Deliverable D8.1

Project Management Handbook

Project Title	BeYond COVID Grant Agreement 101046203
Project Acronym (EC Call)	BY-COVID
WP No & Title	WP8: Coordination, Project Management and Ethical, Legal and Social implications
WP Leaders	Andrea Troncoso, ELIXIR; Juan Arenas, ELIXIR
Deliverable Lead Beneficiary	1 EMBL - EBI/ELIXIR
Contractual delivery date	30/11/2021
Actual Delivery date	30/11/2021
Delayed	No. We uploaded it in March because the Grant Agreement Preparation took until now. The Deliverable was ready on time.
Partner(s) contributing to this deliverable	EMPIRICA
Authors	Andrea Troncoso, Juan Arenas, Nikki Coutts
Contributors	Katharina Lauer, Meropi Papagheorghe, Friederike Schmidt-Tremmel

Acknowledgements (not grant participants)	-----------
Reviewers	BY-COVID Management Board

Log of changes

Date	Mvm	Who	Description
08/11/2021	V1	Andrea Troncoso	Draft version to empirica
22/11/2021	V2	Andrea Troncoso	Draft version to Management Board

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1. Executive Summary

"Coming together is a beginning; keeping together is progress and working together is success"

-Henry Ford

The Project Handbook provides a complete overview of the management and administrative procedures and principles to ensure an efficient execution of the BY-COVID project, thus contributing to the production of high quality project results. It contains all relevant planning information that the consortium partners will use as a framework for delivery during the course of the project, therefore, it is the point of reference for all consortium partners and stakeholders.

The Project Handbook documents the selected approach for implementing the project goals, including the milestones, deliverables and relevant KPIs. It also highlights the key controlling processes to be used, the project policies and rules, and the overall management approach, including, but not limited to management structure, tasks, decision-making procedures, responsibilities and roles. Language adopted throughout the documents aims to be clear and concise.

The Project Handbook is kept up to date throughout the life of the project through annual revisions.

This is a guidance document. It should not be relied upon for making any legal assessments, for which Beneficiaries should always refer to the Grant Agreement (including its annexes)[1] and the Consortium Agreement[2].

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[1] As of the time of this deliverable submission, the BY-COVID Grant Agreement is under preparation.

[2] As of the time of this deliverable submission, the BY-COVID Consortium Agreement is under development.

2. Contribution towards project objectives

The project handbook defines the project process that provides the framework to accomplish all projects objectives within the scope, budget and the required level of quality, therefore, we can say with confidence that this deliverable contributes to all objectives as listed below:

	Key Result No and description	Contributed
Objective 1 Enable storage, sharing, access, analysis and processing of research data and other digital research objects from outbreak research.	1. A research data management practice in European research infrastructures practice that drives discovery, access and reuse of outbreak data and directly links experimental data from HORIZON-INFRA-2021-EMERGENCY-02 transnational access projects into the COVID-19 Data Portal.	Yes
	2. Workflows and processing pipelines that integrate transparent quality management and provenance and are openly shared.	Yes
	3. Research infrastructures on-target training so that users can exploit the platform.	Yes
	4. Engagement so that stakeholders (RI, national centres, policy makers, intergovernmental organisations, funders and end-users) incorporate FAIR and open data in infectious disease guidelines and forward planning.	Yes
Objective 2 Mobilise and expose viral and human infectious disease data from national centres.	1. A comprehensive registry of available data with established procedures to collate data governance models, metadata descriptions and access mechanisms in a pandemic scenario.	Yes
	2. Mechanisms for the initial discovery across data sources based on available metadata at the reference collection.	Yes
	3. Demonstrated transnational linking of real-world data from national surveillance, healthcare, registries and social science data that allow the assessment of variants	Yes

	to serve the research needs of epidemiology and public health.	
	4. Demonstrated assessment of emerging SARS-CoV-2 variants against data generated in the on-going European VACCELERATE clinical trials project to investigate vaccine efficacy.	Yes
Objective 3 Link FAIR data and metadata on SARS-CoV-2 and COVID-19	1. A platform that links normative pathogen genomes and variant representations to research cohorts and mechanistic studies to understand the biomolecular determinants of variant response on patient susceptibility, and disease pathways.	Yes
	2. An open and extensible metadata framework adopted cross-domain that supports comprehensive indexing of the infectious disease resources based on mappings across resources and research domains.	Yes
	3. A provenance framework for researchers and policy-makers that enables trust in results and credit to data submitters, workflow contributors and participant resources.	Yes
Objective 4 Develop digital tools and data analytics for pandemic and outbreak preparedness, including tracking genomics variations of SARS-CoV-2 and identifying new variants of concern.	1. Broad uptake of viral *Data Hubs* across Europe deliver an order-of-magnitude increase in open viral variant detection and sharing.	Yes
	2. Infrastructure and quality workflows mobilised and shared to produce open, normative variant data that is incorporated into national and regional data systems and decision making.	Yes

Objective 5 Contribute to the Horizon Europe European Open Science Cloud (EOSC) Partnership and European Health Data Space (EHDS).	1. Guidelines and procedures for FAIR data management and access will be established, building on work of other guideline producing consortia such as the Global Alliance for Genomics and Health (GA4GH), the 1Mio Genomes Initiative (1MG) and the Beyond One Million Genomes project (B1MG).	Yes
	2. Services, software, protocols, guidelines and other research objects that are openly accessible for reuse by the EOSC Association and the community at large as a foundation for European preparedness for infectious diseases, leveraging developments in EOSC-Life, SSHOC, EOSC-Future, EGI-ACE and other EOSC projects.	Yes
	3. Alignment (both policy and implementation routes) will have been achieved between the data governance strategies for routinely collected health data in the EHDS initiative, including the TEHDAS Joint Action and future EHDS Pilot Actions.	Yes
	4. To empower national centers to build capacity and train platform users and data providers (e.g., from life, social or health sciences), and with experts from across partner institutions collaborating to create training materials for the identified gaps, and to exchange experiences and knowledge.	Yes

3. Project overview

3.1. Basic project information

- Project Call: FAIR AND OPEN DATA SHARING IN SUPPORT TO EUROPEAN PREPAREDNESS FOR COVID-19 AND OTHER INFECTIOUS DISEASES

- Project Title: Beyond COVID

- Project Acronym: BY-COVID

- Grant Agreement Nº: 101046203

- Call topic: HORIZON-INFRA-2021-EMERGENCY-01

- Contracting Authority: REA/ C/ 04

- Project start date: 1st October 2021

- Project end date: 30th September 2024

- Duration: 36 months

- Total cost: €12,011,000

- Grant awarded: €12,000,000

- Number of Beneficiaries: 27

- Number of Affiliated Entities: 26

- Website: http://www.by-covid.org

- Twitter: @BYCOVID_eu

- LinkedIn: https://www.linkedin.com/company/by-covid/

3.2. Short names of the consortium partners

Table 1. All Beneficiaries and Affiliated Entities of the BY-COVID project, as of November 2021. The updated list will always be accessible via the Participant's Portal (login required).

Number	Organisation or Institute name	Acronym or abbreviation
1	EUROPEAN MOLECULAR BIOLOGY LABORATORY	ELIXIR/EMBL-EBI
1.1	CONSIGLIO NAZIONALE DELLE RICERCHE	CNR
1.2	UPPSALA UNIVERSITET	UU
1.3	TARTU ÜLIKOOL	UT
1.4	UNIVERSITÉ DU LUXEMBOURG	UNILU
1.5	ALBERT-LUDWIGS-UNIVERSITÄT FREIBURG	ALU-Freiburg
1.6	STICHTING VUMC	VUmc
1.7	EOTVOS LORAND TUDOMANYEGYETEM	ELTE
2	BARCELONA SUPERCOMPUTING CENTER-CENTRO NACIONAL DE SUPERCOMPUTACION	BSC
2.1	FUNDACIO CENTRE DE REGULACIO GENOMICA	CRG
3	INSTITUTO ARAGONÉS DE CIENCIAS DE LA SALUD	IACS
4	ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK	ECRIN
5	EUROPEAN INFRASTRUCTURE OF OPEN SCREENING PLATFORMS FOR CHEMICAL BIOLOGY EUROPEAN RESEARCH INFRASTRUCTURE CONSORTIUM (EU-OPENSCREEN ERIC)	EUOS
5.1	FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.	ITMP/Fraunhofer
6	EURO-BIOIMAGING ERIC	EURO-BIOIMAGIN

		G
7	BIOBANKS AND BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE CONSORTIUM (BBMRI-ERIC)	BBMRI-ERIC
7.1	UNIVERZITA PALACKÉHO V OLOMOUCI	IMTM/UP
7.2	ACADEMISCH ZIEKENHUIS GRONINGEN	UMCG
7.3	CENTRO DI RICERCA, SVILUPPO E STUDI SUPERIORI IN SARDEGNA SOCIETÀ A RESPONSABILITÀ LIMITATA	CRS4
7.4	THE UNIVERSITY OF NOTTINGHAM	UNottingham
7.5	UNIVERSITA' DEGLI STUDI DI MILANO-BICOCCA	UNIMIB
7.6	ISTITUTO NAZIONALE PER LE MALATTIE INFETTIVE LAZZARO SPALLANZANI-ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO	INMI
8	SCIENSANO	Sciensano
9	THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD	UOXF
10	EATRIS ERIC	EATRIS
10.1	STICHTING LYGATURE	LYGATURE
11	VIB VZW	VIB
12	EMPIRICA GESELLSCHAFT FÜR KOMMUNIKATIONS UND TECHNOLOGIEFORSCHUNG MBH	EMPIRICA
13	INSTRUCT-ERIC	INSTRUCT
13.1	Masarykova univerzita	CEITEC MU
13.2	CONSORZIO INTERUNIVERSITARIO RISONANZE MAGNETICHE DI METALLO PROTEINE	CIRMMP
13.3	AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES	CSIC

	CIENTÍFICAS	
14	INFRAFRONTIER GMBH	INFRAFRONTIER
15	DANMARKS TEKNISKE UNIVERSITET	DTU
16	SIB SWISS INSTITUTE OF BIOINFORMATICS	SIB
17	THE UNIVERSITY OF MANCHESTER	UNIMAN
18	ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM	ERASMUS MC
19	GESUNDHEIT ÖSTERREICH GMBH	GÖG
20	RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	RIVM
21	UNIVERSITETET I OSLO	UiO
22	UNIVERSITETET I TROMSO - NORGES ARKTISKE UNIVERSITET	UiT
23	EUROPEAN UNIVERSITY INSTITUTE	EUI
24	EUROPEAN RESEARCH INFRASTRUCTURE ON HIGHLY PATHOGENIC AGENTS	ERINHA
25	TERVEYDEN JA HYVINVOINNIN LAITOS	THL
26	IRCCS OSPEDALE POLICLINICO SAN MARTINO	HSM
26.1	ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELLE VENEZIE	IZSVe
26.2	ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELLA LOMBARDIA E DELL'EMILIA ROMAGNA BRUNO UBERTINI	IZSLER
27	CESSDA ERIC	CESSDA ERIC
27.1	KONINKLIJKE NEDERLANDSE AKADEMIE VAN WETENSCHAPPEN - KNAW	KNAW/DANS
27.2	TAMPEREEN KORKEAKOULUSÄÄTIÖ SR	TAU-FSD

