GOVERNANCE CHARTER

A public-private partnership for the estimation of brand-specific COVID-19 vaccine effectiveness in Europe

COVIDRIVE

Version 6.0

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GLOSSARY

The definitions in Clause 1 of the Consortium Agreement to which this Governance Charter forms an appendix apply to this Governance Charter.

Action	also referred to as "Project" means all the activities, including research activities, carried out by the Partners as detailed in the Governance Charter.
Collaborative Agreement	means the agreement and all of its appendices, signed by all the authorised representatives of the Core Platform Partners for the setup of the Consortium (Phase 1 of the Action).
Collaboration Agreement	means the agreement and all of its appendices, signed between P95 and all the authorised representatives of the Vaccine Company Partners for the setup of the Consortium (Phase 1 of the Action).
Consortium	means the group of Partners that are parties to the Consortium Agreement. For the avoidance of doubt, the Consortium has no separate legal identity.
Consortium Agreement	means the agreement and all of its appendices, together with amendments, signed by all the authorised representatives of the Partners.
Control	means, with respect to any Partnership Results, Results, Study Results, information, data, or intellectual property right, the possession of (whether by ownership or licence, other than licences granted pursuant to the Consortium Agreement) or the ability of a Partner to grant access to, or a licence or sublicence of, such right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.
Co-coordinators	FISABIO and P95, both COVIDRIVE Partners, are appointed as Co-coordinators to jointly coordinate and manage the Project.
Core Platform Partners	means the group of Partners that are not Vaccine Company Partners.
COVIDRIVE	means the public-private partnership for the estimation of brand-specific COVID-19 vaccine effectiveness in Europe organised under the Consortium Agreement.
COVIDRIVE database	has the meaning given in Section 3.6.

Feasibility report	has the meaning given in Sections 4.1 and 4.3.
Governance Charter	means the present document, which aims at providing an overview of the governance framework of the Action: objectives, guiding principles, stakeholders, roles and responsibilities, legal and regulatory environment, communication and expected tasks and deliverables that will guarantee an efficient and fair execution of the Project.
ICMJE authorship criteria	The International Committee of Medical Journal Editors (ICMJE) recommends that authorship be based on the following four criteria: • Substantial contribution to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND • Drafting the work or revising it critically for important intellectual content; AND • Final approval of the version to be published; AND • Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
Independent Scientific Committee (ISC)	consists of a limited number of external experts with relevant experience/expertise in the field of COVID-19 vaccine effectiveness. Scientific experts representing each of the Co-coordinators act as the secretariat of the ISC.
Informed Consent Form	means the document to inform the Study participants of the purpose of the data collection, data handling and possible risks and benefits of participating in the Study in lay language and document the voluntary decision of the Study participant to participate in the Study. The Informed Consent is adapted to national requirements, translated into the language of the Study participant and approved by the Ethical Committee of the Study Site in which the Study is performed.
ISC Agreement	means the agreement and all of its appendices, together with amendments, signed between P95 and the members of the ISC.
Level 1 data	has the meaning given in Section 3.6.
Level 2 data	has the meaning given in Section 3.6.
Level 3a data	has the meaning given in Section 3.6.

Level 3b data	has the meaning given in Section 3.6.
Level 4 data	has the meaning given in Section 3.6.
Level 5 data	has the meaning given in Section 3.6.
Master Protocol	has the meaning given in Section 3.5.
Master Scientific Documents	has the meaning given in Section 5.1.
Master Study	means a Study conducted under a Master Protocol for common data collection by several Study Requestors.
Master Study Documents	means the documents based on the Partnership Results and the operational Study documents developed for the common benefit of the Consortium.
Partner or Participant	means a legal entity signatory of the Consortium Agreement. Partners are either Core Platform Partners or Vaccine Company Partners.
Partnership Results	means the scientific and technical documents generated in the frame of the Action.
Study Period	Means three consecutive months in which the Study can be started, conducted, closed.
Primary Data Use	means the use of patients' data for the purpose of the Study as defined prior to data collection.
Quality Assurance and Audit Committee (QAAC)	means the committee responsible for the quality management and auditing of the Study or Studies, composed of one quality assurance expert from each Vaccine Company Partners and one quality assurance expert from the Co-coordinators. The Co-coordinators act as the secretariat of the QAAC.
Results	means any tangible or intangible output of the Action such as data, knowledge, know-how or information that is generated in the Action, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights (such as copyright, design rights, patent rights, or similar forms of protection). Results shall not include the Study Results nor any background or sideground.
Secondary Data Use	means the use of patients' data for other purposes than Primary Data Use.

