beneficiaries for one or more beneficiaries, or payment of the balance for the beneficiary/ all beneficiaries[9]:

(a) if the Centre has evidence that the/ a beneficiary has committed *irregularities, fraud* or *breach of obligations* in the award procedure or while implementing the Agreement;
(b) if the Centre has evidence that the/ a beneficiary has committed systemic or recurrent *irregularities, fraud* or serious *breach of obligations* in other grants funded by the Centre or the Union or the European Atomic Energy Community ('Euratom') awarded to the beneficiary under similar conditions and such *irregularities, fraud* or *breach of obligations* have a material impact on this grant; or
(c) if the Centre suspects *substantial irregularities, fraud* or *breach of obligations* committed by the/ a beneficiary in the award procedure or while implementing the Agreement and needs to verify whether they have actually occurred.

II.24.1.2 Procedure for suspension

Step 1 — Before suspending payments, the Centre must send a *formal notification* to the beneficiary/ coordinator:

(a) informing it of:
  (i) its intention to suspend payments;
  (ii) the reasons for suspension;
  (iii) in the cases referred to in points (a) and (b) of Article II.24.1.1, the conditions that need to be met for payments to resume; and
(b) inviting it to submit observations within 30 calendar days of receiving the *formal notification*.

Step 2 — If the Centre does not receive observations or decides to pursue the procedure despite the observations it has received, it must send a *formal notification* to the beneficiary/ coordinator informing it of:

(a) the suspension of payments;
(b) the reasons for suspension;

[9] For multi-beneficiaries, payment of the balance can be suspended only for all beneficiaries. Payment of the balance cannot be suspended for one or more beneficiaries individually.

(c) the final conditions under which payments may resume in the cases referred to in points (a) and (b) of Article II.24.1.1;
(d) the indicative date of completion of the necessary verification in the case referred to in point (c) of Article II.24.1.1.

For multi-beneficiaries, the coordinator must immediately inform the other beneficiaries of the suspension.

The suspension takes effect on the day the Centre sends *formal notification* of suspension (Step 2).

Otherwise, the Centre must send a *formal notification* to the beneficiary/ coordinator informing it that it is not continuing with the suspension procedure.

II.24.1.3 Effects of suspension

During the period of suspension of payments the beneficiary/ coordinator is not entitled to submit any requests for payments and supporting documents referred to in Articles I.4.2, I.4.3 and I.4.4.

For multi-beneficiaries, where the suspension concerns the pre-financing payments or interim payments for one or several beneficiaries only, any requests for payments and supporting documents relating to the participation of the concerned beneficiary or beneficiaries in the action.

The corresponding requests for payments and supporting documents may be submitted as soon as possible after resumption of payments or may be included in the first request for payment due following resumption of payments in accordance with the schedule laid down in Article I.4.1.

The suspension of payments does not affect the right of the beneficiary to suspend the implementation of the *action* as provided for in Article II.16.1 or to terminate the Agreement as provided for in Article II.17.1.

II.24.1.4 Resuming payments

In order for the Centre to resume payments, the beneficiary/ beneficiaries must meet the notified conditions as soon as possible and must inform the Centre of any progress made.

If the conditions for resuming payments are met, the suspension will be lifted. The Centre will send a *formal notification* to the beneficiary/ coordinator informing it of this.

II.24.2 Suspension of the time limit for payments

II.24.2.1 The Centre may at any moment suspend the time limit for payment specified in Articles I.5.2, I.5.3 and I.5.4 if a request for payment cannot be approved because:
(a) it does not comply with the Agreement;
(b) the appropriate supporting documents have not been produced; or

(c) there is a doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

II.24.2.2 The Centre must send a *formal notification* to the beneficiary/ coordinator informing it of:

(a) the suspension; and
(b) the reasons for the suspension.

The suspension takes effect on the day the Centre sends the *formal notification.*

II.24.2.3 If the conditions for suspending the payment deadline are no longer met, the suspension will be lifted and the remaining period will resume.

If the suspension exceeds two months, the beneficiary/ coordinator may request the Centre if the suspension will continue.

If the payment deadline has been suspended because the technical reports or financial statements do not comply with the Agreement and the revised report or statement is not submitted or was submitted but is also rejected, the Centre may terminate the Agreement as provided for in Article II.17.2.1(b) and reduce the grant as provided for in Article II.25.4.

ARTICLE II.25 – CALCULATION OF THE FINAL AMOUNT OF THE GRANT

The final amount of the grant depends on the extent to which the *action* has been implemented in accordance with the terms of the Agreement.

The final amount of the grant is calculated by the Centre at the time of the payment of the balance. The calculation involves the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs and addition of the financing not linked to costs, unit, flat-rate and lump sum contributions

Step 2 — Limit to the *maximum amount of the grant*

Step 3 — Reduction due to the no-profit rule

Step 4 — Reduction due to improper implementation, irregularities, fraud or breach of obligations.

II.25.1 Step 1 — Application of the reimbursement rate to the eligible costs and addition of the financing not linked to costs, unit, flat-rate and lump sum contributions

This step is applied as follows:

(a) If, as provided for in Article I.3.2(a)(i), the grant takes the form of the reimbursement of eligible costs actually incurred, the reimbursement rate specified in that Article is applied to those eligible costs as approved by the Centre for the corresponding categories of costs, for the beneficiary/ beneficiaries and affiliated entities

(b) If, as provided for in Article I.3.2(a) (ii) to (v), the grant takes the form of the reimbursement of eligible unit costs, , lump sum costs or flat rate costs, the reimbursement rate specified in that Article is applied to the those eligible costs as approved by the Centre for the corresponding categories of costs, for the beneficiary/ beneficiaries and affiliated entities;

The accepted amount of volunteers' work for the beneficiary/ beneficiaries and affiliated entities must be limited to the following amount, whichever is the lowest:
(i) the total sources of financing as indicated in the estimated budget set out in Annex III and as accepted by the Centre multiplied by fifty per cent; or
(ii) the amount of volunteers' work as indicated in the final financial statement .

(c) If, as provided for in Article I.3.2(b), the grant takes the form of a unit contribution, the unit contribution specified in that Article is multiplied by the actual number of units approved by the Centre for the beneficiary/ corresponding beneficiaries and affiliated entities;

(d) If, as provided for in Article I.3.2(c), the grant takes the form of a lump sum contribution, the Centre applies the lump sum specified in that Article for the beneficiary/ corresponding beneficiaries and affiliated entities if it finds that the corresponding tasks or part of the *action* were implemented properly in accordance with Annex I;

(e) If, as provided for in Article I.3.2(d), the grant takes the form of a flat-rate contribution, the flat rate referred to in that Article is applied to the eligible costs or to the contribution approved by the Centre for the beneficiary/ corresponding beneficiaries and affiliated entities;

(f) If, as provided for in Article I.3.2(e), the grant takes the form of financing not linked to costs, the Centre applies the amount specified in that Article for the beneficiary/ corresponding beneficiaries and affiliated entities if it finds that [the conditions specified in Annex I were fulfilled][and][the results specified in Annex I were achieved].

If Article I.3.2 provides for a combination of different forms of grant, the amounts obtained must be added together.

II.25.2 Step 2 — Limit to maximum amount of the grant

The total amount paid to the beneficiary/ beneficiaries by the Centre may in no circumstances exceed the *maximum amount of the grant*.

If the amount obtained following Step 1 is higher than this maximum amount, the final amount of the grant is limited to the latter.

If volunteers' work is declared as part of direct eligible costs, the final amount of the grant is limited to the amount of total eligible costs and contributions approved by the Centre minus the amount of volunteers' work approved by the Centre.

II.25.3 Step 3 — Reduction due to the no-profit rule

The grant may not produce a profit forthe beneficiary/ beneficiaries, unless specified otherwise in the Special Conditions.

The profit must be calculated as follows:

(a) calculate the surplus of the total receipts of the action, over the total eligible costs of the action, as follows:

{ receipts of the action

minus

the consolidated total eligible costs and contributions approved by the Centre corresponding to the amounts determined in accordance with Step 1 }

The receipts of the action are calculated as follows:

{ the revenue generated by the *action* for the beneficiary/ beneficiaries and affiliated entities other than non-profit organisations

plus

the amount obtained following Steps 1 and 2 }

The revenue generated by the *action* is the consolidated revenue established, generated or confirmed for the beneficiary/ beneficiaries and affiliated entities other than non-profit organisations on the date on which the request for payment of the balance is drawn up by the beneficiary/ coordinator.

The following are not considered receipts:

(i) in kind and financial contributions made by third parties,
(ii) in case of an operating grant, amounts dedicated to the building up of reserves.

(b) If the amount calculated under (a) is positive, this amount will be deducted from the amount calculated following Steps 1 and 2 in proportion to the final rate of reimbursement of the actual eligible costs of the *action* approved by the Centre for the categories of costs referred to in Article I.3.2(a)(i).

II.25.4 Step 4 — Reduction due to improper implementation, irregularities, fraud or breach of obligations

The Centre may reduce the *maximum amount of the grant* if the *action* has not been implemented properly as described in Annex I (i.e. if it has not been implemented or has been implemented poorly, partially or late), or in case of *irregularity, fraud* or breach of an obligation under the Agreement.

The amount of the reduction will be proportionate to the degree to which the *action* has been implemented improperly or to the seriousness of the *irregularity, fraud* or *breach of obligation*.

Before the Centre reduces the grant, it must send a *formal notification* to the beneficiary/ coordinator:

(a) informing it of:
  (i) its intention to reduce the *maximum amount of the grant*;
  (ii) the amount by which it intends to reduce the grant;
  (iii) the reasons for reduction; and

(b) inviting it to submit observations within 30 calendar days of receiving the *formal notification*.

If the Centre does not receive any observations or decides to pursue reduction despite the observations it has received, it will send a *formal notification* informing the beneficiary/ coordinator of its decision.

If the grant is reduced, the Centre must calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the *action* or to the seriousness of the *irregularity, fraud* or *breach of obligations*) from the *maximum amount of the grant*.

The final amount of the grant will be the lower of the following two:

(a) the amount obtained following Steps 1 to 3; or
(b) the reduced grant amount following Step 4.

ARTICLE II.26 - RECOVERY

II.26.1 Recovery

Where an amount is to be recovered under the terms of the Agreement, the beneficiary/ coordinator[10] must repay the Centre the amount in question.

Where an amount is to be recovered as provided for in Articles II.27.6, II.27.7 and II.27.8, the beneficiary concerned by the audit or OLAF findings must repay the Centre the amount in question. Where the audit findings do not concern a specific beneficiary (or its affiliated

[10] Even if the coordinator was not the final recipient of the amount due.

entities), the coordinator must repay the Centre the amount in question, even if it was not the final recipient of the amount due.

The beneficiary is responsible for the repayment of any amount unduly paid by the Centre as a contribution towards the costs incurred by its affiliated entities.

II.26.2 Recovery procedure

Before recovery, the Centre must send a *formal notification* to the beneficiary concerned:

(a) informing it of its intention to recover the amount unduly paid;
(b) specifying the amount due and the reasons for recovery; and
(c) inviting the beneficiary to make any observations within a specified period.

If no observations have been submitted or if, despite the observations submitted by the beneficiary, the Centre decides to pursue the recovery procedure, the Centre may confirm recovery by sending a *formal notification* to the beneficiary consisting of a debit note, specifying the terms and the date for payment.

If payment has not been made by the date specified in the debit note, the Centre will recover the amount due:

(a) by offsetting it, without the beneficiary's prior consent, against any amounts owed to the beneficiary by the Centre or an executive agency (from the Union or the European Atomic Energy Community (Euratom) budget) ('offsetting');

In exceptional circumstances, to safeguard the financial interests of the Union, the Centre may offset before the due date.

An *action* may be brought against such offsetting before the General Court of the European Union in accordance with Article 263 TFEU;

(b) by drawing on the financial guarantee where provided for in accordance with Article I.5.2 ('drawing on the financial guarantee');

(c) by taking legal action as provided for in Article II.18.2 or in the Special Conditions or by adopting an enforceable decision as provided for in Article II.18.3;

(d) by holding the beneficiaries jointly and severally liable up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (Annex III as last amended).

II.26.3 Interest on late payment

If payment is not made by the date in the debit note, the amount to be recovered will be increased by late-payment interest at the rate set out in Article I.5.6 from the day following the date for payment in the debit note up to and including the date the Centre receives full payment of the amount.

Partial payments must first be credited against charges and late-payment interest and then against the principal.

II.26.4 Bank charges

Bank charges incurred in the recovery process must be borne by the beneficiary, unless Directive 2007/64/EC[11] applies.

ARTICLE II.27 – CHECKS, AUDITS AND EVALUATIONS

II.27.1 Technical and financial checks, audits, interim and final evaluations

The Centre may, during the implementation of the *action* or afterwards, carry out technical and financial checks and audits to determine that the beneficiary/ beneficiaries is/are implementing the *action* properly and is/are complying with the obligations under the Agreement. It may also check the beneficiary's/ beneficiaries' statutory records for the purpose of periodic assessments of lump sum, unit cost or flat-rate amounts.

Information and documents provided as part of checks or audits must be treated on a confidential basis.

In addition, the Centre may carry out an interim or final evaluation of the impact of the *action*, measured against the objective of the programme concerned.

Centre's checks, audits or evaluations may be carried out either directly by its own staff or by any other outside body authorised to do so on its behalf.

The Centre may initiate such checks, audits or evaluations during the implementation of the Agreement and during a period of five years starting from the date of payment of the balance. This period is limited to three years if the *maximum amount of the grant* is not more than EUR 60 000.

The check, audit or evaluation procedures are considered to be initiated on the date of receipt of the letter of the Centre announcing it.

If the audit is carried out on an affiliated entity, the beneficiary must inform that affiliated entity.

II.27.2 Duty to keep documents

The beneficiary/ beneficiaries must keep all original documents, especially accounting and tax records, stored on any appropriate medium, including digitalised originals when they are

[11] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC.

authorised by their respective national law and under the conditions laid down therein, during a period of five years starting from the date of payment of the balance.

The period during which documents must be kept is limited to three years if the *maximum amount of the grant* is not more than EUR 60 000.

The periods set out in the first and second subparagraphs are longer if there are ongoing audits, appeals, litigation or pursuit of claims concerning the grant, including in the cases referred to in Article II.27.7. In such cases, the beneficiary/ beneficiaries must keep the documents until such audits, appeals, litigation or pursuit of claims have been closed.

II.27.3 Obligation to provide information

The beneficiary/ coordinator[12] must provide any information, including information in electronic format, requested by the Centre or by any other outside body authorised by the Centre.

For multi-beneficiaries, where a check or audit is initiated after payment of the balance, the information referred to in the previous subparagraph must be provided by the beneficiary concerned.

If the beneficiary does not comply with the obligation set out in the above subparagraphs, the Centre may consider:

(a) any cost insufficiently substantiated by information provided by the beneficiary as ineligible;
(b) any financing not linked to costs, unit, lump sum or flat-rate contribution insufficiently substantiated by information provided by the beneficiary as undue.

II.27.4 On-the-spot visits

During an on-the-spot visit, the beneficiary/ beneficiaries must allow the Centre staff and outside personnel authorised by the Centre to have access to the sites and premises where the *action* is or was carried out, and to all the necessary information, including information in electronic format.

The beneficiary must ensure that the information is readily available at the moment of the on-the-spot visit and that information requested is handed over in an appropriate form.

If the beneficiary refuses to provide access to the sites, premises and information as required in the first and second subparagraphs, the Centre may consider:

[12] Where appropriate, the Centre may request that a beneficiary provides such information directly instead of the coordinator.

(a) any cost insufficiently substantiated by information provided by the beneficiary as ineligible;
(b) any financing not linked to costs, unit, lump sum or flat-rate contribution insufficiently substantiated by information provided by the beneficiary as undue.

II.27.5 Contradictory audit procedure

On the basis of the findings made during the audit, a provisional report ('draft audit report') must be drawn up. It must be sent by the Centre or its authorised representative to the beneficiary, which must have 30 calendar days from the date of receipt to submit observations. The final report ('final audit report') must be sent to the beneficiary within 60 calendar days of expiry of the time limit for submission of observations.

II.27.6 Effects of audit findings

On the basis of the final audit findings, the Centre may take the measures it considers necessary, including recovery of all or part of the payments made by it, as provided for in Article II.26.

In the case of final audit findings after the payment of the balance, the amount to be recovered corresponds to the difference between the revised final amount of the grant, determined in accordance with Article II.25, and the total amount paid to the beneficiary/ beneficiaries under the Agreement for the implementation of the *action*.

II.27.7 Correction of systemic or recurrent irregularities, fraud or breach of obligations

II.27.7.1 The Centre may extend audit findings from other grants to this grant if:
(a) the beneficiary concerned is found to have committed systemic or recurrent *irregularities, fraud* or *breach of obligations* in other EU or Euratom grants awarded under similar conditions and such *irregularities, fraud* or *breach of obligations* have a material impact on this grant; and
(b) the final audit findings are sent to the beneficiary concerned through a *formal notification*, together with the list of grants affected by the findings within the period referred to in Article II.27.1

The extension of findings may lead to:
(a) the rejection of costs as ineligible;
(b) reduction of the grant as provided for in Article II.25.4;
(c) recovery of undue amounts as provided for in Article II.26;
(d) suspension of payments as provided for in Article II.24.1;
(e) suspension of the *action* implementation as provided for in Article II.16.2;
(f) termination as provided for in Article II.17.2.

II.27.7.2 The Centre must send a *formal notification* to the beneficiary concerned informing it of the systemic or recurrent irregularities, *fraud* or *breach of obligations* and of its intention to extend the audit findings, together with the list of grants affected.

(a) If the findings concern eligibility of costs the procedure is as follows:

Step 1 — The *formal notification* must include:
(i) an invitation to submit observations on the list of grants affected by the findings;
(ii) a request to submit revised financial statements for all grants affected;
(iii) where possible, the correction rate for extrapolation established by the Centre to calculate the amounts to be rejected on the basis of the systemic or recurrent *irregularities, fraud* or *breach of obligations*, if the beneficiary concerned:
- considers that the submission of revised financial statements is not possible or practicable; or
- will not submit revised financial statements.

Step 2 — The beneficiary concerned has 60 calendar days from when it receives the *formal notification* to submit observations and revised financial statements or to propose a duly substantiated alternative correction method. This period may be extended by the Centre in justified cases.

Step 3 — If the beneficiary concerned submits revised financial statements that take account of the findings the Centre will determine the amount to be corrected on the basis of those revised statements.

If the beneficiary concerned proposes an alternative correction method and the Centre accepts it, the Centre must send a *formal notification* to the beneficiary concerned informing it:
(i) that it accepts the alternative method;
(ii) of the revised eligible costs determined by applying this method.

Otherwise the Centre must send a *formal notification* to the beneficiary concerned informing it:
(i) that it does not accept the observations or the alternative method proposed;
(ii) of the revised eligible costs determined by applying the extrapolation method initially notified to the beneficiary.

If the systemic or recurrent *irregularities, fraud* or *breach of obligations* are found after the payment of the balance, the amount to be recovered corresponds to the difference between:
(i) the revised final amount of the grant, determined in accordance with Article II.25 on the basis of the revised eligible costs declared by the beneficiary and approved by the Centre or on the basis of the revised eligible costs after extrapolation; and
(ii) the total amount paid to the beneficiary under the Agreement for the implementation of the *action*;

(b) If the findings concern improper implementation or a breach of another obligation the procedure is as follows:

Step 1 — The *formal notification* must include:

(i) an invitation to the beneficiary concerned to submit observations on the list of grants affected by the findings and
(ii) the correction flat rate the Centre intends to apply to the *maximum amount of the grant* or to part of it, according to the principle of proportionality.

Step 2 — The beneficiary has 60 calendar days from receiving the *formal notification* to submit observations or to propose a duly substantiated alternative flat-rate.

Step 3 — If the Centre accepts the alternative flat rate proposed by the beneficiary, it must send a *formal notification* to the beneficiary concerned informing it:
(i) that it accepts the alternative flat-rate;
(ii) of the corrected grant amount by applying this flat rate.

Otherwise the Centre must send a *formal notification* to the beneficiary concerned informing it:
(i) that it does not accept the observations or the alternative flat rate proposed;
(ii) of the corrected grant amount by applying the flat rate initially notified to the beneficiary.

If the systemic or recurrent *irregularities*, *fraud* or *breach of obligations* are found after the payment of the balance, the amount to be recovered corresponds to the difference between:
(i) the revised final amount of the grant after flat-rate correction; and
(ii) the total amount paid to the beneficiary under the Agreement for the implementation of the *action*.