27.3	ETHNIKO KENTRO KOINONIKON EREVNON	EKKE
27.4	INSTITUTE OF SOCIOLOGY OF THE ACADEMY OF SCIENCES OF THE CZECH REPUBLIC PUBLIC RESEARCH INSTITUTION	ISAS CR
27.5	UNIVERZA V LJUBLJANI	UL, FDV/ADP

3.3 Project acronyms

Table 2. Project Acronyms

Abbreviation	Meaning
BY-COVID	Beyond COVID
BY-COVID-CO	BY-COVID Coordination Office - Management Team
BY-COVID-MB	BY-COVID Management Board (Work Package Leaders)
CA	Consortium Agreement - Agreement concluded amongst BY-COVID beneficiaries for the implementation of the Grant Agreement.
Consortium	The BY-COVID Consortium, comprising the named legal entities.
DMP	Data Management Plan
DoA	Description of Action - Part B
EC	European Commission, represented by the REA, Research Executive Agency as a contracting authority[3]
GA	Annotated Grant Agreement - The agreement signed between the beneficiaries and the EC for the undertaking of the BY-COVID project
BY-COVID-GA	BY-COVID-General Assembly - all project participants. Corresponds with the Consortium.
IC	Indirect Costs
KPI	Key Performance Indicator
MoU	Memorandum of Understanding
PuC	Purchase Costs
PM	Project Manager

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[3] Throughout the document, the EC abbreviation will be used and understood as including the role of the REA as the contracting authority.

PMs	Person months
Project	The sum of all activities carried out in the framework of the Grant Agreement.
QA	Quality Assurance
SEIAB	Scientific, Ethics and Industry Advisory Board
WP	Work Package
WPL	Work Package Leader

3.4. Project summary

BeYond-COVID -BY-COVID- aims to provide comprehensive open data on SARS-CoV-2, and other infectious diseases across scientific, medical, public health and policy domains. The project will have a strong emphasis on mobilising raw viral sequences, helping to identify and monitor the spread of SARS-CoV-2 variants. It will further accelerate access to and linking of data and metadata on SARS-CoV-2 and COVID-19 (e.g., public health data, data on patient outcomes), enable federated data analysis to conform with data protection regulations, and harmonisation and management of meta-data and sample- identifiers, as well as long-term cataloguing to ensure interoperability of national and global efforts.

BY-COVID will build on the One-Health approach, on the latest technological advances, exploiting and contributing to the European Open Science Cloud capabilities for data access and federation as well as relevant standards and policies for managing, sharing and reusing research data. It will also work closely with the ISIDORe project funded through HORIZON Europe as well.

BY-COVID will integrate established national and European infrastructures including ELIXIR, BBMRI, ECRIN, PHIRI and CESSDA. It will build on existing efforts, such as the COVID-19 Data Platform and the Versatile Emerging infectious disease Observatory project-VEO- thereby maximising efficiency. Synergies with the European Health Data Space will be developed.

BY-COVID is a truly interdisciplinary -53 partners from 19 countries- project bringing together stakeholders from the biomedical field, hospitals, public health, social sciences and humanities in an unprecedented and unique effort and will increase European readiness for future pandemics enhance genomic surveillance and rapid-response capabilities. BY-COVID serves as a foundation and demonstrator for interdisciplinary work across country borders. The outputs of the project will allow scientists across multiple domains, including SMEs and industry, to access a range of data that will generate new knowledge on infectious disease.

An overall project summary is available here: BY-COVID Project Summary.

3.5. Project scope and work structure

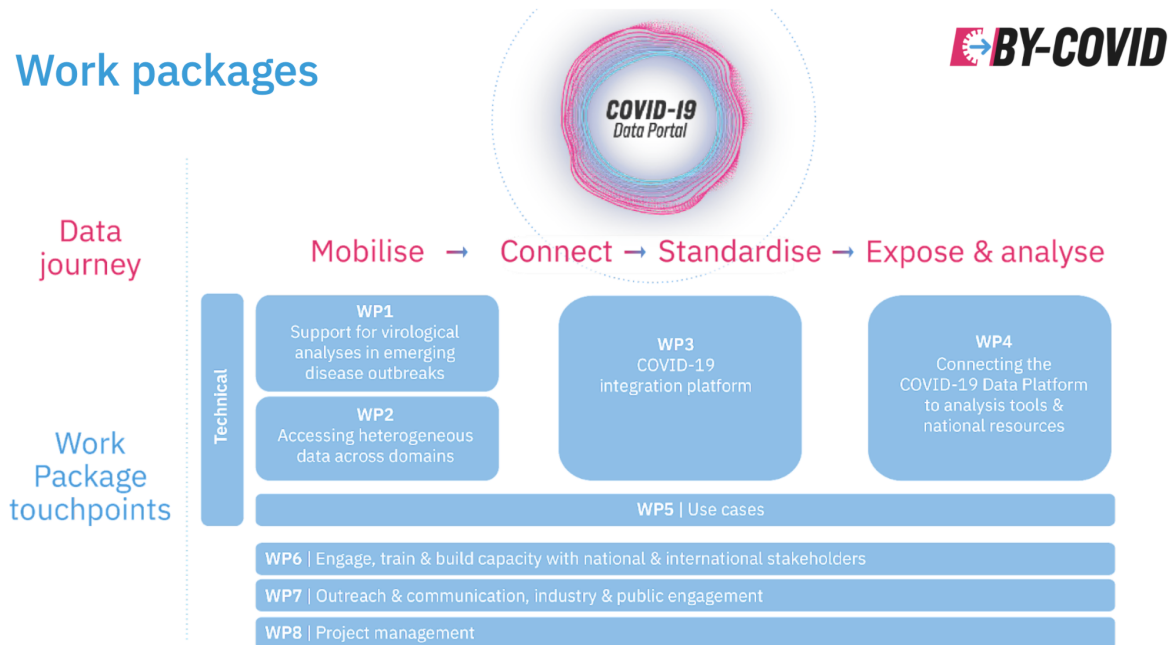The BY-COVID project consists of 8 Work Packages.

Figure 1. BY-COVID interrelationships between work packages

Brief overview of BY-COVID's WPs:

WP1: Support for virological analyses in emerging disease outbreaks (Objectives #2, 4).

WP1 will establish and improve SARS-CoV-2 Data Hubs that, with a globally comprehensive viral sequence and normative variation data sets, provide the foundation for linking genomic surveillance with heterogeneous data across domains. An open call will allow additional Data Hubs to be established and packaging of a rapid deployment "preparedness" Data Hub addresses future pathogen outbreaks.

WP leaders: Guy Cochrane (EMBL-EBI), Clara Amid (Erasmus MC)

WP2: Accessing heterogeneous data across domains and jurisdictions for enabling the downstream processing of COVID-19 and future pandemic episodes data (Objectives #1, 2, 4, 5).

WP2 brings together data resources and catalogues across domains, captures data governance and access procedures. It will align metadata descriptions and other relevant semantic information first within domains (e.g., biomolecular and imaging, clinical and health, survey, etc) and in a second stage (in alignment with WP3 developments) expose a reference catalogue with harmonised metadata descriptions across domains.

WP leaders: Alfonso Valencia/Salvador Capella-Gutierrez (BSC), Antje Keppler (EuroBioImaging)

WP3: COVID-19 integration platform (Objectives #2, 3, 5).

WP3 is focussed on services for the discovery, integration and citation of COVID-19 data by delivering a flexible, tiered metadata discovery system across different domains, metadata standards, and maturity/robustness levels of data sources. This will enable the linking of FAIR data and metadata on SARS-CoV-2 and COVID-19, other infectious diseases and related data, and ultimately increase the potential for collaboration and exploitation of data.

WP leaders: Henning Hermjakob (EMBL-EBI), Mari Kleemola (CESSDA/TAU-FSD)

WP4: Connecting the COVID-19 data platform to analysis tools and local portals (Objectives #3, 4, 5).

WP4 will develop, aggregate and integrate tools for analysis and visualisation of data in the COVID-19 Data Platform. It will provide a provenance framework for tracking of derived data and the transparency and trustworthiness of results which will ultimately improve trust in science. Researchers will be enabled to exploit the large volumes of data for tasks such as identification of variants of concern.

WP leaders: Frederik Coppens (VIB), Petr Holub (BBMRI-ERIC)

WP5: A continuously evolving demonstrator project feeding the changing research questions that surface during an on-going pandemic to solutions (Objectives #3, 4).

WP5 will demonstrate usability of BY-COVID services across disciplines and national borders through continuously evolving demonstrator projects. It will assess viral variants and disease outcomes using real world data, as well as the effectiveness of vaccines against new variants using retrospective clinical trial data and improve the understanding of the mechanistic determinants of variant responses.

WP leaders: Nina Van Goethem (Sciensano), Enrique Bernal Delgado (IACS)

WP6: Engage, train and build capacity with national and international stakeholders (Objectives #1, 3, 4, 5).

WP6 will focus on stakeholder engagement, bottom-up by facilitating knowledge exchange in relation to setting up surveillance systems for pathogens, but also top-down to shape the policy landscape (EOSC, EHDS, and more broadly intergovernmental organisations and funders). Importantly, WP6 coordinates the training and capacity-building that takes place across WPs ensuring alignment and visibility with stakeholders.

WP leaders: Patricia Palagi (SIB), Corinne S. Martin (ELIXIR Hub)

WP7: Outreach, Communication, industry and public engagement (all Objectives).

WP7 will develop and implement the project-wide communications and outreach strategy, ensuring key stakeholders including scientists, industry and SMEs, policy makers and the public have awareness of the project and opportunities to engage, use project outputs and provide feedback to partners.

WP leaders: Andy Smith (ELIXIR Hub), Katharina Lauer (ELIXIR Hub)

WP8: Coordination, project management and ethical, legal and social implications.

WP8 will oversee the project execution ensuring effective and efficient coordination to deliver the project goals, benefits and expected impact within time, scope, budget and with adequate level of quality. It will further address the implementation of ELSI (Ethical, Legal and Social implications) aspects and the data management and sustainability plan.

WP leaders: Juan Arenas Marquez, Andrea Troncoso (ELIXIR Hub)

Key documents with detailed project information about the activities and tasks of each Work package are to be found in:

- Grant Agreement[4]: Contract between the EC and the Consortium establishing the obligations and conditions. An annotated HE version is available here and a detailed overview is part of this document, section 7.
- BY-COVID Description of Action Part A: To be generated once the Grant Agreement is signed. It gathers a project summary, List of beneficiaries, Workplan (Work Packages, Deliverables), Milestones, Risks, Effort in PM, Review meetings.
- BY-COVID Description of Action Part B: Excellence, Impact, Implementation, Members of the Consortium, Ethics and Security. To be uploaded on the Participants' Portal.
- EC Grant Management Data: Requires login into the EC portal

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[4] As of the date of the submission of this deliverable, BY-COVID Grant Agreement is under preparation.

