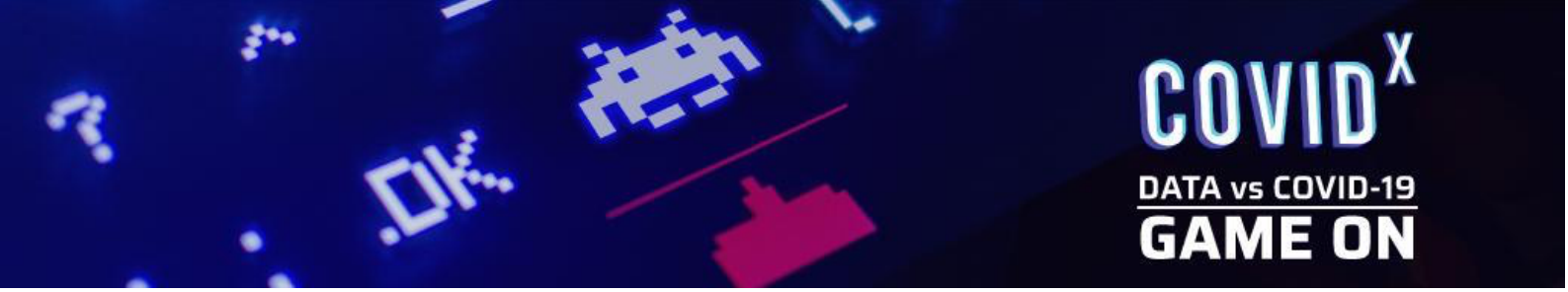

COVID X

COVID EXPONENTIAL PROGRAMME

GRANT AGREEMENT ID: 101016065

OPEN CALL #2

GUIDELINES FOR APPLICANTS

Revision: v.1.1

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DEFINITION OF TERMS AND CONCEPTS

The key terms used throughout the document are defined in Table 1.

Table 1 - Definition of Terms

TERM / EXPRESSION	DEFINITION
COVID-X Consortium or Consortium	Set of legal entities that are cumulatively responsible to implement the COVID-X project as defined in the Grant Agreement for project number 101016065
Applicant	SME or set of legal entities led by an SME that intends to submit or submitted a proposal to the acceleration programme.
Solution	Projects carried out by 3rd parties (outside COVID-X Consortium) that benefit from the COVID-X funding and join the COVID-X Acceleration Programme. The solutions can be either single or team solutions.
Beneficiary or 3rd Party	An SME or a consortium of an SME and Healthcare provider, led by an SME that submitted a proposal to the acceleration programme which was accepted to be funded, and have a signed, or are in the process of signing, a sub-grant agreement.
External Evaluator	Expert hired by the consortium to assist in the evaluation of proposals. External evaluators cannot have conflicts of interest and are bounded by a confidentiality agreement.
Internal evaluation committee	Set of at least 3 appropriately qualified experts of the staff of the consortium, preferably from 3 entities representing the healthcare providers, technical partners, and business partners that are assigned the responsibility of performing evaluations in any stage of the acceleration programme.
Mentor	Person from the consortium that works closely with the beneficiary to foster communication with the consortium and assess progress of the project. The mentor may be part of an evaluation committee.

Other major concepts that need to be clarify with regards the application are defined in Table 2.

Table 2- Essential Concepts

TERM / EXPRESSION	DEFINITION
Scores in evaluation processes	Unless otherwise stated, all evaluation processes will rank each criterion with marks between 1 and 5. Half point scores are not given. Score values will indicate the following assessments: • **1: Fail.** The proposal fails to address the criterion under examination or cannot be judged due to missing or incomplete information. • **2: Very poor.** The criterion is addressed in an unsatisfactory manner. • **3: Poor.** There are serious inherent weaknesses. • **3: Good.** While the proposal broadly addresses the criterion, there are significant weaknesses that would need correcting. • **4: Very Good.** The proposal addresses the criterion well, although certain improvements are possible. • **5: Excellent.** The proposal successfully addresses all relevant aspects of the criterion in question. Any shortcomings are minor.

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TERM / EXPRESSION	DEFINITION
Overall score	When the evaluation is made by a committee the score of each criterion is computed and rounded to the nearest integer before computing the overall score. The overall score is the sum the scores of each criterion multiplied by the respective weight, rounded to the nearest integer value.
Schedule for payments to Beneficiaries	All payments do beneficiaries are dependent on successful evaluation of deliverables in the end of each sprint, and reception by the consortium of the corresponding payment request. All payments will be made with undue delay preferably no later than 30 calendar days after the reception of the financial statement.

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1 EXECUTIVE SUMMARY

This Guide for Applicants contains the basic information needed to guide you in preparing a proposal for submission to the second edition of the **COVID-X Open Call for proposals**. It gives an introduction on how to structure your proposal. It also describes how to submit the proposal and the evaluation criteria.

COVID-X is a H2020 funded project (Grant Agreement No. 101016065) with the mission to bridge the collaboration divide between eHealth solution providers -with emphasis on lean start-ups and small and medium-sized enterprises (SMEs)-, and the healthcare professional system to fight COVID-19. The purpose is four-fold to:

- Boost an end-to-end agile piloting programme of cutting-edge technology in real-world scenarios with access to clinical data.
- provide direct and equity-free funding accelerating the market uptake of the solutions.
- Give access to a tailored Acceleration Programme including business, technical and ethical mentoring for solutions to be commercialized.
- Provide access to the COVID-X Sandbox, a one-stop platform to exploit COVID-19 data sources.

This work will be carried out as part the European Union Coronavirus initiative and in strong collaboration with all the funded projects to accelerate the time to market for promising products. COVID-X is set to fund +30 innovative technologies for combatting COVID-19 from several areas spanning from early detection, innovative diagnostics, personalised care, remote care, healthcare continuity, recovery and others.

The COVID-X project[1] is funded in the scope of the call H2020_SC1-PHE-CORONAVIRUS-2020-2B[2] and involves a consortium of 10 prominent partners from 7 different countries:

[1] https://www.covid-x.eu/

[2] https://cordis.europa.eu/programme/id/H2020_SC1-PHE-CORONAVIRUS-2020-2B

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2 SCOPE OF THE COVID-X SECOND OPEN CALL

The COVID-X project aims to provide to competitive and market oriented European SMEs access to **knowledge, technology, capital and markets,** with the aim to place new products and services in the market with the goals of fighting against the COVID-19 pandemic.

COVID-X will fund EU Companies and Healthcare Providers to boost data-driven solutions with the power to overcome challenges in Diagnosis, Prognosis, and Follow-up. The funding is invested in products with TRL 7+ and [or in the process of] CE marking, covering two profiles:

1. **Single players** (EU Tech SMEs / Start-Ups) validating their solutions at one of COVID-X clinical partners;
2. **Team players** (Tech Provider working with a Healthcare provider that will validate the solution).

The third-party technology providers selected in the open call must integrate their solutions with the COVID-X Sandbox (more information in Section 2.5 COVID-X TECHNOLOGICAL INFRASTRUCTURE) and will enter the COVID-X acceleration programme, with the ambition to streamline the deployment and techno-economic validation of their solutions in the fight against COVID-19.

The COVID-X 2nd Open Call will follow a two-stages approach with the aim of simplifying the applications process, supporting applicants to make better proposals and to reduce the burden in the application process.

The indicative number of projects to be funded in Open Call #2 (OC#2) is 7 (Seven) single solutions and 7 (Seven) team solutions. The number of projects funded may be different depending on the number and quality of the applications received.

The COVID-X 2nd Open Call Stage 1 is running now with the deadline on **22.07.2021 at 17:00 CEST** (Brussels Time), and applicants can submit their online applications via *the F6S platform COVID-X page*[3]. The Stage 1 applicants meeting the set selection criteria and threshold will access **the OC#2 Stage 2 running from 06.08.2021 with the deadline on 16.09.2021 at 17:00 CEST** (Brussels Time).

The OC#2 Application Process Timeline details can be found in 4.1

2.1 COVID-X CHALLENGES

The solutions are required to address one of the six defined clinical challenges in the coronavirus patient's journey. Team solutions can also opt for the open challenge.

2.1.1 Challenge 1 - EARLY DETECTION - PREVENTION

Early-stage detection is crucial to avoid further spread of the disease, reducing the onset of complications and the need for hospitalization. More sophisticated decision-making mechanisms are needed to identify target/priority groups (e.g. subjects more likely to suffer from COVID-19 or those

[3] https://www.f6s.com/covid-x-open-call-2-stage-1/apply

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at risk of a worse clinical outcome), reinforcing massive testing. Additionally, vaccination programs are ongoing all-around EU and the data collection of the vaccinated people could enhance the pandemic management as well as the clinical research, eventually corelating outbreaks with data on vaccination.

2.1.2 Challenge 2 - INNOVATIVE DIAGNOSTICS

Detection of SARS-CoV2 RNA in different secretions is the current gold standard for COVID-19 diagnosis, but with margins of error and delay. Leveraging the power of machine learning or other deep learning approaches to data analysis, new methods for diagnosis can boost the capability, time-response and improve decision-making processes, complementing the effectiveness of PCR testing.

2.1.3 Challenge 3 - PERSONALIZED CARE

A timely and accurate prediction of the course of the disease is a key element to improve the effectiveness of treatment and optimize the resources of the healthcare system. The precision of clinical path increases with retrospective data from previous COVID-19 patients, reinforced with the clinical records of the patient.

2.1.4 Challenge 4 - REMOTE CARE

Subjects diagnosed with a positive prognosis (e.g. mild symptoms and asymptomatic) can be monitored remotely, contributing to reduce saturation at hospitals and reducing risks for spreading the virus. Continuous monitoring of these cases requires timely and swiftly reaction, adopting user design principles and making such experience trustworthy and human-centric.

2.1.5 Challenge 5 - HEALTHCARE CONTINUITY

Care levels and specialties are data silos. Health professionals should rely on up-to-date and precise information about the processes undergone by the subjects during their disease, especially cases suffering new episodes (i.e. reinfections) and/or the chance of suffering from chronic complications.

2.1.6 Challenge 6 – RECOVERY

A significant proportion of subjects that have overcome COVID-19 remain symptomatic, with manifestations interfering with their daily life activities. We need to empower these subjects and to deliver interventions (e.g. rehabilitation) in ways that do not strain the healthcare and/or social system further.

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2.1.7 OPEN CHALLENGE

Team solutions can address challenges #1 to #6 or any other challenge as long as it is in the scope mentioned in the beginning of this section, namely being TRL 7+, and addressing at least one of the two areas specified in point 2.