II.27.8 Rights of OLAF

The European Anti-Fraud Office (OLAF) has the same rights as the Centre, particularly the right of access, for the purpose of checks and investigations.

Under Council Regulation (Euratom, EC) No 2185/96[13] and Regulation (EU, Euratom) No 883/2013[14] OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Union law for the protection of the financial interests of the Union against *fraud* and other *irregularities*.

Where appropriate, OLAF findings may lead to the Centre recovering amounts from the beneficiary.

[13] Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities.
[14] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF).

Moreover, findings arising from an OLAF investigation may lead to criminal prosecutions under national law.

II.27.9 Rights of the European Court of Auditors and EPPO

The European Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939 ('the EPPO') have the same rights as the Centre, particularly the right of access, for the purpose of checks, audits and investigations.

Annex I

Description of the action (Invitation to submit applications – GRANT/2021/PHF/23776, Questions and Answers document, and submitted application)

Invitation to submit applications

ENHANCING WHOLE GENOME SEQUENCING (WGS) AND/OR REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) NATIONAL INFRASTRUCTURES AND CAPACITIES TO RESPOND TO THE COVID-19 PANDEMIC IN THE EUROPEAN UNION AND EUROPEAN ECONOMIC AREA

Reference: GRANT/2021/PHF/23776

Deadline for submission of applications: **12th July 2021**

SM

Table of Contents

1. BACKGROUND

1.1. EU Health Emergency Preparedness and Response Authority (HERA)

As part of the EU Health Union proposals of 11 November 2020, the European Commission has proposed to set up a EU Health Emergency Preparedness and Response Authority (HERA).[1]

HERA's mission will be to enable the EU/EEA Member States to rapidly deploy the most advanced medical measures and other counter measures, to ensure capacity and readiness to respond to cross-border threats and emergencies – whether of natural or deliberate origin.

Equipping the Union with such a mechanism, that addresses all future serious cross-border threats to health, will have to take into account the EU institutional setting, and provide for a coordinated approach to health preparedness while taking into account competences of the Member States in this area.

This new body will complement and create synergies with the work of existing EU Agencies, in particular the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), including once their mandates will be extended after adoption of the revisions proposed by the European Commission on 11 November 2020.

The current planning is that the European Commission will put forward a legislative proposal for HERA in September 2021.

1.2. HERA Incubator

In preparation of the formal establishment of HERA, several preparatory actions have been launched that will serve as a blueprint for the EU's long term preparedness for health emergencies and will pilot some of the aspects that may be covered by the new Authority.

On 17 February 2021, the European Commission launched 'HERA Incubator', which is a new EU bio-defence preparedness plan against SARS-CoV-2 variants.[2]

HERA Incubator focuses on five specific action areas:

1. Rapid detection of SARS-CoV-2 variants
2. Swift adaptation of COVID-19 vaccines (investments in research and innovation)

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0724&from=EN

[2] https://ec.europa.eu/info/sites/default/files/communication-hera-incubator-anticipating-threat-covid-19-variants_en.pdf

3. Setting up a European Clinical Trials Network (VACCELERATE)

4. Fast tracking the regulatory approval process

5. Ramping up industrial production of COVID-19 vaccines against variants of concern

This invitation to submit applications exclusively concerns the selection of projects implementing work under action area 1: Rapid detection of SARS-CoV-2 variants.

1.3. HERA Incubator Action Area 1: Rapid detection of SARS-CoV-2 variants

In response to the emergence of SARS-CoV-2 variants of concern, on 25 February 2021 President Ursula von der Leyen announced that the EU will provide EUR 200 M to strengthen detection of variants and improve knowledge on how they are developing and spreading, under the EU Health Emergency Preparedness and Response Authority (HERA) incubator Action Area 1[3]. The European Commission and ECDC are therefore making substantial investments to increase Member States' capacity to identify and characterise these variants using whole genome sequencing (WGS) and Reverse Transcription Polymerase Chain Reaction (RT-PCR) RT-PCR. Such endeavours have the potential to revolutionise the public health landscape in the EU/EEA, by permitting a more rapid, comprehensive and effective surveillance of infectious diseases. This together with the increased resources foreseen to build-up and operate a European Health Task Force will strengthen the EU/EEA's ability to rapidly detect, delineate and contain current and future public health emergencies. The capacity building is intended to increase Member States' capacity to respond to the Covid-19 pandemic, but also to strengthen WGS and RT-PCR capacity in non-crisis time and for other pathogens.

1.4. ECDC strategy for enhancing routine genomic-based surveillance of infectious diseases

The successful integration of genomic information into traditional epidemiology will be essential for guiding the continued public health response to the COVID-19 pandemic in coming years. Vaccine strategies and compositions as well as relaxation of restrictive measures will be highly dependent on the evolutionary dynamics of SARS-CoV-2, and the best way to gain a fuller understanding of the epidemiological situation at the EU/EEA level is to establish higher sequencing capacities at national level combined with enhanced data reporting for integrated genomic–epidemiologic analysis.

Strengthening capacity and integration of genomic data into EU/EEA surveillance and outbreak preparedness is in line with ongoing ECDC strategic work in microbiology.[4] In 2019 ECDC published an updated version of the "ECDC strategic framework for the integration of molecular and genomic typing into European

[3] https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_21_861

[4] https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-public-health-microbiology-strategy-2018-2022.pdf

surveillance and multi-country outbreak investigations"[5], which outlines its plans for enhancing routine genomic-based surveillance of infectious diseases at both national and EU/EEA levels.

2. OBJECTIVES, ACTORS AND SCOPE

2.1. Objectives and expected outcomes

This invitation aims at supporting activities via the award of grants for action that directly lead to enhanced and/or improved national public health WGS and/or RT-PCR capacity. The activities may target public health laboratories at national, regional and/or local level, and should facilitate integration of genomics and these advanced laboratory methods into disease surveillance and outbreak preparedness and response. To that end, applications under this invitation should aim at delivering results that are directed, tailored and contributing towards the following expected outcomes:

- In the short-term, contribution to the establishment of a sustainable, efficient and high capacity WGS and/or RT-PCR infrastructure for national public health microbiology;
- In the short/medium-term, contribution to early detection and enhanced monitoring of emergent and known SARS-CoV-2 variants at the national and the EU/EEA levels;
- In the medium/long-term, contribution to enhanced genomic-based infectious disease outbreak investigation capacities at regional, national and/or EU/EEA levels;
- In the medium/long-term, contribution to enhanced routine genomic-based surveillance of infectious diseases at the regional, national and/or EU/EEA levels, in accordance with the "ECDC strategic framework for the integration of molecular and genomic typing into European surveillance and multi-country outbreak investigations"; and
- In the long-term, contribution to enhanced preparedness to timely and efficiently address cross-border outbreaks of infectious diseases and pandemics in the future.

2.2. Main actors

Applicant: party which submits an application

Beneficiary: party with whom the Grant Agreement (GA) is signed (see the model GA, Annex IV).

Consortium: A collective group of applicants/beneficiaries. Prior to signature of the grant agreement, they are referred to as lead-applicant (Coordinator) and co-

[5] https://www.ecdc.europa.eu/sites/default/files/documents/framework-for-genomic-surveillance.pdf

applicants. Following signature of the grant agreement, they are referred to as lead-beneficiary (Coordinator) and co-beneficiaries.

Coordinator: the lead-applicant/lead-beneficiary of the consortium that submits the application and signs the grant agreement on behalf of the consortium.

Project manager: a person employed by the coordinator (or by the sole beneficiary, if a mono-beneficiary grant agreement), who will have the overall responsibility for day-to-day project coordination and management, and is the designated contact person for liaising with ECDC and (if applicable) the rest of the consortium. An alternative person also employed by the coordinator shall also be nominated to act as a support and back-up to the Project manager.

Affiliated Entities[6]:

> (a) entities that form a 'sole beneficiary' (i.e. where an entity is formed of several entities that satisfy the criteria for being awarded a grant, including where the entity is specifically established for the purpose of implementing an action to be financed by a grant);
>
> (b) entities that satisfy the eligibility criteria and that do not fall within one of the exclusion situations referred to in Article 136(1) FR and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

Affiliated entities are not party to the grant agreement and do not sign it, however they are listed in its content[7].

2.3. Scope

The setup of national public health WGS and RT-PCR infrastructure for public health microbiology purposes is a national responsibility, and EU/EEA Member States are already at various stages of implementing these technologies for routine testing and characterisation. It is therefore essential that the execution of projects under this invitation are fully aligned with and would complement national public health strategies as well as other on-going investments and capacity-building initiatives. Please note however that in accordance with the principle of additionality activities included the application may add to and/or complement existing activities at the national and/or regional level, but cannot be used for financing already existing activities themselves.

The application must describe the national public health microbiology needs with regards to WGS and/or RT-PCR infrastructure and processes and show how the activities of the application would contribute towards addressing those needs. The application does not need to address all of the identified national needs, but should present a coherent plan of activities that can realistically be achieved within the

[6] Article 187 EU Financial Regulation

[7] More information is provided in section 6 below.

foreseen implementation period (see section 7 below). The application must explicitly show how the proposed activities would support the objective and expected outcomes listed under section 2.1 above.

Applications submitted in response to this invitation may address specific needs related to WGS and/or RT-PCR, i.e. it is possible to focus on needs related to only one of these technologies. Applications that only address one technology do not need to include any information on the needs, strategies etc. related to the technology that is not addressed in the application.

From a process perspective, the application shall describe how the planned activities build on, complement and extend systems and workflows at the national and/or regional levels, The application shall consider all relevant phases of the generic WGS and/or RT-PCR workflow process described below (Figure 1 and Table 1), with particular attention given to the analytical phase and the data sharing phase.

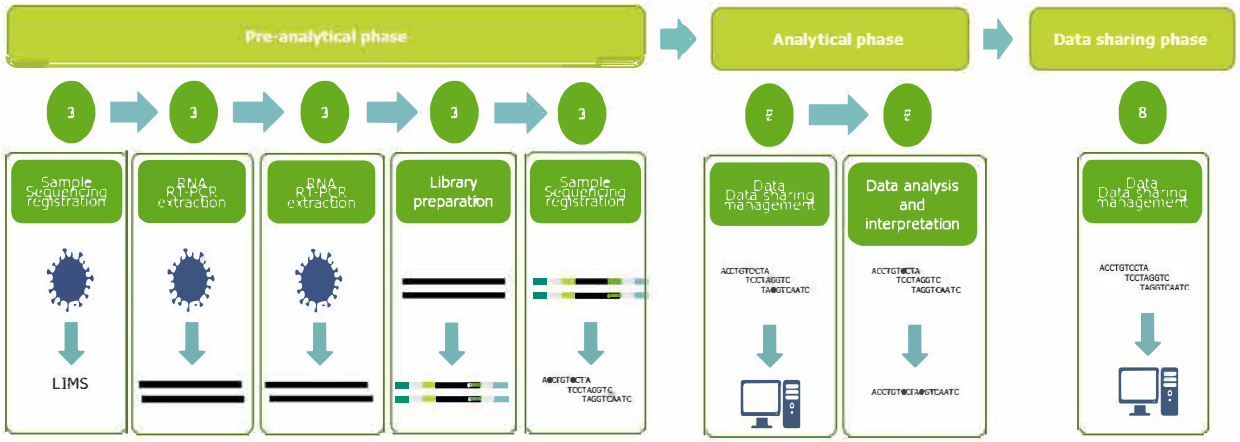

Figure 1: Generic workflow process for SARS-CoV-2 sequencing, data analysis and data sharing

Table 1: Examples of infrastructure for routine high capacity WGS and RT-PCR activities

Phases	Steps	Example of equipment needed	Example of competence needed
Pre-analytical phase	Sample registration	• Computer with access to laboratory information management system (LIMS)	• Laboratory manager • Laboratory technician • Microbiologist
	RNA extraction	• Sample inactivation equipment • RNA extraction robot • Pipetting robot • Fluorometer • Spectrophotometer • qPCR instrument • Fragment analyser • Thermocycler • Magnetic stand • Microplate shaker • Centrifuge • Vortexer	
	RT-PCR		
	Library preparation		
	Sequencing	• Sequencing platform	
Analytical phase	Data management	• Data server • Computer network	• IT technician • Data manager
	Data analysis	• Computer clusters with data analysis software • Computer with cloud computing services	• Computational biologist • Bioinformatician • Virologist • Microbiologist
Data sharing phase	Data sharing	• Computer • Computer clusters with data sharing solutions	• Bioinformatician • Data manager • Microbiologist

2.4. Required Reporting

Successful applicants will be required to submit "interim progress reports" at the end of month 3 and month 6 of the action implementation period. While the applicants should also define some additional technical reporting to document and demonstrate the main results of their work, overreporting should be avoided and applicants are advised to consolidate reports whenever possible.

There are additional mandatory reports that are required as part of the payment arrangements and they are listed in section 13.7 below (see also Article I.4 of the Model Grant Agreement).

3. TIMETABLE

	Stages	Date and time or indicative period
a)	Invitation to apply dispatched	01/06/2021
b)	**Deadline for submitting applications**	**12/07/2021** – 16:00 CEST
c)	Evaluation period	13/07/2021 – 23/07/2021

	Stages	Date and time or indicative period
d)	Clarifications from applicants , including negotiation	26/07/2021 – 06/08/2021
e)	Notification of award	31/08/2021
f)	Signature of grant agreement	29/10/2021

4. BUDGET AVAILABLE

The total ECDC budget for the co-financing of projects (ECDC budget) selected under this invitation is 83,000,000 EUR. For applicants, there is no minimum or maximum amount set for the value of each application. As a guide, ECDC anticipates the receipt of applications in the range of 2,000,000 to 5,000,000 EUR.

ECDC reserves the right not to distribute all the ECDC budget available if the sum of the requested grant (co-financing) from all of the successful applications is less than the total budget mentioned above.

ECDC also reserves the right to reduce the amount of co-financing offered to successful applications if the sum of the requested co-financing from all of the successful applications is above 83,000,000 EUR, and where each application is 5,000,000 EUR or less. If needed, such reductions will be calculated as a percentage which will be applied uniformly across all successful applications.

If ECDC receives an application above 5,000,000 EUR from a successful applicant, ECDC reserves the right to negotiate with that applicant during the clarification phase, and apply a reduction based on the overall estimated budgets received in response to this invitation.

The maximum ECDC contribution will be 90% of the total eligible costs, and the beneficiaries will need to co-finance the remaining (minimum 10%) of the total eligible costs.

5. ADMISSIBILITY REQUIREMENTS

In order to be admissible, applications must be:

- submitted no later than the deadline for submitting applications referred to in section 3;
- dated, readable, accessible and printable and contain all the requested information and all required annexes and supporting documents.
- drafted in one of the EU official languages. Given the exceptional situation, applicants are strongly advised to submit their applications and supporting documents in English. Nonetheless, the choice of language will not play any role in the consideration of the application;
- submitted electronically (see section 16 below) using the forms (where applicable), provided on the dedicated website:

https://ecdc365.sharepoint.com/sites/HERAIncubatorGrantProcedure. The documents to be submitted are:

- Part A of the application: administrative information of the applicant organisation(s), based on the template in Annex I.
- Part B of the application - technical information: based on the template in Annex I, which includes the technical description of the action.
- Part C of the application – Checklist of documents submitted.

  Please note the page limits associated with the different sections of the application. Pages that exceed the limits set in the application template (Annex I) will be disregarded during the evaluation phase.

  It is recommended that Parts A and B be submitted as a single pdf.

- **The following documents must be annexed to the application:**
  - One completed estimated budget for each individual beneficiary and one consolidated budget, as per the Estimated Budget & Consolidated Budget Form (Annex II). It is recommended that the budget forms be submitted in scanned form.
  - Letter of endorsement from the National Coordinator (according to official nominations in ECDC's Stakeholder Relationship Management system [SRM]) confirming that the application is submitted on behalf of the country and addresses the national needs of that country as described in section 6.1. The letter of endorsement should be submitted in scanned form.
  - Completed Declaration on Honour Form and Authorised Signatory Form, submitted in scanned form. (See Annexes III and V)
  - "Financial Identification Form" and "Legal Entity Form" duly signed by the person authorised to sign the Grant agreement.
    - In the case of single applicants, both a Financial Identification Form and a Legal Entity Form are required to be submitted.
    - In the case of a consortium, only the Coordinator is required to submit a Financial Identification Form. Each member of the consortium, including the Coordinator, is required to submit a Legal Entity Form.

    Financial Identification Form and Legal Entity Forms should be submitted in scanned format. The forms are available through links in the List of Annexes below.

    Where the applicant has already signed another agreement or contract with ECDC, please submit a copy of a previously

submitted Legal Entity and Financial identification, unless a change has occurred in the meantime.

In order to assess the applicants' eligibility, the following supporting documents are also requested to be submitted with the Legal Entity Form:

- **Beneficiary - private entity:** extract from the national official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical, only one of these documents is required);
- **Beneficiary - public entity:** copy of the resolution, decision or other official document establishing the public-law entity;
- **Affiliated entity:** documents evidencing structural link to the applicant such as consolidated accounts for the group or statutes or other act/legislation establishing the entities and their connection to each other.

Failure to comply with these requirements will lead to rejection of the application.

6. ELIGIBILITY CRITERIA

6.1. Eligible applicants

The invitation to submit applications is open to (1) single national public health authorities (including institutes and laboratories) or (2) consortium of public health authorities from one country. In the case of consortia, public health authorities at the regional and local level may also be involved.

In both cases 1) and 2), affiliated entities may be included in the application[8].

Only applications from legal entities established in the following countries are eligible:

- EU Member States;
- EEA countries: Iceland, Liechtenstein, Norway.

EU/EEA Member States are encouraged to include the outermost regions and the overseas countries and territories in the scope of this invitation, as and when relevant.

The applications can be submitted by: a single applicant (if awarded, a "mono-beneficiary agreement" will be signed); or by a group of several applicants (consortium) (if awarded, a "multi-beneficiary agreement" will be signed)[9].

[8] See section on Affiliated Entities below.

[9] Unless there is a Sole Applicant/Beneficiary as provided for in Article 187 1 (a), FR, in which case a mono-beneficiary agreement will be signed. See section on Affiliated Entities below for more information.

Consortium

The coordinator and co-applicants shall take appropriate internal measures consistent with the provisions of the grant agreement via conclusion of a consortium agreement, to ensure the proper implementation of the action. The consortium agreement is a private agreement between the coordinator and co-applicants, to set out the rights and obligations amongst themselves. It should complement the grant agreement and must not contain any provision contrary to it. It should provide the framework for successful project implementation (i.e. settle all issues that may hinder cooperation between the different actors for the different parts of the project). This includes authorisation of the coordinator to sign on behalf of the consortium and thus on behalf of the co-applicants. The coordinator must also be authorised to receive funds from ECDC and distribute the corresponding amounts to the relevant parties within the consortium. The consortium agreement should be negotiated and concluded before signing the grant agreement. A copy of the consortium agreement shall be provided to ECDC prior to signature of the grant agreement. For more guidance on content of the consortium agreement, please refer to the Guidance document.

Affiliated Entities

The applicants may apply with affiliated entity(ies). If the applicants are awarded a grant agreement, their affiliated entity(ies) will not become beneficiary(ies) of the action and they do not sign the grant agreement. However, they will participate in the design and in the implementation of the action and the costs they incur may be accepted as eligible costs, provided they comply with all the relevant rules already applicable to the beneficiary(ies) under the grant agreement, inclusive those regarding audits. **Please note that the applicant/beneficiary is liable for the actions of their affiliated entities in the context of the grant.**

Affiliated entity(ies) must not fall within a situation for exclusion (see section 8 below) and must satisfy the same eligibility criteria as the applicant.

Entities having a structural (legal or capital) link with the applicants may qualify as affiliated entities. For more information on affiliated entities please refer to the Guidance document.

Supporting documents

To ensure that the projects accurately address national needs **each country may only submit one application**, and **a letter of endorsement is requested from each country's National Coordinator** (as per ECDC's official nominations). The letter should confirm support for the activities to be financed for the applicants and any affiliated entities, and that the activities are fully aligned with national public health strategies as well as on-going investments and capacity-building initiatives in this area. The letter shall be uploaded as an annex together with the other elements of the application.