Note: Documents above are particularly important for new joiners to understand the ambition of the project and the framework in which we have to operate.

4. Project management structure

"Have the stamina to work on something until it comes right"

-Mary Robinson

4.1. Project governing model

BY-COVID workflow will be planned and monitored through two main governing bodies: the Management Board and the General Assembly, led by the Project Coordinator. Both bodies will be supported by an independent Scientific, Ethics and Industry Advisory Board, SEIAB.
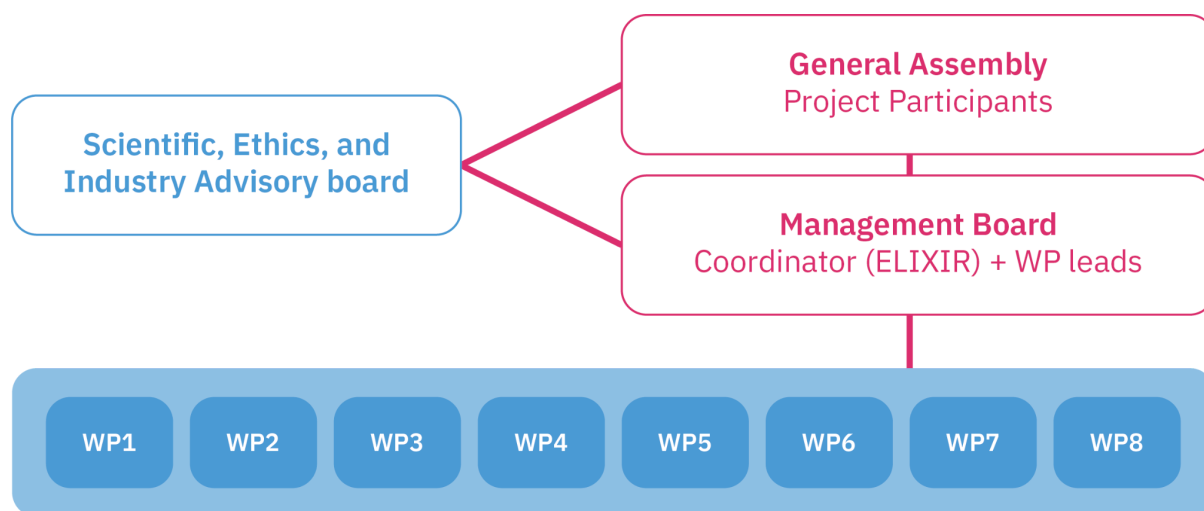

Figure 2. Governing Model of the BY-COVID project

4.2. Project coordination and management

The BY-COVID Coordination team (BY-COVID-CO) will establish effective project governance and internal communication procedures to allow the flow of information within the project. It will also fulfil the administrative tasks associated with the management of the project.

Management of the project is the overall goal of Work Package 8 (WP8) in the BY-COVID Project. This entails overseeing the project execution, ensuring effective and efficient coordination across all activities and participants to deliver the project goals, benefits and expected impact within time, scope and budget and with an adequate level of quality. WP8 specific objectives are:

- O8.1: Establishment of the governance structure mobilising the project resources and developing the project guidance, taking diversity into account

- O8.2: Efficient and effective project execution and monitoring collecting project KPIs and tracking risk and opportunities to assist the project boards in making informed decisions at all levels

- O8.3: Implementation of ELSI aspects and the data management plan

- O8.4: Evaluate, develop and implement a sustainability plan relevant project result All tasks will contribute to the incremental version of the project handbook that will define and update the different plans and processes, including the monitoring of project metrics and lessons learned, which will contribute to the continuous improvement of EC funded projects.

4.3 Description of roles and responsibilities

In the following section, the roles of major stakeholders in the BY-COVID project are described alongside the responsibilities, expectations, rights and duties of each participant in the project.

4.3.1. Project Coordinator

Table 3. Project Coordinator details

Name	Niklas Blomberg
Organisation	ELIXIR Hub
Email	niklas.blomberg@elixir-europe.org
Role	ELIXIR Hub is appointed as Coordinator.
	The Coordinator is and shall be a central point of contact between the Beneficiaries and the EC in particular regarding the management of the Grant.
	Specific duties: Legal signatory, legal responsibility for a contract, budget oversight and control, submission of deliverables and milestones to EC, chair of GA and MB. The Coordinator is supported by the Project Management Team in regards to the financial and contractual administration of the project.

4.3.2 Project Management Team (BY-COVID-CO)

The Project Management team (BY-COVID-CO) will be led by the ELIXIR Project Management Office and leverage their experience and processes for managing large, international consortia to ensure timely delivery and effective communication and collaboration across WPs, and towards internal and external stakeholders.

Table 4. BY-COVID-Coordination Team

Name	Katharina Lauer/Andrea Troncoso/Juan Arenas Marquez / Nikki Coutts /Ellie Taverner
Organisation	ELIXIR Hub
Email	by-covid-coordination@elixir-europe.org
Role	The BY-COVID-CO is responsible for the day-to-day execution of the Project, providing the necessary project management support to deliver the Project. In particular, the BY-COVID-CO is responsible for the following tasks and activities: ● implementation of all management and organisational tasks ● scheduling of decisions ● monitoring the achievement of set milestones ● timely submission of deliverables ● organisation and documentation of the meetings of the Project Bodies ● dissemination of all relevant information and action items across the Consortium ● accounting for all financial aspects of the Project and ensuring timely submission of all required reports to the EC.

The BY-COVID-CO will support and report on the execution of the project work plan and budget utilisation, providing the mechanism to identify and manage project risks and opportunities.

Communication dynamics will be promoted across the project, keeping the right level of engagement among stakeholders. Slack and Google Drive will be collaboration tools used

from the first stages of the Project. These tools will guarantee the means for efficient communication within the Consortium, fulfilling internal communication needs.

Meetings

The BY-COVID-CO team meets on a weekly basis.

4.3.3. Work Package Leaders

BY-COVID Work Package Leads (BY-COVID-WPLs) are responsible for overseeing the technical progress of the project and ensuring interoperability and alignment of co-dependent tasks across work packages. They are also responsible for presenting the work carried out by the WP to the European Commission and for the content of their WP activities within the periodic reports.

WPLs are responsible for the proper execution of the DoA and the implementation of the decisions of the BY-COVID Management Board (BY-COVID-MB). The WPLs collectively make up the MB. They are expected to identify issues, risks and opportunities within the technical tasks of the Project and take appropriate actions to ensure the project delivers the anticipated benefits both at the work package and project level. Risks or opportunities that cut across more than one work package should, together with a suggested action, be elevated to the BY-COVID-MB during the monthly meetings. The WPLs, as the BY-COVID-MB and via the Coordinator, report on the project progress to the BY-COVID-GA at least every 12 months.

WPLs are responsible for filtering project information from the BY-COVID-MB meetings to their work packages via their dedicated WP distribution lists, during their regular meetings, or via other communication means they deem fit, e.g. Slack. WPLs are responsible for scheduling their own WP meetings, creating and circulating an agenda, and taking and disseminating minutes.

In the case of beneficiaries not performing their roles, WPLs are expected to promptly document the situation and raise it with the BY-COVID-CO in order to swiftly address reputational or technical risk for the consortium.

In BY-COVID, each WP is co-led by two leading institutions. Both leads are expected to attend the MB meetings, but where a WPL is unable to attend and her/his deputy neither, it will be accepted that one co-lead attends. In specific cases, they may deputise to a predefined Deputy Work Package Leader.

Contact: by-covid-wpls@elixir-europe.org

For more information, please refer to the ELIXIR Hub document Work Package Leader's Good Practice Guide[5].

4.3.4. Task Leaders

Each Work Package is broken down into tasks and sub-tasks. Each Task Lead is responsible for prompt and on-time performance and fulfilment of the assigned task and subtask as per the Description of Action (DoA) in cooperation with all task participants and liaising with the respective WPL.

The Task Leads must ensure that the fulfilment of their task activities is accomplished in due time in line with the commitments identified in the DoA.

Task Leads shall promptly notify the WPL of any significant problem or delay likely to affect the completion of the assigned task. Each participant must ensure timely contribution to the allocated tasks, as requested by each Task lead and/or WPLs. Any encountered issue should be discussed with the Task Lead and, if needed, escalate to the WPL level.

The designated task leaders are presented in Table 5 below.

Table 5. BY-COVID Task Leaders

Task #	Task Leader	Organisation
T1.1	Guy Cochrane	EMBL-EBI
T1.2	Carla Cummins	EMBL-EBI
T1.3	Clara Amid	ERASMUS MC
T1.4	Carla Cummins	EMBL-EBI
T2.1	Philip Gribbon	EU-OS
T2.2	Jordi Rambla	CRG
T2.3	Enrique Bernal-Delgado	IACS
T2.4	Vasso Kalaitzi, Simon Saldner	KNAW/DANS
T2.5	Salvador Capella-Gutierrez	BSC

T2.6	Salvador Capella-Gutierrez	BSC
T3.1	Mari Kleemola	CESSDA/TAU-FSD
T3.2	Henning Hermjakob	EMBL-EBI
T3.3	Henning Hermjakob	EMBL-EBI
T3.4	Romain David	ERINHA
T4.1	Hedi Peterson	UT
T4.2	Petr Holub	BBMRI-ERIC
T4.3	Stian Soiland-Reyes	UNIMAN
T4.4	Bjorn Gruning	ALU-Freiburg
T4.5	Salvador Capella-Gutierrez	BSC
T4.6	Saskia Hiltemann	Erasmus MC
T5.1	Nina Van Goethem	Sciensano
T5.2	Enrique Bernal-Delgado	IACS
T5.3	Jacques Demotes	ECRIN
T5.4	Marialuisa Lavitrano, Marek Ostaszweski	UNIMIB, UNILU
T6.1	Kathi Lauer	ELIXIR Hub
T6.2	Jose-Maria Carazo, Veli Stroetmann	CSIC, EMPIRICA
T6.3	Corinne Martin, Marianna Ventouratou	ELIXIR Hub, EMBL-EBI
T6.4	Patricia Palagi	SIB
T7.1	Erin Haskell	ELIXIR Hub
T7.2	Kathi Lauer	ELIXIR Hub, UU
T7.3	Wannes Van Hoof	Sciensano
T7.4	Andrew Smith	ELIXIR Hub

T8.1	Andrea Troncoso, Meropi Papagheorghe	ELIXIR Hub, EMPIRICA
T8.2	Andrea Troncoso, Meropi Papagheorghe	ELIXIR Hub, EMPIRICA
T8.3	Michaela Mayrhofer	BBMRI-ERIC
T8.4	Michaela Mayrhofer	ELIXIR Hub

This list will be updated accordingly and kept in tis live version of the Handbook, stored in our Google Drive.