2.2 COVID-X PILOT SITES

The single solutions will be validated by making use of clinical information provided by one of the three project pilot sites that belong to the COVID-X Consortium. These sites are located in Italy, Spain and Sweden, and each site is focused on the specific clinical challenges.

2.2.1 Instituto Clinico Humanitas

Location. Milan, Italy

Profile. Instituto Clinico Humanitas (ICH) provides healthcare services for about 1 million patients/year. During COVID-19 pandemic, ICH treated 3,000 patients (about 150 ICU, 1,000 hospitalized and 2,000+ managed by ER).

Objective. Fast, accurate and combined analysis of clinical data available in ER, diagnostic imaging (CT for ICH) and historical profile of patients. Detecting, classifying and treating infected patients as early as possible. Efficient patient-centered diagnostic and AI-based solutions for cross analysis between clinical and radiological data to assess personalized clinical paths and treatments.

Resources. Combination of CTs and aggregated datasets (90+ features per patient), viral load (positive, weak positive or negative), clinical records and real historical data from the first COVID-19 wave from ICU, hospitalized patients and ER department. Metadata and additional features are available for a subgroup of the included CTs. Anonymized features from clinical records will be available in Italian..

2.2.2 Hospital Clinico San Carlos

Location. Madrid, Spain

Profile. Hospital Clinico San Carlos is a tertiary care center covering a population of 300K+ citizens. From the beginning of the pandemic, this centre has attended 3,000+ hospitalized patients diagnosed with COVID-19.

Objective. The main interest of the health professionals caring for hospitalized patients with COVID-19 is to be able to swiftly and precisely diagnose this condition and assess its prognosis. In particular, the hospital is interested to identify “exceptions to the rule”; i.e. subjects belonging to risk groups but who will fully recover with no or minor complications, and vice versa.

Resources. Data from covid patients since March 2020 until now. Real-world data generated at the emergency department, hospitalization and Intensive Care Unit, including: codified diagnoses, comorbidities, procedures at discharge (ICD10), codified treatment during stay, admin data on

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admission and discharge (and motive), admission at ICU, and microbiology tests (e.g. Polymerase Chain Reaction).

2.2.3 Karolinska Institutet

Location. Stockholm, Sweden

Profile. Karolinska Institutet (KI) is one of the world's leading medical universities, advancing knowledge about life and striving towards better health for all. KI is Sweden's single largest centre of medical academic research and offers the country's widest range of medical courses and programmes. Since 1901 the Nobel Assembly at KI has selected the Nobel laureates in Physiology or Medicine.

Objective. KI aims to enhance the data collection from patients with potential COVID-19 diagnosis, meaning enhancing the pre-diagnostic processes and clinical pathways with AI based developed components

Resources. KI will use its CLEOS software program for history-taking to acquire a COVID-19 related medical history from any patient desiring an acute medical consultation because the patient is experiencing an intercurrent, non-specific illness, e.g., fever, cough, abdominal pain, for fears they have COVID-19 infection. CLEOS will be used by patients contacting the program's COVID-19 portal from home and by patients presenting to emergency departments (ED) in Stockholm.

2.3 AVAILABLE DATA SETS AND VARIABLES

Table 3 describes the available sets of data and variables on the COVID-X Pilot Sites working with Single Solutions.

Table 3- High-level clinical data characteristics

	HOSPITAL CLINICO SAN CARLOS	INSTITUTO CLINICO HUMANITAS	KAROLINSKA INSTITUTET
HOSPITALIZATION			
Administrative data (length-of-stay, Service, internal transfers, cause of discharge…)	X	X	X
Diagnosis and procedures at discharge	ICD10	ICD9	X
Treatment prescribed and administered during admission	X	X	X
Labwork (complete blood cell count, chemistry,	Non protocolized, performed by medical	X	X

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	HOSPITAL CLINICO SAN CARLOS	INSTITUTO CLINICO HUMANITAS	KAROLINSKA INSTITUTET
coagulation testing, D-Dimer, IL-6…)	decision based on the clinical manifestations		
Imaging test (chest X-ray, CT scan…)		Non protocolized, performed by medical decision based on the clinical manifestations	
Clinical notes		Only extracted features available for a subgroup of patients (in Italian)	
EMERGENCY DEPARTMENT			
Administrative data (length-of-stay, Service, internal transfers, cause of discharge…)	X	X	
COVID-19 related clinical manifestations	X	X	
Clinical scores (SOFA, NEWS…)	X		
Vital Signs (blood pressure, temperature…)	X	X	X
Diagnosis and procedures at discharge	X	X	
Treatment prescribed and administered during admission	X	X	X
Labwork (complete blood cell count, chemistry, coagulation testing, D-Dimer, IL-6…)	Non protocolized, performed by medical decision based on the clinical manifestations	X	X
Imaging test (chest X-ray, CT scan…)		CT at admission in the emergency department. In addition, other imagine test non	X

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	HOSPITAL CLINICO SAN CARLOS	INSTITUTO CLINICO HUMANITAS	KAROLINSKA INSTITUTET
		protocolized, performed by medical decision based on the clinical manifestations	
Clinical notes		Only extracted features available for a subgroup of patients (in Italian)	
INTENSIVE CARE UNIT			
Administrative data (length-of-stay, Service, internal transfers, cause of discharge…)	X	X	X
Clinical scores (SOFA, NEWS…)	X		
Vital Signs (blood pressure, temperature…)	X		
Treatment prescribed and administered during admission	X	X	X
Labwork (complete blood cell count, chemistry, coagulation testing, D-Dimer, IL-6…)	Non protocolized, performed by medical decision based on the clinical manifestations	X	X
Imaging test (chest X-ray, CT scan…)		Non protocolized, performed by medical decision based on the clinical manifestations	
Clinical notes		Only extracted features available for a subgroup of patients (in Italian)	

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2.4 MAPPING BETWEEN CHALLENGES AND PILOT SITES ON OC#2

Table 4 identifies the challenges each pilot site is intending to address in the Open Call #2 as well as the total number of projects that can be supported.

Table 4 - Mapping between challenges and pilot sites

CHALLENGE / PILOT SITE	HOSPITAL CLINICO SAN CARLOS	INSTITUTO CLINICO HUMANITAS	KAROLINSKA INSTITUTE
#1 - Early Detection			Yes
#2 - Innovative Diagnostics	Yes	Yes	Yes
#3 - Personalized Care	Yes	Yes	
#4 - Remote Care			Yes
#5 - Healthcare Continuity			
#6 – Recovery			
Total number of startups	**3**	**2**	**2**

2.5 COVID-X TECHNOLOGICAL INFRASTRUCTURE

COVID-X envisions the provision of the COVID-X Sandbox and its Data-driven services, as the enabling core data-driven technological platform for aggregating, curating, structuring, cataloguing and providing seamless access to anonymized health data from historical data sets of Clinical partners, and, when needed, to data from open data sources, as well as to streaming data from connected medical devices/apps. These are augmented by security, information visualization and data analytics/federated validation services. The purpose of the COVID-X Sandbox is to provide core services both to Clinical partners/data providers to ingest data into the Sandbox, and to Third Parties/Solution Providers to integrate their solution with the Sandbox and consume and manage data.

The COVID-X Sandbox is based on a highly modular architecture, built as a mesh of containerised microservices. The key advantages of this architectural approach are that it offers simplicity in building and maintaining applications, flexibility and scalability, while the containerized approach makes the applications independent of the underlying system. Figure 1 presents an overview of the building blocks that comprise the architecture of the COVID-X Sandbox, final release. Each component within the Sandbox architecture implements and delivers one or more of the aggregated Sandbox services, which for the final release are: i) data integration, ii) data harmonization, filtering and cataloguing, iii) data storage, querying and retrieval, iv) security in data access, v) data visualization, vi) API gateway for interaction with third party solutions. Instances of the COVID-X Sandbox will be installed both at a

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cloud computing infrastructure or at the provided infrastructure of Clinical partners according to needs.

In this release, additional open and publicly available datasets will be ingested in the Sandbox and all services of the 1st release will be updated. In addition, the federated learning/validation module will be introduced, to permit the deployment of federated learning/validation edge nodes in the targeted hospitals enabling remote and secure re-training/validation of relevant AI algorithms over diverse types of data (numerical, textual, time-series, images such as scans, etc.) across many data providers (Clinical partners) providing the same types of health data, while maintaining the integrity and security of data and meeting the hospitals needs to properly handle personal health data (since federation is done by installing the software locally at Data providers' sites, instead of moving sensitive data to third party infrastructures). The federated learning module will encompass another counterpart at the centralized cloud-based Sandbox system to retrain/validate AI models with data coming from open data sources, if/when needed.

More information about the COVID-X Sandbox:

- COVID-X Sandbox Description (https://rebrand.ly/COVID-X_Sandbox_Services_Description)
- FAQ COVID-X Sandbox (https://rebrand.ly/COVID-X_FAQ_Sandbox)
- COVID-X Deliverable 2.1 - Sandbox design & Datalake creation and ingestion (https://rebrand.ly/COVID-X_D2_1_Sandbox_Design_Datalake_Creation_Ing)
- COVID-X Deliverable 2.2 - First Sandbox implementation and services provision (https://rebrand.ly/COVID-X_D2_2_First_Sandbox_Implement_Serv_Prov)