6.2. Eligible activities

The following types of activities are eligible under this invitation to submit applications:

- Purchase of laboratory infrastructure/equipment, IT infrastructure and software such as that listed in Table 1;
- Purchase of WGS and RT-PCR reagents and supplies (also for diagnostic use);
- Organisational alignment to make optimal use of the purchased infrastructure/equipment and supplies in the overall structure and processes of the applicants, including:
    - The implementation of (automated) sample workflows and data management processes to facilitate the generation, integration and interpretation of WGS and/or RT-PCR data for public health information and action;
    - Processes needed to facilitate data sharing. This would include processes to facilitate or enhance the timely reporting of data to ECDC and/or other supra-national institutions, and the sharing of data in the public domain (e.g. in genetic sequence databases and repositories);
- Commercially available training activities related to the use of the equipment for the implementation of the activities of the application;
- Personnel needed to implement the activities of the application; and
- Consultancy services, if it can be demonstrated that such services are essential for the implementation of the activities of the application.

Please note that the activities of the application could be adding to and/or complementing existing activities at the national and/or regional level, but cannot be used for financing already existing activities themselves. For instance, the purchase of a new sequencer, the required additional reagents and consumables as well as the added staff resources needed to operate that sequencer would be considered eligible activities under the grant, but operational and maintenance resources for an existing sequencer already in routine use would not.

7. IMPLEMENTATION PERIOD

Activities included in the action must not have started before the date of receipt of the award letter indicating that the application has successfully passed the evaluation. Should an applicant require to start activities following award, but prior to signing the grant agreement, this shall be indicated in the application.

The activities are foreseen to be implemented over an estimated period of 13 months, and completed by **30 September 2022**[10].

[10] This timeline is indicative and could be subject to change. However, at this stage applicants shall proceed on the basis outlined herein: completion of activities by 30 September 2022.

8. EXCLUSION CRITERIA

8.1. Exclusion[11]

The authorising officer shall exclude an applicant or affiliated entity in certain circumstances. Applicants or affiliated entities will be excluded where:

a) the applicant or affiliated entity is bankrupt, subject to insolvency or winding-up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended, or it is in any analogous situation arising from a similar procedure provided for under EU or national laws or regulations;

b) it has been established by a final judgment or a final administrative decision that the applicant or affiliated entity is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the applicable law;

c) it has been established by a final judgment or a final administrative decision that the applicant or affiliated entity is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the applicant belongs, or by having engaged in any wrongful intent or gross negligence, including, in particular, any of the following:

   i. fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of eligibility or selection criteria or in the performance of a contract, a grant agreement or a grant decision;

   ii. entering into agreement with other applicants with the aim of distorting competition;

   iii. violating intellectual property rights;

   iv. attempting to influence the decision-making process of the Commission during the award procedure;

   v. attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;

d) it has been established by a final judgment that the applicant or affiliated entity is guilty of any of the following:

   i. fraud, within the meaning of Article 3 of Directive (EU) 2017/1371 of the European Parliament and of the Council and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;

   ii. corruption, as defined in Article 4(2) of Directive (EU) 2017/1371 or Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997,

[11] References to applicant in Section 8 shall be read to apply to affiliated entities also.

or conduct referred to in Article 2(1) of Council Framework Decision 2003/568/JHA, or corruption as defined in the applicable law;

iii. conduct related to a criminal organisation, as referred to in Article 2 of Council Framework Decision 2008/841/JHA;

iv. money laundering or terrorist financing within the meaning of Article 1(3), (4) and (5) of Directive (EU) 2015/849 of the European Parliament and of the Council;

v. terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;

vi. child labour or other offences concerning trafficking in human beings as referred to in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;

e) the applicant or affiliated entity has shown significant deficiencies in complying with main obligations in the performance of a contract, a grant agreement or a grant decision financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an authorising officer, OLAF or the Court of Auditors;

f) it has been established by a final judgment or final administrative decision that the applicant or affiliated entity has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;

g) it has been established by a final judgement or final administrative decision that the applicant or affiliated entity has created an entity in a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations of mandatory application in the jurisdiction of its registered office, central administration or principal place of business;

h) it has been established by a final judgement or final administrative decision that an entity has been created with the intent referred to in point (g);

i) for the situations referred to in points (c) to (h) above, the applicant or affiliated entity is subject to:

i. facts established in the context of audits or investigations carried out by European Public Prosecutor's Office after its establishment, the Court of Auditors, the European Anti-Fraud Office or the internal auditor, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body;

ii. non-final judgments or non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics;

iii. facts referred to in decisions of persons or entities being entrusted with EU budget implementation tasks;

iv. information transmitted by Member States implementing Union funds;

v. decisions of the Commission relating to the infringement of Union competition law or of a national competent authority relating to the infringement of Union or national competition law; or

vi. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.

8.2. Remedial measures

If an applicant or affiliated entity declares one of the situations of exclusion listed above (see section 8.1), it should indicate the measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines. The relevant documentary evidence which illustrates the remedial measures taken must be provided in annex to the declaration. This does not apply for situations referred in point (d) of section 8.1.

8.3. Rejection from the invitation for applications

The authorising officer shall not award a grant to an applicant who:

a. is in an exclusion situation established in accordance with section 8.1[12];

b. has misrepresented the information required as a condition for participating in the procedure or has failed to supply that information;

c. was previously involved in the preparation of calls for application documents where this entails a distortion of competition that cannot be remedied otherwise.

The same exclusion criteria apply to affiliated entities and consortium members.

8.4. Supporting documents

All applicants, including single applicants, consortia and any affiliated entities must provide a declaration on their honour (Annex III) certifying that they are not in one of the situations referred to in articles 136 (1) and 141 (1) FR.

This obligation may be fulfilled in one of the following ways:

For mono-beneficiary grants:

(i) the applicant signs a declaration in its name and on behalf of its affiliated entities; OR

[12] Article 136 (1) FR

(ii) the applicant and its affiliated entities each sign a separate declaration in their own name.

For multi-beneficiary grants:

(i) the coordinator of a consortium signs a declaration on behalf of all applicants and their affiliated entities; OR
(ii) each member in the consortium signs a declaration in its name and on behalf of its affiliated entities; OR
(iii) each applicant in the consortium and each affiliated entity sign a separate declaration in their own name.

9. SELECTION CRITERIA

Only applications that meet the exclusion and eligibility criteria will be assessed on the basis of the selection criteria.

An evaluation of the quality of the applications and of the capacity of the applicant(s) will be subsequently carried out in accordance with the evaluation criteria set out in the section 10 below. There are two types of evaluation criteria: selection and award criteria.

In the case of affiliated entities forming **one** applicant (the "sole beneficiary"), as specified in section 2.2 and 6.1 above, the above requirements apply to each one of those entities.

9.1. Financial capacity

Applicants must have stable and sufficient sources of funding to maintain their activity throughout the duration of the grant and to participate in its funding. Applicants are not required to submit supporting documentation as part of their application. **Please note that verification of financial capacity does not apply to public bodies[13].**

However, in respect of other types of entities, ECDC may request the following supporting documents:

- an audit report produced by an approved external auditor certifying the accounts for the two last financial years.

and

EITHER

- the profit and loss account as well as the balance sheet for the last financial year for which the accounts were closed;

[13] Article 198(5) (c) Financial Regulation

- for newly created entities: the business plan might replace the above documents;

OR

- the table provided for in the application form, filled in with the relevant statutory accounting figures, in order to calculate the ratios as detailed in the form.

Following the assessment of the requested documents, if ECDC considers that financial capacity is weak, ECDC may:

- request further information;
- decide not to give pre-financing;
- decide to give pre-financing paid in instalments;
- where applicable, require the joint and several financial liability of all the co-beneficiaries.

If ECDC considers that the financial capacity is insufficient the application may be rejected.

9.2. Operational capacity

Applicants must have the relevant expertise and experience, know-how, qualifications and resources to successfully implement their tasks in the action and contribute their share.

In this respect, each applicant has to submit a declaration on their honour (Annex III), and complete the operational capacity section of the Application Form (Annex I).

In the case of affiliated entities forming **one** applicant (the "sole" beneficiary), as specified in section 6.1, the above requirements apply to each one of those entities.

10. AWARD CRITERIA

The award criteria allow the quality of the applications submitted to be evaluated in relation to the set objectives and priorities. They enable the selection of applications which ECDC can be confident will meet its needs and preferences. The following award criteria and sub-criteria will be used:

1. Clarity and pertinence of the objectives:
    a) The specific objectives are clearly described, and appropriately address the requested scope as described in section 2.3 above.
    b) The specific objectives are realistic and achievable within the foreseen implementation period (see section 7 above)
2. Quality and efficiency of the implementation:
    a) The work plan (including tasks, reports and milestones) is clearly described, and appropriate for the execution of the activities of the action

b) The human and financial resources required for the execution of the action are well justified and in line with the work plan

3. Impact:

a) The application clearly describes in what ways the activities of the application would contribute towards the expected outcomes described in section 2.1.

11. EVALUATION AND AWARD PROCEDURE

This invitation to submit applications is subject to the standard submission and evaluation procedure.

Applications will be checked against formal requirements (admissibility and eligibility) and each applicant will be evaluated by an evaluation committee against the selection criteria and award sub-criteria. A preliminary evaluation report will be drawn up, including a list of adjustments and/or corrections required of each successful application prior to the award of the grant.

Successful applicants will be requested to clarify and correct their applications during the clarification phase, which may also include the negotiation on overall ECDC contribution to applications requesting more than 5,000,000 EUR (see section 4 above). This phase will involve a dialogue between the applicants and ECDC in order to address the technical or financial aspects of the project that were identified in the list of adjustments and/or corrections of the preliminary evaluation report, and may require extra information from the applicants' side. At the end of the clarification period, the evaluation report will be finalised with information on how the items on the list of adjustments and/or corrections have been addressed.

Unsuccessful applicants will be informed about their evaluation result (see the indicative timetable in section 3 above).

12. LEGAL COMMITMENTS

In the event the application for a grant is awarded, a grant agreement detailing the conditions of cooperation will be sent to the applicant, as well as information on the procedure to formalise the grant agreement between the parties. See the Model Grant Agreement, Annex IV.

Two copies of the original agreement must be signed, first by the coordinator (for a consortium) or sole beneficiary and returned to ECDC immediately. ECDC will sign it last.

13. FINANCIAL PROVISIONS

13.1. Form of the grant

The grant takes the form of reimbursement of costs actually incurred.

The grant will be defined by applying a maximum co-financing rate of 90% to the eligible costs actually incurred and declared by the beneficiary (see Articles I.13.1 and II.20.1 of the Model Grant Agreement, Annex IV).

13.2. Eligible costs

Eligible costs shall meet all the **criteria stated in the Articles I.10 and II.19.1 of the Model Grant Agreement**, Annex IV.

13.2.1. Eligible direct costs

The eligible direct costs for the action are those costs which are identifiable as specific costs directly linked to the performance of the action and which can therefore be booked to it directly.

The applicant shall carefully review the requirements for each cost eligible. Failure to do so runs the risk of these costs being considered ineligible.

The direct costs eligible under this grant are the following:

(a) the costs of personnel, including but not limited to personnel under an employment contract or seconded. This cost is defined in article II.19.2 a) of the Model Grant Agreement.

(b) the costs of purchase of equipment(s) defined in article I.10 of the Model Grant Agreement.

(c) the costs of consumables and supplies defined in articles II.10.1 and II.19.2 d) of the Model Grant Agreement

(d) the costs entailed by subcontracts defined in articles II.11 and II.19.2 f) of the Model Grant Agreement (see below section 13.6 c))

(e) the duties, taxes and charges paid by the beneficiary, notably value added tax (VAT), (for activities carried out by a Member State public authority as a non-taxable entity, the VAT will be ineligible) defined in articles I.10 and II.19.2 h) of the Model Grant Agreement

(f) the cost of audit.

13.2.2. Eligible indirect costs (overheads)

Indirect costs are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A flat-rate amount of 7% of the total eligible direct costs of the action is eligible as indirect costs, representing the applicant's general administrative costs which can be regarded as chargeable to the action/project.

See Article II.19.3 of the Model Grant Agreement for details of the eligible indirect costs.

13.3. Balanced budget

The consolidated budget and estimated budget(s) of the action must be attached to the application form (Annex I). The budgets (Annex II) must have revenue and expenditure in balance.

The budget must be drawn up in euros.

The applicants must ensure that the beneficiaries are able to co-finance the minimum 10% of the total eligible costs which are necessary to carry out the action.

Co-financing of the action by the applicants may take the form of:

- the beneficiary's own resources,
- income generated by the action or work programme,
- financial contributions from third parties.

13.4. Calculation of the final grant amount

The final amount of the grant is calculated by ECDC at the time of the payment of the balance. The calculation involves the steps described in Article II.25 of the Model Grant Agreement (Annex IV).

13.5. Other financial conditions

a) Non-cumulative award

An action may only receive one grant from the European Union (EU) budget. In no circumstances shall the same costs be financed twice by the EU budget. To ensure this, applicants shall indicate in the grant application that the action is not double-funded by the EU budget.

b) Non-retroactivity

Activities included in the action must not have started before the date of receipt of the award letter indicating that the application has successfully passed the evaluation.

c) Implementation contracts / subcontracting

The beneficiary can have recourse to subcontracting of tasks of the action and awarding of contracts necessary for the implementation of the action within the framework of the conditions established in Articles II.10 and II.11 of the Grant Agreement (Annex IV).

It is important to highlight that subcontracting shall not cover the core tasks of the action as defined by the applicant in the application. This shall be duly documented in the relevant section of the application (Annex I).

Failure to comply with the conditions runs the risk of these costs being ineligible costs.

d) Financial support to third parties

This Invitation to submit applications does not envisage provision of financial support to third parties via the action.

13.6. Reporting and payment arrangements

The beneficiary must request the following payments, provided that the conditions of the grant agreement are fulfilled (e.g. payment deadlines, ceilings, etc.). The payment requests shall be accompanied by the documents provided below and detailed in the Model Grant Agreement, Article I.4 (Annex IV).

Payment request	Accompanying documents
First **pre-financing payment** corresponding to 60% of the maximum grant amount, within 30 days of signature of the grant agreement.	
Second **pre-financing payment** corresponding to 30% of the maximum grant amount. To be requested once 70% of the first pre-financing payment has been consumed. The total amount of pre-financing payments shall not exceed 90% of the maximum grant amount.	(a) Interim progress report (b) statement on the use of the first pre-financing instalment, used to cover costs of the action. See Article I.4.2 of the Model Grant agreement (Annex IV)
Payment of the balance ECDC will establish the amount of this payment on the basis of the calculation of the final grant amount (see section 13.5 above). If the total of earlier pre-financing payments is higher than the final grant amount, the beneficiary will be required to reimburse the amount paid in excess by the ECDC through a recovery order.	(a) final technical report; (b) final financial statement; (c) summary financial statement aggregating the financial statements already submitted previously. (d) a certificate on the financial statements and underlying accounts See Article I.4.4 of the Model Grant agreement (Annex IV)

14. PUBLICITY AND VISIBILITY

Please refer to the Model grant agreement (Annex IV), Article II.8 for visibility of Centre funding.

15. PUBLIC ACCESS TO DOCUMENTS

All documents presented by the applicant become the property of ECDC and are deemed confidential. In the general implementation of its activities and for the processing of grant procedures in particular, ECDC observes Regulation (EC) No. 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

16. PROCEDURE FOR THE SUBMISSION OF APPLICATIONS

Applications must be submitted by the deadline set out under section 3.

No modification to the application is allowed once the deadline for submission has elapsed. However, if there is a need to clarify certain aspects or to correct clerical mistakes, ECDC may contact the applicant during the evaluation process.[14]

Applicants will be informed in writing about the results of the selection process.[15]

Application forms are available at:
https://ecdc365.sharepoint.com/sites/HERAIncubatorGrantProcedure.

Requests for additional information received less than five working days before the final date for submission of applications may not be processed.

Applications must be submitted by uploading them to https://ecdc365.sharepoint.com/sites/HERAIncubatorGrantProcedure.

- **Contacts**

In writing only, to the following email address: [redacted] With GRANT/2021/PHF/23776 in the subject line.

LIST OF ANNEXES

- **DOCUMENTS TO BE COMPLETED BY APPLICANTS:**

- Annex I - Application form and checklist of documents to be provided
- Annex II – Estimated Budget & Consolidated Budget Form
- Annex III – Declaration on Honour
- Legal Entity Form (Link)
- Financial Identification Form (Link)
- Annex V - Authorised Signatory Form

- **DOCUMENTS FOR INFORMATION:**

- Annex IV - Model Grant Agreement

[14] Article 200 FR
[15] Article 200 FR

Questions & Answers document

Reference: Grant/2021/PHF/23776

09 July 2021 Version 7.0

Please note that this document is a publication of all questions received and answers provided for the invitation to submit applications.

Table of contents

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

1. General questions

a. Can the deadline be extended?

The deadline for submission of applications is **Monday 12th July at 16:00 CEST.** It is currently not foreseen that the deadline will be extended.

Date question received: 01/06/2021

b. Will this become the standard routine for submitting applications to HERA or will the EU Funding&tender Portal take over after HERA is completely established?

The mechanism on how applications will be handled by HERA is a matter for the European Commission and is, to the best of ECDC's knowledge, yet to be agreed upon.

Date question received: 25/06/2021

c. It has been stated that the deadline for submission cannot be prolonged, however, we would like to make sure it is still the case?

We confirm that currently it is still the case that the deadline will not be prolonged. The deadline for submission of applications is still **Monday 12th July at 16:00 CEST**.

Date question received: 06/07/2021

2. Preparing the application

a. Among the "commercially available training activities related to the use of the equipment", do you consider that inter-laboratory training to assess the reliability of the sequencing results of the different platforms involved in the project is an eligible cost?

We do consider inter-laboratory training (for example to assess the reliability of the sequencing results of the different platforms involved in the project) as an eligible activity. Therefore, costs associated with the inter-laboratory training activities are eligible, provided that they are a) required to be able to successfully implement project's objectives, and b) not already funded from another source of EU/ECDC funding.

Date question received: 16/06/2021

b. The main or only Beneficiary will be our NIH. Does this pose any limitation for the co-financing of the project? In other words, probably the co-financing will be from the MoH, is this a problem? If so, does this mean that the Applicant has to be the MoH?

If there is a structural link between the NIH and the MoH, then the NIH could apply with the MoH as an affiliated entity.

If the NIH has no structural link with the MoH (no financial nor legal link between the two parties), then the contribution from the MoH can be considered as a financial contribution

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

from a third party*. Alternatively, a consortium can be setup incorporating the MoH as a co-applicant.

* See Annex II Budget, of the Invitation to Submit Applications.

Date question received: 18/06/2021

c. Can the co-financing of the project be in-kind? Can the MS co-finance with work or other types of resources?

The project cannot be funded through in-kind contributions from third parties. However, although the Member State organisations outside of the applicants cannot contribute work, these may provide a *financial* contribution to the action.

Please note that the resources of the beneficiary can be attributed to their contribution, i.e. Member State organisations that are part of the applicants may contribute to the co-financing of the activities using work or other types of resources.

Date question received: 18/06/2021

d. We could have the necessity to finance also the regional laboratories. Is this possible without the constitution of a consortium?

The financing of regional laboratories is possible without forming a consortium. If the regional laboratories have a link with the applicant, particularly a legal or capital link, or alternatively if all the entities i.e. the applicant and the regional laboratories, can be considered to have a link to the state, they can be treated as affiliated entities. The link for affiliated entities in the public sector can, for example, entail different levels of the structure established for public authorities in the case of decentralised administration (for example, national, regional, local public administrations can be considered affiliated.) If they are completely separate legal entities, with no link to the applicant or the state, then it is possible to subcontract the regional laboratories.

Date question received: 18/06/2021

e. We would like to have clarification related to the institutions, which can participate in the project. The eligibility criteria describe the eligible applicant as (1) a single national public health authority (including institutes and laboratories) or (2) a consortium of public health authorities from one country.

In our country, there are some laboratories and institutions, which do not have the status of the public health institution, however, they are involved in the monitoring of variants in accordance with the national strategy for molecular-biological surveillance of SARS-CoV-2. These institutions/laboratories are mostly from the academic sphere, nevertheless, they are practically involved in the SARS-CoV-2 monitoring activities at the regional and national level.

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

These scientific institutions contribute to the sequencing, bioinformatic analyses and setting of the quality control of sequencing data.

Also, the national node for bioinformatics infrastructure and the national infrastructure are involved in the monitoring activities by storing the metadata and raw data (fastq files) in their safe repository.

e. Can these scientific institutions be involved, e.g., be a part of the consortium, despite the fact that they do not have an official status of a public health institution?

These specific types of scientific institutes could be considered as affiliated entities of the national public health institute, as they fulfil the requirement to "have a link with the beneficiary [...] which is neither limited to the action nor established for the sole purpose of its implementation". For example, the link may be established through a national strategy of molecular-biological surveillance of SARS-CoV-2 as determined by the state, and that link would need to exist independently of the award of the grant. Evidence of the allocation of roles to the relevant entities by the state and a copy of the strategy to prove the link should be provided as part of the application.