4.4 Decision-making and advisory bodies

4.4.1. General Assembly (BY-COVID-GA)

The General Assembly (BY-COVID-GA) is the ultimate decision-making body and it is composed of representatives of all project beneficiaries that have delegated the decision making to the Management Board. The BY-COVID-GA will be informed of the project progress in a timely manner (Management Board meeting minutes circulated to all partners). The BY-COVID-GA shall not deliberate and decide validly unless two-thirds (2/3) of its Members are present or represented (quorum). If the quorum is not reached at a meeting, decisions should be taken by correspondence as specified in Clause 6.2 of the Consortium Agreement.

If necessary, each Beneficiary shall also be entitled to nominate a replacement Representative in the event that the original Representative is unable to attend any scheduled meetings of the BY-COVID-GA.

Meetings

The BY-COVID-GA will meet face to face once a year to be updated on the project progress and plans.

The Coordinator - or his deputy- shall chair the General Assembly. The Chairperson of the General Assembly shall:

- be responsible for the convening of meetings, preparation and distribution of the agenda and minutes for meetings of the General Assembly; and

- chair meetings of the General Assembly.

Where the Chairperson of the General Assembly cannot attend a General Assembly meeting, the General Assembly shall nominate a replacement to chair the meeting for the

purposes of such meeting of the General Assembly only, provided that the replacement must be a Representative. Such replacement shall be deemed Chairperson of the General Assembly.

See Section 6 of the Consortium Agreement[6] for further information regarding the General Assembly.

Table 6. BY-COVID General Assembly members

Participant	BY-COVID-GA member
ELIXIR / EMBL-EBI	Niklas Blomberg, Juan Arenas
BSC	Alfonso Valencia
IACS	Sandra Garcia-Armesto
ECRIN	Maria Panagiotopoulou
EUOS	Katja Herzog
EURO-BIOIMAGING	Antje Keppler
BBMRI-ERIC	Michaela Th. Mayrhofer
Sciensano	Nina van Goethem
UOXF	Susanna-Assunta Sansone
EATRIS	Gary Saunders
VIB	Frederik Coppens
EMPIRICA	Veli Stroetmann
INSTRUCT	Claudia Alen Amaro
INFRAFRONTIER	Michael Raess
DTU	Frank Møller Aarestrup
SIB	Patricia Palagi
UNIMAN	Carole Goble

[6] As of November 2021 the Consortium Agreement is under development.

ERASMUS MC	Marion Koopmans
GOG	Alexander Degelsegger-Márquez
RIVM	Chantal Reusken
UiO	Gard Thomassen
UiT	Nils P. Willassen
EUI	David Levine
ERINHA	Audrey Richard
THL	Markus Perola
HSM	Paolo Romano
CESSDA-ERIC	Mari Kleemola

4.4.2. Management Board

The BY-COVID Management Board (BY-COVID-MB) is composed of the Project Coordinator and of BY-COVID Work Package Leaders. It is responsible for ensuring alignment and coordination across Work Packages and for the successful execution of the project.

The BY-COVID-MB shall be responsible for the overall execution of the Action, the quality of the action, alignment across all Work Packages, decision making and the initial finding of amicable solutions for any disputes between the Beneficiaries relating to the execution of the Action. The BY-COVID-MB will ensure the smooth operation of the Action and guarantee that all efforts are focused towards the Action Objectives, Deliverables and Milestones. This will be achieved by regular monthly meetings and thorough reviews of progress reports. It will also ensure that all Beneficiaries are regularly updated on scientific progress.

BY-COVID-MB members shall have named deputies to ensure proper representation in all meetings. The Management Board will be supported by the BY-COVID-CO.

Meetings

The Management Board will meet once a month.

A Representative of the Project Coordinator will act as the chairperson of the Management Board (the "Chairperson of the Management Board") and shall:

A. with assistance from the BY-COVID-CO, be responsible for the convening of meetings, preparation and distribution of the agenda and minutes for meetings of the Management Board;

B. and chair meetings of the Management Board.

Where a Work Package Leader is unable to attend a meeting they may send their predefined Deputy Work Package Leader.

See section 6 of the Consortium Agreement[7] for further information regarding the Management Board.

Table 7. BY-COVID Management Board members

Role	BY-COVID-MB Member
Project Coordinator	Niklas Blomberg (ELIXIR Hub)
WP1 Leader	Guy Cochrane (EMBL-EBI), Clara Amid (Erasmus MC)
WP2 Leader	Alfonso Valencia, Salvador Capella-Gutierrez (BSC), Antje Keppler (EuroBioimaging)
WP3 Leader	Mari Kleemola (CESSDA/TAU-FSD), Henning Hermjakob (EMBL-EBI)
WP4 Leader	Frederik Coppens (VIB), Petr Holub (BBMRI-ERIC)
WP5 Leader	Nina van Goethem (Sciensano), Enrique Bernal-Delgado (IACS)
WP6 Leader	Corinne Martin (ELIXIR Hub), Patricia Palagi (SIB)
WP7 Leader	Andrew Smith (ELIXIR Hub), Katharina Lauer (ELIXIR Hub)
WP8 Leader	Andrea Troncoso (ELIXIR Hub)

Contact: by-covid-wpls@elixir-europe.org

Table 8. BY-COVID Management Board Deputies

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[7] As of November 2021 the Consortium Agreement is under development.

Role	Management Board Deputy
Project Coordinator	Katharina Lauer(ELIXIR Hub)
WP1 Leader	Guy Cochrane(EMBL-EBI), Clara Amid (Erasmus MC)
WP2 Leader	Laura Portell (BSC), Aastha Mathur (EuroBioimaging)
WP3 Leader	Katja Moilanen(CESSDA/TAU-FSD), Henning Hermjakob (EMBL-EBI)
WP4 Leader	Miguel Roncoroni (VIB), Michaela Mayrhofer (BBMRI-ERIC)
WP5 Leader	Marjan Meurisse (Sciensano), Francisco Estupiñán-Romero (IACS)
WP6 Leader	Katharina Lauer, Andy Smith (ELIXIR Hub) and (SIB)
WP7 Leader	Andrew Smith (ELIXIR Hub), Katharina Lauer (ELIXIR Hub)
WP8 Leader	Juan Arenas (ELIXIR Hub)

4.4.3 SEIAB (Scientific, Ethics and Industry Advisory Board)

BY-COVID will make use of the Scientific, Ethics and Industry Advisory Board (SEIAB) for progress review and external advice. The SEIAB will provide recommendations for the scientific strategy of this project. The SEIAB includes independent experts in life science areas, ethics, infectious diseases and economy, whose backgrounds cover science and industry.

Meetings

The SEIAB meets once a year or ad hoc by request of the BY-COVID-CO or the MB. They provide direct feedback to the MB.

Section 6 of the Consortium Agreement[8] contains further information about the SEIAB.

Table 9. BY-COVID SEIAB members. This table will be updated after the 2nd Management Board Meeting on 16 December 2021

SEIAB member	Affiliation

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[8] As of November 2021, the Consortium Agreement is under development.

Gloria Gonzalez Gacio	BITAC, Spain. Field: Data integration and standards
Peter van Heusden	U Western Cape, South Africa. Field: Infectious diseases
Philippe Guerin	IDDO, France-United Kingdom. Field: Infectious diseases
Juliane Fluck	ZBMed, Germany. Field: Medical informatics
	We are contacting 3 more possible members in the coming months.

Contact: BY-COVID-SEIAB@elixir-europe.org

4.4.4 Meetings with the EC Project Officer

The BY-COVID-CO will coordinate meetings with the EC Project Officer upon need and when requested by this official representative of the European Commission.

There are two official meetings that will tentatively take place at month 18 and 36, the Mid-Term review and Final review meetings.

4.4.5 Summary of meetings

Table 10. BY-COVID meetings chart

Meeting	Period	How	Goal
Regular meetings with PO (Project Officer) + EC Internal Experts	Every 6 months or less.	Video Conference Content to be defined with PO. **Attendance:** EC, CO & WPLs when needed **Owner**: BY-COVID-CO	Project Monitoring
BY-COVID-GA **(General Assembly)**	Yearly	Content to be defined with BY-COVID-MB **Attendance:** All beneficiaries. **Owner**: BY-COVID-CO	Informing and reflecting on the work done and future steps.
BY-COVID-MB **(WP Leaders)**	Monthly TC, last Thursday of each month	TC or F2F collocated with other meetings.	BY-COVID WP alignment.

		Owner: BY-COVID-CO	
SEIAB (Scientific, Ethic, Industry Advisory Board)	At least once a year (GA) or by GB request	TC or collocated with MB/ GA meetings **Attendance:** SEIAB, CO, MB **Owner**: BY-COVID-CO	Independent advice.
Bilateral meetings	As requested	**Attendance:** WP leader **Owner**: BY-COVID-CO	Align and implement BY-COVID DoA with WPs activities.
WP regular meetings	Monthly or according to WPs plan	According to WP needs **Owner:** WP Leaders	Organisation of work plan and tasks.
BY-COVID-CO meetings	Weekly	**Attendance:** Coordination team **Owner:** Project Manager	Align and implement BY-COVID.
Regular review meetings	M18 and M36	F2F in EC premises TBC due to pandemic situation. **Attendance:** PO, EC and external experts , coordinator and WP leaders **Owner:** EC	Assess Project performance.

4.5. Communications management

The communications management process determines how to communicate most efficiently and effectively to the various stakeholders. It defines and documents the communication items content, format, frequency, the audience and expected results. It also defines how to communicate project status and the assignment of activities to the various stakeholders, and the communication strategy for each stakeholder, based on their interests, expectations and influence in the project.

The BY-COVID communication strategy is a formal project deliverable that is due in M06 (March 2022) D7.1 Dissemination, Exploitation and Communication Plan. Once this deliverable is submitted, it will be linked to this Project Handbook.

4.5.1. Internal Communications Plan

The BY-COVID Consortium will adopt the following approach to communications:

- Use of electronic mail as the main tool for communication within the consortium.

- Slack[9] is available for instant messaging, sharing and VC. Group communication channels were created by BY-COVID-CO.

- Documentation of discussions, agreements and decisions made by phone is encouraged. Specifically, video or phone conferences should always have an agenda and minutes, which should be made available through the BY-COVID Google Drive and in the appropriate folder.

- Several distribution lists have been initially created which can be used by any participant depending on the subject of the message. Additional lists may be created as the project evolves, if necessary. The BY-COVID-CO team will be responsible for updating the below-mentioned lists with the information received from participants. When a list is used, care should be taken by participants to use the "reply to all" feature only when relevant. The table below shows the distribution lists created by the time of publishing this deliverable.