Secondary Data Use Requestor	means an entity that requests access to the COVIDRIVE database for Secondary Data Use.
Steering Committee (SC)	is the decision-making body of the Consortium, responsible for its strategic direction and allocation of budget and resources.
Study	means a COVID-19 vaccine effectiveness (CVE) study requested by a specific Study Requestor to be performed in the framework of the Action.
Study Contributor	Also referred to as "Study Site or "Site"," is an institution that collects/owns data of interest for Studies, and that signs a Study Contributor Agreement with P95 after being selected via a study-specific selection process. The Study Contributor is part of the Study Team for the specific Study.
Study Contributor Agreement	means the agreement and all of its appendices, together with amendments, signed by P95 and a Study Contributor.
Study Coordination Team	has the meaning given in Section 2.9.
Study Master File	has the meaning given in Section 5.5.
Study Requestor	means the Partner that requests to perform a specific Study.
Study Results	means the results and conclusions of the Study, including • Level 4 data • Level 5 data • any Study reports (e.g. progress, interim and final reports).
Study Results Scientific Primary Publication	The primary publication prepared by the Study Team produced for a scientific peer review journal, abstract/oral or poster presentation at a scientific conference which presents Study Results.
Study Sponsor	means the organisation which takes on the responsibility – on behalf of the Consortium – to initiate, manage and finance the Studies, as well as ensuring the operational/administrative coordination of the network of Study Contributors.
Study Team (ST)	means the team that carries out the conduct of the Study and includes experts from the Co-coordinators, Study Contributors and Study Requestors. • The Restricted Study Team (Restricted ST) is made up of experts from the Co-coordinators and Study Contributors.

	• The Full Study Team (Full ST) is the Restricted ST plus the experts from the Study Requestors.
Third Party	means an entity that is not a Partner in the Consortium.
Vaccine Company Partner	means a Partner that is a pharmaceutical company.

ABBREVIATIONS

AZ	AstraZeneca
CA	Consortium Agreement
CDA	Confidential Disclosure Agreement
CDSIC	Clinical Data Interchange Standards Consortium
COVID-19	COronaVIrus Disease 2019
CRS	COVIDRIVE Research Server
CT	Coordination Team
CV	Curriculum vitae
CVE	COVID-19 vaccine effectiveness
DIA	Drug Information Association
DRIVE	Development of Robust and Innovative Vaccine Effectiveness
ECDC	European Centre for Disease prevention and Control
eCRF	Electronic case report form
EDC	Electronic data capture
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EnCePP	European network of Centres for Pharmacoepidemiology and Pharmacovigilance
EQA	External Quality Assessment
EU	European Union
EU PAS	European Union Post Authorisation Studies
eSMF	Electronic Study Master File
eTMF	Electronic Trial Master File
FISABIO	Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunidad Valenciana
FTE	Full-time equivalent
GDPR	General Data Protection Regulation
GSK	GlaxoSmithKline plc
GxP	Good “x” practice
HCP	Health Care Professionals
I-MOVE	Influenza – MOnitoring Vaccine effectiveness in Europe
ICH GCP	International Conference on Harmonisation Good Clinical Practice

ICMJE	International Committee of Medical Journal Editors
IMI	Innovative Medicines Initiative
ISC	Independent Scientific Committee
IT	Information Technologies
IVE	Influenza Vaccine Effectiveness
J&J	Johnson & Johnson
LCS	Lab-Confirmed SARS-CoV-2
MAH	Marketing Authorisation Holder
mRNA	Messenger ribonucleic acid
NITAG	National Immunisation Technical Advisory Group
PCR	Polymerase Chain Reaction
PHI	Public Health Institute
PI	Principal Investigator
QAAC	Quality Assurance and Audit Committee
QCMD	Quality Control for Molecular Diagnostics
RDP	Remote Desktop Protocol
RMP	Risk Management Plan
RT-PCR	Reverse-Transcriptase Polymerase Chain Reaction
SAP	Statistical Analysis Plan
SARS-CoV-2	Severe Acute Respiratory Syndrome CoronaVirus 2
SC	Steering Committee
SCT	Study Coordination Team
sFTP	secure File Transfer Protocol
SME	Small and Medium Enterprise
ST	Study Team
tDMP	template Data Management Plan
THL	Finnish institute for health and welfare (Terveyden ja Hyvinvoinnin Laitos)
TMF	Trial Master File
UK	United Kingdom
US	United States
VE	Vaccine Effectiveness
WG	Working Group

DOCUMENT HISTORY

Version	Date	Description
V5.3	25 May 2021	First agreed version across all consortium partners and integrated in the Consortium Agreement
V6.0	16 January 2023	Second agreed version approve by all consortium partners and integrated in the first amendment of the Consortium Agreement. Addition of several sections, in particular a new section on open access for Secondary Data Use. Overall update of sections formerly included in version 5.3. Alignment with the Consortium Agreement.