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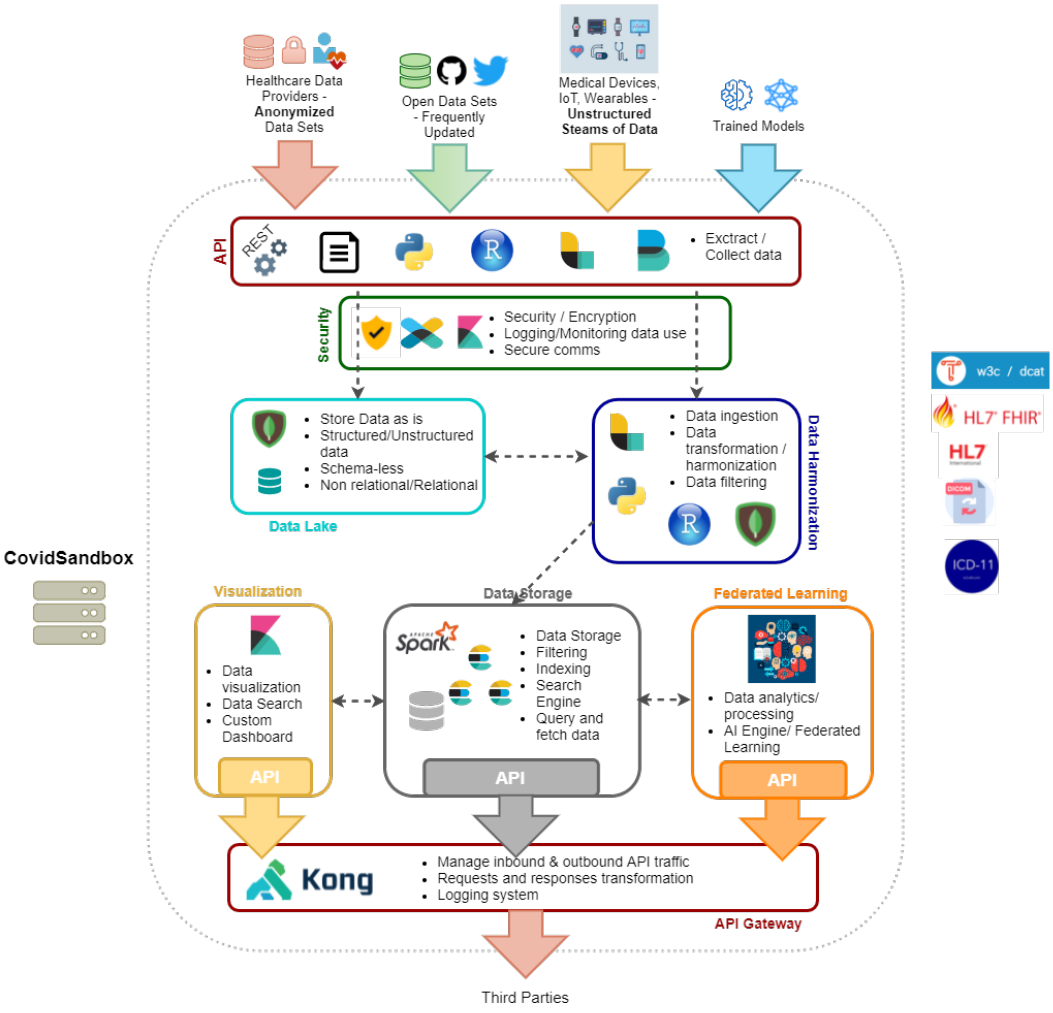

Figure 1 - The COVID-X Sandbox Architecture, Final fully-featured Release

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3 RULES AND CONDITIONS

COVID-X invites market-oriented SMEs and Start-Ups to provide innovative products to help fight the COVID-19 pandemic. All applicants will have to abide by all general requirements described in Sections from 3.1 to 3.14 to be considered eligible for the second Open Call:

3.1 TYPE OF BENEFICIARY

The accepted applicants for the COVID-X Open Call are **companies** (single solutions: SMEs and Start-Ups) **and consortia of companies** (team solutions: 1 SME or Start-Up + Healthcare provider) developing solutions, ensuring that:

FOR THE SMES AND STARTUPS:

- An SME will be considered as such if complying with the European Commission Recommendation 2003/361/EC[4] and the SME user guide[5]. As a summary, the criteria which define an SME are:
    a. Independent (not linked or owned by another enterprise), in accordance to Recommendation 2003/361/EC.
    b. Headcount in Annual Work Unit (AWU) less than 250.
    c. Annual turnover less or equal to €50 million OR annual balance sheet total less or equal to €43 million.
- It is a technology provider providing innovation to the healthcare sector.
- Start-ups that do not have yet annual turnover or balance sheets are also considered eligible given that they fulfil the criteria (a) and (b) of the SME definition.
- In case an SME is awarded a sub-project, it will remain eligible even if, at a certain point during the sub-project execution, it does not fulfil criteria (b) or (c) of the SME definition.
- The organisations should not have had convictions for fraudulent behaviour, other financial irregularities, unethical or illegal business practices;
- The participating organisations should not have been declared bankrupt or have initiated bankruptcy procedures;
- It is not under liquidation or is not an enterprise under difficulty according to the Commission Regulation No 651/2014, art. 2.18;
- It is not excluded from the possibility of obtaining EU funding under the provisions of both national and EU law, or by a decision of either national or EU authority.
- Please note that a signed version of the ***Honour Declaration*** and the ***SME Declaration*** are mandatory for a proposal submission for the technology provider. These are submitted in the Application Stage 1. You can find these documents in Section 4.4 of this guideline.

[4] European Commission Recommendation 2003/361/EC. LINK

[5] SME definition: Please check "User guide to the SME definition" available at LINK

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FOR THE HEALTHCARE PROVIDERS (ONLY FOR TEAM SOLUTIONS)

- It is a technology adopter/user receiving innovation to its healthcare company.
- The organisations should not have had convictions for fraudulent behaviour, other financial irregularities, unethical or illegal business practices;
- The participating organisations should not have been declared bankrupt or have initiated bankruptcy procedures;
- It is not under liquidation or is not an enterprise under difficulty according to the Commission Regulation No 651/2014, art. 2.18;
- It is not excluded from the possibility of obtaining EU funding under the provisions of both national and EU law, or by a decision of either national or EU authority.
- Please note that a signed version of the ***Honour Declaration*** is mandatory for the healthcare organization. This is submitted in the application stage 1. You can find this document in Section 4.4 of this guideline.

3.2 ELIGIBLE COUNTRIES

Applicants from the following countries are eligible to receive funding through this Open Call:

- It is a legal entity established and based in one of the EU Member States or an H2020 Associated country as defined in H2020 rules for participation[6].

3.3 TRL AND TECHNOLOGICAL AREAS

In accordance with the text of the call in which COVID-X was funded, the maturity of the **projects to be considered for funding must be above TRL7.**

Annex G of the H2020 programme[7] defines the names of the TRL levels but is lacking a concrete definition of each level. In the context of COVID-X, the definition of TRL levels is depicted in Table 5:

Table 5- TRL Level definitions

TRL LEVEL	DEFINITION
TRL 1 – basic principles observed	Scientific literature reviews, market surveys initiated and assessed. Scientific research begins to be translated into applied R&D.
TRL 2 – technology concept formulated	Research ideas and protocols developed. Hypotheses generated. Invention begins, applications are speculative and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.

[6] https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-a-countries-rules_en.pdf
[7] https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf

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TRL 3 – experimental proof of concept	Active R&D is initiates. This includes analytical studies and laboratory studies to physically validate the analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.
TRL 4 – technology validated in lab	Basic technological components are integrated to establish that they will work together. This is relatively low fidelity compared with the eventual system.
TRL 5 – technology validated in relevant environment	The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment.
TRL 6 – technology demonstrated in relevant environment	Representative model or prototype system is tested in a relevant environment such as a high-fidelity laboratory environment or in a simulated operational environment.
TRL 7 – system prototype demonstration in operational environment	**Prototype near or at planned operational system. Represents a major step up from TRL 6 by requiring demonstration of an actual system prototype in an operational environment.**
TRL 8 – system complete and qualified	**Technology has been proven to work in its final form and under expected conditions. In most cases this TRL represents the end of true system development.**
TRL 9 – actual system proven in operational environment	**Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluations.**

TECHNOLOGICAL AREAS

Proposals should address technologies which are currently demonstrated and that **fall into one of the following areas:**

- fast, cost-effective and easily deployable sampling, screening, diagnostic and prognostic systems, including new methods for screening of lungs, using for example AI or advanced photonics solutions, to detect the presence of the pathogen related parameters especially in an early stage of infection;
- innovative data-driven services and tools combining data assets from various relevant privately held and/or publicly available sources. These could include AI-based solutions exploiting such data and possibly additional sensor-based signals, for diagnostics, prevention, treatment, or rehabilitation.

3.4 CE MARKING

In accordance with the text of the call in which COVID-X was funded, project to be supported **must have CE marking or close to achieve certification.**

The EU Medical Device Regulation[8], (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and

[8] https://ec.europa.eu/health/md_sector/new_regulations_en

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Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, entered into force on May 26th, 2017, applying as of May 26th, 2021, establishes a new set of rules to be complied by medical devices. The same regulation and guidance documents clearly define the transition rules as well as the timeframe in which CE marking acquired before May 26th, 2021 is valid.

Among extensive guidance documents provided by the European Commission we would like to highlight the "*Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745*"[9] which defines the criteria for the qualification on software falling within the scope of the new medical device regulation.

During the evaluation process, the evaluators need a clear picture about the intended use of the software (for instance, if it is designed for doctors in relation with the patient data) impacting the possible status of a medical device, and the possible classification category in which the software falls. The European Commission has produced a tool for evaluating if your software is considered as medical device: "Is *your Software a Medical Device*?"[10].

3.5 INTEGRATION WITH THE COVID-X SANDBOX

All projects must integrate the technological infrastructure provided by the project the COVID-X Sandbox (Section 2.5). Two COVID-X documents framing the infrastructure, *The Ethical and Legal Framework*[11] in conjunction with the *Anonymization Guide*[12] define the legal framework, the ethical procedures, and the best practices all projects must follow when designing and implementing the infrastructure.

Applications must specify how they will integrate the COVID-X Sandbox in their solutions, as well as how the anonymization practices defined in the Anonymization Guidelines will be applied.

3.6 FINANCIAL SUPPORT

The Open Call provides a maximum financial support of **150.000 EUR per team solutions projects** (100.000 EUR to be allocated to the tech provider and 50.000 EUR to be allocated to the clinical partner) and, **100.000 EUR per single solution projects with 100% funding rate.** This funding is allocated as a lump sum for each beneficiary, and therefore, if the projects respect the principle of non-double funding by the EC, no detailed budget specification is needed.

The European Commission will monitor that COVID-X beneficiaries and the third-party beneficiaries comply with the conditions for financial support to third parties. In this regard, third party beneficiaries shall allow the European Commission, the European Anti-fraud (OLAF) and the Court of Auditors to exercise their powers of control on documents, information, even stored on electronic media.

[9] https://ec.europa.eu/health/sites/default/files/md_topics-interest/docs/md_mdcg_2019_11_guidance_en.pdf
[10] https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_mdsw_en.pdf
[11] https://rebrand.ly/COVID-X_D1_1_Ethical_Legal_Framework
[12] https://rebrand.ly/COVID-X_Anonymization_Guide

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All payments are dependent on successful evaluation of deliverables and reception by the consortium of the corresponding payment request by the third party. All payments will be made with undue delay preferably no later than 30 calendar days after the reception of the financial statement.

3.7 ORIGIN OF THE FUNDS

Any selected proposer will sign a dedicated Sub-Grantee Funding Agreement with the COVID-X consortium. **The funds attached to the Sub-Grantee Funding Agreement come directly from the funds of the European Project COVID-X funded itself by the European Commission, and remain therefore, property of the EU until the payment of the balance, whose management rights have been transferred to the project partners in COVID-X via European Commission Grant Agreement Number 101016065.**

As it can be seen in the Sub-Grantee Funding Agreement template, this relation between the sub-grantees and the European Commission through COVID-X project carries a set of obligations to the sub-grantees with the European Commission. It is the task of the sub-grantees to accomplish them, and of the COVID-X consortium partners to inform about them.