Please refer to section 2.2 of the Invitation to submit applications, for more information on the main actors.

Date question received: 18/06/2021

f. In case it is decided that there is a consortium as a main actor in the grant call (not a mono-beneficiary), is it possible that the grant agreement is concluded between ECDC and the coordinator (lead-applicant from the consortium), but the ECDC funds are directly distributed to all the beneficiaries in the consortium (not through the Coordinator)?

Or is it mandatory that the funds are provided to the Coordinator who then distributes the amounts to the co-applicants?

No, it is not possible for payments to be made directly from ECDC to the individual consortium members. It is indeed mandatory for the funds to be paid to the Coordinator, and for the Coordinator to subsequently make any payments to the rest of the consortium members (i.e. co-applicants).

Date question received: 21/06/2021

g. Our institute has already filled and signed the following documents in former applications to ECDC. All documents are dated 2019. There have been no changes with regard to the information included but I have noticed that there have been some small changes in the forms. Do we have to fill and sign all forms again?

As per Section 5 of the invitation to submit applications:

* legal entity form – a copy of the previously submitted form may be provided, unless a change has occurred in the meantime.

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone [redacted]
www.ecdc.europa.eu

SM

* financial identification form - a copy of the previously submitted form may be provided, unless a change has occurred in the meantime.

* declaration on honour – the template provided as part of the invitation should be completed, signed and submitted in scanned form.

* authorised signature form - the template provided as part of the invitation should be completed, signed and submitted in scanned form.

Date question received: 25/06/2021

h. The grant applications shall include a letter of endorsement of the national coordinator. The national coordinator for our institute is employed at our institute. Do we have to include a letter of endorsement from the institute addressed to the institute?

No, it is not necessary to provide a letter of endorsement if the national coordinator is employed at the applicant's institute. The application should state that the national coordinator is employed by the applicant's institute.

Date question received: 25/06/2021

i. Project budgets [applications] are expected to be between 2 to 5 million euros. Do these estimated figures refer to the total cost, or to the 90% ECDC Contribution?

The estimated figures relate to the co-financing by ECDC of 90%. *As a guide, ECDC anticipates the receipt of applications in the range of 2,000,000 to 5,000,000 EUR*. The maximum ECDC contribution will be 90% of the total eligible costs, and the beneficiaries will need to co-finance the remaining (minimum 10%).

Date question received: 30/06/2021

j. Purchase costs are eligible according to the invitation, but in article II.19.2.c of the Model Grant Agreement, it is established the depreciation principle for eligibility of equipment costs. Nevertheless, in the same article afterwards reads:

"By way of exception, the full cost of purchase of equipment may be eligible under the Special Conditions, if this is justified by the nature of the action and the context of the use of the equipment or assets;"

j. Our question is, considering the specificities of this invitation, and the short time expected for the project execution, would it be admissible to charge the full cost of purchasing equipment?

Please refer to the Special Conditions, Article I.10 – Eligibility of Costs, of the Model Grant Agreement, in particular footnote 8. The full cost of the purchase of equipment is considered an eligible cost, as this is justified by the nature of the action. Please note that the grant takes the form of reimbursement of a maximum of 90% of the eligible costs of the action, therefore the beneficiary shall contribute a minimum of 10% of the total eligible costs of the action, which include equipment costs.

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

Date question received: 30/06/2021

k. We are a national public health agency and we want to apply in partnership with several partners: a national agency for [public health-related field(s) such as food safety etc], hospitals, private research foundations and a national bioinformatics infrastructure (all involved in the national research strategy and in sequencing activities).

k. Among these entities, which are considered to be public health authorities? In other words, which ones would be applicants / beneficiaries and which ones would be affiliated entities?

The organisations which are considered to be public health authorities would be defined by the national legislation or by some other mechanism applicable in the jurisdiction for allocating responsibility for public health to particular organisations. Entities that are not considered to be public health authorities according to the above definition may be considered affiliated entities to one or more of the participating public health authorities (see also question 2.e. above). Affiliated entities have a link with the applicant but are not party to the grant agreement.

It is for the applicant to determine the composition of the organisations applying, for example, whether a consortium is appropriate and if so, who will act as the coordinator. The applicant must also determine whether to include affiliated entities in the application. There are several different options available.

For example, an application can be submitted by:

- a sole applicant,
- a sole applicant with affiliated entities,
- a consortium,
- a consortium with affiliated entities.

For further information, see the section on affiliated entities in the Guidance Document.

Date question received: 02/07/2021

l. In part B, point 3 "Methods and Work Plan" it is written that the limit of this point is 4 pages. Does this include the tables with milestones and reports and the section 3.1 about risks?

ECDC appreciates that the limitation on the number of pages may be somewhat ambiguous for this section. To give each applicant the maximum chance of presenting their work plan properly, the four page limit will therefore be applied to the text of section 3, i.e. with the three tables (lists of milestones, deliverables and risks) being allowed in addition to a maximum four page text for the entire section 3.

Date question received: 02/07/2021

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

m. Could you please confirm we have to download the files of the proposal in "Upload area"? Is there anything else to do to confirm the submission of the proposal?

Yes, the documents related to your application should be uploaded to the upload area. Each country has a dedicated library, which is visible and available to all the contact points in receipt of the invitation to submit applications. The upload area is within the dedicated library, see the menu on the left, and the finalised application and all supporting documents must be saved in the upload area before the submission deadline of 12th July at 16:00 CEST. Please note that any applications submitted in any other way will be disregarded. ECDC will consider the version of the application and supporting documents uploaded to the dedicated website by the submission deadline of 12th July at 16:00 CEST as the final version.

There is no other mechanism to confirm submission, however, if you wish to send an e-mail to [redacted] informing us of your submission, thatwould be appreciated.

Date question received: 02/07/2021

n. Why is technical & scientific staff put together in the same category in the budget?
The costs for scientific staff are considerably higher. Of course we can always calculate an average amount, but this will be too low for scientists and too high for technicians.

The number of categories for the personnel costs have been limited in order to reduce the amount of information the applicants are required to provide. The technical & scientific staff costs have however been separated into two separate categories: 'senior' and 'junior'. The applicants themselves decide on which staff are included in which category. In total there are four different categories of personnel in the Estimated Budget form of each applicant (Annex II): Project management, Senior technical & scientific staff, Junior technical & scientific staff, and Administration & financial management.

It is correct that an average amount should be calculated for all of the categories relevant to the action (it is not mandatory to include staff for all categories, if not justified by the nature of the included activities). The applicant should calculate the average monthly cost per FTE (Full-Time Equivalent) as well as how many person-months of each staff category will be used for the project. For example, if one applicant expects four junior technical and/or scientific staff members to work 20% on the project for 13 months then the number of person-months for Junior technical & scientific staff would be 4*0.2*13 = 10.4 person-months.

The relevant section of the Estimated Budget Form to be completed:

Category 1. Personnel	
1.1 Project management	0
1.2 Senior technical & scientific staff	0
1.3 Junior technical & scientific staff	0

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

1.4 Administration & financial management	0
Sub-total for cost category 1	***0***

Date question received: 05/07/2021

o. I'd like to know if the application has to be submitted:
   - by the National Coordinator himself?
   - by the entity which is asking for the grant (of course with the National Coordinator endorsement letter included)?
   - by any of the interested parts for the Country?
   - by potentially all the parties (meaning that different persons and entities can insert different documents)?

The application can be uploaded by any designated person(s) in your country, as long as they have been granted access to the dedicated website.

Countries are of course free to organise the work on their application as they see fit; however ECDC would recommend that work on the documents by multiple persons is done outside of the dedicated website, with the final version(s) then uploaded to the dedicated website by a single individual.

Date question received: 05/07/2021

p. The eligibility of VAT is not clear to us. In "ARTICLE I.10 - ELIGIBILITY OF COSTS" of the Model Grant Agreement it says:

"the value added tax (VAT) is considered as an ineligible cost in case the activities described in Annex I are carried out by a non-taxable entity"

p. Does this mean that for the public institute, the VAT is not considered eligible? This would cause a problem for us, because we have to pay VAT when we purchase goods and services and it is not deductible for us.

Article I.10 shall be read together with Article II.19.

Article I.10 (2) has been included in the Model grant agreement in order to ensure that non-taxable entities that do not pay VAT do not include VAT as an eligible cost.

Therefore, for beneficiaries that are non-taxable entities but are required to pay VAT, for example, as a result of requirements of national law, this cost could be considered as an eligible cost. This will require to be justified by provision of supporting evidence demonstrating the payment of VAT by such beneficiary and that VAT is not deductible (Article II.19.2 (k)).

Date question received: 05/07/2021

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

q. As is specified in the application affiliated entities need to fill out the Declaration of Honour. [Can you please confirm that this is the case?]
We have some questions relating to this which we find conflicting. Please if you can assist us in understanding what is it that we have misunderstood.

- An affiliated entity cannot be part of a consortium. However, the Declaration of honour template includes the line "authorised to represent the consortium".
- An affiliated entity should not be considered an applicant. In the template it is stated "declares that the applicant is fully eligible in accordance with the criteria set out in the invitation to submit applications;" etc. 1-4 on the first page of the template and on additional places in the template.

The Declaration on Honour (Annex III) has now been updated to reflect the difference between applicant and affiliated entity. The Declaration on Honour version 2 is available on the dedicated website: https://ecdc365.sharepoint.com/sites/HERAIncubatorGrantProcedure.

Please note, any applicants or affiliated entities that have already signed the Declaration on Honour prior to this notification are not required to sign the Declaration again. All Declaration on Honours will be checked as part of the evaluation, and any necessary amendments will be requested.

Date question received: 07/07/2021

r. It is stated in the Guidance document regarding affiliated entities that no obligations can be placed on them. This conflicts with the responsibilities that are required to be declared in the declaration of honour; [please clarify?]

From the Guidance document page 12:
What level of responsibility does an affiliated entity have?
As an affiliated entity will not be party to the grant agreement with ECDC, no obligations can be placed on them, thus the applicant has to take on that burden on the affiliated entity's behalf.

Whilst affiliated entities are listed in the Grant Agreement, they are not party to the Grant Agreement, nor are they required to sign the Agreement. The Grant Agreement therefore provides for the obligation for the beneficiary to ensure that its affiliates comply with a number of obligations. The minimum obligation that the beneficiary must ensure according to the EU Financial Regulation is that its affiliates respect the right of checks and audits of the Commission, OLAF and the Court of Auditors. The Declaration on Honour is a separate part of the application process, and is required to be completed by affiliated entities (or by the applicant on behalf of the affiliated entities – please refer to section 8.4 of the invitation for more information).

Date question received: 07/07/2021

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

s. In the "invitation letter" it is indicated that "application must be signed by a duly authorized representative of the applicant", since in the word and excel templates of Annex I and II there are not a specific boxes for the signatures, should this signatures be applied in the last pages of both the annexes?

The signature of the Declaration on Honour by the duly authorised representative of the applicant is sufficient. It is not necessary to have the application form and estimated budget forms signed in addition.

Date question received: 07/07/2021

t. Can you please specify what documentation that is needed to be included in the application for subcontractors?

Please complete section 5.1.4 of the Application Form (Annex I to the Invitation to Submit Applications). Details of which tasks will be subcontracted etc should be provided; please see the instructions of that section. In addition, Cost Category 4 - Subcontracting (if applicable) in the Estimated Budget Form (Annex II) should also be completed.

Date question received: 06/07/2021

u. Related to the Grant (for WGS national infrastructures), are the costs involved with building adaptation also eligible?
Since the necessary purchase of sequencing equipment will also involve building adaptation.
In Table 1 of the Invitation to Submit Applications (on page 6), it is not included as an example. We ask this as we will need to expand the current facilities dedicated to WGS to improve the sequencing capacity in our Institute.

Building adaption costs in order to accommodate the activities of the action are considered to be eligible costs.

Date question received: 07/07/2021

v. Is it possible to update the submitted application?
In detail: if we upload today our current version to make sure, the application is on the platform in time (given unforeseen technical problems), can we upload an updated version on Monday before 4pm?

It is possible to update a submitted application right up until the deadline of 16:00 on the 12th July. ECDC will only access the documents after the deadline for submission has closed.

Date question received: 08/07/2021

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

w. We are wondering if the "Requested grant (amount in €)" is the total budget cost of the project or the remaining 90% of the budget after the self-funding has been subtracted?
This needs to be filled in in Part A, administrative information [of the Application Form].

The requested grant amount equates to the 90% of the total eligible costs, i.e. the total eligible costs for the action minus 10% co-financing by the applicant.

Date question received: 08/07/2021

x. The National Coordinator is concerned about a potential conflict of institutional interest at a national level, with the entity they are endorsing in the application. How should this be addressed?

The National Coordinators have been appointed by their respective countries, in accordance with the Coordinating Competent Bodies: structures, interactions and terms of reference *. It is in their capacity as National Coordinators that they have been asked to endorse one national application, which is deemed to best meet the needs of the country in response to the invitation to submit applications. The considerations and reasoning behind these decisions are a matter of national concern.

Please refer to the template for the endorsement letter included in the Guidance Document, it is noted that any further information relevant to the endorsement of the application may be provided by the applicant.

*https://www.ecdc.europa.eu/sites/portal/files/media/en/aboutus/governance/competent-bodies/Documents/coordinating-competent-bodies-structures-terms-of-reference-and-interactions-w-Annexes.pdf

Date question received: 09/07/2021

y. Should all documents be physically signed or are electronically signed documents accepted for uploading?

Preferably, the Letter of Endorsement, Declaration on Honour(s), and any Financial Identification Forms or Legal Entity Forms should be signed, and a scanned copy uploaded to the dedicated website. Alternatively, a QES (qualified electronic signature) can be used, and the documents uploaded.

Date question received: 09/07/2021

z. Staffing costs: it will be very difficult to attract talents for temporary one-year contracts so what are the modalities you plan for permanent contracts? Are we expecting permanent HERA funding to cover staffing costs or are you expecting member states to cover this budget?

As stated in the invitation to submit applications, the specific HERA Incubator funds used to implement this initiative are only available for a limited implementation period. Decisions on additional funding availability from HERA and/or HERA Incubator beyond that time frame are within the remit of the European Commission.

Date question received: 09/07/2021

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

3. Consortium agreements

a. Must this consortium agreement be attached when submitting the application (before July 12th)?

In the Invitation to submit, it's stipulated that "The coordinator and co-applicants shall take appropriate internal measures consistent with the provisions of the grant agreement via conclusion of a consortium agreement, to ensure the proper implementation of the action" and "This includes authorization of the coordinator to sign on behalf of the consortium and thus on behalf of the co-applicants". "The consortium agreement should be negotiated and concluded before signing the grant agreement. A copy of the consortium agreement shall be provided to ECDC prior to signature of the grant agreement".

It is not required to submit a copy of the signed consortium agreement along with the application. If it is available at the time of submission, please include it. However, a copy of the consortium agreement will be required prior to signature of the grant agreement. At the application stage you should draw up a draft consortium agreement. This enables you to discuss and agree on how to handle important (and possibly sensitive) matters. The draft can then be used as a starting point for further discussions if the application is accepted.

Date question received: 17/06/2021

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

Enhancing Whole Genome Sequencing (WGS) and/or Reverse Transcription Polymerase Chain Reaction (RT-PCR) national infrastructures and capacities to respond to the Covid-19 pandemic in the European Union and European Economic Area

Template for Application

Part A: Administrative Information
&
Part B: Technical Information
&
Part C: Checklist

Annex I

Ref. Grant/2021/PHF/23776

GENERAL INSTRUCTIONS AND GUIDELINES

TABLE OF CONTENTS

PART A: ADMINISTRATIVE INFORMATION

Title of Application

Grant/2021/PHF/23776 - Enhancing Whole Genome Sequencing (WGS) and/or Reverse Transcription Polymerase Chain Reaction (RT-PCR) national infrastructures and capacities to respond to the Covid-19 pandemic in the Czech Republic.

Requested grant (amount in €): **3 065 518**

LEGAL NOTICE – Non–Retroactivity

Applicants are informed that, under the Financial Regulation applicable to the general budget of the European Union, no grants may be awarded retrospectively for actions already completed. In those exceptional cases where applicants demonstrate the need to start the action before the agreement is signed, expenditure eligible for financing may not have been incurred before the date of receipt of the award letter indicating that the application has successfully passed the evaluation.

Does the applicant envisage to start the action before the agreement is signed, due to the current exceptional emergency situation of the COVID pandemic?

Yes	*No*
☒	☐

If yes, what start date does the applicant envisage?

Date of award notification	*Other*	
☒	☐	If Other, please specify[1]: _____

Other explanation (Please specify):

N/A

[1] Estimated start date September 2021 at the earliest. If envisaged start date is prior to the date of award notification, the start date will be automatically changed to the date of award notification

Details of Applicant(s)

1.1 IDENTITY OF THE APPLICANT (Coordinator in case of a consortium[2])
Official name in full: National Institute of Public Health
Acronym: NIPH
Official legal form: Budgetary organization of the Ministry of Health
Place of establishment or registration: Srobarova 49/48, Prague 10, 100 00 CZ
VAT number (if applicable): CZ75010330

The legal details of the applicant are attached in the LEGAL ENTITY FORM ☒

1.1.1 Applicant Organisation	
Acronym	**Name (official name in full)**
N/A	N/A

The legal details of the other applicants are attached in LEGAL ENTITY FORMS ☐.

1.2 CONTACT PERSON RESPONSIBLE FOR THE APPLICATION	
Family name: [redacted]	First Name [redacted]
Position/Function: [redacted]	
Telephone: [redacted]	Mobile: [redacted]
E-mail address: [redacted]	
1.3 PROJECT MANAGER FOR ACTION (If different from contact person above)	
Family name [redacted]	First Name: [redacted]
Position/Function/Mandate: [redacted]	
Telephone: [redacted]	Mobile: [redacted]
E-mail address: [redacted]	

[2] Will sign the Grant Agreement on behalf of the consortium and be the main contact point for ECDC. Please note that only one applicant can be the coordinator.

1.4 BACK-UP PROJECT MANAGER FOR ACTION	
Family name: [redacted]	First Name: [redacted]
Position/Function/Mandate: [redacted]	
Telephone: [redacted]	Mobile: N/A
E-mail address: [redacted]	
1.5 LEGAL REPRESENTATIVE (PERSON AUTHORISED TO SIGN THE GRANT AGREEMENT)[3]	
Family name: [redacted]	First Name: [redacted]
Position/Function/Mandate: [redacted]	
Telephone: [redacted]	Mobile: [redacted]
E-mail address: [redacted]	

Any change in the addresses, phone numbers or e-mail, must be notified in writing to the ECDC Authorising Officer. The If not, ECDC will not be held responsible in the event that it cannot contact an applicant.

1.6 IDENTITY OF THE AFFILIATED ENTITIES (if applicable)		
Official name of affiliated entity in full:	Acronym of applicant to whom the entity is affiliated:	Official legal form:
Public Health Institute Ostrava	NIPH	Medical facility set up by the Ministry of Health
Public Health Institute Usti nad Labem	NIPH	Medical facility set up by the Ministry of Health
Faculty of Science, Charles University	NIPH	Public University
Institute of Molecular Genetics of the Czech Academy of Sciences	NIPH	Public research institution
Biology Centre, Czech Academy of Sciences	NIPH	Public research institution
Centre for Infectious Animal Diseases in Czech University of Life Science Prague	NIPH	Public University
The Institute of Molecular and Translational Medicine	NIPH	Public University

[3] As stated in the Authorised Signatory Form, Annex V of the Invitation to submit applications.

1.7 UNION FUNDING (Sole applicant)
An action may only receive one grant from the EU budget. In no circumstances shall the same costs be financed twice by the EU budget. The applicant confirms that the applicant or any of the affiliated entities have not received any EU funding for the same action or part of the action during the same financial year. ☒ YES ☐ NO

1.8 BANK DETAILS OF THE APPLICANT (Coordinator in case of a consortium)

The bank details are attached in the FINANCIAL IDENTIFICATION FORM (FIF) ☒.