A more detailed document history tracker is available upon request.

EXECUTIVE SUMMARY

COVIDRIVE is a not-for-profit public-private partnership that facilitates the conduct of COVID-19 vaccine effectiveness (CVE) studies in Europe to support the region's public health response and to address vaccine companies' regulatory obligations. This multi-stakeholder partnership brings together public institutions (FISABIO - Spain, THL - Finland), small and medium enterprises (P95 – Belgium), and vaccine companies including AstraZeneca (UK), Bavarian Nordic (Denmark), CureVac (Germany), Janssen (Belgium), GSK (Belgium), Moderna (US), Novavax (US), Sanofi (France) and Valneva (France).

COVIDRIVE is facilitating the conduct of observational studies on COVID-19 vaccine effectiveness. In addition to the assessment of brand-specific CVE, key areas of interest include duration of vaccine protection, effectiveness against disease caused by newly emerging SARS-CoV-2 strains, effectiveness against severe COVID-19 disease and effectiveness in special risk groups such as immunocompromised, frail individuals or subjects with chronic conditions or existing comorbidities. COVIDRIVE leverages an Influenza vaccine effectiveness platform (built in DRIVE[1]), which provided annual brand-specific influenza vaccine effectiveness estimates to the European Medicines Agency (EMA).

This Governance Charter provides an overview of the governance framework of COVIDRIVE (objectives, guiding principles, stakeholders, roles and responsibilities, legal and regulatory environment, communication and expected tasks/deliverables) to guarantee efficient and fair execution of the Action and production of high-quality Partnership Results. The principles herein are implemented through the Consortium Agreement. Ways of working and priorities may be adapted (upon agreement by the Partners) to fit the Partners' needs, the changing COVID-19 situation and related changes to the implementation of the vaccination programmes.

This document provides a trusted and transparent framework to guide other potential multi-stakeholder public-private long-term collaborations to conduct vaccine studies in Europe. It is made publicly available on the COVIDRIVE website.

[1] DRIVE (Development of Robust and Innovative Vaccine Effectiveness) was an Innovative Medicines Initiative Project (July 2017- June 2022).

1 BACKGROUND

Section 1 presents the situation at the time COVIDRIVE was set up. Adjustments were made afterwards and up-to-date information is provided in the next sections.

1.1 COVID-19 pandemic and COVIDRIVE genesis

The COVID-19 pandemic has affected all aspects of our lives in an unprecedented way. A collaborative effort among all stakeholders is crucial to successfully control the global public health crisis. While non-pharmaceutical interventions were initially used to slow down the spread of COVID-19, the development and swift global deployment of safe and effective vaccines against COVID-19 play a crucial role in the control of this public health crisis. Upon (conditional) marketing authorisation of the first COVID-19 vaccines, EU regulations require that the safety and effectiveness of these vaccines are being timely monitored. The EMA has recommended to make use of existing/established EU efforts and encourages a common approach to assess COVID-19 vaccines in real-life settings.

Because of the uncertainties related to the timing of the COVID-19 vaccines' market authorisations, the national decisions on which vaccines to purchase, the different timelines of vaccines distribution, the national vaccination prioritisations and the fragmented market share, it is challenging to predict the level of vaccine brand uptake and ensure sufficient sample size for CVE studies. This necessitates the setup of a large study network with a wide geographical coverage.

The idea to launch a public-private partnership for brand-specific COVID-19 vaccine effectiveness monitoring (COVIDRIVE) was presented to the *Vaccine Europe* partners in November 2020 and supported by the *Vaccines Europe Experts Task Force for COVID-19 vaccines, epidemiology and pharmacovigilance*.

COVIDRIVE is leveraging an existing vaccine effectiveness platform (DRIVE) which provides yearly brand-specific influenza vaccine effectiveness (IVE) estimates to the EMA. The DRIVE project (https://www.drive-eu.org) is an ongoing 5-year IMI (innovate medicines initiative) project, launched in July 2017 to respond to an EMA regulatory commitment requiring vaccine companies to provide yearly brand-specific IVE estimates. Despite a challenging feasibility, DRIVE has successfully set up a strong and efficient data collection platform through a network of independent study sites across the EU, and has established a quality-controlled information technology (IT) platform and pooled analysis infrastructure alongside appropriate governance (https://www.drive-eu.org/index.php/governance/).