3.8 NUMBER OF COMPANIES TO BE FUNDED

The number of projects that were selected in the Open Call #1 is 3 (three) single solutions and 13 (thirteen) team solutions.

The indicative number of projects to be selected in the Open Call #2 is 7 (Seven) single solutions and 7 (Seven) team solutions.

Depending on the quality of the proposals and the budget allocation, the consortium may decide to select a different number of projects in the second edition of the acceleration programme.

3.9 LANGUAGE

English is the only official language for COVID-X. Submissions done in any other language will not be eligible and will not be evaluated. English is also the only official language during the whole execution of the COVID-X programme. This means that all communication will be in English and all deliverables will only be accepted if in English.

3.10 DOCUMENTATION FORMATS

Unless otherwise stated in specific questions of the application form, any document requested in any of the phases must be submitted electronically in **PDF format without restrictions for printing.**

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3.11 MULTIPLE SUBMISSIONS

Only one proposal will be accepted for funding per SME. In case an SME submit more than one proposal, all proposals that they have submitted will be automatically excluded from the evaluation process.

3.12 ABSENCE OF CONFLICT OF INTEREST

Applicants shall not have any actual or/and potential conflict of interest with the COVID-X selection process and during the whole project implementation. All cases of conflict of interest will be assessed case by case. COVID-X consortium partners, its affiliated entities, employees and permanent co-operators cannot become a recipient of financial support via the open call. This would be in breach of the European Commission's rules.

3.13 ETHICAL ISSUES

COVID-X complies with the fundamental ethical issues particularly those outlined in the "European Code of Conduct for Research Integrity".

All applicants must submit a self-assessment ethics questionnaire, available in the Proposal Template, to confirm that their proposal does or does not have ethical issues. If you must answer "Yes" to any of the questions in the template, you may contact COVID-X Helpdesk for guidance, if needed. The COVID-X consortium may check during the evaluation of a proposal if this declaration is in line with the contents of the proposal itself and reserves itself the right to contact the companies for clarification and eventually take necessary steps depending on the ethical issues. If a project passes the second stage, the applicants will commit to send any relevant approvals and documentation, and certainly before the experimental part raising ethics issues commences. If an applicant declared that their project proposal may have ethical issues, an ethics review will be carried out. COVID-X consortium will identify and invite external experts on ethics to participate in the evaluation. **Proposals that fail to properly address ethical issues or inadequately deal with privacy aspects will be rejected**.

3.14 DATA PROTECTION

To process and evaluate applications, COVID-X will need to collect Personal and Industrial Data. F6S Network Limited, as the Project Coordinator will act as Data Controller for data submitted through the F6S platform for these purposes. The F6S platform's system design and operational procedures ensure that data is managed in compliance with The General Data Protection Regulation (EU) 2016/679 (GDPR). Each applicant will accept the F6S terms to ensure coverage.

Please refer to https://www.f6s.com/terms to check F6S platform data privacy policy and security measures.

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4 PROPOSAL SUBMISSION PROCESS

4.1 OVERALL PROCESS

The Open Call#2 runs in two subsequent application phases, and the objective is to simplify the application process, helping applicants to make better proposals and reduce the burden in the application process. The 1st Application Stage proceeds a first evaluation of the received applications, all eligible applications enter the 2nd Application Stage. This first evaluation makes sure that the selected solutions meet the key selection criteria (essentially TRL7+, CE-marking and technical implementation aligned the goals of the project).

Table 6 - OC#2 Application Process in 2 Stages

	ELEMENTS	TIMELINE
Application Stage 1	Fill in and submit application including: - **Proposal Template,** an Online form on F6S. - **Proposal Supplement (Application Stage #1),** added in PDF (limited to 10-pages + the cover). - **Honour Declaration** specific one for each participating organization, in PDF format. - **SME Declaration**, in PDF format.	Launch date 03.06.2021 Submission deadline **22.07.2021** **at 17:00 CEST** (Brussels Time)
Application Stage 1 - Internal evaluation	COVID-X Consortium performs internal checks the eligibility criteria of the applications (TRL levels, CE marking, Technical implementation plan and foreseen impact). The applications are ranked and selected for the Application Stage 2. **The eligible applicants are informed with a message to submit their application in the Stage 2.**	23.07 – 06.08. 2021
Application Stage 2	Fill in and submit application including: - **Proposal Template,** an Online form on F6S. - **Proposal Supplement (Application Stage #2),** added in PDF (limited to 30-pages + the cover, including more specific questions about the project) - **Pitch deck presentation** about the project (limited to 10 slides + cover)	Launch date 7.8.2021 Submission deadline **16.9.2021** **at 17:00 CEST** (Brussels Time)
Application Stage 2 – External remote evaluation	An external evaluation board reviews the received proposals scoring them based on the evaluation criteria (Excellent, Impact and Implementation). The evaluators rank the applications and selected the top-ranked projects in online interviews.	17.9 – 01.10.2021

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Application Stage 2 – Online interviews	Applicants pitch the project to the evaluators, and the evaluators ask questions about elements they want to clarify regarding the application.	02.10 – 16.10.2021
Announcement of the results	All applicants receive a written letter about approval or rejection of their project. The successful projects start the onboarding phase in the COVID-X Acceleration Programme.	End of October

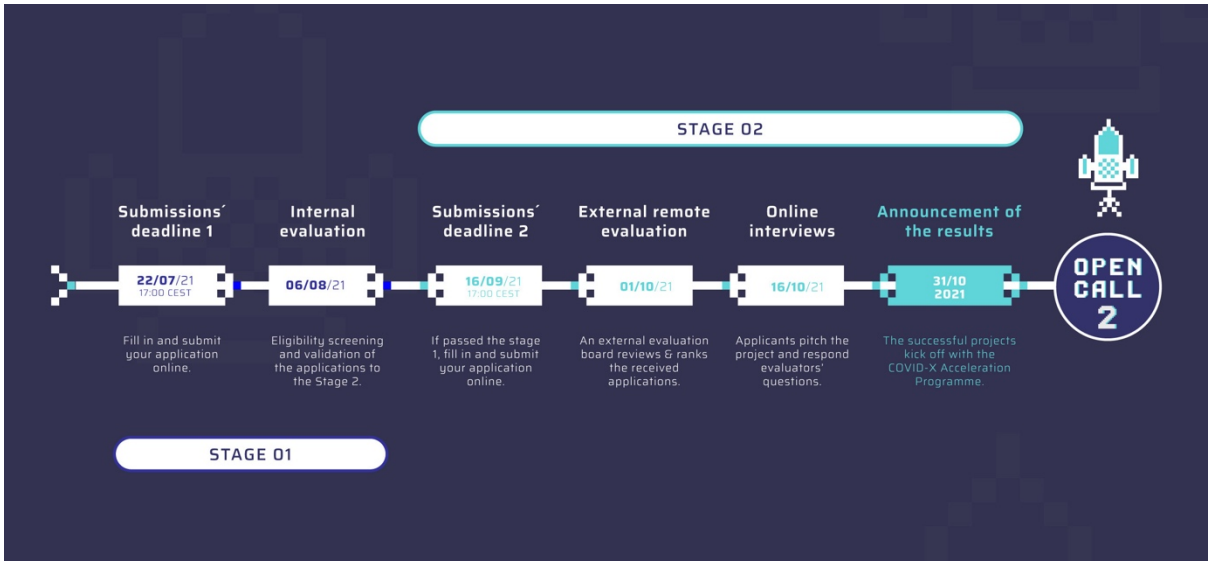

Figure 2: OC#2 Timeline with all key deadlines

4.2 OPEN CALL #2 PUBLICATION

The Open call is defined by the following documents (with direct links to access the documents in Sections 4.4 and 4.5):

- **Guidelines for Applicants:** This present guide aims to assist potential applicants**.** The document provides a full set of information regarding the Open Call for Proposals for the COVID-X project.
- **Application Stage #1:**
  - ***Proposal Template,*** an online application form, available at F6S platform (www.f6s.com/covid-x).
  - ***Proposal Supplement (Application Stage #1),*** a word document providing information on proposal schedule, timing, Ethical & Security details.
  - ***Honour Declaration,*** which declares that all conditions of the acceleration process are accepted by an SME / Healthcare provider legal representative. One dedicated declaration is required for each partner.
  - ***SME Declaration***, which evaluates the status of the SMEs participating at an acceleration process. This is only for the SME partner.

- **Application Stage #2:**

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- ***Proposal Template,*** an online application form, available at F6S platform (www.f6s.com/covid-x).
- ***Proposal Supplement (Application Stage #2),*** a word document providing information on proposal schedule, timing, Ethical & Security details.
- ***Pitch deck template***, template for the pitch deck providing a very general list of slides with bullet points to explain the desired content.

- **Other relevant documents for the contract preparation (if selected):**
  - ***Bank account information,*** which collects information on the applicant(s)' bank account where the COVID-X payments will be sent to. Example of the document: https://rebrand.ly/COVID-X_OC2_Bank_account_form
  - ***Sub-grant Agreement Template,*** which provides a template of the sub-grant agreement that the successful applicants will be requested to sign. Example of the document: https://rebrand.ly/COVID-X_OC2_Sub_grant_agreement_template
  - *An updated version of* ***Honour Declaration,*** which declares that all conditions of the acceleration process are accepted by an SME / Healthcare provider legal representative. One dedicated declaration is required for each partner.
- ***Frequently Asked Questions & answers*** published at the community feed (www.f6s.com/covid-x).

4.3 PROPOSAL PREPARATION

Please follow the steps:

1. For the proposal preparation, the applicants are requested to apply online and answer to all mandatory questions (with no exception) at: www.f6s.com/covid-x. Moreover, applicants must submit all the requested documents established for each application stage. The lack of any of the documents will negatively affect the eligibility of the company for the evaluation process.
2. **In the application stage #1**, applicants that do not accept the terms and conditions and do not sign and upload to the f6s platform the completed ***Honour Declaration*** and the ***SME Declaration*** will not be eligible.
3. Be concrete and concise. Open questions have characters' limitations. Please examine all the acceleration process/ open call documents and attend the various online and physical events promoted by the COVID-X projects (covid-x.eu/).
4. It is highly recommended to submit your proposal well before the deadline. If the applicant discovers an error in the proposal, and provided the call deadline has not passed, the applicant may request the F6S COVID-X team to re-submit the proposal (for this purpose please contact us at support@f6s.com). **However, COVID-X is not committed that resubmission in time will be feasible in case the request for resubmission is not received by the F6S COVID-X team at least 48 hours before the call deadline.**

It is strongly recommended not to wait until the last minute to submit the proposal. Failure of the proposal to arrive in time for any reason, including network communications delays or working from multiple browsers or multiple browser windows, is not acceptable as an extenuating circumstance. The time of receipt of the application as recorded by the submission system will be definitive.