Table 11. Mail Distribution Lists

Distribution list	Description
BYCOVID-coordination@elixir-europe.org	ELIXIR Hub BY-COVID Coordination team
BY-COVID-Partners@elixir-europe.org	All project participants signed up to BY-COVID mailing lists
BY-COVID-Admin@elixir-europe.org	BY-COVID admin contacts + ELIXIR Hub BY-COVID Coordination team
BY-COVID-Legal@elixir-europe.org	BY-COVID Legal contacts + ELIXIR Hub BY-COVID Coordination team
BY-COVID-PIs@elixir-europe.org	BY-COVID Principal investigators + ELIXIR Hub BY-COVID Coordination team
BY-COVID-WPLs@elixir-europe.org	Management Board + ELIXIR Hub BY-COVID Coordination team

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[9] Temporary link, that will expire in two weeks. If you need access to Slack, please contact bycovid-coordination@elixir-europe.org

BY-COVID-WP1-Analysis-Support@elixir-europe.org	BY-COVID WP1, leads and members + ELIXIR Hub BY-COVID Coordination team
BY-COVID-WP2-Accessing-Data@elixir-europe.org	BY-COVID WP2, leads and members + ELIXIR Hub BY-COVID Coordination team
BY-COVID-WP3-Integration-Platform@elixir-europe.org	BY-COVID WP3, leads and members + ELIXIR Hub BY-COVID Coordination team
BY-COVID-WP4-Data-Platform@elixir-europe.org	BY-COVID WP4, leads and members + ELIXIR Hub BY-COVID Coordination team
BY-COVID-WP5-Demonstrator@elixir-europe.org	BY-COVID WP5, leads and members + ELIXIR Hub BY-COVID Coordination team
BY-COVID-WP6-Engage-Train@elixir-europe.org	BY-COVID WP6, leads and members + ELIXIR Hub BY-COVID Coordination team
BY-COVID-WP7-Communication@elixir-europe.org	BY-COVID WP7, leads and members + ELIXIR Hub BY-COVID Coordination team
BY-COVID-WP8-Project-Management@elixir-europe.org	BY-COVID WP8, leads and members + ELIXIR Hub BY-COVID Coordination team
BY-COVID-Communications@elixir-europe.org	Communication representatives at an institutional level
BY-COVID-core-WP8@elixir-europe.org	BY-COVID WP8 task leads + ELIXIR Hub BY-COVID Coordination team
BY-COVID-SEIAB@elixir-europe.org	BY-COVID Scientific, Ethics and Industry Advisory Board members and BY-COVID Coordination team

4.5.2. Email guidelines

Good practice when using email is essential.

1. Project related mails should be tagged with project short name "BY-COVID" and also indicate when action is required (ACTION REQUIRED, FEEDBACK REQUIRED).

2. Participants must respond promptly to any email received. When that is not possible, at least acknowledgement of receipt of all messages is strongly recommended, especially when answering an explicit request.

3. Carefully consider whether "reply to all" is required.

4. All emails sent to any of the mailing lists created so far should start with "BY-COVID" in the subject section and senders should add the subject of the message.

5. When individual messages between participants are exchanged, use of the same tag is strongly encouraged (e.g. BY-COVID: WPL meeting_agenda).

6. Messages need to be concise but clear, especially when requests are made.

7. Message text should include the content needed for the recipient to action the requests

8. Deadlines must be made explicit.

9. No relevant issues for the work to be performed should remain unclear.

10. When feasible avoid sending emails out of working hours or indicate a reply is not expected outside of working hours.

4.5.3. Dissemination

Dissemination is an important activity for all EC projects, which requires that the scientific work and its results are made openly available, as early as possible and in a form that is easily accessible, understandable and reusable[10].

WP7 "Outreach and communication, industry and public engagement" is in charge of communications, dissemination and exploitation and will submit Deliverable 7.1 with all specific actions related to communicating , disseminating and exploitation opportunities of the BY-COVID project results.

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[10] See the EC's Open Science policy:
https://ec.europa.eu/info/research-and-innovation/strategy/strategy-2020-2024/our-digital-future/open-science_en

The EC also provides an enriched approach to communication and dissemination in Horizon Europe research and innovation for project participants[11]

5. Project reporting

5.1. Deliverables

5.1.1. Who generates project deliverables?

As official results of the project, deliverables deserve special attention and are generated and reviewed according to specific procedures. As a general rule, the generation of deliverables is a responsibility of the corresponding work package lead beneficiary and the process will be supervised by the corresponding WPL. The lead beneficiary will be responsible for drafting the deliverable and gathering contributions from work package participants as appropriate. Prior to submission to the EC, deliverables will undergo an internal review process that is detailed below.

5.1.2. Deliverable structure, guidance and tips

Project deliverables are to be submitted at specific times that will be stated in the DoA and as of the date of the submission of this deliverable, are detailed in the Participant's Portal.

Note: The"expected delivery date" listed in the DoA always refers to the last date of any month. e.g. 'June 2022' means '30th June 2022' / 'Feb 2022' means '28th Feb 2022'.

Deliverables reflect the results achieved during the lifetime of the project, and they are important documents to assess the progress achieved.

Each deliverable must use the deliverable template prepared by the BY-COVID Communications Team that can found in the Templates folder on the BY-COVID Google Drive[12].

The name of Deliverables and Milestones should be written in the following format:

BY-COVID_Dx.x_NAME_OF_THE_DELIVERABLE

BY-COVID_Mx.x_NAME_OF_THE_MILESTONE

The template has six predefined sections, that can be adapted depending on the nature of the deliverable:

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[11] https://ec.europa.eu/research/participants/docs/h2020-funding-guide/other/event210609.htm
[12] https://drive.google.com/drive/folders/1cxSNL4oxRVw-dsLPUI7p6OpIKdifD8GR

- Executive Summary (Max ½ page, should provide an overview of the work carried out and the conclusion)

- Contribution Towards Project Objectives (indicate with Yes/No if the deliverable contributes to the key result)

- Introduction (1-1 ½ pages, describe deliverable scope and the methodology to be applied)

- Description of Work Accomplished (Describe what has been done. Interactions with other WPs? Collaboration with external partners/projects? Dissemination activities carried out?)

- Results (Present and discuss the results obtained)

- Conclusion

- Impact (Present and discuss the impact obtained)

- Next Steps

- Deviation from Description of Action (If applicable, describe the deviation from the Description of Action and the justification and plans to avoid this deviation impacting the work plan)

5.1.3. Deliverable review process

5.1.3.1. Review for quality

The review process must use the following quality criteria as reference.

As regards to content:

- Completeness: Information must address all aspects related to the purpose for which the information is produced. On the other hand, redundancy of information must be avoided, as it obscures the clarity of documents.

  - Related indicators: Missing content, Redundancy.

- Accuracy: Information contained in the document must be reliable and must correspond with reality. This means that all background information used in the reports should be appropriately supported by references. Foreground information should be sufficiently supported so that misinterpretation is avoided. Use of statistically validated objective data is to be prioritised.

- ○ Related indicators: Error, Insufficient references/objective supporting data, Ambiguity.
- Relevance: Information used in the document should be focused on the key issues and be written in a fashion that takes into consideration its target audience.
  - ○ Related indicators: Irrelevant information.
- Depth: all information used should be provided to the depth needed for the purpose of the document.
  - ○ Related indicators: Lacking detail, Excessive detail.

As regards to appearance and structure:

- Adherence to standards: it is important that deliverables are prepared with uniform appearance and structure so that, even if they are produced by different authors, they appear as originating from a single initiative.
  - ○ Related indicators: Lack of uniformity in presentation.

5.1.3.2. The review process

Within the BY-COVID project, the review process shall be coordinated by the BY-COVID-CO.

A. As and when a deliverable approaches due, it will appear in the monthly project monitoring report three months prior to submission deadline. A link to the deliverable template will be provided, as well as guidelines for producing the document.

B. If the WPL themselves will not be drafting the deliverable, it is their responsibility to forward the request to the appropriate WP member(s), who will be undertaking the task of drafting the deliverable (the deliverable authors).

C. The Deliverable Lead must nominate a minimum of two reviewers. Before informing the BY-COVID-CO of who the reviewers will be they should seek agreement from the nominated reviewers. The reviewers should ideally be from a different WP and have a thorough understanding of the deliverable topic so they can provide sufficient technical critique/review. If it is deemed that the review by someone with additional expertise is required, e.g. such as a case where a deliverable has a focus on ethical or regulatory/legal issues, members of any of the Advisory Boards of the BY-COVID project may also be asked to be a reviewer.

D. The deliverable author(s) should work on their deliverable within their Work Package folder on the BY-COVID Google Drive.

E. Where more than one person is producing the deliverable, the lead deliverable author should create a Table of Contents and assign responsibilities to the other authors.

F. If the WPL(s) do not draft the report themselves, once the first draft of the document is produced by the author(s), they will be expected to have the WPLs review it to assess the content from a scientific/technical perspective.

G. Reviewers will be expected to check the deliverable against the quality criteria described in section 5.1.3.1. above. Any suggested edits or comments should be made within the Google Doc which allows for a collaborative working environment. The deliverable author(s), must then proceed with the amendments or comments on the reviewed document.

H. 1.5 weeks prior to the deliverable due date, the final draft of the document should be submitted to the BY-COVID-CO, by emailing them a link to the Google Doc version on the BY-COVID Google Drive.

I. The BY-COVID-CO will distribute the link to the MB for a final review, allowing the MB seven (7) days to review it. Once approved, the BY-COVID-CO (on behalf of the Project Coordinator) will convert the Google Doc to PDF and submit the final document to the EC via the Participant Portal.

J. In addition, the BY-COVID-CO will upload all public deliverable reports to Zenodo and notify the Consortium. The final document will also be available on the BY-COVID Google Drive in the Deliverables and Milestones folder[13].

During the whole process, it is recommended that there is one responsible author that acts on behalf of all authors and communicates with them for evolving the document.
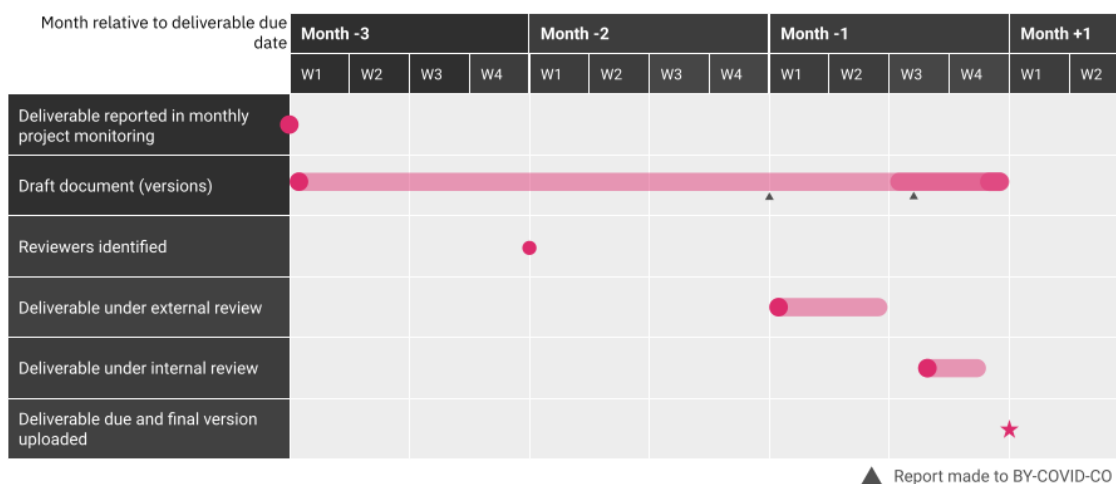
5.1.3.3. Illustrative timelines

1. Three months prior to the due date, the deliverable will appear in the monthly project monitoring report with a link to the pre-prepared deliverable template.