1.9 Operational Capacity

The **National Institute of Public Health** (NIPH) is a budgetary organization of the Ministry of Health. The legal status and tasks of the institute are postulated by paragraph 86 of Law No. 258/2000, in the wording of Law no. 320/2002 and provision of the Minister of Health no. 31334/2002 from 17. 12. 2002. The statutory representative is the Director who is named and recalled by the Minister of Health on the proposal of the Chief Public Health Officer of the Czech Republic. Paragraph 86 of the cited law states that the mission of the Institute is to cover a spectrum of activities comprising of creation of the basis for national public health policy, health promotion and protection, providing methodical reference activities and monitoring related to public health, research of the environmental impact on human health, international collaboration, post-graduate education in medical fields and health-related education of the general public. The National Institute of Public Health is authorized to collate such personal health-related data associated with disease prevention, monitoring long-term trends of infectious disease incidence, occupational health hazards and the epidemiology of drug dependence, and transmit that data to public health facilities. The Centre for Epidemiology and Microbiology (CEM) consists of ten departments/units, the CEM Accreditation Unit, National reference center for healthcare associated infections and Bacterial Genetics Laboratory. The CEM National Reference Laboratories (NRLs) focus on a wide range of infectious diseases and pathogens. **To respond the SARS-CoV-2 pandemic, the NIPH closely collaborates with academic workplaces listed below which provide quality management, training, and dissemination of knowledge. These workplaces act in this application as affiliated entities. The National Reference Laboratory NRL for Influenza and Respiratory Viruses under the leadershdip of [redacted] has been recognized and approved by ECDC/WHO as a reference laboratory for SARS-CoV-2.**

Operational Capacity:

STAFF: senior researchers: 2.5, junior researchers: 2, senior technitian 1, technitian junior: 3 , plus cooperating and capacity supporting staff from NRL for Enteroviruses NIPH: senior researcher 1, senior technician 2, junior technician 1, administrative -0,5.

EQUIPMENT:

Virus isolation and infection material manipulation: BSL 2 laboratory" 5 items of Biohazard cabinets class II, one CO2 incubator, 2 items of -80°C freezer

BSL-3 laboratory, Biohazard box class II, CO2 incubator, 2 items of-80°C freezer

PCR and molecular biology laboratories: 5 dedicated and separated rooms: 5 items of PCR box, NA isolation machines: King Fisher Flex II (Thermofisher), MagNa Pure Compact (Roche), Zybio EXM 3000 (Zybio Inc), Liquid Handling Platform: ep Motion 5073 (Eppendorf), PCR cyclers – real time: CFX 96 (BioRad). 2 items of LC480 2 (Roche), AUS diagnostic system, PCR cycler (end point): 2 items of T100 (BioRad), horizontal electrophoresis – BioRad, biosystem 200 (Azure), QIAxper (Quiagene), Eppendorf centrifuge 5430 (Eppendorf)

NGS – lab: MiSeq (Illumina), TapeStation 4150 (Agilent), Eppendorf centrifuge 5430 (Eppendorf), CFX96 C1000 Touch RT detection (Biorad), CFX C1000 touch thermo cycler (Biorad), M220 Focused ultrasonicator (Covaris), Qbit 4 fluorometer (ThermoFisher), Laminar flow cabinet (ESCO), PCR box (BioSan)

Plus other miscellaneous standard laboratory equipment.

Electronic resources and databases: NIPH thank to the project CzechELib (https://www.czechelib.cz/en/) has an unlimited access to the following data resources, ScienceDirect - Freedom Collection (Elsevier), SpringerLink (Springer), Wiley Online Library (Wiley), EbscoHost (EBSCO), Scopus (Elsevier), Web of Science (Clarivate Analytics), Micromedex (Truven). Other resources used by NIPH/NRL: International Reagent Resource (https://www.internationalreagentresource.org/), GISAID (gisaid.org) and web sites enabled by data shared via GISAID; ISIN (Information System of Infectious Disease); Nextclade (Nextstrain, ECDC, WHO, CDC and PHE recommendation (influenza, SARS, RSV), TESSY/EPI Pulse.

Regional Public Health Institutes in Ostrava and Usti nad Labem (PHIO, PHIUL) are medical facilities set up by the Ministry of Health, providing a wide range of health and laboratory services related to health and the environment. RPHIs work closely with the NRL for Influenza and Respiratory Viruses (NIPH) in the framework of sequencing surveillance and genotypization of samples positive for SARS-CoV-2. [redacted] have long experiences in the field of microbiology with a focus on molecular biological methods.

Ostrava molecular biology laboratory equipment: 7 dedicated separated rooms, BLS 2 section: two items of Biohazard cabinet class II, Bravo (Agillent), molecular biology section: Liquid Handling Platform: OT-2 (Opentrons) 2x, NA isolators: King I King Fisher Flex II (Thermofisher sci.), CroBEE (Geneproof), two items of each: QIAcube (Quiagene), EZ1 (Quiagene), Nextractor (Genolution), PCR cyclers: two items of PTC-200 (Thermofisher sci.), Trio 48 (Biometra), real time PCR cyclers: BioRad: CFX96 (6x), CFX384 (1x), ABI 7500 Fast (Thermofisher sci.), ABI 3130 (Thermofisher sci.), NeumoDx diagnostic system, -80°C freezer, Plus other miscellaneous standard laboratory equipment.

Usti nad Labem: Biohazard cabinet class II 4x, PCR box, NA isolators: MagPurix 12A (Zinexts), 2x Zybio EXM3000 (Zybio Inc.), 1x Nextractor NX-48S (Genolution Inc), end-point PCR cycler Swift MiniPro (ESCO), real-time PCR cyclers: 3x SmartCycler (Cepheid), 2x RotorGene Q (Qiagen), 2x CFX 96 (BioRad). Mic (Bio Molecular Systems Pty), GeneXpert – 2 bloks (Cepheid), centrifuge WPC001 (Genolution Inc.), reverse hybridization system TwinCubator (HainScience).

The Institute of Molecular and Translational Medicine (IMTM) was established as a national node for European Infrastructure for translational Medicine (EATRIS-ERIC) to roof translational medicine activities in the Czech Republic. The Institute is integrated with the University Hospital in Olomouc, licensed to work with genetically modified organisms, radioactivity, BSL2 and BSL3 pathogens, laboratory animals, the diagnostic laboratories of the Institute are accredited ISO 17025 and 15189 with access to GMP and GLP facilities. [redacted] IMTM researchers developed high-throughput testing methods for SARS-CoV-2 virus including proprietary CE IVD certified solutions for self-sampling of biological material by gargling (GARGTEST) and magnetic-beads nucleic acid isolation kit, both licensed to academic spin-off company IntelliMed, s.r.o. The IMTM developed proprietary cloud-based laboratory management and information system CovIT for laboratories involved in testing of COVID-19. In 2020-21, more 1.5 million COVID-19 results were reported via CovIT to health care professionals and epidemiologists. IMTM tested over 200.000 samples for COVID-19 by PCR methods, established the largest biobanking collection of SARS-CoV-2 viruses, performed large scale seroprevalence study (9.600 participants).

Faculty of Science, Charles University is partially positioned in Centre BIOCEV built with the support of the European Regional Development Fund. [redacted] are work leaders on the H2020 ERC and Twinning grants. In a response to pandemic, more than 100 volunteers from the BIOCEV participated on the testing samples for the detection of SARS-CoV-2 infection under the leadership of [redacted] and the groups in BIOCEV additionally participated in a validation of testing approaches such as pooling of samples and development of direct RT PCR from saliva's. The group of [redacted] participated in sequencing and analyzing samples by the whole genomic sequencing for the purposes of surveillance, sequenced 649 samples by now and participate in compilation of regular reports (virus.img.cas.cz). BIOCEV is fully equipped for the testing, sequencing, and analyses of clinical samples; it possesses the BSL2+ laboratory for manipulation with infectious samples, core facility for sequencing with MiSeq and computers with sufficient capacity and software for bioinformatical analyses.

Institute of Molecular Genetics, CAS, the laboratory of [redacted] focuses on applications of high-throughput sequencing, including single-cell approaches, and develops bioinformatical tools and. It is involved in functional genomics research of several

models of malignant and immune diseases and collaborates regularly with clinicians. It conducts research on genomics of endogeneous retroviruses. The laboratory forms the local node of the Pan-European ELIXIR bioinformatics research infrastructure and curates and maintains the database of mitochondrial sequences coming from the ancient DNA samples AmtDB and the database of human endogenous retroviruses HERVd. As a part of National surveillance of the coronavirus, the laboratory has processed over 600 genomic sequences of the SARS-CoV-2 virus, helped to establish the surveillance strategy, and provides data management. It participates in compilation of regular reports and maintains the database of coronaviral sequences in the Czech Republic (virus.img.cas.cz). The laboratory is equipped with Illumina NextSeq 500 sequencer, computational clusters with over 200 CPUs, extensive, fast, secured and back-upped storage.

Biology Centre, CAS, is already actively participating in national SARS-Cov-V2 genomic surveillance program. As such, the institute is well equipped for sequencing and bioinformatics of SARS-Cov-V2 WGS including the Oxford Nanopore Sequencer and local computer cluster (320CPUs, 3,5TB RAM 4 Tesla V100 GPUs). The laboratory of [redacted] is experienced in genomics and bioinformatics including analysis pipeline implementation and software development. BC ais also participating in analyses of SARS-Cov-V2 genomes including variant detections and scanning for novel mutations (virus.img.cas.cz). We have also developed software for the Detection and removal of cross-contaminations in transcriptomic NGS datasets: https://github.com/kolecko007/WinstonCleaner.

Centre for Infectious Animal Diseases (in CINeZ) was established at the Czech University of Life Sciences as a research center focused on problematics of infectious animal diseases. CINeZ employs researchers with many experiences in research of various pathogens including coronaviruses. CINeZ is fully equipped to perform RT-qPCR and subsequent sequencing analyses of biological samples in normal laboratory set up or even under field conditions in the mobile research laboratory CZU mobiLAB. In near future, CINeZ will open its own BSL3 laboratory. [redacted] has wide experiences with various zoonotic viruses and leads national projects "P01010050 / 2020_11_02 - Use of molecular beacon probes in LAMP detection of SARS-CoV-2 and its differentiation from influenza virus" and "TP01010050 / 2020_S_02 - Development of a rapid LAMP test for SARS-CoV-2 detection".

Link to affiliated entities: Recently all affiliated entities have been connected within the preparation and implementation of the National Sequencing Surveillance Strategy (NSSS) and some of them have been a part of the network associating the laboratories under NSSS as the sequencing centers: NRL/NIPH, IMG, IMTM, BC CAS. Further, PHIO, PHIUL, NRL/NIPH, IMTM have been also the part of the NSSS as sentinel laboratories. The CINeZ has been cooperating with NRL/NIPH in the project of the setup the multiplex LAMP procedure to detect SARSCoV-2, influenza A and influenza B virus. Experts from CINeZ also helped the NRL/NIPH to build the capacity during the initial time of COVID pandemic on the voluntary base. The IMG and NRL/NIPH started with the bio-informatics cooperation in October 2020, and based on this activity, the Czech bioinformatics consortium have been set up at the beginning of 2021, FoS CU has been one of the most important member of this consortium as well as BC CAS. In the period of the epidemic wave caused by alfa variant in the Czech Republic FoS CU have been involved in sequencing.

The cooperation between the public health institutions (NIPH, PHIO, PHIUL) can be recognized as long term in many areas. As part of ensuring external quality control for the field of medical microbiology, PHIO and PHIUL use the External Quality Assessment Programs (EQAPs) of microbiology and parasitology NRLs in many fields, direct (culture, PCR) and indirect (serology) diagnostics of infectious diseases.

A large part of the cooperation with the NIPH consists of confirmation of samples in the National Reference Laboratories, in which the positivity of antibodies against selected agents (NRL for viral hepatitis, NRL for HIV / AIDS) or typing of detected infectious agent (NRL for meningococci, NRL for enteroviruses, NRL for Influenza and Respiratory Viruses).

The possibility of cooperation in exceptional cases, such as local epidemics or population studies, is also important. Cooperation with local measles epidemics in 2014 and 2018 or viral hepatitis A in 2017 and 2018 can be mentioned here. An important project in which the public health institutes participated was the Serological Surveys. The staff of the National Reference Laboratories are also consulted on small-scale clinical studies concerning, for example,

vaccination (antibody levels after the use of conjugate vaccines - HiB / tetanus, vaccination against tick-borne encephalitis in the elderly population, vaccination of splenectomized persons, etc. Public health institutions are also connected in other then microbiology area, for example, health promotion, population health monitoring, the environmental monitoring, and also in the specialized postgraduate education of health care professionals. Contracts could be provided on request.

The translated document of National Sequencing Surveillance Strategy (NSSS) has been sent in separated file as the supplement of this Annex.

Publications

PART B - TECHNICAL INFORMATION

Title of Application

Grant/2021/PHF/23776 - Enhancing Whole Genome Sequencing (WGS) and/or Reverse Transcription Polymerase Chain Reaction (RT-PCR) national infrastructures and capacities to respond to the Covid-19 pandemic in the Czech Republic.

1 Problem Analysis Including Evidence Base

The WGS sequencing of SARS-CoV-2 in the Czech Republic is performed from the March 2020 by NRL (NIPH). From February 2021 NRL was incorporated under a sequencing support by ECDC and loosely organized group of public health and academic institutions, most of them are organized under the activity COG-CZ initiated by NRL and Czech Academy of Science. Several of these institutions in collaboration with NIPH have become a part of a network associating the laboratories under the National Sequencing Surveillance Strategy (NSSS). The National Sequencing Surveillance Strategy of SARS-CoV-2 has been kicked off in June 2021 as a common activity of Ministry of Health (MoH) and NIPH. This strategy covers all 14 administrative regions of the Czech Republic and it involves 17 sentinel laboratories and 8 sequencing centers (Figure 1). There are 2 strategies for the sample collection and sequencing. The first portion of samples

***Figure 1**: The network of sentinel laboratories (left) and sequencing centres involved in National Sequencing Surveillance Strategy (NSSS).*

intended for whole genome sequencing WGS is based on targeted sampling strategy, that includes the samples: 1) from local outbreaks, 2) the samples based on results of genotypization (PCR) with a suspicion on VOC/VOI/VUM, 3) according to the clinical symptoms and severity (all hospitalized patients under 50 years of age), 4) vaccination failure, 5) reinfection. The second part of surveillance strategy is focused on the representative portion of samples selected from different geographical areas, time periods, population of a different demographic characteristics and samples across the spectrum of disease severity. The sentinel laboratories are responsible for the sample collection, nucleic acid isolation and a delivery of RNA to the sequencing laboratories. Those sentinel laboratories should collect the representative pool of samples, ideally the 10 % of positive samples. The targeted value of this strategy is 4 500 samples per week. Regarding the technical platforms used for WGS, it is dominated by Illumina (NextSeq, MiSeq) and supplemented by Oxford Nanopore. Real sequencing performance in the year 2021 is shown in the Figure 2. Although it was higher than the sequencing performance in the year 2020, the number of sequenced samples rarely exceeded 300 samples per week and thus the monitoring of the evolution of virus variants during the autumn and spring waves was not possible. The sequencing capacity of the Czech Republic has been also strengthened by the Saxony cross-border initiative organized from Dresden that was introduced from February/March for the two regions "Liberecky" and "Ustecky" to monitor the direction of the virus transmission in Saxony region (Germany), the Czech Republic and Poland.

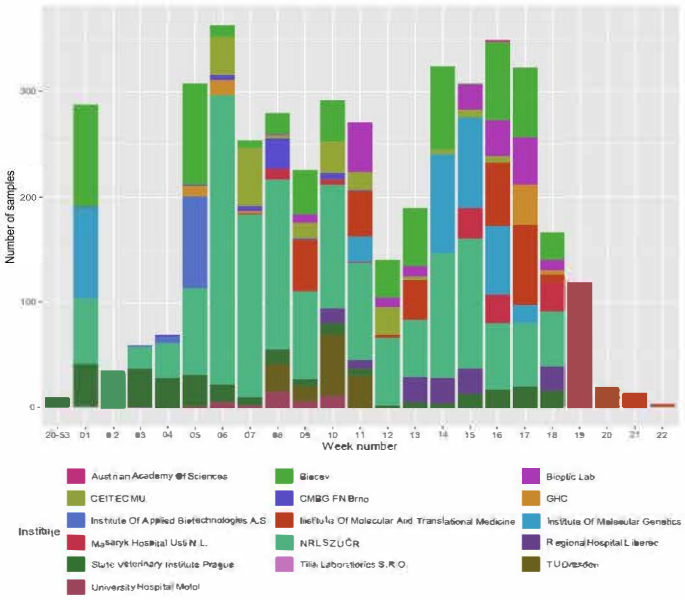

***Figure 2**: Numbers of sequenced SARS-CoV-2 samples in the Czech Republic in weeks of 2021 coloured by sequencing laboratories*

If the laboratory detects variant (mutation), it is obliged to report these findings to the web based nationwide notification system "Infectious Diseases Information System" (ISIN), where the relevant Regional Public Health Authority have an access. Concerning the variants and mutation surveillance by genotypization NRL provides the methodological support and guidance to the diagnostic laboratories dealing with SARS-CoV-2. NRL also serve as the confirmatory centre and provide the genotypization service for those laboratories which cannot implement the genotypization from the capacity purposes. NRL prepares WGS reports for public health authorities (MoH and for regional epidemiologist) and laboratories on weekly bases. A biweekly report based solely on WGS sequencing has been published by academic consortium COG-CZ.

The generic workflow process for SARS-CoV-2 sequencing and data analysis and sharing needs improvements in every step but as the as the weak points were identified – **lack of automation, small sequencing capacity, insufficient central data keeping and analysis**.

In the proposal we would like to address the identified weak points by investing into human resources, instruments, mapping of virus distribution and pipelines and work protocols. Specifically:

1. Automation of preparation of sequencing libraries.
2. Build capacities for sequence data storage and centralized pipelines for their analyses.
3. Enhance the capacity of a rapid variant detection system by establishing a method involving a combination of PCR and MassARRAY analysis.
4. Perform retrospective analysis of samples from the critical phase of epidemic, representative population survey of human population in the autumn 2021.
5. Develop a methodology and semi-automation of the process of generation of regular reports to national public health authorities, to ECDC and to the general public.
6. Increase the professional capacity of laboratory experts and epidemiologists and simultaneously increase of the general population with preventive measures to protect public health.

The co-financing of the project will be provided by the coordinating institution (NIPH) through financial support of the Ministry of Health.

2 Goals and Objectives of the Action

2.1 General Objective and Expected Outcomes of the Action

The general objective of the action is to enhance and/or improve national public health WGS and/or RT-PCR capacity. Results should be directed, tailored and contributing towards the following expected outcomes:

- In the short-term, contribution to the establishment of a sustainable, efficient and high capacity WGS and/or RT-PCR infrastructure for national public health microbiology;
- In the short/medium-term, contribution to early detection and enhanced monitoring of emergent and known SARS-CoV-2 variants at the national and the EU/EEA levels;
- In the medium/long-term, contribution to enhanced genomic-based infectious disease outbreak investigation capacities at regional, national and/or EU/EEA levels;
- In the medium/long-term, contribution to enhanced routine genomic-based surveillance of infectious diseases at the regional, national and/or EU/EEA levels, in accordance with the "ECDC strategic framework for the integration of molecular and genomic typing into European surveillance and multi-country outbreak investigations"; and
- In the long-term, contribution to enhanced preparedness for timely and effective response in cross-border outbreaks of infectious diseases and pandemics.