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4.4 APPLICATION STAGE 1 – PROPOSAL SUBMISSION

The **F6S platform** will be the entry point for all proposals' submission to COVID-X Open Calls, interested applicants should register at the COVID-X F6S page (www.f6s.com/covid-x). Only proposals submitted within the Call duration will be accepted.

Proposals submitted by any other means will not be considered nor evaluated. Only the documentation included in the application will be considered by evaluators. A complete proposal comprises 4 components:

- **Proposal Template,** an online application form, available at F6S platform (www.f6s.com/covid-x).
- **Proposal Supplement (Application Stage #1),** a word document providing information on proposal schedule, timing, Ethical & Security details.
    - Download the Proposal Supplement Stage 1:

      https://rebrand.ly/COVID-X_OC2_Proposal_Suplement_Stage1
- **Declaration of Honour** that declares that all conditions of the COVID-X Programme and application process are accepted by an SME/ Healthcare organisation legal representative.
    - Download the Declaration of Honour for SMES: https://rebrand.ly/COVID-X_OC2_SME_Declaration_of_Honour
    - Download the Declaration of Honour for Healthcare Providers: https://rebrand.ly/COVID-X_OC2_HealthcareProv_Declaration_of_Honour
- **SME Declaration**, which evaluates the status of the SMEs participating in the application process.
    - Download the SME Declaration: https://rebrand.ly/COVID-X_OC2_SME_Declaration

Submissions will be done ONLY via the F6S platform on www.f6s.com/covid-x. A full list of proposers will be drafted containing their basic information for statistical purposes and clarity (which will be also shared with the European Commission for transparency).

The application reception will close as indicated in **Section 4.1**. There will not be any deadline extensions unless there is a Force Majeure situation (e.g. a major problem caused by the F6S platform and not by the proposers, makes the system unavailable for a long period).

The length of the **Proposal Supplement (Application Stage #1)** is limited to 10 pages, excluding cover page.

4.5 APPLICATION STAGE 2 – PROPOSAL SUBMISSION

PLEASE, BE AWARE THAT THIS SECTION IS ONLY APPLICABLE FOR STAGE 2 PROPOSALS. ONLY COMPANIES THAT HAVE PASSED THE FIRST STAGE WILL BE INVITED TO SUBMIT THE STAGE 2 PROPOSAL.

The **F6S platform** (www.f6s.com/covid-x) will be the entry point for all proposals' submission to COVID-X Open Calls. Only proposals submitted within the Call duration will be accepted.

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Proposals submitted by any other means will not be considered nor evaluated. Only the documentation included in the application will be considered by evaluators. A complete proposal comprises 3 components:

- **Proposal Template,** an online application form, available at F6S platform (www.f6s.com/covid-x).
- **Proposal Supplement (Application Stage #2),** a word document providing information on proposal schedule, timing, Ethical & Security details.
    - If selected in the stage 2, the proposal supplement stage 2, required for the submission, will be shared with you.
- **Pitch deck template**, template for the pitch deck providing a very general list of slides with bullet points to explain the desired content.
    - If selected in the stage 2, the pitch deck template, required for the submission, will be shared with you:

Submissions will be done ONLY via the F6S platform on www.f6s.com/covid-x.

The application reception will close as indicated in **Section 4.1**. There will not be any deadline extensions unless there is a Force Majeure situation (e.g. a major problem caused by the F6S platform and not by the proposers, makes the system unavailable for a long period).

The length of the **Proposal Supplement (Application Stage #2)** is limited to 30 pages, excluding cover page.

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5 PROPOSAL EVALUATION AND SELECTION

5.1 PROPOSAL ELIGIBILITY CRITERIA

The following proposals eligibility criteria also apply:

i. Proposals must have a **clear European dimension,** and contribute towards European Union digitization, **targeting clear economic and societal impact**.

ii. **Each SME may submit only one (1) proposal at COVID-X Open Call #2. Multiple submissions are a disqualify factor**. In case an SME submit more than one proposal, all proposals that they have submitted will be automatically excluded from the evaluation process.

iii. **SMEs may participate in maximum one (1) accepted sub-project.** SMEs that have entered or have been invited to enter the COVID-X programme, even if they have not signed the contract for any reason, they are automatically excluded from participating in Open Call #2 even if they submit a different proposal.

iv. **SMEs may re-submit at Open Call #2 a proposal that has not entered Open Call #1.** However, it is mandatory to flag that this is a resubmission and clearly explain the improvements that they have made.

v. **Proposals from Linked SMEs[13] must demonstrate that there is no risk of double funding.** The fundamental principle underpinning the rules for public expenditure in the EU states that no costs for the same activity can be funded twice from the EU budget, as defined in the Article 111 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation. In the case of proposals submitted by linked SMEs, all must clearly state the differences between them including but not limited to, technical aspects, market strategy and team composition, so that it remains no doubt that there is no risk of double funding. To properly assess these concerns COVID-X may assign all proposals to the same set of evaluators and, should any doubt remain, exclude all proposals.

vi. **The maximum amount of direct funding that a SME may receive via COVID-X is 100.000 EUROs via any mean.**

vii. **The maximum amount of direct funding that a Healthcare provider may receive via COVID-X is 50.000 EUROs via any mean.**

5.2 APPLICATION STAGE 1

STEP 1. ELIGIBILITY CHECK

A manual filtering process will be held to discard non-eligible proposals will follow the checklist. Eligibility criteria check will verify:

a. The proposing entity is a legal entity eligible for EC funding under the rules of H2020 [Y/N]

b. The proposing entity is an SME as defined in section 3.1 “Definition of SME” [Y/N]

[13] Please check the definition of Linked SME at “User guide to the SME definition” available at LINK and include the relevant information in the document **SME Declaration.**

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c. The proposing entity is either a technology provider or technology adopter/user or provides innovation in the target areas of the project [Y/N]
d. Are the participation rules as expressed in section 3.2 “SME Eligibility” followed [Y/N]
e. In the case of Team Solutions is the consortium lead by an SME and the second element an Healthcare Provider [Y/N]
f. Is the participation rule as expressed in section 3.3 “Proposal Eligibility” followed [Y/N]
g. Is the proposal written in the English Language [Y/N]?
h. Are all required documentation: ***all the documents*** *submitted correctly (filled with text and using the dedicated templates)* [Y/N]

Proposals being marked as non-eligible will get a rejection letter including the reasons (a to h) for being catalogued as non-eligible. No further feedback on the process will be given.

STEP 2. INTERNAL EVALUATION

The goal of the Application Stage 1 is to filter the proposals that are aligned with the COVID-X project, meet the impact expected and are feasible in the time scope of the project.

The proposals that pass the eligibility check will move to Application Stage 1 evaluation, where an internal evaluation committee (see table 1) will evaluate the proposals according to the following criteria:

Table 7 Pre-Screening evaluation criteria

CRITERIA	DESCRIPTION	WEIGHT
EXCELLENCE	Projects must demonstrate a clear set of objectives aligned with the definition of the COVID-X OC and with the general objectives of the project. The Excellence is evaluated according to the following criteria: • Clarity and pertinence of the objectives. • Excellence, innovation and quality of the objectives. • The solution is data driven. • The TRL and CE marking is in the scope of the programme.	1/3
IMPLEMENTATION	The datasets required are available in the COVID-X Sandbox, the technical integration is feasible in the timeframe of the acceleration programme, and the draft of the implementation plan is realistic.	1/3
IMPACT	Proposals must demonstrate impact on the COVID-X ecosystem and its contribution to meeting the overall project objectives. The impact is evaluated according to the following criteria: • Strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global markets; and, where relevant, by delivering such innovations to the markets. • Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to	1/3

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	communicate the project, and to manage research data where relevant. • The viability of the proposed go to market strategy and business model	

Section "DEFINITION OF TERMS AND CONCEPTS", at the beginning of this document defines how Individual criteria will be scored and how the final score is computed.

The length **of the proposal supplement is limited to 10 pages**, excluding cover page. In the pre-screening stage the threshold for each criterion will be ***three (3) out of five (5)***, while the overall score threshold will be **eleven (11) out of fifteen (15).** Proposals that do not meet the minimum thresholds will be excluded from the acceleration programme.

STEP 3. RANKING AND SELECTION

At the end of the evaluation process all proposals will be ranked in a single list, independent of the topic(s) that it targets. The criteria for the ranking of the proposals will be semi-automatic following the rules below:

- **Rule 1:** The proposals will be ranked based on their overall score (sum of the criterion 1 to 3).
- **Rule 2:** In case following Rule 1 there are proposals in the same position, priority will be given to proposals that have higher Alignment (Criterion 1).
- **Rule 3:** In case following Rule 2 there are proposals in the same position, priority will be given to proposals that have higher Feasibility (Criterion 2).

In case following Rule 3 there are still proposals in the same position, and the position of on the rank allows places at least one on them in the short list for interview, the COVID-X will invite all the proposals in the same position to the second phase.

The indicative number of proposals to be invited to the Second Application Stage is three times higher to the number of projects to be funded via the Open Call #2 (as defined in Section 2). Depending on the number and quality of proposals received electable to move to the Application Stage 2, COVID-X consortium may adjust the number of proposals invited to present proposal at this stage. The eligible applicants are invited with a message on 30.7.2021 to submit their application in the Application Stage 2.

5.3 APPLICATION STAGE 2

PLEASE, BE AWARE THAT THIS SECTION IS ONLY APPLICABLE FOR STAGE 2 PROPOSALS. ONLY COMPANIES THAT HAVE PASSED THE FIRST STAGE WILL BE INVITED TO SUBMIT THE STAGE 2 PROPOSAL.

STEP 1. PROPOSAL RECEPTION

Submissions will be done ONLY via the F6S platform (on www.f6s.com/covid-x). A full list of proposers will be drafted containing their basic information for statistical purposes and clarity (which will be also shared with the EC for transparency).

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The application reception will close as indicated in section 4.1. There will not be any deadline extensions unless there is a Force Majeure situation (e.g. a major problem caused by the F6S platform and not by the proposers, makes the system unavailable for a long period).

The length **of the proposal supplement is limited to 30 pages**, excluding cover. **The length of the project pitch deck is limited to 10 slides**, excluding cover. Please note that the template for the **proposal supplement** specifies page limits per section.