2. Two months (60 days) prior to the due date, author(s) identify the reviewers and inform the BY-COVID-CO.

   a. If multiple people will be producing the deliverable, the lead author should create a Table of Contents and assign responsibilities to the other authors.

   b. Author(s) produce the first draft of the deliverable report.

   c. If the author(s) are not the WPLs, they must have the WPLs review the deliverable report.

3. 1 month (30 days) prior to the due date, the author(s) must send the draft report to the BY-COVID-CO by emailing them a link to the Google Doc version on the BY-COVID Google Drive. The BY-COVID-CO will review the draft for formatting

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before forwarding it to the pre-identified reviewers, allowing them two weeks to provide comments directly within the Google Doc.

   a. Reviewers' input is gathered within the Google Doc using suggested edits and comments.

   b. Author(s) generate a revised version of the document taking on board the suggestions and comments of the reviewers.

4. 1.5 weeks (10 days) prior to the due date, author(s) must send the final version to the BY-COVID-CO emailing them a link to the Google Doc version on the BY-COVID Google Drive. The BY-COVID-CO will then circulate the document (via emailed link) to the MB (all WPLs) and the GA (Countries) for final review, allowing them seven (7) days to review the document. The OG are encouraged to make any suggestions or comments directly within the Google Doc.

5. Three days prior to the due date, the author(s) provide the BY-COVID-CO with the consolidated, final version.

6. The Coordinator (or the BY-COVID-CO on their behalf) will convert the Google Doc to PDF and upload the final version in the Participant Portal and to Zenodo.

7. The final version of the document is also uploaded to the 'Submitted' folder within the respective reporting period subfolder (e.g. RP1, RP2, RP3) in the 04. Deliverables and Milestones folder[14] on the BY-COVID Google Drive.

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[14] https://drive.google.com/drive/folders/1i8WQ7BR6fAObvDJg4MJi8MNq7t53oQx9

Note: Although the illustrative timeline starts three months prior to the due date with drafting beginning two months prior to it, this process can begin earlier if the authors wish, and deliverables can be submitted ahead of schedule.

In case of time constraints, an exceptional streamlined procedure for the deliverables may apply upon agreement with the MB.

A tracker with the deliverable due dates is available on the BY-COVID Google Drive[15].

5.1.8. List of Deliverable Authors

The most up-to-date list of Deliverable Authors list is available on the BY-COVID Google Drive[16] and the Participant's Portal.

5.2. Milestones

Each milestone must use a clean copy of the milestone template[17] and must not exceed one slide. It is the responsibility of the Milestone Lead organisation[18] to produce the milestone report or to deputise the responsibility to someone else upon their agreement.

5.2.1. Illustrative timelines

1. 3 months prior to the due date, the milestone will appear in the monthly project monitoring report with a link to the pre-prepared milestone template
2. 1.5 months (45 days) prior to the due date, if the author(s) are not the WPLs, they must have the WPLs review the milestone before submitting it.
3. 1.5 weeks (10 days) prior to the due date, author(s) must send the final version to the BY-COVID-CO by emailing them a link to the Google Doc version on the BY-COVID Google Drive. The BY-COVID-CO will then circulate the document (via emailed link) to the MB (all WPLs) for final review, allowing them seven (7) days to provide any comment. The MB are encouraged to make any suggestions or comments directly within the Google Doc however, this shouldn't be a time consuming process for the MB.
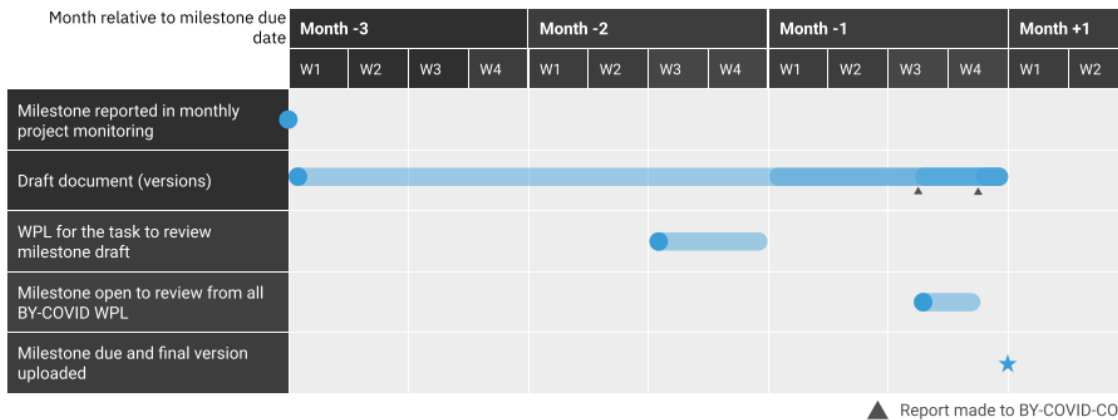4. Three days prior to the due date, the author(s) provide the BY-COVID-CO with the final version.

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[15] https://docs.google.com/spreadsheets/d/1abzvqo3sLsF1e0o7tGIYgsybAa9yJAQInSv0ciU--fk/edit#gid=1091470126

[16] https://docs.google.com/spreadsheets/d/1B_sK9Q8uwAQEOGY-PRBG08HbMgSrlKGE-MCrArKdXW0/edit#gid=858182447

[17] https://drive.google.com/drive/folders/1cVxZtW5UyunJP4ISPzrv4p_7qc7CRsur

[18] https://docs.google.com/spreadsheets/d/1abzvqo3sLsF1e0o7tGIYgsybAa9yJAQInSv0ciU--fk/edit#gid=1091470126

5. The Coordinator (or the BY-COVID-CO on their behalf) will convert the Google Doc to PDF and upload it in the Participant Portal.
6. The final version of the document is also uploaded to the 'Submitted' folder within the respective reporting period subfolder (e.g. RP1, RP2, RP3) in the 04. Deliverables and Milestones folder[19] on the BY-COVID Google Drive.

Month relative to milestone due date	Month -3				Month -2				Month -1				Month +1	
	W1	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4	W1	W2
Milestone reported in monthly project monitoring	●													
Draft document (versions)	●▬▬▬▬▬▬▬								●▬▬▬		▲	▲		
WPL for the task to review milestone draft						●▬▬								
Milestone open to review from all BY-COVID WPL											●▬			
Milestone due and final version uploaded												★		

▲ Report made to BY-COVID-CO

A tracker with the milestone due dates is available on the BY-COVID Google Drive[20].

5.3. Progress reporting

5.3.1. EC Project Periodic Technical Reports

Throughout the entire project execution period (1st October until 30th September 2024), the Consortium is required to submit, in due time, two technical reports to the EC using the template periodic report provided in the EC Participant Portal[21]. The project is officially divided into 2 periods for both progress and financial reporting to the EC:

- RP1: 1st September 2021 to 28th February 2023 (M1-18)[22]

- RP2: 1st March 2022 to 31st August 2024 (M19-36)

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[19] https://drive.google.com/drive/folders/1RwHcsPXTaXKhIMtnaYbuzTVRIT1_8J06

[20] https://docs.google.com/spreadsheets/d/1abzvqo3sLsF1e0o7tGIYgsybAa9yJAQInSv0ciU--fk/edit#gid=1091470126

[21] As of today, the template is not available but the online manual provides in depth information. https://webgate.ec.europa.eu/funding-tenders-opportunities/display/OM/Online+Manual

[22] This periodicity might change under Horizon Europe, and it will be timely informed.

In compliance with the rules that will be specified in the BY-COVID Grant Agreement (Periodic reports – Request for interim payments), periodic reports have to be submitted to the EC within 60 days after the end of each reporting period.

Based on the template of Horizon 2020, and to be amended once the Horizon Europe is available, the periodic technical report must include the following:

- an explanation of the work carried out by the beneficiaries;

- an overview of the progress towards the objectives of the action, including milestones and deliverables identified in Annex 1 of the Grant Agreement;

    - an explanation justifying any differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;

    - an overview of the exploitation and dissemination of the results and, if required in Annex 1, an updated 'plan for the exploitation and dissemination of the results'.

    - an overview of the communication activities;

- a summary for publication by the EC;

- the answers to the 'questionnaire', covering issues related to the action implementation and the economic and societal impact, notably in the context of the EC and the Horizon Europe key performance indicators and EC and the Horizon Europe monitoring requirements.

Each partner shall send or provide within the technical report template, as requested, information about the work performed and efforts devoted in the corresponding period to the BY-COVID-CO, within 30 calendar days after the end of the reporting period. Effort figures can however be requested by the BY-COVID-CO at any point during the project. For the purpose of accountability, beneficiaries are requested to keep track of their efforts at the task/activity level. This facilitates the linkage between effort and progress when reporting to the EC.

The Periodic Technical Report template provided by the EC will also be found on the BY-COVID Google Drive. This template will be used for each of the Periodic Technical Reports unless the EC produces an amended version throughout the course of the BY-COVID project.

Detailed instructions on the submission of the periodic technical report will be provided by the BY-COVID-CO to all partners in advance of the reporting deadline.

5.3.2. Financial Reporting

Disclaimer: Beneficiaries must always ensure they follow the EC financial reporting guidelines. The details provided here are valid at the date of the document submission but may be superseded by changes to EC rules. See the Financial Reporting Guidelines available on the ONLINE Manual on EC Participant Portal[23] for further information.

As with all EC Horizon 2020 projects, each BY-COVID project beneficiary has a budget, which comprises the estimated costs that will be incurred during the project lifecycle. These costs can be covered with EC funding. Total funding received by a beneficiary cannot exceed its costs (i.e. it cannot yield a profit derived from participation in the project).

EC funding follows EC reimbursement rules, which imply in the BY-COVID project a maximum 100% of the costs reimbursed for eligible project activities. EC funding is paid in several instalments: an initial payment of 40% (pre-financing) at the beginning of the project, one periodic interim payment reimbursing the costs reported and accepted in the Periodic Report (up to a total amount of 95% of the total funding for a beneficiary), and a final payment of the remaining of the total funding including the 5% Guarantee Fund.

Budgeted efforts and costs will be available in the DoA. When agreed by the BY-COVID-MB, budgets can be adjusted by transfers of amounts between beneficiaries or between budget categories (or both) during the project life. This may not require an amendment, if the action is implemented as described in DoA. In case of subcontracting, these costs should be included in the DoA (via Amendment if needed) to make sure they are accepted by the EC as costs claimed.

5.3.2.1. Eligible costs

Costs which are categorised as eligible may be claimed for reimbursement. In order to consider project costs as eligible and therefore be approved by the EC, they must fulfil the following general conditions:

- they must be actually incurred by the beneficiary;

- they must be incurred in connection with the action as described in the DoA and necessary for its implementation;

- they must be determined in accordance with the usual accounting principles of the beneficiary;

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[23] https://webgate.ec.europa.eu/funding-tenders-opportunities/display/OM/Online+Manual

- they must be incurred during the duration of the project, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report;

- they must be recorded in the beneficiaries' accounts;

- they must comply with the applicable national law on taxes, and social security;

- they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

- they must be indicated in the estimated overall budget in the DoA.