2.2 Specific Objective(s) of the Action

Specific Objective ID	[2.2.1] Specific Objective Title and Description
1	Automation of preparation of sequencing libraries

Process Indicator(s)	Target value
Publish call for tender – 2 pipetting NGS robotic machines (conditional tender)	1
Publish call for tender - 1 archiving system (conditional tender)	1
Acquisitions of the 2 pipetting NGS robotic machines	2
Acquisitions and installation of the archiving system	1
Connection of Omics Genomic laboratory to the NGS SARS-CoV-2 reporting system (ISIN).	1
Set up and verification of the standard operation procedure (SOP) of NGS library preparation and archiving system.	2
Operator admission and staff training	2
Output Indicator(s)	**Target value**
D1.1: Two installed pipetting automats, validated protocols and standard operation procedure (SOP) for NGS library preparation (Delivery in month 5)	1
D1.2: Archiving system (AS) is verified and connected to LIS data, the records/samples are accessible and AS enables easy storage and retrieval of archived samples. (Delivery in month 8)	1
Outcome/Impact Indicator(s)	**Target value**
Reaching the weekly sequencing capacity	376
SARS-CoV-2 sequences stored in GISAID (expected 5% failure)	2 800
Archives of SARS-CoV-2 samples, viral strains, standards, primers	15 000

Specific Objective ID	[2.2.2] Specific Objective Title and Description
2	Capacities for sequence data storage and management

Process Indicator(s)	Target value
Publish call for a tender	1
Purchase of the server (50TB NAS with a raid-6 array)	1
Data and services transferred from the transitional storage at ELIXIR-CZ/CESNET	5 000 genomes
Output Indicator(s)	**Target value**
D2.1: Installed and operating server (Delivery in month 6)	1
Outcome/Impact Indicator(s)	**Target value**
Stored individual data	7 000 genomes

Specific Objective ID	[2.2.3] Specific Objective Title and Description
3	Establishing of bioinformatics pipelines for semi-automatic analysis of WGS data

Process Indicator(s)	Target value
Preparation and verification of pipeline for NGS data retrieval	1
Development of algorithms for automatic NGS data analysis	4
Development of algorithms for merging of NGS data and metadata	1
Output Indicator(s)	**Target value**
D3.1: Scripts for metadata retrieving and data analysis (Delivery in month 8)	8
D3.2: Scripts for NGS data and metadata retrieving and analyses, followed by the merge assembled into workflow (Delivery in month 9)	9
D3.3: Public health data reports summarizing spread and frequency of SARS-CoV-V2 variants and mutations in the Czech Republic for policy making authorities (Delivery in month 12)	25
Outcome/Impact Indicator(s)	**Target value**
Infrastructure set up for NGS data assembled into the automatic workflow with a clear outcome for the public health authority	1

Specific Objective ID	[2.2.4] Specific Objective Title and Description
4	Enhancing the capacity of a rapid variant detection system by monitoring a large set of mutations by a method involving a combination of RT-PCR and MassARRAY analysis

Process Indicator(s)	Target value
Publish a call for tender: 3 pieces of PCR-MassARRAY system (MALDI TOF technology based) - open system adopted to the detection at least 36 mutations in two end point PCR amplicons	1
Acquisitions of the 3 PCR-MassARRAY system (MALDI TOF technology based) - open system	3
Instruments' installation and staff training	3
Adaptation and verification of standard operation procedure for sample analysis	1
Output Indicator(s)	**Target value**
D4.1: Verified SOP for sample analysis (Delivery in month 5)	1
D4.2: Report on analyzed samples (min 10 000) (Delivery month 11)	1
Outcome/Impact Indicator(s)	**Target value**
Reaching minimal weekly operational capacity for sample analyses	1 500

Specific Objective ID	[2.2.5] Specific Objective Title and
5	Perform a retrospective analysis of samples from critical phases of the SARS-CoV-2 epidemic in the Czech Republic

Process Indicator(s)	Target value
Selection of archived samples for sequencing	4 000
Selection of laboratories involved in the NSSS with capacity to sequence	3
Output Indicator(s)	**Target value**
D5.1: Report on sequences of samples uploaded in GISAID (included 3 800 samples, expected 5% failure) (Delivery in month 11)	1
D5.2: Report characterizing diversity of SARS-CoV-2 and its development in time during the autumn-spring 2020/21 waves in the Czech Republic (Delivery in month 13)	1
Outcome/Impact Indicator(s)	**Target value**
Science based evidence of virus evolution under specified circumstances as a base for the future policy making decision and definition of public health strategies.	1

Specific Objective ID	[2.2.6] Specific Objective Title and Description
6	Perform a population survey in 2021/2022 in order to determine the degree of subthreshold spread of the virus in the population and critical elements enabling mitigation.

Process Indicator(s)	Target value
Selection of inclusion criteria for target population	1
Creating a questionnaire	1
Distributing the sample collection kits and questionnaires	100 000
Analysis of returned samples for SARS-CoV-2	Max 20 000
Output Indicator(s)	**Target value**
D6.1: Report on percentage of positive samples (expected return rate of 20 %) (Delivery in month 5)	1
D6.2: Report on sequences of samples uploaded in GISAID (included 500 samples, expected 5% failure) (Delivery in month 6)	1
D6.3: Report characterizing diversity of SARS-CoV-2 within targeted population the Czech Republic (Delivery in month 12)	1
Outcome/Impact Indicator(s)	**Target value**
Updated tools for the surveillance of SARS-CoV-2, influenza and respiratory viruses based on self-sampling of targeted population as a base for the future policy making decision and definition of public health strategies.	1

Specific Objective ID	[2.2.8] Specific Objective Title and Description
7	Develop infrastructure to facilitate the timely reporting of genotype data to ECDC and other supra-national institutions, and the sharing of data in the public domain

Process Indicator(s)	Target value
Standardizing of procedure for data mining from central public health databases (ISIN) and diagnostic laboratories	1
Setup the workflow to analyze population wide distribution of genotypes in the Czech Republic	1
Implementation of reporting workflow to incorporate virus genotype data from Czech Republic into ECDC and GISAID EpiCoV	1 per week
Output Indicator(s)	**Target value**
D7.1: SOP for the data mining from public health sector databases (Delivery in month 9)	1
D7.2: Reports published in public domain of ECDC and GISAID EpiCoV including genotype data (Delivery in month 12)	5
Outcome/Impact Indicator(s)	**Target value**
Enhanced surveillance capability and capacity to contribute to the international database with timely and actual data for future policy making and definition of public health strategies at the EU level.	1

Specific Objective ID	[2.2.9] Specific Objective Title and Description
8	Increasing the professional capacity of laboratory experts and epidemiologists, deepening interdisciplinary cooperation between institutions with different specializations

Process Indicator(s)	Target value
Organization of the individual consultations and participation at the laboratory meetings	100
Organization of the interdisciplinary webinars for epidemiologist and diagnostic laboratories on good practices in data reporting of SARS-CoV-2, and methodology of their interpretation (target number of participants – 200)	10
Publication of training materials online, via project website	10
Output Indicator(s)	**Target value**
D8.1: Report on individual consultations, laboratory meetings interdisciplinary webinars (Delivery in month 10)	1
Outcome/Impact Indicator(s)	**Target value**
Operational interdisciplinary network of laboratory and public health experts across the Czech Republic	1

3 Methods and Work Plan

Objective 1: Automatization of preparation of sequencing libraries ([redacted]. Purpose is to assemble a pipeline for preparation of the sequencing libraries, which would involve minimum human labor and decrease the cost. The targeted throughput 376 samples weekly (four 96 plates without controls) would not be sufficient during outbreaks but would suffice for long term surveillance in periods when the viral load is low. If the acute work does not fill the capacity, it will be used for preparation of libraries for objectives 5-7. For the pipeline we plan to purchase two pipetting automats for preparation of sequencing libraries and one archiving system to store the samples. One pipetting automat and the archiving system would be installed by the supplier in the National reference laboratory for respiratory diseases (NIPH) and the second pipetting automat in the Omics Genomic laboratory (FoS CU). The supplier will provide service and train technicians partially paid from this project. While the robot in NIPH will be used for routine work, the instrument in FoS CU will in future be used for validation of protocols for preparation of libraries of other pathogens. The archiving system will enable the NRL the long term storage/archiving of samples, nucleic acids, viral strains and other important material under electronic archive instead of the traditional paper based insufficient system.

Objective 2: Building capacities for sequence data storage and management [redacted]). At present, the Czech Republic uses tight cooperation with the Large bio/informatics infrastructures ELIXIR-CZ and CESNET, for the analysis of SARS-CoV-2 virus sequencing data and their storage. The data is stored on a dedicated server with restricted access. All software necessary for the analysis of the data is installed on the server. Analyzed data are uploaded to GISAID and presented to the state administration, professionals, media and non-expert audience using regular reports by NIPH and by the IMG website https://virus.img.cas.cz. The data is stored in an anonymized form with a unique key, which links the data to the state Infectious Disease Information System, where also patient metadata are available and accessible to hygienic stations and physicians. Ministry of Health of the Czech Republic requires also the raw sequencing data are stored under its administration, i.e., at NIPH. Therefore, the data and services will be transfered to a newly purchased data server (50TB NAS with a raid-6 array), which will be integrated into the existing infrastructure at NIPH. The central storage system will allow direct connection and integration into the Institute of Health Information and Statistics of the Czech Republic.

Objective 3: Establishing of bioinformatics pipelines for semi-automatic analysis of WGS data [redacted]). Large number of whole genome sequences is going to be generated during the work on the planned proposal and by the national surveillance program for monitoring of SARS-CoV-V2 virus. For these efforts to be useful, it is necessary to have analytical tools available to automate the process of distilling important information from the data and the aim of this objective is to prepare such tools specifically tailored to Czech Republic. We will prepare set of scripts that will be pipelined together to generate series of tables and charts showing the mutations and variants frequencies along the timeline (per week) and regions (the twelve administrative regions in Czech Republic). We will also implement an automated monitoring for presence of emerging new mutations and variants. The generated datasets could be then used to create reports for policy making authorities and ECDC. Scripts will be relatively easily modifiable to add or remove outputs in order to generate new data presentation needed by these authorities or ECDC.

Objective 4: Enhancing the capacity of a rapid variant detection system by monitoring a large set of mutations by a method involving a combination of PCR and MassARRAY analysis [redacted]).

The other strategy to support the rapid detection of mutation of concern and/or variants of concern/variants of interests/ variants under monitoring is the adaptation of the technology based on combination of RT – PCR using mass spectrometry instead of fluorescent probes. There should be three laboratories within the public health's institutes (NIPH, PHIUL and PHIO) as a reference center to cover Czechia and Moravia region. Enhancing the capacity of Reverse Transcription Polymerase Chain Reaction (RT-PCR) for rapid variant detection will be reached by the implementation of the combination of RT-PCR with MassARRAY analysis in real time instead of real time fluorescent probes implementation. The MassARRAY analysis of PCR amplicons enables monitoring of a large set of mutations in one step, recently offered commercial RUO kit allows up

to 41 point mutation (SNP) detection in 2 PCR reaction including conservative SARS RNA target detection and internal controls using human gene GADPH. The common system of the multiplex RT –PCR allows to detect in one multiplex PCR reaction theoretically maximum five of point mutation, but there is a must to add also a control target in one multiplex reaction and this must diminishes the maximal detectable SNP to 4 in a one PCR reaction. Using the combination of PCR with mass array detection of SNP is a modified high throughput alternative strategy to the RT-PCR genotypization process. This alternative strategy resembles by its output the partial Sanger sequencing with the low throughput (obviously 8 to 16 samples/30 hours), but in contrary to this method it could be easily adapted to high throughput, with minimum of 1 to 48 samples in one run which typically takes less than 10 hours. The technology could also be used for the investigation of the environmental samples (waste water), and for the monitoring of antivirotic resistance, for the other not only respiratory viruses detection and many other future applications. System enables laboratories to cost-effectively process from hundreds up to thousands of samples per day with a single instrument, the three laboratories does not have such huge capacities, but it will remain the challenge for the future. The method has been published:

[redacted]

Objective 5: Perform a retrospective analysis of samples from critical phases of the SARS-CoV-2 epidemic in the Czech Republic ([redacted].

The Institute of Molecular and Translational Medicine, Faculty of Medicine and Dentistry, Palacky Univesity in Olomouc (www.imtm.cz) was involved in SARS-CoV-2 diagnostics from the beginning of pandemic in the Czech Republic. It served primarily the region of Central Moravia, but also other regions of the Czech Republic. Since the IMTM operates BSL-3 laboratories, all SARS-CoV-2 positive samples were archived as a primary material and/or isolated RNA. In combination with available clinical metadata, the biobank represents unique opportunity to follow-on and understand better the import and local evolution of the virus, depending on the (non)pharmacological interventions. Current biobank comprises >10.000 virus samples and is available for retrospective RT-PCR genotyping and/or WGS analysis. Bioarchived samples are partly in the form of primary samples and/or isolated RNA. In order to distribute the workload and achieve the Objective 5 indicators timely, proposed research activities will be performed jointly among the academic project participants already experienced with SARS-CoV-2 whole genome sequencing (WGS) and variant analysis. Namely the preparation of NGS libraries will be performed by [redacted]groups (IMTM and CINeZ), while the sequencing will be done at the IMTM facilities. Bioinformatic analysis and reporting will be realized jointly with groups of [redacted] (IMG and BC CAS). Current technical infrastructure, sequencing capacity (>4.000 samples/month) and skills of academic partners of the project are adequate for retrospective sequencing of proposed cohort. The competence is also evidenced from the recent publication and GISAID entries from the first year of the pandemic. Research work will start in month 1 with selection of samples with sufficient viral load for WGS. With expected 5% failure rate we expect to upload approx. 3.800 viral genomes to GISAID till month 11 (D5.1). The report characterizing diversity of SARS-CoV-2 and its development in time during the autumn-spring 2020/21 waves in the Czech Republic will be delivered in month 13 (D5.2). This activity will also help Czech public health institutions to gain critical routine skills in sequencing and analyses of extrahuman genomes. Moreover, science based evidence of virus evolution under specified circumstances and preventive measures will be exploited as a base for the future policy making decision and definition of public health strategies.

Relevant publication:

[redacted]

Data from the First Year of the Pandemic. *Microorganisms* **2021**, *9*, 1671. https://doi.org/10.3390/microorganisms9081671

Objective 6: Perform a population survey in 2021/2022 in order to determine the degree of subthreshold spread of the virus in the population and critical elements enabling mitigation ([redacted].

Rapid evolution of the virus and the risk of (re)introduction of VOCs, particularly immune-escape variants, represents real risk for further management of epidemics in the Czech Republic. The Central Europe population is known to resist vaccination campaigns and vaccine coverage against preventable respiratory infections is low (e.g. approx. 5% for influenza). Current surveys indicate that 30% of SARS-CoV-2 vaccine hesitants, particularly younger individuals. Thus, according to current estimations, vaccination coverage will unlikely exceed 65%. This may not be enough to stop coronavirus transmission in the population if new emerging variants will dominate in CR. To better understand and map the viral load in the population and to map distribution of the virus variants in the Czech Republic, we will invite approx. 100.000 inhabitants to participate in a population-based survey using self-sampling kits distributed by post. During October/November 2021, samples will be collected by gargling and delivered to central laboratories for analysis by sensitive pooling method. Positive samples will be genotyped using RT-PCR method to distinguish major VOCs and virus genome will be sequenced. SARS-CoV-2 variants will be analyzed in the context with available metadata and reported to international databases. Focused population-based survey will be repeated during winter-spring season 2021/2022 in the regions most affected by the infection. This objective will enable to better understand the contribution VOCs to population based morbidity/mortality and to evaluate efficacy of individual or combined (non)pharmacological interventions. Current discussions with the Czech Ministry of Health also indicates potential interconnection of proposed virus prevalence study with seroprevalence study. Combining both studies could contribute to better understanding of SARS-CoV-2 spread by immune versus naïve individuals.
In terms of feasibility, the project partner IMTM was already involved in self-sampling studies (>10.000 individuals) for cervical cancer screening program (NCT04226313, see: https://clinicaltrials.gov/ct2/show/NCT04226313?term=HPV&cntry=CZ&draw=2&rank=2). The IMTM researchers were also involved in the SARS-CoV-2-CZ-Preval study aiming at quantification of the prevalence of individuals with a history of SARS-CoV-2 coronavirus infection in the Czech population, except for those diagnosed with COVID-19 by methods based on direct detection of SARS-CoV- 2, including individuals with a subclinical course of the disease (NCT04401085, see https://clinicaltrials.gov/ct2/show/NCT04401085?term=PREVAL&draw=2&rank=1). Within this study, more than 27.000 participants were enrolled, who are potentially available for further studies proposed in objective 6.

From feasibility point of view, the study design, protocol and informed consents will be prepared in month 1, then distributed to potential study participants in months October-December 2021 by post service. Returned self-collected gargling samples (https://www.gargtest.com/en/) will be tested in the IMTM laboratories by highly sensitive pooling technique with current capacity (10.000 tests/day). In parallel, VOCs analysis by the PCR methods and NGS will be performed jointly with project participants till month 7 with final report available in month 12. Objective 6 is independent on strengthening of technical infrastructure of public health institutes, however those institutions will directly benefit from implementation of both activities in training and future studies. Updated tools for the surveillance of SARS-CoV-2, influenza and respiratory viruses based on self-sampling of targeted population as a base for the future policy making decision and definition of public health strategies.

Relevant publications:

[redacted]

Objective 7: Develop infrastructure to facilitate the timely reporting of genotype data to ECDC and other supra-national institutions, and the sharing of data in the public domain [redacted]. We plan to connect case-based data of reported case from ISIN with GISAID EpiCoV data via a unique personal identification number (UPIN) and with an electronic laboratory request sample number of each case. The result should be a database of all WGS case-based data. We plan to prepare regular data reports for all relevant stakeholders, including Regional Public Health Authorities. Purpose of this objective is to develop human curated semiautomatic procedure for summarizing the genotype data and performing quality epidemiological analysis by standardized methodologies, which will then be regularly reported to ECDC and public. We plan to hire full time statistician/epidemiologists, who will be responsible to put together and operate such analytical pipeline and prepare the reports.

Objective 8: Increasing the professional capacity of laboratory experts and epidemiologists, deepening interdisciplinary cooperation between institutions with different specializations [redacted]. The aim is to increase professional capacity and capability and to strengthen the interdisciplinary cooperation and to encourage the knowledge transfer. Target groups are the experts from field laboratories, regional and national epidemiologists, other public health specialists. We would like to support the community of practice, where discussions happen, and exchange of opinions and experience is promoted. We recommend active participation of representatives of all professional groups. NRL will organize monthly on-line consultation meetings on sequencing, genomic surveillance and molecular epidemiology for laboratories participating in the national surveillance for SARS-CoV-2 to provide them with methodological support, professional recommendations, and updates. NIPH in cooperation with affiliated entities will organize 2 - 4 interdisciplinary webinars with participation of the public health microbiologists, epidemiologists, biostatisticians, researchers, and other relevant stakeholders. One onsite conference would take place (if the epidemiological situation will allow). We plan to disseminate outcomes from the connected laboratory and epidemiological data on COVID-19 molecular-biological surveillance on the webinars and publish training materials. Ad hoc online lectures on a specific topic would be organized if needed.

Implementation of every objective will be carried out as explained above and under the supervision of the responsible objective leader. The planned timetable and a list of milestones are provided below. Investments will be made in accordance with national legislation through transparent tenders organized by the project manager.
The Project Coordinator [redacted] is responsible for monitoring of the overall progress of the project. The Project Manager ([redacted] will support the coordinator and WP leaders in their administrative, financial, dissemination and communication organization role. The Project Steering Committee (PSC), comprising of all Objective Leaders (OLs), will act as a managerial decision-making body for the project and will be responsible for supporting the Project Coordinator. The PSC will aim to reach a consensus wherever possible. If no consensus can be reached, decisions will be taken after a simple majority vote. The PSC will hold monthly teleconferences. OLs tasks will be to control the progress of the scheduled work within their respective Objectives in terms of technical achievement, planned deliverables and expenses and to inform the PSC on meetings of the adherence to the plan and any deviations. The reports will be prepared by the project manager based on the inputs from PC and PSC. Reports will be submitted by PC. The co-financing of the project will be provided by the coordinating institution (NIPH) through financial support of the Ministry of Health.

Coordination between the leading applicant and the affiliated entities will be actively managed by the project office established at the applicant organization and it will be led by the nominated project manager. In order to ensure the overall strategic focus of the project and achieve maximum results around strengthening the infrastructure at national level, the standard project management principles, based on the PRINCE2 methodology, will be applied. These project management tools will include, among others – the monthly project management meetings, internal reporting process, online repository with working documents, etc. Risk, quality and data management processes will be monitored at the level of project management office via electronic tools.

Obj./ month	Mo1	Mo2	Mo3	Mo4	Mo5	Mo6	Mo7	Mo8	Mo9	Mo10	Mo11	Mo12	Mo13
1				M1	D1.1		M2	D1.2					
2				M1		D2.1						M4	
3								D3.1	D3.2			M4; D3.3	
4				M1	D4.1		M2				D4.2		
5										M3	D5.1		D5.2
6					D6.1	D6.2						M5; D6.3	
7									D7.1			M4; D7.2	
8										D8.1		M5	

Note: Interim progress reports summarizing accomplishments across all individual project objectives will be submitted in month 03 and month 06.