COVID-19 and influenza are both respiratory infectious diseases with similar clinical symptoms, respiratory specimens and laboratory tests, making influenza study networks well suited to also study COVID-19. So, the DRIVE study platform, governance, tools and methods can be adapted to meet the specificities of COVID-19 vaccine effectiveness (CVE) studies and thus allow for fast start-up at reduced costs. This resource efficiency would be further enhanced through joint funding by several vaccine companies and through leveraging existing public health capacities. In addition, ensuring a good coordination between public health institutes and vaccine companies will optimise health care practitioner (HCP) resources in data collection. COVIDRIVE aims to get reliable and timely data; in full

compliance with the competition laws COVIDRIVE will facilitate post-authorisation harmonisation on methods and regulatory pathways as well as sharing CVE results and liaising with other EU initiatives/EU institutions to enhance high-quality CVE monitoring.

1.2 COVIDRIVE partnership development plan

This section should be considered as background information.

The following action plan was set up in November 2020 in order to onboard Consortium Partners with the aim to be ready to initiate a first brand-specific CVE study by the end of May 2021. The action plan is graphically represented in Figure 1:

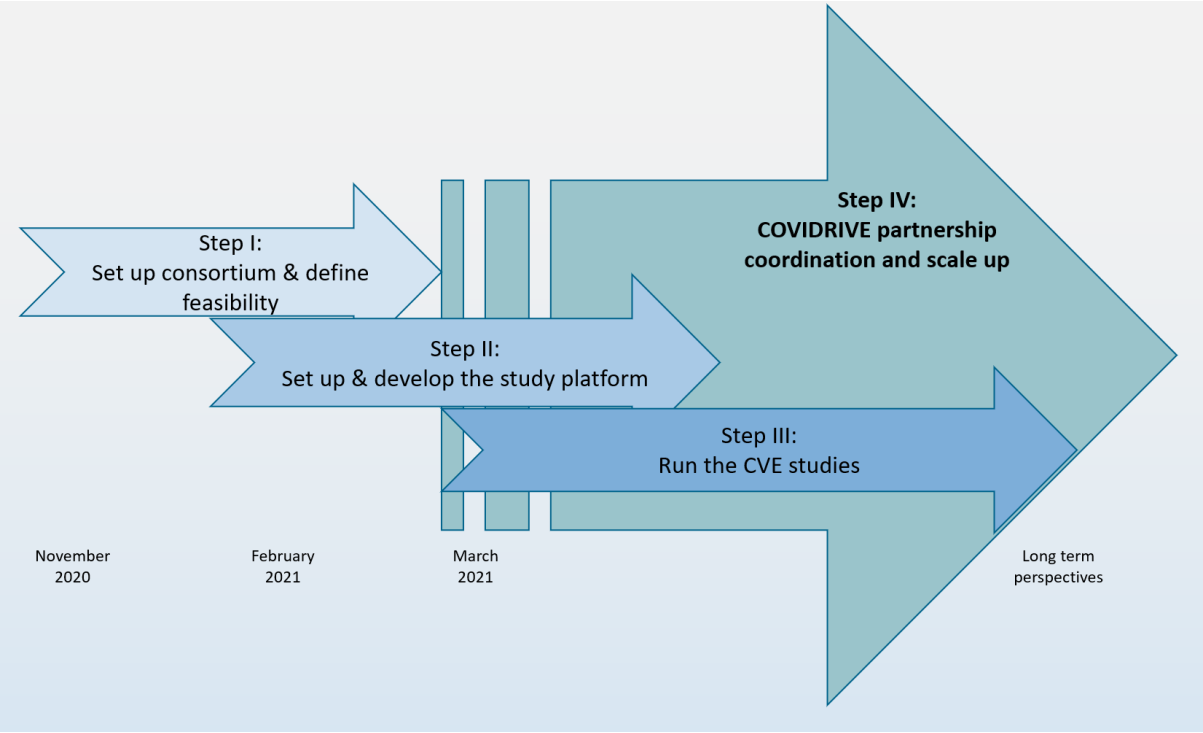


Figure 1. Action plan of the COVIDRIVE partnership

<u>Step I: Setting up the COVIDRIVE partnership</u>

Step I (November 2020 to February 2021) is the first level of engagement: confirmation by each Vaccine Company Partner by signing a Collaboration Agreement with P95 (one of the two Co-coordinators of COVIDRIVE), confirmation of Core Platform Partners by signing a Collaborative Agreement with P95 and confirmation of willingness to participate by potential Study Contributors (public health institutes or research institutes, Study Contributors network) by signing a letter of intent.

After signing of the Collaborative and Collaboration agreements, COVIDRIVE Partners co-develop the following deliverables:

- Feasibility Report

- Consortium Agreement, and
- Governance Charter.