STEP 2. EXTERNAL REMOTE EVALUATION

An external evaluation board with experience in the health domain, technologies and business development will review each proposal, scoring them based on the following criteria:

Table 8 External Remote Evaluation Criteria

CRITERIA	DESCRIPTION	WEIGHT
EXCELLENCE	Projects must demonstrate a clear set of objectives aligned with the definition of the COVID-X OC and with the general objectives of the project. The Excellence is evaluated according to the following criteria: ● Clarity and pertinence of the objectives; ● Excellence, innovation and quality of the objectives. ● The solution is data driven. ● The TRL and CE marking is in the scope of the programme	1/3
IMPACT	Applicants must define a clear set of deliverables aligned with the objectives of the OC. Proposals must demonstrate impact on the COVID-X ecosystem and its contribution to meeting the overall project objectives. The impact is evaluated according to the following criteria: ● Strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global markets; and, where relevant, by delivering such innovations to the markets; ● Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant. ● the viability of the proposed business model; readiness to present to investors & corporates	1/3
IMPLEMENTATION	Applicants must provide credible evidence that the project delivery team has the necessary skills, infrastructure and management experience to be able to deliver the project in the timeframe of the acceleration programme. The quality and the efficiency of the implementation will be evaluated according to the following criteria: ● Coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks and resources, justification of resources; ● Describe the solution specification and testing, piloting/ deployment steps that they aim to implement and consequently its value/benefit for the industry;	1/3

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CRITERIA	DESCRIPTION	WEIGHT
	● Appropriateness of the skills and experience of the project delivery team.	

Section "DEFINITION OF TERMS AND CONCEPTS" at the beginning of this document defines how Individual criteria will be scored and how the final score is computed.

The threshold for each criterion will be be ***three (3) out of five(5)***, while the overall score threshold will be **eleven (11) out of fifteen(15).** Each evaluator will record his/her individual opinion of each proposal on an Individual Evaluation Report. They will then communicate to prepare a single consensus Evaluation Summary Report (ESR) for each proposal, representing opinions and scores on which the evaluators agree and which they will sign.

STEP 3. INTERMEDIATE RANKING AND SELECTION

At the end of the evaluation process all proposals will be ranked in a single list, independent of the topic(s) that it targets. The criteria for the ranking of the proposals will be semi-automatic following the rules below:

- **Rule 1:** The proposals will be ranked based on their overall score (sum of the criterion 1 to 3).
- **Rule 2:** In case following Rule 1 there are proposals in the same position, priority will be given to proposals that have higher impact (Criterion 2).

In case following Rule 2 there are still proposals in the same position, and the position of on the rank allows places at least one on them in the short list for interview, the COVID-X will invite all the proposals in the same position to the interview process.

STEP 4. ONLINE INTERVIEW

The top-ranked projects of the external remote evaluation will be invited to an online interview, which aims to deeply understand project concept, team skills & competence, capacity and willingness to exploit the results. The indicative number of proposals to be invited to the online interview is two times higher to the number of projects to be funded via the Open Call #2 (as defined in Section 2).

The interview may take 30 minutes. If the evaluation committee needs, the interview may be extended. Applicants will make a pitch presentation of the project of up to 10 minutes and answer questions from the panel during the remaining time.

The interviews will be carried out by an internal evaluation committee (see table 1) and will evaluate the following criteria:

Table 9 Online Interview Evaluation Criteria

CRITERIA	DESCRIPTION	WEIGHT
EXCELLENCE	Same definition of point 4.2.6	1/4
IMPACT	Same definition of point 4.2.6	1/4

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IMPLEMENTATION	Same definition of point 4.2.6	1/4
TEAM	Quality of the team and benefit that the team can extract from the acceleration programme	1/4

Section "DEFINITION OF TERMS AND CONCEPTS" at the beginning of this document defines how Individual criteria will be scored and how the final score is computed.

As the purpose of the interview is to clarify comments from the External Experts, the scores of the interview will replace the scores provided by the external experts in criteria Excellence, Impact and Implementation.

The threshold for each criterion will be ***four (4) out of five (5)***, while the overall score threshold will be **fourteen (14) out of twenty (20).**

If during interview applicants do not commit to what has been presented in application form, these will be rejected. If after the interview the evaluation panel still has doubts the team may be requested to answer additional questions in writing.

STEP 5. CONSENSUS MEETING MATCHMAKING

After the interview's, evaluators will gather to discuss the evaluated proposal, to generate a common scoring, to report the evaluation as well as allocate single solutions to the COVID-X healthcare providers.

The allocation of single solutions to healthcare providers will be made using the following process:

1. Proposals will be ranked according to the overall score of the online interview.
2. Starting from the top, single solutions will be matched with the healthcare providers in the order provided in the application form by each applicant.
3. If single solution proposal cannot be assigned to a healthcare provider because the capacity of healthcare providers is allocated the proposal is rejected.
4. The process follows until all available slots in healthcare providers are occupied or there are no more single solutions eligible to be allocated.

One the Single Solutions are selected, the budget available for the team solutions is reassessed eventually increasing the indicative number of team solutions to be funded in the first acceleration programme. **The consortium will select the top team solutions from the list until the budget available is allocated.**

Notes:

When the consortium needs to untie scores of proposals to decide which will be funded the following rules will apply:

1. The proposal with highest score in the team criteria of the online interview phase will be selected.
2. The proposal with highest score in the team business criteria of the online interview phase will be selected.
3. The proposal with highest score in the overall evaluation of the external evaluation phase will be selected.
4. The proposal with highest score in the team impact criteria of the external evaluation phase will be selected.

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5. The proposal with highest score in the team impact implementation of the external evaluation will be selected.
6. The internal committee will convene and decide between the tied proposals to select which one will be selected.

This phase is taking place after the interviews are conducted, during the second half of October.

STEP 6. RANKING OF THE PROPOSAL, SELECTION AND GRANT AGREEMENT INVITATION

After the Open Call evaluation conclusion and projects selection, the COVID-X coordinator will start the contract preparation in collaboration with the proposals' coordinator that have been evaluated in the short list. The Contract preparation will go via an administrative and financial checking (and potentially into technical or ethical/security negotiations) based on the evaluators' comments. On a case-by-case approach, a phone call or teleconference may be needed for clarification.

The objective of the contract preparation is fulfilling the legal requirements between COVID-X consortium and every beneficiary of the call. The items covered will be:

- Inclusion of the comments (if any) in the Evaluation Summary Report of the proposals and mapping to the Sub-grant agreement (contract).
- To validate the status information of the SME, the following documents will be required:
    - **SMEs declaration:** signed and stamped. In the event the applicant declares being non-autonomous, the balance sheet and profit and loss account (with annexes) for the last period for upstream and downstream organizations should also be provided.
    - **Status Information Form**. In case this is not a start-up, it includes the headcount (AWU), balance, profit & loss accounts of the latest closed financial year and the relation, upstream and downstream, of any linked or partner company. In case it is a start-up, legal document of the official founding date.
    - **Legal existence**. Company Register, Official Gazette or other official document per country showing the name of the organisation, the legal address and registration number and a copy of a document proving VAT registration (in case the VAT number does not show on the registration extract or its equivalent).
    - In cases where the **number of employees and/or the ownership is not clearly identified**: any other supporting documents which demonstrate headcount and ownership such as payroll details, annual reports, national regional association records, etc. In case it is a start-up, legal document of the official founding date and declaration of ownership.
    - **SME Bank account information:** The account where the funds will be transferred will be indicated via a form signed by the SME legal representative and the bank representative. The account should be a business bank account of the SME. For information, you can consult an example of the Bank Account information form to be provided: https://rebrand.ly/COVID-X_OC2_Bank_account_form

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It should be emphasised that each **SME should provide at contract preparation time a valid VAT[14] and PIC[15]. Failure to provide the VAT number and PIC Number will automatically result in proposal rejection**.

The request, by COVID-X consortium, of the above documentation will be done including deadlines. In general, the sub-project negotiation should be concluded within 2 weeks. An additional week may be provided by the COVID-X coordinator in case of a significant reasoning. In case negotiations have not been concluded within the above period, the proposal is automatically rejected and the next proposal in the reserve list is invited.

At the end of the negotiation phase, the **sub-grantee funding agreement** will be signed between the COVID-X Consortium represented by its coordinator (F6S) and the Budget Holder (UPM) and the beneficiary SME.

Please note that the sub-grantee funding agreement/contract will cover the complete programme.

For information, you can consult an example of the sub-grantee funding agreement:
https://rebrand.ly/COVID-X_OC2_Sub_grant_agreement_template

5.4 REDRESS PROCESS

Within 3 working days of the delivery of a rejection letter considering the proposal as non-eligible or an ESR that ranks the proposal below the selection borderline, the proposer may submit a request for redress if s/he believes the results of the eligibility checks have not been correctly applied, or if s/he feels that there has been a shortcoming in the way his/her proposal has been evaluated that may affect the final decision on whether to enter the Acceleration programme or not.

In that case, an internal review committee of the COVID-X consortium will examine the request for redress. The committee's role is to ensure a coherent interpretation of such requests, and equal treatment of applicants.

Requests must be:

- Related to the evaluation process or eligibility checks.
- Clearly describe the complaint.
- Received within the time limit (3 working days) from the reception of a rejection letter considering the proposal as non-eligible or the ESR information letter delivered.
- Sent by the SME legal representative that has also submitted the proposal.

The committee will review the complaint and will recommend an appropriate course of action. If there is clear evidence of a shortcoming that could affect the eventual funding decision, it is possible that all or part of the proposal will be re-evaluated.

Please note:

[14] To be checked at European Commission services such as LINK
[15] To be checked at the European Commission services at LINK

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- This procedure is concerned only with the evaluation and/or eligibility checking process. The committee will not call into question the scientific or technical judgement of appropriately qualified experts.
- A re-evaluation will only be carried out if there is evidence of a shortcoming that affects the final decision on whether to fund it or not. This means, for example, that a problem relating to one evaluation criterion will not lead to a re-evaluation if a proposal has failed anyway on other criteria.
- The evaluation score following any re-evaluation will be regarded as definitive. It may be lower than the original score.

Only one request for redress per proposal will be considered by the committee. All requests for redress will be treated in confidence and must be sent to Project Coordinator via the F6S platform.

In case a proposal under the redress procedure is re-evaluated and the new evaluation score is higher, it will be compared with the proposal that has entered the acceleration programme with the lowest ranking. The comparison will use the ranking rules as expressed in section 5.3 (Step 5). In case the proposal under the redress procedure ranks higher then both proposals will be invited to enter the acceleration phase.