3.1 List of milestones			
Del. no.	**Title**	**Description**	**Due date (in months)**
M1	Supplier contracts signed	Selection of supplier for the items and closing of purchase contracts, milestone linked to Objective 1, 2, 4	4
M2	Weekly sequencing capacity reached	Reaching the planned weekly sequencing capacity, milestone linked to Objective 1, 4	7
M3	Actual data acquired	Completed analysis of returned archived human samples, milestone linked to Objective 5	10
M4	Integration of data flow achieved	Completed integration of data flow into current system, milestone linked to Objective 2, 3, 7	12
M5	Operational national SARS-CoV2 screening network	Operational network of specialist workplaces providing reliable information for policy making and general public, milestone linked to Objective 6,8	13

3.2 List of Reports			
Del. no.	**Title**	**Linked to milestone**	**Due date (end of month, in months from start of the project)**
R1	Interim progress report	M1-5	Month 3, 6
R2	Statement on the use of the previous pre-financing instalment	M1-5	Month 3, 6

3.2 List of Reports			
Del. no.	**Title**	**Linked to milestone**	**Due date (end of month, in months from start of the project)**
R3	Final Financial Report	M1-5	*With request for final payment in month 13*
R4	Final Technical Report	M1-5	*With request for final payment in month 13*
D4.2:	Report on analyzed samples (min 15 000)	M1, M2	Month 13
D5.1	Report on sequences of samples uploaded in GISAID (included 3 800 samples, expected 5% failure)	M3	Month 11
D5.2	Report characterizing diversity of SARS-CoV-2 and its development in time during the autumn-spring 2020/21 waves in the Czech Republic	M3	Month 13
D6.1	Report on percentage of positive samples (exp. return rate of 20%)	M5	Month 5
D6.2	Report on sequences of samples uploaded in GISAID (included 500 samples, expected 5% failure)	M5	Month 6
D6.3	Report characterizing diversity of SARS-CoV-2 within targeted population the Czech Republic	M5	Month 13
D7.1	SOP for the data mining from public health sector databases	M4	Month 9
D7.2	Reports published in public domain of ECDC and GISAID EpiCoV including genotype data (Delivery in month 12)	M4	Month 12
D8.1	Report on individual consultations, laboratory meetings interdisciplinary webinars	M5	Month 13

3.1 Risk Analysis and Mitigation

ID	Risk Title/Description	Likelihood	Impact	Proposed Risk Treatment and contingency plan
R1	Delivery delays for key equipment purchased as part of the objective 2 and 3	3	4	Initiate equipment procurement processes as early as possible in the action. Consider alternate suppliers if unexpected delays occur.
R2	Failure to optimize the setup of robotic RNA isolation and library preparation.	3	5	The setting up and servicing will be performed by supplier as the part of the contract. We will prepare enough samples to rigorously test the performance of the instruments during the initial period.
R4	Failure to find a quality candidates for positions opened as a part of the proposal.	3	5	Immediately after receiving information that the proposal will be funded, we will advertise these position in the job market via public and institutional channels available to us.
R5	Legal issues who can get access to the data under GDPR	2	4	Early consultations with GDPR experts
R6	Failure to develop infrastructure to facilitate the timely reporting of WGS data to ECDC and other supra-national institutions, and the sharing of data in the public domain	3	5	To initiate closer cooperation with the Institute of Health Information and Statistics of the Czech Republic (UZIS) for connecting of current parts of ISIN database.
R7	Indicators of objective 1,4,6, will not be fulfilled due to low incidence of SARS-Cov-2 during the project period	3	3	In some cases the capacity will be used for analysis of retrospective samples.
R8	Failure to organize webinar due to work overload of the personnel	3	2	Postpone the meetings and provide training materials online

4 Impact: Potential contribution towards the expected outcomes

4.1 Establishment of a sustainable, efficient and high capacity WGS and/or RT-PCR infrastructure for national public health microbiology

The proposed activities intend to build upon and improve the National Sequencing Surveillance Strategy of SARS–CoV-2 of the Czech Republic that has been approved in June 2021. This strategy creates the basic necessary network of diagnostic and sentinel laboratories and sequencing facilities. The added value of the proposed activities relies namely in:

- Improving sustainability and capacity building of the sequencing by automation of sample handling in two essential laboratories in the Czech Republic settled within NIPH and FoS CU, by robotization of NGS library preparation.
- Improving the archivation capacity and capability of NRL. NRL manages the collection of virus strains from 1957. NRL regularly distributes the viral strains (VOC/VOI/VUM of SARS-CoV-2, influenza strains) to the research laboratories, to the local diagnostic kit manufacturers.
- Improvement of the capability of the Czech sequencing laboratories by automation of data collecting and work flow (the establishment of a pipeline for raw data NGS analysis, epidemiological analysis of metadata and reporting). This will allow the surveillance system to run long term with less human effort and it will support the sustainability of the National Sequencing Surveillance Strategy.
- The automation of certain steps in data sharing and analysis mentioned above will lead to the increase in efficiency and cutting the cost of the surveillance and it will contribute to high throughput surveillance system and capacity building. It will also shorten the time of reaction and thus enables the efficient and tailored measures from the public health authority, and facilitate the decision making process and thus improve the capability.
- Increasing the capacity of sequencing of SARS-CoV-2.
- The automatic pipeline for the NGS data quality control contribute to the upload of the reliable WGS data to the international database GISAID.
- Increasing the capacity of the mutation of concern/interest by the adaptation of MassARRAY method, rapid detection of mutation of interest and/or genotypization will shorten the reaction time from the sampling to identification of variant of potential epidemiological impact.
- Implementation of the scientific board of laboratories enables the expert support of routine microbiological laboratories in the implementation of the new protocols and methods. This cooperation will promote the development of operational interdisciplinary network of laboratory and public health experts across the whole Czech Republic.
- The connection of the laboratory outputs and the automatic workflow of data analysis will contribute to strengthening of the capabilities to investigate the virus characterization, in terms of severity, transmissibility and the resistance to antivirotics, or resistance to vaccines.

4.2 Early detection and enhanced monitoring of emergent and known SARS-CoV-2 variants at the national and the EU/EEA levels

Automation of multiple steps in the procedure will lead to speeding up the whole process starting with positive nasopharyngeal swab and resulting in periodic epidemiological report. This is very important point for arranging a quick response system to the threats posed by the emerging variants of SARS-CoV-2 or by any other emerging pathogen with the possible clinical and epidemiological impact. Our goal is to shorten the period between the sampling to the final report and virus identification and characterization to 7 days. So that the report to ECDC (TESSY – EPI Pulse)/WHO will be sent in requested time frame.

The automatic epidemiological summary will provide the timely and detailed response. It will not stop at the variant identification step but will move deeper to the monitoring of individual mutations and their frequencies across time and regions. This will enhance the monitoring network capacity and enable to spot newly emerging or imported potentially risky mutations or variants.

The implementation of MassARRAY that enables at least detection of 36 SNP into the protocol of standard genotypization as an additional method to the gentypization by qPCR, will enable the enlargement of the spectrum of confirmed known variants with a minimal delay and without the necessity of whole genome sequencing. So during the epidemiological peaks will relief the sequencing centers and provides the comparative information about the virus evolution. The early detection will have direct impact to the early response and early reports in regional, national and EU level. The MassARRAY spectrometry also requires very basic bioinformatics knowledge so that the protocol and primers could be easily changed and thus the spectrum of mutation (SNP) variant detection could be rapidly enlarged.

4.3 Enhanced genomic-based infectious disease outbreak investigation capacities at regional, national and/or EU/EEA levels

The instrumentation, human resource, connection to the scientific community, system of training and know-how acquired during the proposed project will improve the ability of NIPH and public health authorities to respond to outbreaks of other infection diseases (not only SARS-CoV-2) and will uplift the quality and abilities of this Health control institution.

The SARS-CoV-2 surveillance strategy, the workflow for automatic data analysis, and the system of collection and shipment of the samples, the establishment of the network of basic diagnostic laboratories, the sentinel laboratories and sequencing centers could be easily adopted to any other emerging situation with the epidemiology impact.

Also the data analysis and the workflow for data analysis will be prepared as open system and thus it could be adopted to any other emerging situation.

The rapid response will help to solve the investigation of outbreaks and the network of the laboratories will increase the capacity for outbreak investigation.

4.4 Enhanced routine genomic-based surveillance of infectious diseases at the regional, national and/or EU/EEA levels

As mentioned in the previous points, the enhanced semi-automatization of the process of sample selection-handling-sequencing-data analysis will allow this process to run routinely long term. Give the universality of the genomic-based monitoring, the procedures can be easily adapted to monitor on the infection diseases in the future. Also the tight cooperation between the public health institutes, scientific institutes and universities will contribute to the closer connection between those two independent communities and also it will also enable the smooth integration of students in public health and thus build the capacities for the future.

Also the data analysis and the workflow for data analysis will be prepared as open system and thus it could be adopted the standard routine surveillance of influenza and other respiratory viruses. Science based evidence of virus evolution under specified circumstances will be a base for the policy making decision and definition of public health strategies.

4.5 Enhanced preparedness to timely and efficiently address cross-border outbreaks of infectious diseases and pandemics in the future

The surveillance system developed by combination of NSSS and the actions proposed here will naturally be applicable not only to long-term population surveillance but also to specific tasks, like the monitoring of cross-border imports of infectious agents.

The capacities building and outcome from the automatic data workflow will support the ability to respond rapidly to cross border outbreaks. It also enables the early report to the international systems (e.g. EWRS, EPI Pulse, TESSY). That contributes to the registration and investigation of the cross border threats.

Enhanced surveillance capability and capacity will contributes to the international database with timely and actual data for the future policy making decision and definition of public health strategies at the EU level.

5 Budget

5.1 Content description and justification

The co-financing of the project will be provided by the coordinating institution (NIPH) through financial support of the Ministry of Health. The budget was build putting together the personnel cost, the investment – equipment reasonable needs and the disposable and other goods and services defined by each involved institution to meet the project targets in total 13 months of implementation .

5.1.1 Personnel

NIPH:

The project manager [redacted] project back up project manager [redacted] legal representative [redacted]

The scientific team of NIPH will consist of:

Microbiologists – molecular biologists: senior researchers (SR) [redacted], junior researchers [redacted] and seven technicians to ensure the project coordination, the capacity for NGS, genotypization, data output and reporting.

Epidemiologists/biostatistians (SR), [redacted] and a project part time epidemiologist (JR),[redacted] (SR) to coordinate data analyses.

PHIO and PHIUL:

Microbiologists (SRs) [redacted] and [redacted] and two technicians to ensure the implementation of MassARRAY analyses into the genotypization.

CINeZ:

The team of the CZU will consist of three persons to ensure PCR analyses and sequencing of samples (objective 5 and 6): J[redacted] (SR), [redacted](JR),a technician ([redacted].

BC CAS

[redacted](JR), the Bioinformatician programmer -the design and implementation of the scripts for automatic data analyses.

[redacted] (SR) [redacted] (SR) - the implementation of the NGS data analyses.

FoS CU

Microbiologists and bioinformaticians: [redacted](SR), [redacted] (JR) , technicians [redacted] and person to be hired) responsible for WGS library preparation and sequencing, assembly and annotation of raw WGS SARS-CoV-2 data

IMG

[redacted](SR), [redacted] (SR) and data manager (JR to be hired) – responsible for set up the data storage at NIPH, transfer the data from the current storage at ELIXIR-CZ/CESNET and maintain the databases and pipelines in the transitional period, the design and implementation of the scripts for automatic output of WGS data intu the surveillance strategy system.

IMTM:

Molecular genetics [redacted] (SR), laboratory manager (JR) IT technician, laboratory technician, to ensure the population survey and restrospective analyses.

5.1.2 Equipment

NIPH: Server, pipetting NGS robotic machines and MassARRAY analyser to ensure the safe data storage, to build the NGS capacity and to strengthen the genotypization capacity and capability.

PHIO and PHIUL: MassARRAY analysers (two pieces) to ensure to strengthen the capacity of genotypization.

FosCU A pipetting NGS robotic machine to strengthen the NGS capacity by automatic library preparation.

5.1.3 Other goods and services

NIPH: Audit and financial statements, sample transportation and archiving, genotypization enhancing capacity, MassARRAY service contract, MassARRAY consumables and chemistry, administration of the project, official documents translation.

PHIUL/PHIO: Genotypization enhancing capacity: RT-PCR with MassARRAY detection service contract,

CINeZ: NGS library preparation and sequencing of samples (objective 5 and 6)

FosCU: RNA isolation and NGS library preparation, NGS

IMTM: Self-sampling kit and its packaging and distribution expenses

5.1.4 Subcontracting

NIPH:

The subcontracting item consists of several minor subcontracted services of external experts, whose capacities are necessary to collect, store, safe, secure, manage and analyze data and/or samples (NRL) – Objective 1, 2, . The substantial portion of subcontract funds are intended for the data security stored in the new server in NIPH to meet the requirements of the cybersecurity in term of The EU's new Cybersecurity Strategy for the Digital Decade (objective 2). Also secure website that will be developed for this purpose (objective 3, 7, 8). The subcontract finances are also intended for the subcontracting of the minor short term rentals of opening temporary regional operations, for logistic services, if necessary.

The services of external expert will cover:

- Objective 1: The external expertize for the setup the archiving system and its connection with the existing LIS. NRL has been archiving the thousands of samples – primary clinical material (nasopharyngeal/oropharyngeal swabs, broncho-alveolar lavages, post mortem section material, serum/plasma) RNA isolates, RNA/DNA standards, antisera standards, viral strains of SARS-CoV-2, but the archive is managed only by paper work.
- Objective 2: The setup the data security management concerning storage and transport the raw sequencing data with case based metadata to meet the requirements of the cybersecurity in term of The EU's new Cybersecurity Strategy for the Digital Decade.
- Objective 3, 7 and 8: The website for the electronic reports and the learning material for epidemiologists and microbiologists involved in the public health measures against COVID-19.
    - D3.3: Public health data reports summarizing spread and frequency of SARS-CoV-V2 variants and mutations in the Czech Republic for policy making authorities
    - D7.2: Reports published in public domain of ECDC and GISAID EpiCoV including genotype data
    - Objective 8: Publication of training materials online, via project website (Material from webinars for epidemiologists and diagnostic laboratories on good practices in data reporting of SARS-CoV-2, and methodology of their interpretation (target number of participants – 200)
- Short term rentals and others (e. g. logistic services – sample distribution and management)

5.2 Financial Contributions from Third parties

Third Party	
Linked to applicant (acronym)	NIPH
Official name in full	Ministry of Health of the Czech Republic
Official address	Palackého nám. 375/4, 128 00 Nové Město, CZ
Estimated amount of funding to be provided for the action	340 613 €
Conditions or reservations for receiving the contributions (if any)	N/A

5.3 Detailed Budget

See Annex II.

PART C: CHECK-LIST FOR APPLICANTS

All sections of the application form have been filled in, where appropriate, in accordance with the guide for applicant or any other document provided as guidance related to the action concerned.	☒
The budget annex has been duly filled in and is included.	☒
Legal details have been included in the Legal Entity Form. (If consortium, each member to provide details)	☒
Bank details have been included in the Financial Identification Form.	☒
The Authorised Signatory Form has been filled in, signed and submitted.	☒
Letter of endorsement by National Coordinator	☒
Declaration on honour (DoH) has been signed and submitted. (If consortium, each member to provide DoH)	☒
Affiliated entities: Declaration on honour, mentioned in letter of endorsement & proof of link to applicant	☒

HERA Grant

From: [redacted]
Sent: 18 August 2021 17:43
To: HERA Grant
Cc: [redacted]

Subject: Re[2]: Submission of application HERA ref. GRANT/2021/PHF/23776 - Clarification
Attachments: Annex I Application form and Checklist Grant_2021_PHF_23776 CZ_ revised2.pdf; HERA DoHFoSCU rev2.pdf; HERA Power of Attorney_FoSCU rev2.pdf; HERA_DoH_NIPHrev2.pdf; List of revisions 2 PHF-23776 -18-8-21.pdf; Annex II Budget Grant_2021_PHF_23776 revised 2.xlsx

Follow Up Flag: Follow up
Flag Status: Completed

Dear ECDC Procurement team,

Thank you again for your reply, patience and instructions related to the revision and clarification of the documents HERA ref. GRANT/2021/PHF/23776.

We have checked your comments to the application and we have revised it accordingly. You will find the list of revisions in the attached file: List of revisions 2 PHF-23776 -18-8-21.pdf.

We are sending also the other required and revised documents, you will find them as attachment.

- 2nd revision of Application form Annex I
- 2nd revision of Application form Annex II
- Declaration of Honour version 2 of affiliated entity FoSCU
- Declaration of Power of Attorney of FoSCU
- Declarations of Honour of NIPH (no other changes in Annex I than required)

[redacted]

and

[redacted]

SM

[redacted]

Centrum Epidemiology and Microbiology of National Institute of Public Health

Srobarova 49/48

Prague, ZIP 10000

Czech Republic

[redacted]

Centrum Epidemiology and Microbiology of National Institute of Public Health

Srobarova 40
Prague, ZIP 10042
Czech Republic

Odesilatel [redacted]

Datum: 16-08-2021 18:36

Příjemce: [redacted]

Kopie: [redacted]

[redacted]

Předmět: **RE: Submission of application HERA ref. GRANT/2021/PHF/23776 - Clarification**

[redacted]

Thank you for your submission of revised application documents for the abovementioned grant procedure in response to the request for clarifications. The following points need to be further clarified. Deadline for submitting the corrected application is Wednesday 18th August.

A general note: While we appreciate your efforts to produce a separate document with responses to the clarifications, in some cases corresponding changes also need to be included in the application documents (Application Forms Part A and B, and the Estimated Budget) since these will form annexes to the grant agreement for all successful applications.

- As described in the first request for clarifications: Given that the system improvements will be implemented quite late in the project, it is not clear how the applicant will have time to execute the activities under objectives 5 and 6 prior to the end date of the project (September 2022). While the overall content of these objectives is considered to be in scope, more clarity is needed on their feasibility during the project's lifetime, without overburdening the last months and/or not finish the activities by the final date 30 September 2022 (Please note that the finalisation of the final project reporting will be required within 30 days of the end of the project). Please clarify the viability of objectives 5 and 6 within the timeline.

    - A paragraph about the feasibility of objectives 5 and 6 should be clearly present in the Application Form Part B rather than merely in the separate clarifications response document. This paragraph should also emphasise how the execution of these objectives will benefit the (post-project) national public health work.

- As described in the first request for clarifications: Please provide a more detailed explanation on the costs related to subcontracting the Application Form Part B, Section 5.1.4. In addition, please include the title of the subcontracting in the 4.1 subcategory of the Estimated Budget.

    - Explanations have been provided in the appropriate sections; however please note that costs related to scientific publications are not eligible for funding under these grants. Please remove all references to such activities from both section 5.1.4. of the Application Form Part B as well as from the Estimated Budget (subcategory 4.2 on rows 24 and 88).

SM

- Declaration on Honour – Declaration on Honour for Univerzita Karlova is signed electronically. The level of this e-signature is not a Qualified Electronic Signature (QES), which is the only level explicitly recognized to have the equivalent legal effect of hand-written signatures. There have been changes introduced in the process of validation of e-signatures and therefore we kindly ask you to please provide the copies of the forms signed with a blue ink by e-mail. Please see the information on the types and levels of the e-signature **here**.

Please send the corrected Application Form, Estimated Budget and Declaration on Honour ensuring no other changes are made to the application, other than those requested.

It would be much appreciated, if the requested documents could be emailed to ECDC a[redacted] as soon as possible, but no later than 18:00 CEST, 18th August 2021. We appreciate that the deadline is very tight but unless we have the required information by then we may not be able to finalise the evaluation in time.

Thank you in advance for your cooperation.

Kind regards,

ECDC Procurement

From: [redacted]
Sent: 09 August 2021 17:09
To: [redacted]
Cc: [redacted]

[redacted]

Subject: Re: Submission of application HERA ref. GRANT/2021/PHF/23776 - Clarification

EXTERNAL EMAIL!

Do not click on any links, open attachments or reply, unless you recognise the sender's email address [redacted]

Dear ECDC Procurement team,

Thank you for your reply and instructions related to the revision and clarification of the documents HERA ref. GRANT/2021/PHF/23776

We have checked your comments to the application and we have revised it accordingly. You will find the list of revisions in the attached file: List of revisions PHF-23776.

We are sending also the other required and revised documents, you will find them as attachment.

- Revised Application form Annex I:Annex I Application form and Checklist Grant_2021_PHF_23776 CZ_ revised

- Revised Application form Annex II:Annex II Budget Grant_2021_PHF_23776 revised

- Declarations of Honour version 2 of affiliated entities: BC CAS, CINeZ, FoSCU, IMG, IMTM, on the upgraded second version of form.

- Declaration: Power of Attorney of CINeZ

- Translated National Sequencing Surveillance Strategy (NSSS)

[redacted]

and

Centrum Epidemiology and Microbiology of National Institute of Public Health

Srobarova 49/48

Prague, ZIP 10000

Czech Republic

--- Původní zpráva----

Odesilatel: [redacted]

Datum: 02-08-2021 18:01

Příjemce: [redacted]

Kopie:

[redacted]

Předmět: **Submission of application HERA ref. GRANT/2021/PHF/23776 - Clarification**

Dear Applicant,

Thank you for your submission of an application for the abovementioned grant procedure.