The funding of step I comes from Vaccine Companies that signed the Collaboration Agreement. The funding is allocated and distributed by P95 among the other Core Platform Partners engaged in the co-development of COVIDRIVE.

Step II: Development of study platform and infrastructure

Step II (starting February 2021) is the second level of engagement, in which the foundation of the COVIDRIVE partnership is developed (including the Consortium set up with its respective governance bodies, Master Scientific Documents, IT infrastructure) to be ready to start the CVE studies by the end of May 2021.

Legally, Step II consolidates the COVIDRIVE partnership via the following agreements:

- Vaccine companies become COVIDRIVE Vaccine Company Partners (and members of the SC) by signing the Consortium Agreement.
- Public health institutes/other research institutes interested are asked to confirm their willingness to become (1) COVIDRIVE Core Platform Partners (members of the SC) by signing the Consortium Agreement and/or (2) COVIDRIVE Study Contributors.

The funding of Step II comes from Vaccine Company Partners. P95 allocates and distributes the funding among the Core Platform Partners according to the arrangements set forth in the Consortium Agreement. This funding (budget) contributes to develop the Master Scientific Documents (e.g., Master Protocol, master statistical analysis plan (SAP) and master mock report), the setup and maintenance of the platform and the coordination of the partnership. All those components constitute the partnership development and activities.

During this phase, FISABIO and P95 co-coordinate the development of Master Scientific Documents with the Partners:

- master study protocol(s) to assess CVE at the brand level, adapted to up-to-date national vaccination programmes,
- master SAP for pooled analysis across European sites, and
- master mock report to present the CVE results (e.g. overview of SARS-CoV-2 virus circulation, COVID-19 vaccines' specificities and graphs/tables to present brand-specific CVE estimates) agreed to a priori.

However, depending on time and resource constraints, COVIDRIVE Partners may decide and agree collectively to postpone the development of some Master Scientific Documents for the benefit of timely starting the first Studies (see Step IV). This should be appropriately reflected in the budget engaged in Step II.

Step III: Study conduct and reporting

The COVIDRIVE partnership aims to be ready to initiate Studies by end of May 2021. Upon a request from one or more COVIDRIVE Partners, a ST is set up to, in collaboration with the selected Study Contributor(s), develop Study-specific scientific documents, adapt the Master Scientific Documents and the platform from the partnership, and to conduct the Study.

The funding of a Study comes from the Study Requestor(s) leveraging public health capacities of the COVIDRIVE Sites network. The total Study budget is allocated and distributed among the appropriate Core Platform Partners and the Study Contributors by P95.

Step IV: Partnership coordination and scale-up

The COVIDRIVE partnership moves to a scale-up and coordination phase with continuous development of methods and on-boarding of new COVIDRIVE Partners and Study Contributors. The partnership aims to conduct various studies which may advance knowledge on COVID-19 and COVID-19 vaccines.

This Step IV is supported by the Consortium Agreement signed in Step II and which is planned to be renewed every two years upon COVIDRIVE Partners' agreement. The funding of Step IV includes the overall partnership coordination, IT maintenance, study network scale-up and the development of Master Scientific Documents not previously developed in Step II. The funding of Step IV will come from participating COVIDRIVE Vaccine Company Partners, under the Consortium Agreement.

The action plan as defined above in November 2020 is used to guide and ensure a good track of the key activities needed to be ready to start the first CVE study by the end of May 2021. Nevertheless, the action plan may be slightly adapted to fit the COVIDRIVE Partners' needs, the changing and pressured COVID-19 pandemic situation and related changes to the implementation of the vaccination programmes.

1.3 Governance Charter content

The present document aims at providing an overview of the governance framework of COVIDRIVE: objectives, guiding principles, stakeholders, roles and responsibilities, legal and regulatory framework, communication and expected tasks/deliverables that will guarantee an efficient and fair execution of COVIDRIVE and production of high-quality Partnership Results. In particular, the COVIDRIVE Governance Charter aims to:

- define partnership vision, objectives and guiding principles, building up on the contents of the Consortium Agreement,
- list Partners' roles, responsibilities and tasks, besides those listed in the Consortium Agreement,
- describe governance bodies, their composition, roles, responsibilities and interactions,
- define expected Partnership Results (deliverables),
- describe decision-making processes,

- describe study and data workflow,
- describe legal and regulatory environment, and
- define communication strategy and plan.

This document aims to propose a trusted and transparent framework to guide multi-stakeholder public-private long-term collaborations to conduct vaccine studies in Europe. Ways of working and priorities may be adapted (upon agreement by the COVIDRIVE Partners) to fit the COVIDRIVE Partners' needs, the changing COVID-19 situation and related changes to the implementation of the vaccination programmes.