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6 RESPONSIBILITIES OF BENEFICIARIES

The selected SMEs are indirectly beneficiaries of European Commission funding. As such, they are responsible for the proper use of the funding and ensure that the recipients comply with obligations under H2020 specific requirements as described in Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) [1] The obligations that are applicable to the recipients include[16]:

6.1 CONFLICT OF INTEREST

Beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the sub-project is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('conflict of interests').

They must formally notify to the COVID-X coordinator without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation. The COVID-X coordinator may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

If the sub-contract consortium member breaches any of its obligations, the sub-contract may be automatically terminated. Moreover, costs may be rejected.

6.2 DATA PROTECTION & CONFIDENTIALITY

During implementation of the sub-project and for four years after the end of the sub-project, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at sub-contract signing time ('confidential information').

If a beneficiary SME requests, the Commission and the COVID-X consortium may agree to keep such information confidential for an additional period beyond the initial four years. This will be explicitly stated at the sub-contract.

If information has been identified as confidential during the sub-project execution or only orally, it will be confidential only if this is accepted by the COVID-X coordinator and confirmed in writing within 15 days of the oral disclosure. Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The sub-project consortium may disclose confidential information to the COVID-X consortium and to the selected reviewers, who will be bounded by a specific Non-Disclosure Agreement.

[16] The obligations described here are not binding and may be modified, refined or additional obligations may be inserted during the sub-project negotiation if needed.

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6.3 PROMOTING THE ACTION AND GIVE VISIBILITY TO THE EU FUNDING

The beneficiary SMEs must promote the sub-project, the COVID-X project and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner and to highlight the financial support of the EC. The COVID-X Communication team will guide and support these communication activities.

Unless the European Commission or the COVID-X coordinator requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.), any publicity, including at a conference or seminar or any type of information or promotional material (brochure, leaflet, poster, presentation etc.), and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem;

(b) display the COVID-X logo and

(c) include the following text:

For communication activities: *"This project has indirectly received funding from the* European Union's Horizon 2020 research and innovation programme *under project COVID-X (grant agreement No 101016065)".*

For infrastructure, equipment and major results: *"This [infrastructure][equipment][insert type of result] is part of a sub-project that has indirectly received funding from the* European Union's Horizon 2020 research and innovation programme *under project COVID-X (grant agreement No 101016065)".*

When displayed in association with a logo, the European emblem should be given appropriate prominence. This obligation to use the European emblem in respect of projects to which the EC contributes implies no right of exclusive use. It is subject to general third-party use restrictions which do not permit the appropriation of the emblem, or of any similar trademark or logo, whether by registration or by any other means. Under these conditions, the Beneficiary is exempted from the obligation to obtain prior permission from the EC to use the emblem. Further detailed information on the EU emblem can be found on the Europa web page.

Any publicity made by the beneficiary SME in respect of the project, in whatever form and on or by whatever medium, must specify that it reflects only the author's views and that the EC or COVID-X project is not liable for any use that may be made of the information contained therein.

The EC and the COVID-X consortium shall be authorised to publish, in whatever form and on or by whatever medium, the following information:

- the name of the beneficiary SME;
- contact address of the beneficiary SME;
- the general purpose of the project;

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- the amount of the financial contribution foreseen for the project; after the final payment, and the amount of the financial contribution actually received;
- the geographic location of the activities carried out;
- the list of dissemination activities and/or of patent (applications) relating to foreground;
- the details/references and the abstracts of scientific publications relating to foreground and, if funded within the sub-project, the published version or the final manuscript accepted for publication;
- the publishable reports submitted to COVID-X;
- any picture or any audio-visual or web material provided to the EC and COVID-X in the framework of the project.

The beneficiary SME shall ensure that all necessary authorisations for such publication have been obtained and that the publication of the information by the EC and COVID-X does not infringe any rights of third parties.

Upon a duly substantiated request by the sub-project coordinator on behalf of any sub-project member, the COVID-X, if such permission is provided by the EC, may agree to forego such publicity if disclosure of the information indicated above would risk compromising the beneficiary's security, academic or commercial interests.

6.4 FINANCIAL AUDITS AND CONTROLS

The European Commission (EC) will monitor that COVID-X beneficiaries and the beneficiary SME comply with the conditions for financial support to third parties set out in Annex 1 of the COVID-X grant agreement and may take any action foreseen by the grant agreement in case of non-compliance vis à vis the beneficiary concerned.

Moreover, the EC may at any time during the implementation of the COVID-X project and up to 5 (five) years after the end of the COVID-X project, arrange for financial audits to be carried out, by external auditors, or by the EC services themselves including the European Anti-Fraud office (OLAF). The audit procedure shall be deemed to be initiated on the date of receipt of the relevant letter sent by the EC. Such audits may cover financial, systemic and other aspects (such as accounting and management principles) relating to the proper execution of the grant agreement. They shall be carried out on a confidential basis.

The beneficiary SME shall make available directly to the EC all detailed information and data that may be requested by the EC or any representative authorised by it, with a view to verifying that the grant agreement is properly managed and performed in accordance with its provisions and that costs have been charged in compliance with it. This information and data must be precise, complete and effective.

The beneficiary SME shall keep all sub-project deliverables and the originals or, in exceptional cases, duly authenticated copies – including electronic copies – of all documents relating to the sub-project contract for up to five years from the end of the project. These shall be made available to the EC where requested during any audit under the grant agreement.

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To carry out these audits, the beneficiary SME shall ensure that the EC´s services and any external body(ies) authorised by it have on-the-spot access at all reasonable times, notably to the sub-project applicant offices, to its computer data, to its accounting data and to all the information needed to carry out those audits, including information on individual salaries of persons involved in the project. They shall ensure that the information is readily available on the spot at the moment of the audit and, if so requested, that data be handed over in an appropriate form.

On the basis of the findings made during the financial audit, a provisional report shall be drawn up. It shall be sent by the EC or its authorised representative to the beneficiary concerned, which may make observations thereon within one month of receiving it. The Commission may decide not to consider observations conveyed or documents sent after that deadline. The final report shall be sent to the beneficiary concerned within two months of expiry of the aforesaid deadline.

On the basis of the conclusions of the audit, the EC shall take all appropriate measures which it considers necessary, including the issuing of recovery orders regarding all or part of the payments made by it and the application of any applicable sanction.

The European Court of Auditors shall have the same rights as the EC, notably right of access, for the purpose of checks and audits, without prejudice to its own rules.

In addition, the EC may carry out on-the-spot checks and inspections in accordance with 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.

6.5 INTERNAL COMMUNICATION

The coordinator of the solution should:

- Provide any notice be in writing to the COVID-X project coordinator;
- Notify immediately any change of persons or contact details to the COVID-X coordinator. The address list shall be accessible to all concerned.

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7 CHECKLIST FOR APPLICATION SUBMISSION

1) **Does your planned work fit with the call for proposals?** Check that your proposed work does indeed address one of the topics open in this call.
2) **Does your proposal address data solutions and artificial intelligence technology?** Check that your proposed work does indeed address the domains of the call in one of the challenges.
3) **Is your proposal eligible?** The eligibility criteria are given in chapter 3 "Proposal Eligibility Criteria". In particular, make sure that you satisfy the minimum participation requirements (entity from eligible countries).
4) **Is your proposal complete?** Have you completed all mandatory questions?
5) **Does your proposal fulfil questions requests/ comments?** Proposals should be precise, concise and must answer to requested questions, which are designed to correspond to the applied evaluation. Omitting requested information will almost certainly lead to lower scores and possible rejection.
6) **Have you maximised your chances?** There will be strong competition. Therefore, edit your proposal tightly, strengthen or eliminate weak points.
7) **Have you submitted your proposal before the deadline?** It is strongly recommended not to wait until the last minute to submit the proposal. Failure of the proposal to arrive in time for any reason, including network communications delays, is not acceptable as an extenuating circumstance. The time of receipt of the message as recorded by the submission system will be definitive.
8) **Have you provided the necessary documents?**
    - Application Stage #1 documents required: Online form on F6S; Proposal Supplement (Application Stage #1 – 10 pages); Honour Declaration (a dedicated version for each partner if a Team solution); and, SME Declaration.
    - Application Stage #2 documents required: Online form on F6S; Proposal Supplement (Application Stage #2 – 30 pages); and, Project pitch Deck.
9) **Do you need further advice and support?** You are strongly advised to communicate with the COVID-X team via the COVID-X blog in the F6S platform and via info@covid-x.eu .

Do not forget that it is mandatory the applicant SME to have a valid VAT number and PIC number during contract preparation time.

8 CONTACTS

The COVID-X consortium will provide information to the applicants only via the F6S blog, so that the information (question and answer), will be visible to all participants.

- More info at: https://covid-x.eu/
- Apply via: https://www.f6s.com/covid-x-open-call-2-stage-1/apply
- F6S support team: support@f6s.com
- Online Q&A: https://www.f6s.com/covid-x/discuss
- To contact the COVID-X consortium: info@covid-x.eu .

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9 ADDITIONAL INFORMATION

9.1 COVID-X ACCELERATION PROGRAMME

This programme includes 4 key phases:

- The onboarding phase preparing the start of the of the programme;
- Three sprints from Sprint 1 to Sprint 3.

9.1.1 ONBOARDING PHASE

After the proposal has been accepted, the Beneficiary will start the onboarding process. The goal of this phase is to prepare the work to be performed during the acceleration programme. Three processes need to be carried out in parallel:

- Contract Preparation and signature.
- Acceleration services tailoring: The Beneficiary and the consortium will identify from the pool of services the ones that will be more relevant to achieve the project goals and design a personalized acceleration programme.
- Submission of the full ethics application to the relevant Ethical Committee including the study protocol: The beneficiary must prepare and submit the research protocol for approval by the relevant Ethical Committee documents as soon as possible and later than the 1st month (M1) of the programme.

During the onboarding phase, each onboarded solution will be assigned at least one mentor. The mentor will communicate with the project team on a regular basis to overview the progress and to provide technical or business advice.

The COVID-X programme requires the meetings to be held once every two weeks. Mentors and teams will decide the schedule and agenda for the meetings.

9.1.2 SPRINT 1

Starting in November 2021, it has the duration of 3 months. The completion of the onboarding phase is desirable as delays will impact but not prevent the success of the project, and the possibility of releasing funds to the beneficiary in the expected timeframes.

Project implementation will start in M01. The duration of this sub-phase will be approximately 3 months, covering project months M1 to M3.

The project must complete the work defined in the work plan provided in the Proposal Supplement (Application Stage #2) for this period. Moreover, during the first sprint, the SME must participate in various teaching webinars and/or bootcamp events to extend their knowledge on the COVID-X domains and commercialization/business training.