We are in the process of conducting the evaluation and have the following clarifications:

- Application Form Part A – The requested grant amount is stated as the total eligible costs of the action (3,473,394EUR), whereas the amount stated should reflect the grant amount which is the total ECDC contribution (3,126,054EUR). Please insert the requested grant amount, based on any corrections made to the Estimated Budget. Please see below.

- Application Form Part A – 1.6: The acronyms of the affiliated entities have been entered into the second column, instead of the acronym of the applicant to whom the entity is affiliated. Please insert the acronym of the applicant.

- Application Form Part A – 1.9 Operational Capacity: The National Reference Laboratory (NRL) for Influenza and Respiratory Viruses under the National Institute of Public Health (NIPH), as well as the Regional Public Health Institutes (RPHI) in Ostrava and Usti nad Labem are mentioned as key institutions involved in implementing the project. Please provide more details on the existing relevant technical infrastructure at NRL and RPHI in the context of this application.

- Application Form Part B: It is not clear that the purchase of the MassARRAY system is within scope this invitation which focuses on RT-PCR and WGS. A more detailed clarification of the intended use of this system and its utilisation for RT-PCR and WGS would therefore be needed in order to assess the eligibility of the related activities, and a clarification is required for objective 4 on page 17 ("Enhancing the capacity of a rapid variant detection system by monitoring a large set of mutations by a method involving a combination of PCR and MassARRAY analysis").

- Activities related to objectives 7 and 10 are not in scope of this invitation and therefore not considered as eligible activities. Please remove these objectives from the application, and revise the Application Form Part B and Estimated Budget accordingly.

SM

- Given that the system improvements will be implemented quite late in the project, it is not clear how the applicant will have time to execute the activities under objectives 5 and 6 prior to the end date of the project (September 2022). While the overall content of these objectives is considered to be in scope, more clarity is needed on their feasibility during the project's lifetime, without overburdening the last months and/or not finish the activities by the final date 30 September 2022 (Please note that the finalisation of the final project reporting will be required within 30 days of the end of the project). Please clarify the viability of objectives 5 and 6 within the timeline.

- According to the invitation to submit applications, the interim progress reports are mandatory at months 3 and 6; Please update section 3.2. (List of reports) accordingly, and section 3.1 (List of milestones), if relevant.

- In the implementation / GANTT chart on page 19, most of the milestones and reports are scheduled to be delivered in months 12 and 13. Please consider revising this table to ensure that deliverables are more evenly spaced out over the course of the project, and consider combining milestones and reports in particular at the end of the project in order to reduce the burden of reporting.

- It is not clear from the application how coordination between the application leadership and the affiliated entities will be managed, in order to ensure the overall strategic focus of the project and achieve maximum results around strengthening the infrastructure at national level. Please provide additional information on this topic in the Application Form Part B.

- Please revise the financial resources, and in particular the budget allocated to consumables, due to the required changes to the objectives and tasks (see requests for clarifications above) in the Application Form Part B, Section 5 and the Estimated Budget.

- Please revise the financial resources to reflect the maximum project duration of 13 months, in the Application Form Part B, Section 5 and the Estimated Budget.

- Please provide a more detailed explanation on the costs related to subcontracting the Application Form Part B, Section 5.1.4. In addition, please include the title of the subcontracting in the 4.1 subcategory of the Estimated Budget.

- Estimated Budget – The Financial Contribution of the Beneficiary has not been completed, and therefore the Total Revenue figure is incorrect. Please complete row 36. Any revisions to the scope or cost categories should also be reflected in the corrected Estimated Budget.

- Link to affiliated entities: Please provide additional information about previous cooperation between the applicant and the affiliated entities.

In the preamble of the MoUs, there is a reference to "*The Parties began their cooperation during the COVID-19 pandemic. They jointly participated in the development of diagnostic methods for SARS-CoV-2 detection, laboratory diagnosis of infection and implementation of a system for monitoring SARS-CoV-2 virus variants by means of the whole genome virus sequencing.*" We understand that this is a reference to the national strategy on COVID-19 in Czech Republic. Please provide a copy of this strategy, in order to supplement evidence of the necessary link between SZU and the respective affiliated entities.

- Declarations on Honour for BC CAS, CINeZ, FoSCU IMG, IMTMhave been submitted on the first version of the Declaration on Honour published by ECDC. During the grant procedure, it was brought to our attention that the DoH did not cover the affiliated entities, and a version 2 was published on the dedicated website. Please see Questions and Answers version 7, 2(q). Could you please arrange for BC CAS, CINeZ, FoSCU IMG, IMTMto complete the updated DoH attached. We would appreciate it if the DoHs could be signed and a scanned version emailed to the email address indicated below.

Please send the corrected Application Form, revised Estimated Budget and Declarations on Honour, ensuring no other changes are made to the application, other than those requested.

It would be much appreciated, if the requested documents could be emailed to ECDC at [redacted] as soon as possible, but no later than 18:00 CEST, 9th August 2021.

Thank you in advance for your cooperation.

Kind regards,

ECDC Procurement

Annex III

Estimated budget

Annex II - CONSOLIDATED AND ESTIMATED BUDGET OF THE ACTION

GRANT/2021/PHF/23776 HERA

Name of beneficiary/consortium member: National Institute of Public Health

Direct eligible costs	Amount in EUR
Category 1. Personnel	
1.1 Project management	51,260
1.2 Senior technical & scientific staff	296,583
1.3 Junior technical & scientific staff	211,143
1.4 Administration & financial management	136,394
Sub-total for cost category 1	***695,381***
Category 2. Equipment	
2.1 Laboratory equipment	1,025,850
2.2 IT equipment	14,000
2.3 Other	3,092
Sub-total for cost category 2	***1,042,941***
Category 3. Other goods & services	
3.1. Consumables (incl. reagents and supplies)	1,130,450
3.2 Training on equipment purchased for the action	7,356
3.3 Other	257,616
Sub-total for cost category 3	***1,395,422***
Category 4. Subcontracting *(if applicable)*	
4,1 Cyber security expertise for data storage and management (NIPH server), and prc	25,715
4,2 The external expertize for the setup the archiving system and its connection with	7,000
4,3 Short term rentals and others (e. g. logistic services)	6,000
Sub-total for cost category 4	***38,715***
Category 5. Audit	
Costs associated with obtaining certificates on financial statements	10,840
Sub-total for cost category 5	***10,840***
Total direct eligible costs	**3,183,300**
Indirect eligible costs	
7 % of direct eligible costs	222,831
TOTAL ELIGIBLE COSTS OF THE ACTION	3,406,131

Total ECDC contribution (Maximum 90% of eligible costs)/ Requested ECDC grant	**3,065,518**
Financial contribution of the beneficiary(ies), own resources	0
Income generated by the action	0
Financial contributions from third parties earmarked to the eligible costs	340,613
Total revenue	**3,406,131**

SM

DETAILS OF ESTIMATED COSTS FOR THE PERIOD STATED ABOVE

Category 1. Personnel costs			
	Number of person-months	Monthly cost	Amount in EUR
1.1 Project management	13	3943.089431	51,260
1.2 Senior technical & scientific staff	107.25	2765.346768	296,583
1.3 Junior technical & scientific staff	93.6	2255.804953	211,143
1.4 Administration & financial management	44.2	3085.843419	136,394
		Subtotal category 1 Personnel costs	**695,381**

Category 2. Equipment			
	Unit cost	Number of units	Amount in EUR
2.1 Laboratory equipment			
System for sample archiving	140534.2625	1	140,534
MassARRAY System	213003.0972	3	639,009
Robotic station for pippeting	121747.6423	2	243,495
qPCR cycler	22485.482	0	0
PCR box	2810.68525	1	2,811
Miscellaneous laboratory equipment (total)			0
		Subtotal Laboratory equipment	**1,025,850**
2.2 IT equipment			
Server	14000.02323	1	14,000
			0
			0
			0
Miscellaneous IT equipment (total)			0
		Subtotal IT equipment	**14,000**
2.3 Other equipment			
Statistical software	3091.753775	1	3,092
			0
			0
			0
		Subtotal Other equipment	**3,092**
		Subtotal Category 2 Equipment	**1,042,941**

Category 3. Other goods & services	Amount in EUR
3.1. Consumables (incl. reagents and supplies)	1,130,450
3.2 Training on equipment purchased for the action	7,356
3.3 Other *(specify below)*	
3.3.1 MassARRAY system servis	87,272
3.3.2 Sample shipment	162,602
3.3.3 Official translation of documents	7,743
Subtotal sub-category 3.3 Other	257,616
Subtotal category 3 Other goods & services	**1,395,422**

Category 4. Subcontracting (Title/Description)	Amount in EUR

4,1 Cyber security expertise for data storage and management (NIPH server), and prc	25,715
4,2 The external expertize for the setup the archiving system and its connection with	7,000
4,3 Short term rentals and others (e. g. logistic services)	6,000
Subtotal category 4 Subcontracting	**38,715**

Category 5. Audit	Amount in EUR
5,1 Audit and financial statements	10,840
5.2	0
5.3	0
Subtotal category 5 Audit	**10,840**

Annex IV (a) Model interim progress report

Interim progress report

Enhancing Whole Genome Sequencing (WGS) and/or Reverse Transcription Polymerase Chain Reaction (RT-PCR) national infrastructures and capacities to respond to the Covid-19 pandemic in <country>

Grant agreement: ECDC/GRANT/2021/<x> Project period: from <dd/mm/yyyy> t <dd/mm/yyyy>

<Date>

<Please follow the structure of this template when preparing your report.

The report should be concise and readable. Duplication between sections should be avoided.

The blue guidelines in this template should be deleted before the final version of the report is submitted.>

Explanation of the work carried out by the beneficiaries and overview of the progress made

<Please explain the work carried out during the period covered by the report. Please include an overview of the project's progress towards its specific objectives, as well as a summary of any deliverables and milestones attained during the period>

Your text…

Impact

<Please include in this section whether the information on how your project will contribute to the expected outcomes included in Annex I of the grant agreement is still relevant or needs to be updated. In the latter case, please provide a brief update.>

Your text…

Deviations from the work plan

<Please explain the reasons for and consequences of any major deviations from the work plan as described in Annex I to the grant agreement.>

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

Tasks

<Please include explanations for tasks not fully implemented, critical objectives not fully achieved and/or not being on schedule. Please explain also any proposed corrective actions and the potential impact this may have on other tasks, on the available resources and/or on the planning.>

Your text...

Use of resources

<Please provide a brief overview of the resources used during the period, with a focus on major equipment purchases or other items with a high monetary value.>

Your text...

Subcontracting not included in the grant agreement (*if applicable*)

<Please refer to Article II.11 of the Grant Agreement for the conditions governing subcontracting in order to provide the required information:

a) the work (the tasks) performed by a subcontractor which may cover only a limited part of the project;

b) explanation of the circumstances which caused the need for a subcontract, taking into account the specific characteristics of the project;

c) the confirmation that the subcontractor has been selected ensuring the best value for money or, if appropriate, the lowest price and avoiding any conflict of interests;

d) Etc. >

Your text...

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

Annex IV (b) Model final technical report

Final technical report

Enhancing Whole Genome Sequencing (WGS) and/or Reverse Transcription Polymerase Chain Reaction (RT-PCR) national infrastructures and capacities to respond to the Covid-19 pandemic in <country>

Grant agreement: ECDC/GRANT/2021/<X> Project period: from <dd/mm/yyyy> to <dd/mm/yyyy>

<Date>

<Please follow the structure of this template when preparing your report.

The report should be concise and readable. Duplication between sections should be avoided.

The blue guidelines in this template should be deleted before the final version of the report is submitted.

Please note that Part A of this report will be published on ECDC's website. The beneficiary/coordinator must ensure that Part A of the report does not include confidential information.>

Part A

General objective and expected outcomes of the action

<This section is pre-filled. Do not add text>

The general objective of the HERA Incubator action "Enhancing Whole Genome Sequencing (WGS) and/or Reverse Transcription Polymerase Chain Reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic" was to enhance and/or improve national public health WGS and RT-PCR capacity. Results were expected to contribute towards the following expected outcomes:

- In the short-term, contribution to the establishment of a sustainable, efficient and high capacity WGS and/or RT-PCR infrastructure for national public health microbiology;
- In the short/medium-term, contribution to early detection and enhanced monitoring of emergent and known SARS-CoV-2 variants at the national and the EU/EEA levels;
- In the medium/long-term, contribution to enhanced genomic-based infectious disease outbreak investigation capacities at regional, national and/or EU/EEA levels;
- In the medium/long-term, contribution to enhanced routine genomic-based surveillance of infectious diseases at the regional, national and/or EU/EEA levels, in accordance with the "ECDC strategic framework for the integration of molecular and genomic typing into European surveillance and multi-country outbreak investigations"; and
- In the long-term, contribution to enhanced preparedness to timely and efficiently address cross-border outbreaks of infectious diseases and pandemics in the future.

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

Overview of the project's objectives

<Please include a brief description of your project's specific objectives>

Your text...

Overview of the project's results

<Please include a brief description of your project's results>

Your text...

Impact

<Please describe how the results of your project has contribute to the expected outcomes as specified above.>

Your text...

Future plans

<Please provide a description of any future plans to continue to build on the results and infrastructures created under your project.>

Your text...

Identified needs and areas for further development (if applicable)

<If relevant, please describe any identified needs or areas of development that could benefit from support and/or coordination at the EU/EEA level. Please make specific suggestions as to what type of support would be needed, and what benefits and added value that would bring at the local, regional, national and/or European level.>

Your text...

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

Part B

Deviations from the work plan

<Please explain the reasons for and consequences of any major deviations from the work plan as described in Annex I to the grant agreement.>

1) Tasks

<Please include explanations for tasks not fully implemented, critical objectives not fully achieved. Please explain also any corrective actions carried out and the impact this had on the rest of the project.>

Your text…

2) Use of resources

<Please provide a brief overview of the resources used during the project, with a focus on major equipment purchases or other items with a high monetary value.>

Your text…

3) Subcontracting not included in the grant agreement (*if applicable*)

<Please refer to Article II.11 of the Grant Agreement for the conditions governing subcontracting in order to provide the required information:

a) the work (the tasks) performed by a subcontractor which may cover only a limited part of the project;

b) explanation of the circumstances which caused the need for a subcontract, taking into account the specific characteristics of the project;

c) the confirmation that the subcontractor has been selected ensuring the best value for money or, if appropriate, the lowest price and avoiding any conflict of interests;

d) Etc. >

Your text…

European Centre for Disease Prevention and Control (ECDC)
Gustav den III:s Boulevard 40, 169 73 Solna, Sweden
Phone: [redacted]
www.ecdc.europa.eu

SM

Annex V - CONSOLIDATED MODEL FINANCIAL STATEMENT

GRANT/2021/PHF/23776 HERA

Name of consortium leader / Coordinator or name of all beneficieries (for multi-beneficieries applications):

Period from _____ to _____

Direct eligible costs	Amount in EUR
Category 1. Personnel	
1.1 Project management	0
1.2 Senior technical & scientific staff	0
1.3 Junior technical & scientific staff	0
1.4 Administration & financial management	0
Sub-total for cost category 1	***0***
Category 2. Equipment	
2.1 Laboratory equipment	0
2.2 IT equipment	0
2.3 Other	0
Sub-total for cost category 2	***0***
Category 3. Other goods & services	
3.1. Consumables (incl. reagents and supplies)	0
3.2 Training on equipment purchased for the action	0
3.3 Other	0
Sub-total for cost category 3	***0***
Category 4. Subcontracting *(if applicable)*	
4.1	0
4.2	0
4.3	0
Sub-total for cost category 4	***0***
Category 5. Audit NB. Costs covering the audit certificates should be foreseen by beneficiaries who anticipate an ECDC contribution of more than €300,000.	
Costs associated with obtaining certificates on financial statements.	0
Sub-total for cost category 5	***0***
Total direct eligible costs	**0**
Indirect eligible costs	
7 % of direct eligible costs	0
TOTAL ELIGIBLE COSTS OF THE ACTION	0

Total ECDC contribution (Maximum 90% of eligible costs)/ Requested ECDC grant	**0**
Financial contribution of the beneficiary(ies), own resources	0
Income generated by the action	0
Financial contributions from third parties earmarked to the eligible costs	0
Total revenue	**0**

Annex V - MODEL FINANCIAL STATEMENT

GRANT/2021/PHF/23776 HERA

Name of beneficiary / affiliated entity: _____

Period from _____ to _____

Direct eligible costs	Amount in EUR
Category 1. Personnel	
1.1 Project management	0
1.2 Senior technical & scientific staff	0
1.3 Junior technical & scientific staff	0
1.4 Administration & financial management	0
Sub-total for cost category 1	***0***
Category 2. Equipment	
2.1 Laboratory equipment	0
2.2 IT equipment	0
2.3 Other	0
Sub-total for cost category 2	***0***
Category 3. Other goods & services	
3.1. Consumables (incl. reagents and supplies)	0
3.2 Training on equipment purchased for the action	0
3.3 Other	0
Sub-total for cost category 3	***0***
Category 4. Subcontracting *(if applicable)*	
4.1	0
4.2	0
4.3	0
Sub-total for cost category 4	***0***
Category 5. Audit	
Costs associated with obtaining certificates on financial statements.	0
Sub-total for cost category 5	***0***
Total direct eligible costs	**0**
Indirect eligible costs	
7 % of direct eligible costs	0
TOTAL ELIGIBLE COSTS OF THE ACTION	0

Total ECDC contribution (Maximum 90% of eligible costs)/ Requested ECDC grant	**0**
Financial contribution of the beneficiary(ies), own resources	0
Income generated by the action	0
Financial contributions from third parties earmarked to the eligible costs	0
Total revenue	**0**

SM

DETAILS OF ESTIMATED COSTS FOR THE PERIOD STATED ABOVE

Category 1. Personnel costs	
Sub-category	Amount in EUR
1.1 Project management	0
1.2 Senior technical & scientific staff	0
1.3 Junior technical & scientific staff	0
1.4 Administration & financial management	0
Subtotal category 1 Personnel costs	**0**

Category 2. Equipment			
	Unit cost	Number of units	Amount in EUR
2.1 Laboratory equipment			
			0
			0
			0
			0
Miscellaneous laboratory equipment (total)			0
Subtotal Laboratory equipment			**0**
2.2 IT equipment			
			0
			0
			0
			0
Miscellaneous IT equipment (total)			0
Subtotal IT equipment			**0**
2.3 Other equipment			
			0
			0
			0
			0
Subtotal Other equipment			**0**
Subtotal Category 2 Equipment			**0**

Category 3. Other goods & services	Amount in EUR
3.1. Consumables (incl. reagents and supplies)	0
3.2 Training on equipment purchased for the action	0
3.3 Other *(specify below)*	
3.3.1	0
3.3.2	0
3.3.3	0
Subtotal sub-category 3.3 Other	0
Subtotal category 3 Other goods & services	**0**

Category 4. Subcontracting (Title/Description/Purpose)	Amount in EUR
4.1	0

4.2	0
4.3	0
Subtotal category 4 Subcontracting	**0**

Category 5. Audit	Amount in EUR
5.1	0
5.2	0
5.3	0
Subtotal category 5 Audit	**0**

Annex IX

Model Request for Payment

Payment request for grant agreement ECDC/HERA/2021/XXX

Enhancing Whole Genome Sequencing (WGS) and/or Reverse Transcription Polymerase Chain Reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic in the European Union and European Economic Area

Copy to be sent to:

Cc: [redacted]

Original to be posted to:
European Centre for Disease Prevention and Control (ECDC)
Att: Finance and Accounting
Gustav III:s boulevard 40
169 73 Solna
Sweden

<Date of the payment request >

Name of the beneficiary:

Period covered by the payment request: from [insert the date] to [insert the date]

Amount: EUR xx

Dear Sir/Madam,

I hereby request [a second pre-financing payment] [payment of the balance] under the grant agreement mentioned above.

The amount requested and the supporting documents are according to [Article I.4.2] [Article I.4.4] of the special conditions of the grant agreement.

Please find attached the following supporting documents:

-

Declaration on honour

I hereby certify that the information contained in this payment request is full, reliable and true, and is substantiated by adequate supporting documents that can be checked.

I hereby certify that the costs declared have been incurred and can be considered as eligible in accordance with the grant agreement.

Yours faithfully,

Beneficiary: function, name and surname

Signature