2 COVIDRIVE: VISION, OBJECTIVES, PARTNERS, ACTIVITIES/DELIVERABLES AND STRUCTURE

2.1 Vision and objectives

The COVIDRIVE partnership aims to conduct Studies in Europe through a public-private multi-stakeholder approach. The partnership's objectives are to:

- build a sustainable partnership supported by the following components: COVIDRIVE Partners and scientific community, the platform, Study documents & processes, Study Contributors network and regulatory pathway,
- develop joint methodological and technical resources to undertake Studies in Europe,
- set up a network of Study Contributors across Europe, able to conduct multi-centre observational Studies covering several countries and reaching sufficient/representative COVID-19 vaccination coverage and sample size,
- leverage already established public health capacities, optimise HCP resources in primary data collection and mutualise their contribution to several Studies when relevant,
- allow fair and reasonable access to the data collected through the network of Study Contributors for secondary use,
- explore new ways of cooperation within the partnership, if approved by the SC, and
- welcome new partners and Study Contributors in the partnership.

These objectives will be pursued in full compliance with competition law. The Vaccine Company Partners will only discuss issues that are strictly necessary to reach those objectives within the scope of the collaboration as defined in this Governance Charter and no competitively sensitive information will be exchanged among COVIDRIVE partners that are competitors. The Partners will strictly adhere to the competition law guidelines and the GDPR.

2.2 Partners

FISABIO, P95, Sanofi in collaboration with GSK and THL founded COVIDRIVE and signed a Collaborative Agreement in January 2021. The Consortium Agreement was first signed by FISABIO, P95, THL, Sanofi, GSK, AstraZeneca, CureVac and Janssen in July 2021. Novavax, Moderna and Valneva joined COVIDRIVE in December 2021. Bavarian Nordic joined in June 2022.

As of June 2022, the COVIDRIVE Partners are:

- **Core Platform Partners:**
    - P95: Small and medium enterprise (SME) founded in 2011 as a consulting business in epidemiology and pharmacovigilance. Engaged in COVIDRIVE genesis from DRIVE experience. Since June 2021, co-coordinating (jointly with FISABIO) the COVIDRIVE partnership, executing the legal and financial tasks, setting up and maintaining the

COVIDRIVE platform, developing Master Scientific Documents, supporting the expansion and maintenance of the COVIDRIVE network and being the Study Sponsor of the CVE studies.

- FISABIO: Not-for-profit entity affiliated to the regional government of Valencia (Spain), with its own legal status. Oversees vaccine research and public health activities in the Valencia region. Engaged in COVIDRIVE genesis from DRIVE experience. Since June 2021, co-coordinating (jointly with P95) the COVIDRIVE partnership, developing Master Scientific Documents, leading the expansion and maintenance of the COVIDRIVE network.
- THL: Finnish expert agency that provides reliable information on health and welfare for decision-making and activities in the field. Engaged in COVIDRIVE genesis from DRIVE experience. Since June 2021, engaging in COVIDRIVE to create synergies with public health institutes and developing Master Scientific Documents.

- **Vaccine Company Partners:**
  - AstraZeneca is a pharmaceutical company, holding a conditional marketing authorisation for a COVID-19 vaccine in Europe. Since June 2021, AstraZeneca is participating in the development of the partnership, contributing to the Master Scientific Documents and Governance Charter, and planning a Study through COVIDRIVE.
  - Bavarian Nordic is pharmaceutical company, developing a COVID-19 vaccine candidate. Since June 2022 Bavarian Nordic is participating in the development of the partnership, contributing to the Master Scientific Documents and Governance Charter, and planning a Study through COVIDRIVE.
  - Janssen is a pharmaceutical company, holding a conditional marketing authorisation for a COVID-19 vaccine in Europe. Since June 2021, Janssen is participating in the development of the partnership, contributing to the Master Scientific Documents and Governance Charter, and planning a Study through COVIDRIVE.
  - CureVac is a biotechnological company developing a mRNA COVID-19 vaccine. Since June 2021, CureVac is participating in the development of the partnership, contributing to the Master Scientific Documents and Governance Charter, and planning a Study through COVIDRIVE.
  - Sanofi is a pharmaceutical company jointly developing a COVID-19 vaccine candidate with GSK, currently under review of an application for conditional marketing authorisation by the EMA. Sanofi is the marketing authorisation holder of this candidate vaccine. Engaged in COVIDRIVE genesis from DRIVE experience. Since June 2021, Sanofi is participating in the development of the partnership, leading the Governance Charter development and updates, contributing to the Master Scientific Documents, and planning a Study through COVIDRIVE.
  - GSK (GlaxoSmithKline) is a pharmaceutical company developing COVID-19 vaccine candidates and a monoclonal antibody for early treatment of COVID-19. Engaged in COVIDRIVE genesis from DRIVE experience. Since June 2021, GSK is participating in

the development of the partnership, contributing to the Governance Charter development, the Master Scientific Documents, and planning a Study through COVIDRIVE.