Beneficiaries should take into account, in the day-to-day administration of the project, some practical advice that may facilitate their financial management.

Beneficiaries need to:

- be aware of their own budget distribution;

- coordinate their financial flows: budget, funding, expenditure, justification, payments;

- avoid inconsistencies between efforts spent in the project (recorded in time sheets) and personnel cost justification.

'Budget' refers to costs that each partner is expected to incur, as declared in the DoA. The amount contributed by the EC is called 'funding' or 'EC contribution', and corresponds to 100% of the eligible costs. A beneficiary has to justify its total budget in order to get the expected funding in full. The actual costs incurred during the project (the 'practical' implementation of the planned budget) is called the 'expenditure'. These costs will conform to EC rules and therefore be justifiable. Lastly, 'payments' refer to the actual amounts transferred to the partners' accounts during the project. These depend on the funding of each partner and the justification accepted by the EC, and cannot exceed the total funding of each beneficiary.[24]

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[24] In the event these terms change in HE, they will be accordingly updated in this document.

6. Project processes

6.1. Risk management

6.1.1. Risk identification and categorization

An initial list of key project risks has been identified during the preparation of the Action and a respective table of identified risks is in the Participant's Portal, as a new procedure under Horizon Europe. All beneficiaries are asked to screen their activities with regards to additional new risks and to promptly notify the BY-COVID-CO of any significant new risk(s) having the potential to affect the completion of the assigned WP.

6.1.2. Risk assessment, registry and action plan

The BY-COVID-CO will add any new risks, including a description of the possible impact, to the risk register (BY-COVID Project Monitoring and EC Portal) and bring any additional risk(s) to the attention of the BY-COVID-MB.

Prioritization of the risks will be based on the possible impact (I) and the probability (II) of realization of the risk. Based on the prioritization appropriate mitigation activities and/or contingency plans will be developed.

A mitigation plan for each identified risk has to be developed by the concerned work package and the BYCOVID-CO and presented to the BY-COVID-MB as part of the risk management process. The list of identified risks are part of the BY-COVID Project Monitoring tool.

6.1.3. Risk monitoring

The risk register will be reviewed by the BY-COVID-CO on a monthly basis informing the BY-COVID-MB of any significant change when it happens or at least every six months in the regular meetings. WPLs and Task leads are asked to actively contribute to this activity which will be overseen by the Project Coordinator and BY-COVID-CO.

An update of the risk assessment activity, including the major risks identified with their corresponding mitigation and contingency plans, will be included in the Periodic Report to be submitted to the European Commission. Newly identified risks will be communicated to the EC via the EC project continuous monitoring tool (requires EC login).

The BY-COVID-CO will drive the risk management process, dealing with the identification, assessment and follow-up of threats and opportunities likely to affect the project performance as a whole.

Concrete actions arising from the analysis of the risks will be included in the project monitoring tool and distributed to participants and WP involved on a monthly basis via the automatic report generated and distributed by theBY-COVID Project Monitoring tool.

For any questions contact BYCOVID-coordination@elixir-europe.org.

6.2. Issue management

The project issue management process defines the activities related to identifying, documenting, assessing, prioritizing, assigning, resolving and controlling issues. It is a four step process that the Project Management Team (BY-COVID-CO) executes whenever required throughout the project lifecycle:

1. Issue Identification: Issues can be identified by any project stakeholders throughout the project lifecycle, using different communication channels such as meetings and emails (BYCOVID-coordination@elixir-europe.org). The issues are registered in the Issue Log.

2. Issue Assessment and Action Recommendation: a first informal assessment by BY-COVID-CO, considers the category, impact, urgency of the issue, followed by a more detailed analysis to identify the root cause and recommend a solution. This information is documented in the Issues Log tab in the BY-COVID Project Monitoring tool and used as input to the appropriate decision makers (based on the escalation process). The decision is also documented in the Issues Log.

3. Actions Implementation: After issues are evaluated and the remediation actions approved, the BY-COVID-CO will incorporate these actions into the appropriate project related documentation such as the Change Log tab in the BY-COVID Project Monitoring.

4. Issue Control: During the regular BY-COVID-MB meetings the status of the issues related actions incorporated into the BY-COVID Project Monitoring will be revised, and new issues identified.

Concrete actions arising from the analysis of the issues will be included in the project monitoring tool and distributed to participants and WP involved on a monthly basis via the automatic report generated and distributed by the BY-COVID Project Monitoring tool.

For any questions contact: BYCOVID-coordination@elixir-europe.org

6.3. Project change management

The project change management process defines the activities related to identifying, documenting, assessing, approving, prioritising, planning and controlling changes, and communicating them to all relevant stakeholders. It is a five step process that the Project Management Team (BY-COVID-CO) executes whenever required throughout the project lifecycle:

1. Change Identification: a request for a change can be submitted formally via an email to BY-COVID-CO (BYCOVID-coordination@elixir-europe.org), or can be identified and raised during meetings as a result of decisions, issues or risks. The requested change should then be captured in the Change Log section of the BY-COVID Project Monitoring tool including information to identify the change, such as the requestor, a short description, identification date, etc.

2. Change Assessment and Action Recommendation: the size and impact of the change on the project scope, schedule, cost, quality, risk, and other project boundaries is assessed, whereafter a recommended action will be documented by BY-COVID-CO in the Change Log section of the BY-COVID Project Monitoring tool.

3. Change Approval: the approval of a project change will be determined by the type and impact of the change requested and in line with best practice in EC grant. For low impact change requests which do not require formal approval by the EC, BY-COVID-CO will advise who must approve the change, be it BY-COVID-CO, the BY-COVID-MB or the BY-COVID GA. If a formal change to the Grant Agreement is required then the BY-COVID-CO will use the information provided in the Change Log as an input to the formal amendment request that will be submitted to the EC after the approval or the GA or the BY-COVID-GA depending on the type of the change. Only when a significant change is requested or a number of smaller requests have been received, will an amendment request be submitted to the EC.

4. Change Implementation: the activities related to the implementation of approved changes will be documented by the BY-COVID-CO in close collaboration with the EC.

5. Change Control: new or open changes will be identified/reassessed by the BY-COVID-CO, using the Change Log section of the BY-COVID Project Monitoring tool and will be brought to the attention of the BY-COVID-MB, the BY-COVID-GA or the GA in due course.

For any questions contact BYCOVID-coordination@elixir-europe.org.

6.4. Quality management

The implementation and execution of BY-COVID follows the principles of Horizon 2020 and European Commission rules and are more specifically defined in the Grant Agreement, the Description of Action and in the Consortium Agreement provisions. The procedures described in this section shall not replace any of the established agreements within the consortium or with the EC, or any of the EC guidelines for project implementation. The project will be managed according to EC best practice with a dedicated communications effort.

BY-COVID will explore the establishment and operation of a suite of high-quality communications channels, periodic project monitoring including work plan execution, quality assurance, data management, use of resources, innovation management activities, and risks.

BY-COVID quality objectives are to:

- Ensure that all the project related activities and deliverables are fulfilling the scientific and technical quality expectations and are following available quality and compliance standards issued by the EC under the Horizon Europe funding scheme[25].

- To define the processes and assets to be utilised by all consortium partners to meet these objectives and to provide support to partners to achieve the required quality and to monitor adherence to the standards set for the project, in alignment with the DoA.

- Ensure compliance with agreed Horizon Europe and EC rules, applicable law and regulations, incl. but not limited to data privacy, handling of funds and ethics. To promote gender equality in the project and science and society issues related to the research activities conducted within the project will be also addressed, looking for suitable guidelines.

6.4.1. Quality policy

The generic quality policy adopted by BY-COVID builds upon the following set of principles:

- Quality and its pursuit are regarded as important for every individual activity within the project;

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https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

- Criteria and standards by which the quality of both the results of the project and the processes involved in their production will be identified;

- Description of the tools, methods and techniques to be employed in order to ensure quality will be shared among participants;

- Provisions must be made for monitoring quality during the process and recording compliance and deviation.

Taking into consideration the overall quality policy, quality standards are to be applied to all the work undertaken throughout the project.

6.4.2. Project quality control

The overall quality control of the project results includes the coordination of quality review for all project outputs prior to their submission to the EC.

It is crucial for the project to ensure that deliverables, as official results of the project, are reviewed and checked for quality. This may also apply to other outcomes of the project that are addressed to parties external to the project.

The present document is focusing only on the general methods implemented to ensure quality of written materials delivered to the EC and other partners external to the Consortium. A document produced in a project generally aims to provide information concerning the work, its progress or the derived results. Each document should thus be carefully drafted with rich content, a clear structure and a professional presentation. The three basic aspects for building quality into project documents are content, appearance and timing. It is generally accepted that the relative importance of each document varies, and it is important that overzealous quality criteria do not compromise timing if marginal benefit to the project is minimal.

For more information about the process, see section 5.1.3. Deliverable review process.

6.5. Key Performance Indicators (KPIs)

The outcomes and impact of the project in relation to the call text will be assessed against Key Performance Indicators. A full list of the KPIs as identified in the proposal can be viewed in this preliminary spreadsheet.

These KPIs can easily be monitored, from the project onset and will be refined in WP6. Progress against these KPIs must be reported to the governance boards, to inform project planning and management, looking forwards (rather than post-hoc assessment), ensuring corrective actions are taken as and when they are needed. Some of these indicators already form part of ELIXIR's suite of indicators, which are used to monitor the infrastructure's

performance (mostly internally-facing) and impact (mostly externally-facing), in line with ESFRI's current work on ensuring that the infrastructures it has recognised are adequately monitored.

6.6. Data management plan

The Data Management Plan (DMP) will be defined and updated throughout the project lifecycle as part of Task 8.3. The initial version of the DMP must be created by BBMRI-ERIC in the first six months of the project within WP8 (D8.2) according to the project scope and the EC requirements.

Any questions regarding the DMP should be directed to the BY-COVID coordination team (BYCOVID-Coordination@elixir-europe.org).

6.7 Internal conflict resolution and escalation

Conflicts are situations in which one or both parties perceive a threat. They are considered to be critical issues and can be raised by any of the project stakeholders. The Project Management Team should proactively identify, log and raise such issues for resolution.

In the event that an internal conflict arises at a given time, the project coordination and the management structure is formulated to support a bottom-up approach with respect to its resolution.

- Conflicts amongst Beneficiaries in any given activity should be discussed at the Work Package (WP) level with the help of the respective Work Package Leaders (WPLs).

- If unresolved, the issue will escalate to the BY-COVID-CO that will then use mediation to objectively aim to solve the issue involving all parties affected.

- If unresolved and when the issue is significant enough, the BY-COVID-CO could then make a proposal :

  - To the BY-COVID-MB if the issue has very limited operation impact and can be resolved at this level. if it is a strategic issue, to amicably resolve the issue.