The generic goals of Sprint 1 are:

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- Define the KPIs to be used in project monitoring (KPIs definition milestone): The Beneficiary with support from the mentor will create D1 Project KPIs to be submitted until the end of M01 of the acceleration programme. The basis for the KPIs is the information included in the implementation section of the proposal. The mentor will provide guidance but is not responsible for the deliverable.
- Complete the technical integration with the COVID-X Sandbox.
- Get approval from the Ethical Committee. This may depend on your country-specific laws.

The specific goals of Sprint 1, as well as the initial KPIs to be used to monitor the project should be defined by the Beneficiary in the implementation section of the proposal.

9.1.2.1 SPRINT 1: EVALUATION

During the first sprint there will be two evaluation stages:

KPIS EVALUATION

At the end of sub-project's month (M01), a remote review will take place to evaluate the definition of the KPIs. One week before the review, the sub-project coordinator should submit deliverable ***D1: KPIs definition***.

The review will be performed by an Internal evaluation committee via a teleconference platform (e.g. Skype or WebEx). The sub-project will make a short presentation of the KPIs.

After the review, the sub-project coordinator will receive a review report, including comments and potential recommendations. The report will also state if the D1 is accepted or not.

- On acceptance of the D1 Deliverable, the sub-project coordinator will be requested to submit a payment request document (template will be provided) requesting the intermediate voucher of 10% of the grant.
- On rejection of the D1 Deliverable, or in case of not satisfactory review, the sub-project coordinator will be requested to resubmit the deliverable, payment will not be made.

1st SPRINT EVALUATION

At the end of month M3, a remote review will take place to evaluate the project progress. One week before the review, the solution leader should submit the deliverable D2 Presentation and Technical report of sprint 1.

The review will be performed by an Internal evaluation committee via a teleconference platform (e.g. Skype or WebEx). The solution leader will make a short presentation of the progress.

After the review, the sub-project coordinator will receive a review report, including comments and potential recommendations. The report will also state if the D2 is accepted or not.

- On acceptance of the D2 Deliverable, the sub-project coordinator will be requested to submit a payment request document (template will be provided) requesting the intermediate voucher of 30% of the grant.

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- On rejection of the D2 Deliverable, or in case of not satisfactory review, the sub-project coordinator will be requested to resubmit the deliverable, payment will not be made. The sub-project must continue project implementation.

9.1.3 SPRINT 2

Sprint 2 starts after successful completion of Sprint 1 and has the duration of 3 months. The project must complete the work defined in the work plan provided in the Proposal Supplement (Application Stage #2) for this period as well as address comments from the reviewers.

During this sprint, the SME must participate in various teaching webinars and/or bootcamp events to extend their knowledge on the COVID-X domains and commercialization/business training. Additionally, the Beneficiary may need to attend one physical event in Europe.

The generic goals of Sprint 2 are:

- Validation of the Data Model. since your solution is mainly data-driven, we expect that you finalize and validate your data-model by the end of sprint 2.
- Agreement on IP. Even the agreement on IP should be addressed in Sprint2 (or before).

The specific goals of Sprint 2 should be defined by the Beneficiary in the implementation section of the proposal.

9.1.3.1 STEP 2.2 SPRINT 2 EVALUATION

At the end of sub-project month M6, a review will take place to evaluate the project progress. The review will be preferably face to face in a venue to be announced. One week before the review, the solution leader should submit the deliverable D3 Presentation and Technical report of sprint 2.

In the case the review cannot be physical, it will be performed by an Internal evaluation committee via a teleconference platform (e.g. Skype or WebEx). The solution leader will make a short presentation of the progress. The solution leader will make a short presentation of the progress.

After the review, the sub-project coordinator will receive a review report, including comments and potential recommendations. The report will also state if the D3 is accepted or not.

- On acceptance of the D3 Deliverable, the sub-project coordinator will be requested to submit a payment request document (template will be provided) requesting the intermediate voucher of 30% of the grant.
- On rejection of the D3 Deliverable, or in case of not satisfactory review, the sub-project coordinator will be requested to resubmit the deliverable, payment will not be made. The sub-project must continue project implementation.

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9.1.4 SPRINT 3

Sprint 3 starts after successful completion of Sprint 2 and has the duration of 3 months. The project must complete the work defined in the work plan provided in the Proposal Supplement (Application Stage #2) for this period as well as address comments from the reviewers.

During this sub-phase, the SME must participate in various teaching webinars and/or bootcamp events to extend their knowledge on the COVID-X domains and commercialization/business training. Additionally, the Beneficiary may need to attend one physical event in Europe.

The generic goals of Sprint 3 are:

- Full validation of the product -- this means that by the end of Sprint 3 the validation of your solution is accomplished and that you have completed the journey in the Covid-X programme.
- Completion of the feasibility study – this means an overview of the work done and the results for the main actions described in the proposal (e.g. market study, freedom to operate, technical tests). This document should include the conclusion of the action, i.e. an updated status of the business idea that was described in the application.

The specific goals of Sprint 3 should be defined by the Beneficiary in the implementation section of the proposal.

9.1.4.1 STEP 3.2 SPRINT 3 EVALUATION

At the end of sub-project month M9, a review will take place to evaluate the project progress. The review will be preferably face to face in a venue to be announced. One week before the review, the sub-project coordinator should submit the deliverable D4 Presentation and Technical report of sprint 3.

In the case the review cannot be physical, it will be performed by an Internal evaluation committee via a teleconference platform (e.g. Skype or WebEx). The solution leader will make a short presentation of the progress. The solution leader will make a short presentation of the progress.

After the review, the sub-project coordinator will receive a review report, including comments and potential recommendations. The report will also state if the D4 is accepted or not.

- On acceptance of the D4 Deliverable, the sub-project coordinator will be requested to submit a payment request document (template will be provided) requesting the intermediate voucher of 30% of the grant.
- On rejection of the D4 Deliverable, or in case of not satisfactory review, the sub-project coordinator will be requested to resubmit the deliverable, payment will not be made. The sub-project must continue project implementation.

9.2 EVALUATION SUMMARY

Each project will go through 5 evaluations, each one highlighting the end of a phase.

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Table 10 Project evaluations

Evaluation 1			
When	Open Call #2	Estimated project month	Before project start
Mean	Proposal submission		
If successful	The company signs the contract and enters the programme phase		
Evaluation 2			
When	COVID-X KPIs definition	Estimated project month	End of M1
Mean	Deliverable D1 KPIs definition.		
If successful	The beneficiary receives 10K€ (SMES) or 5K€ (Healthcare providers) of the budget as lump sum.		
Evaluation 3			
When	Remote Review	Estimated project month	End of M3
Mean	Deliverable D2: Sprint 1 Technical report and presentation		
If successful	The beneficiary receives 30K€ (SMES) or 15K€ (Healthcare providers) of the budget as lump sum.		
Evaluation 4			
When	Physical or remote review	Estimated project month	End of M6
Mean	Deliverable D3: Sprint 2 Technical report and presentation		
If successful	The beneficiary receives 30K€ (SMES) or 15K€ (Healthcare providers) of the budget as lump sum.		
Evaluation 5			
When	Physical or remote review	Estimated project month	End of M9
Mean	Deliverable D4: Sprint 3 Technical report and presentation		
If successful	The beneficiary receives 30K€ (SMES) or 15K€ (Healthcare providers) of the budget as lump sum.		

The sub-project coordinator should deliver at least one (1) week in advance all relevant deliverables, so that the reviewers will be able to be prepared. During the review, the sub-project members should present their work, answer questions, and demonstrate their experiment.

After each successful evaluation and within **5 working days**, the sub-project coordinator should send the relevant payment request document to the coordinator. Additional conditions and eligibility criteria have already been described in the previous sections.

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9.3 ACCELERATION PROGRAMME DELIVERABLES

The following subsection defines the deliverables already planned as part of the acceleration programme. Beneficiaries may be required to provide additional data to monitor project implementation.

Table 11 Definitions of Acceleration programme deliverables

TERM / EXPRESSION	DEFINITION
D1. KPIs Definition	Deliverable where the KPIs proposed in the application stage are refined, agreed with the mentor, and approved by the consortium. The KPIs will be the tool to assess project performance and must be reported to the mentor.
D2. Sprint 1 Technical report and presentation	Evaluation materials to be provided by the beneficiary to the consortium at the end of each sprint. The report and the presentation will be used by the internal evaluation committee to assess project progress.
D3. Sprint 2 Technical report and presentation	
D4. Sprint 3 Technical report and presentation including the feasibility study	
Full ethics application	Clinical partners usually require the definition of a research protocol (document that describes the project) and the approval of a local Ethical Committee before starting a research with a third party. The Ethical Committee verifies the ethical, formal compliance and feasibility of the study before giving an approval, rejection or request of clarification/amendments.

10 COVID-X EVENTS

COVID-X will organise physical events in Europe to the teams involved. The events will be compulsory to attend in person. At least one representative per team will be required on each event, although it is strongly advised that at least two people attend.

Failing to attend any of the mandatory events defined at the beginning of each phase by COVID-X will automatically disqualify the team from COVID-X programme.

The foreseen events are:

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Table 12 List of programme events

EVENT	SCOPE	WHERE	WHEN	DURATION	MANDATORY
Sprint 2 mid-term event	Business mentoring and/or demo session	TBD	M4 or M5	2 days	Yes
Sprint 2 evaluation	Evaluation of Sprint 2	TBD	End of M6	2 days	Yes
Sprint 3 mid-term event	Business mentoring and/or demo session	TBD	M7 or M8	2 days	Yes
Sprint 3 evaluation & demo day	Evaluation of Sprint 3 and demo day	TBD	End of M9	3 days	Yes

Please note that the locations and dates at the above table are indicative and not binding. They may be modified during the execution of the program.

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11 REFERENCES

[1] Digital Innovation Initiatives based on European Networks of Competence Centres in H2020, available online at https://smartanythingeverywhere.eu/smart-anything-everywhere/

[2] REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

[3] EUROPEAN COMMISSION, Directorate-General for Communications Networks, Content and Technology, "Guidance note on financial support to third parties under H2020", Annex K. "Actions involving financial support to third parties",

http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-k-fs3p_en.pdf

[4] H2020 Call Objective ICT-04-2017 TOPIC: Smart Anything Everywhere Initiative, https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/ict-04-2017.html

[5] Medical Device EU Regulation - Regulation (EU) 2017/745 - Regulation (EU) 2017/746 - Regulation 2020/561 https://ec.europa.eu/health/md_sector/new_regulations_en

[6] Guidance on Qualitification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR: https://ec.europa.eu/health/sites/default/files/md_topics-interest/docs/md_mdcg_2019_11_guidance_en.pdf

[7] Is your Software a Medical Device, Author: European Commission https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_mdsw_en.pdf

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