- Moderna is a pharmaceutical company, holding a conditional marketing authorisation for a COVID-19 vaccine in Europe. Since January 2022, Moderna is participating in the development of the partnership, contributing to the Master Scientific Documents and Governance Charter, and planning a Study through COVIDRIVE.
- Novavax is a biotechnology company holding a conditional marketing authorisation for a COVID-19 vaccine in Europe. Since January 2022, Novavax is participating in the development of the partnership, contributing to the Master Scientific Documents and Governance Charter, and planning a Study through COVIDRIVE.
- Valneva is a pharmaceutical company holding a conditional marketing authorisation for a COVID-19 vaccine in Europe. Since January 2022, Valneva is participating in the development of the partnership, contributing to the Master Scientific Documents and Governance Charter, and planning a Study through COVIDRIVE.

2.3 Key activities and deliverables

Several key activities are planned within COVIDRIVE at Consortium level, including activities related to the conservation and expansion of the COVIDRIVE community, activities related to study preparedness and activities related to project management.

Conservation and expansion of the COVIDRIVE community

1. **Study Contributors network coordination and expansion**: activities are reported in two deliverables; (1) feasibility report and (2) set of pre-qualified Study Contributors (documented assessment). Those two deliverables may be regularly updated.
2. **Communication tools** (website, Veeva Vault, mailing list): these are milestones
3. Setup and coordination of the **ISC and QAAC**: these are milestones.
4. **Regulatory pathway** and screening of regulatory activities focusing on EU and relevant for CVE: these are ongoing activities.
5. **COVIDRIVE public relation management** (incl. funding opportunities, attending conferences, dissemination activities): this is an ongoing activity.
6. **COVIDRIVE governance update:** this deliverable may be updated based on SC decision and pending to evolution of the COVIDRIVE community

Study Preparedness

7. Setup and maintenance of the **electronic data capture (EDC) systems and COVIDRIVE Research Server (CRS)**: these are milestones.
8. **Master scientific documents**: activities are reported in four types of deliverables: (1) Master Protocols, (2) master SAPs, (3) master mock reports and (4) master web annex specification documents.

9. **Master technical documents**: activities are reported in two deliverables: (1) template data management plan (tDMP), (2) template monitoring plan.
10. **Master analytical and statistical scripts** for fast analysis: these are milestones.

Project management

11. **Coordination and management of the COVIDRIVE community**: these are ongoing activities.

The following activities are planned at Study Requestor-level:

a) **Study Requestor-specific scientific documents**: activities are reported in three types of deliverables: (1) protocol, (2) SAP, (3) reports (progress, interim and final).
b) **Study Requestor-specific technical documents**: activities are reported in two deliverables: (1) data management plan and (2) monitoring plan.
c) **Selection of the Study Contributors:** this is a milestone.
d) **Study Contributors coordination and management** (contract, payment, supporting ethics committee approval, data collection/transfer): these are ongoing activities prior to and during study conduct.
e) **Study-specific EDC and CRS system administration** (data protection officer, user access management, file transfer): this is an ongoing activity.
f) **ISC and QAAC coordination at Study level**: this is an ongoing activity.
g) **Study Requestor-specific analysis and report**: this is a milestone.
h) **Study Requestor-specific publication** (publication of Study Results): activities are reported in one deliverable: peer-reviewed scientific primary publication.

2.4 COVID-19 Vaccine Effectiveness Studies

The partnership intends to conduct COVID-19 vaccine effectiveness (CVE) studies which might fall under the following scope:

- overall and/or vaccine type and/or brand-specific,
- severe, mild and/or asymptomatic COVID-19 disease outcomes,
- hospital and/or primary care setting(s),
- population(s) targeted by the vaccination and/or population(s) of special interest,
- mid-term and/or long-term CVE,
- CVE by genetic variants,
- CVE by time since vaccination and/or by calendar time, and

- CVE by disease level of severity.

2.5 Partnership structure

COVIDRIVE is a not-for-profit public-private consortium. The overall structure of the COVIDRIVE partnership is presented in Figure 2, displaying the governance bodies and key functions. It is based on the governance framework of the DRIVE study platform and adjusted to the COVID-19 situation. It follows key guiding principles for public-private collaboration aiming to:

- promote scientific exchanges between several stakeholders with various expertise and experience,
- optimally steer joint efforts towards the desired outcome within the time and resource constraints,
- allow efficient decision-making,
- guarantee scientific integrity of the CVE results, and
- guarantee good quality standards.