  - To the BY-COVID General Assembly if it is a non-strategic issue

At all stages, beneficiaries can reach out to the BY-COVID-CO in case they feel a request has not been adequately dealt with.

7. Configuration management

7.1. Storage of project management artefacts

Project repository

The Project Management Team has created a structured BY-COVID Google Drive to store the project management artefacts following the same folder convention per sub-folder.

Table 12. Project repository structure.

Top Level Folders	Content
1. Project MASTER File	Master document with details from the project: contact lists, effort distribution, lists of deliverables & milestones, GANTT chart etc
	Project monitoring spreadsheet - contains details of all actions, events, deliverables and milestones, along with due dates and templates - monthly reports are generated from this for all partners/WPs. It includes the email address of the partners' participants that are relevant for the monitoring and control activities: PIs, Deputies, administrative, financial and legal contacts.
2. Legal Documents	Legal documents pertaining to the project: Consortium Agreement, Grant Agreement, Description of Action, amendments, contracts etc
3. WPs	Working folders for the WPs
4. Deliverables & Milestones	Repository for project deliverables and milestones (templates, working drafts and submitted documents)
5. Project meetings, Events & TCs	Details of all project meetings and events (agendas, minutes slide presentations etc)
6. Periodic Reporting	Financial and periodic reports from all project partners

7. Guidance and Templates	Project handbook, containing guidance pertaining to all aspects of the project (processes, communications, management structure and responsibilities etc)
	Project templates: deliverables, milestones, agendas, minutes, slide presentations etc
8. Project Communications and Outreach Materials	Project branding & style guidelines, press releases, articles, presentations, newsletters etc
9. Grant Agreement Preparation	Working documents for the preparation of the grant agreement

For any assistance with creating new folders, please contact bycovid-coordination@elixir-europe.org.

Utilisation of project repository is covered in 8.4 File Exchange and Repository

7.2. Naming convention of project management artefacts

The latest version of a detailed, controlled Documents Version Policy outlining the project naming conventions and other configuration management guidance will be included in D6.2 Data Management Plan (M06-March 2022).

7.3. Versioning of project management artefacts

All project management artefacts are under version control.

7.4. File Exchange and Repository

7.4.1 BY-COVID Repository

A Google Drive has been created for BY-COVID to be used as a repository of relevant information and files which facilitates the exchange of documents within the consortium (i.e. meeting minutes, documents in progress, final versions and other relevant reports or announcements). The BY-COVID Google Drive also provides a calendar of meetings and events, upload of files, and tracking of important milestones and events at both the project and Work Package level.

- All beneficiaries have been enabled access to the BY-COVID Google Drive once they have signed up to the mailing lists. Access can be granted after filling in the registration form[26].

- The latest version of the BY-COVID contact list is uploaded on the BY-COVID Google Drive, in the BY-COVID list. The up-to-date participants' contact information with clear information of who is included in every mailing list mentioned above will be based on the periodic updates by each of the Work Package Leaders.

- The use of de facto standards based on Google Docs for electronic document exchange among participants is required when possible. PDF format can alternatively be used to avoid excessive size of files when no editing is required. BY-COVID uses Google Drive as a project management tool that is simultaneously used as a document management system. The BY-COVID Google Drive provides a place to store, secure and organize the consortium documentation which helps to ultimately control the quality of documents and conformity of processes.

The tool has capabilities available to set permissions on a file or folder. These clear access rights can be rapidly degraded or defeated entirely by the system admin (coordinator) of the consortium. Users with proper visibility rights and access permission can fuel quality control of the project.

Additionally, a document version history is an efficient way to track who has edited files and when. This platform allows users to revert to an earlier version if the file becomes corrupted or if errors are introduced.

With the notification feature available, each person with permission can invite other consortium participants on document edits and to track changes to a document stored in a shared folder simultaneously.

BY-COVID uses Google Drive to manage quality of the documents and processes by enhancing the centralization of digital assets, promote maintenance of quality and support backup and data protection.

Any publication in BY-COVID is governed by Annex 5 and Article 16 of the Grant Agreement and Article 8.4 of the Consortium Agreement. Scientific Publications and Communication to the public will be covered by WP7 Deliverable 7.1 due in M06.

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[26] https://docs.google.com/forms/d/e/1FAIpQLSfU2qVLaN_8E9t-bttmQ-npU--bmaSiEwk_dyN0Xfv1yM_05Q/viewform

The Documents Versioning Policy outlined in 7.2. is key to clean and consistent archiving; especially towards the mid/end phase of the project when an increasing number of digital outputs and documents are created. Using the same tag for email subjects and for the documentations in attachments, fuels clear communication and leads to reduced email burden and duplication of work.

8. Key legal document

8.1. The Grant Agreement

The Grant Agreement (GA) is the main legal document underpinning the project's execution – effectively, a contract between the beneficiaries and the EC. It is first signed by the EC and the Coordinator. Each beneficiary then accedes to the Grant Agreement by executing an accession form. The Grant Agreement mainly provides information on the grant (parties, duration, start date, budget, etc.), obligations of the Beneficiaries towards the EC (such as reporting requirements), as well as the intellectual property framework and other legal conditions. The Grant Agreement is dated 1st October 2021 and has the GA Number 101046203

The Grant Agreement core document includes a standard text describing the general rules and regulations governing EC projects, including financial rules (e.g. which costs are acceptable, how payments are handled, etc.), Intellectual Property Rights (IPR) (who owns the results, how access to such results is enabled, etc.) and other general conditions applicable to EC projects. These generic provisions can be supplemented (but not contravened) with project-specific provisions via a Consortium Agreement (see below), which enables projects to set out their specific IPR detailed rules, governance mechanisms, etc.

Beyond its core terms and conditions, mostly standard text, the Grant Agreement also includes the following annexes, which form an integral part of the contract:

8.1.1. Annex 1. Description of the action (DoA)

The most extensive and important Annex to the Grant Agreement is the Description of Action (DoA), which comprises the technical description of the work to be undertaken in the project (work packages, tasks, deliverables, milestones), the description and roles of the different partners, allocated effort in person-months, and budget details. The DoA is derived from the original proposal submitted to the EC for evaluation and approval, and it is the benchmark against which project progress will be judged. Compared to the rest of the Grant Agreement and annexes, which are mostly model texts, the DoA is specific for each project. It is important to remember that the DoA is an integral part of the Grant Agreement, and therefore it is a contractual commitment of all beneficiaries.

8.1.2. Annex 2. Estimated Budget for the action

This Annex refers to the overall budget for the BY-COVID Project and includes the budget details for all project beneficiaries. This document is automatically generated by the EC Participant Portal.

8.1.3. Annex 3. Accession form for beneficiaries

This form is required to be signed by all the project beneficiaries to formally accede to the BY-COVID Grant Agreement. If a new beneficiary joins the project, this form will be requested to be signed by the new institution joining the project.

8.1.4. Annex 4. Model for the Financial statement

This form refers to the summary of costs to be reported by those partners receiving EC funding for each reporting period.

8.1.5. Annex 5. Specific rules for carrying out the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement, the call conditions and all legal obligations under applicable EU, international and national law. Section 2 of the Model Grant Agreement specifies the content of this annex.

 The signed Grant Agreement and its annexes will be available on the BY-COVID Google Drive[27] once finalised.

8.1.6. Changes to the Grant Agreement

The Grant Agreement can and must be changed whenever any important project parameter changes: partnership, project duration, budget, etc. Implementation of such changes must follow a specific procedure called 'Grant Agreement amendment'. Most changes that trigger Grant Agreement amendments relate to updates in the Description of Action (DoA) (e.g. changes in tasks and deliverables, changes in efforts allocated, changes in partner's teams, budget transfers across beneficiaries, etc.). These can be relatively minor, in which case they tend to be grouped and implemented together in one go, or major, which might trigger an amendment on their own, especially if it is urgent that the change is officially entered into the contract.

Grant Agreement amendments are submitted to the EC by the Coordinator on behalf of the Consortium. This implies that the Consortium must be aware of and approve any proposed changes before the amendment is requested.

The BY-COVID-CO will be responsible for following-up on amendments to the Grant Agreement during the project.

The procedure is as follows:

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[27] https://drive.google.com/drive/folders/1fnSik__m6fmVA-0RIZki_Nh5H5I15F3o

1. The Project Management team (BY-COVID-CO) will keep track of all needed amendments. Meetings and communications with the beneficiaries affected will enable the BY-COVID-CO to compile all the necessary information to support the changes.
2. The list of modifications will be circulated to the General Assembly for their information and approval.
3. The BY-COVID-CO will prepare the following documentation:
    a. A new version of the DoA with the modifications in track changes.
    b. A first version of a "Request Letter" to be sent to the EC Project Officer including the changes.
    c. Other documents needed to request modifications.
4. The BY-COVID-CO will circulate an amended version of the DoA to the Management Board for validation. The approval by the BY-COVID-MB will be required for any Amendment to the Grant Agreement.
5. As a final step the Coordinator, supported by the BY-COVID-CO, will submit on behalf of the Consortium, the Request Letter, the new version of the DoA and all the additional documentation required by EC for the changes submitted.
6. Once approved, the new version of the DoA will also be accessible in the BY-COVID Google Drive in the appropriate amendment folder.

The Grant Agreement may be affected by other types of minor changes which do not constitute an amendment, but which must be communicated to the consortium or to the EC through an information procedure. In any case, beneficiaries should contact the BY-COVID-CO to confirm the procedure to follow for any modification needed.

For more information about the procedure, review the updated version of the Online Manual, for funding and tenders.

9. Ethical considerations

Within BY-COVID no human biosamples will be collected. BY-COVID focuses on the use of data which will be done with respect to the relevant European and national ethical and legal frameworks. BY-COVID aims to improve the discoverability, accessibility and reusability of already existing health data from research infrastructures, hospitals and institutes. It is the first time that a project aims to include a broad range of data, from socioeconomic and public health data to molecular and clinical trials data.

Work Package 8 will be in charge of gathering an independent group of experts for the creation of the Scientific, Ethics and Industry Advisory Board (SEIAB). This board will ensure that data sharing through the BY-COVID platform respects the basic ethical

principles. Moreover, the use of data in the use cases will - if necessary – also be approved by the local ethical approval committees. We are closely following up with the work of the Beyond 1M genomes project (ELSI working group).

Although the work in the BY-COVID does not imply any critical ethical issue, its ultimate goal to enable a sharing of genomic and health data on a large scale across Europe will come with major ethical, legal and social implications. For this reason, an ELSI team will be set up as part of Task 8.3 to study the legal, ethical and social implications of this initiative and provide a framework of policies, guidelines and legal analyses as well as practical recommendations that can be translated into technical solutions.

More details about BY-COVID ethical approach will be part of D8.2 in its Data Management Plan. As of today, the **Ethical Summary Report**[28] provides a more detailed insight about this topic.

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[28] https://docs.google.com/document/d/1dke-VhDfoCLpXc9aQUBx1ZQ6EF1WfJt6RgVDOclJADQ/edit#