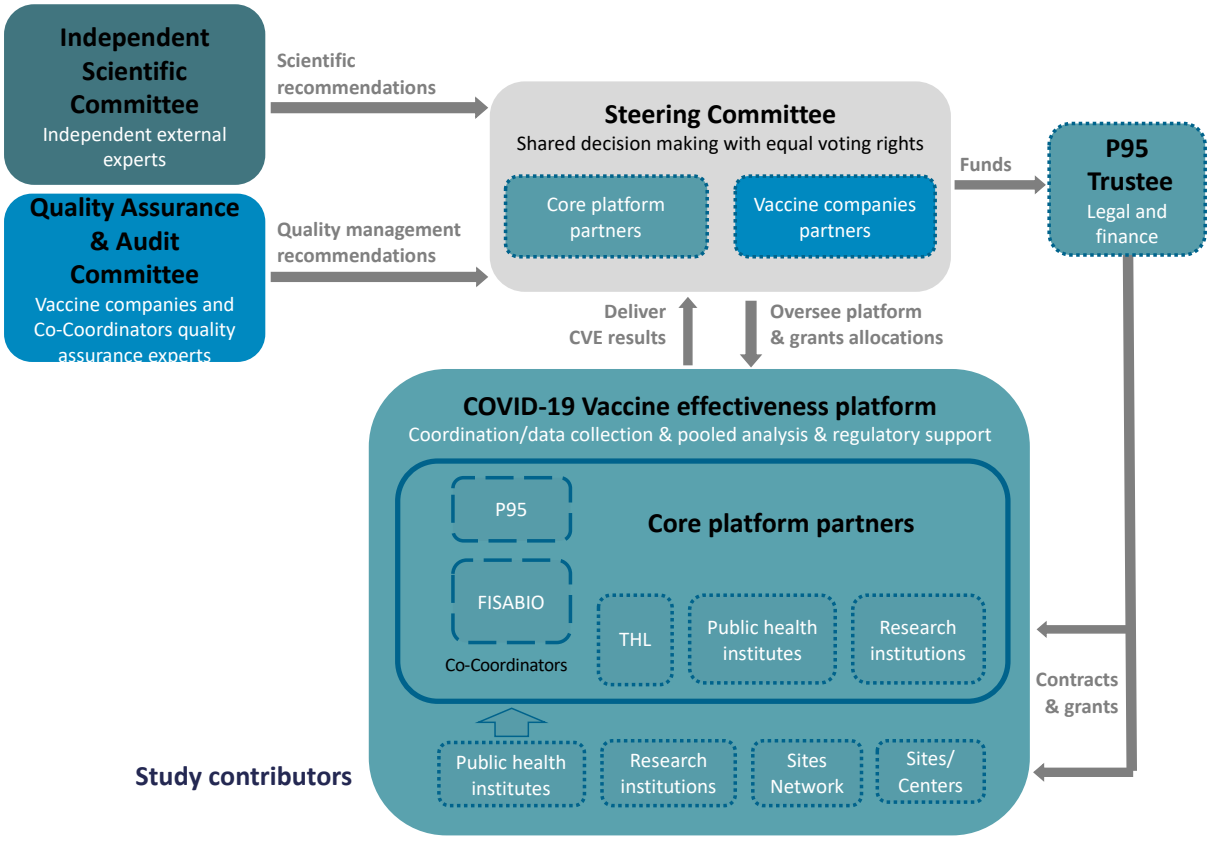


Figure 2. COVIDRIVE governance structure

COVIDRIVE's way of working is based on the following principles (Figure 3):

- At the partnership level, **decision-making** is carried out by the *SC.*

- The **implementation and management** of the COVIDRIVE consortium is performed by the Co-*Coordination.* Master Scientific Documents and technical **documents** are generated by the *Technical Working Group*.
- **Scientific review and recommendation** of the Master Scientific Documents and Study-specific scientific documents is overseen by the *ISC.*
- **Quality management and audit** of the partnership and studies is overseen by the *Quality Assurance and Audit committee (QAAC)*.
- **Financial management,** which includes the role of managing the partnership and Studies' budgets and distributing funds among the Core Platform Partners and Study Contributors is performed by *P95*.
- At the Study level, **decision-making** is performed by the corresponding *ST*.
- The development of Study Requestor's **specific scientific documents** is the responsibility of the corresponding *ST*.

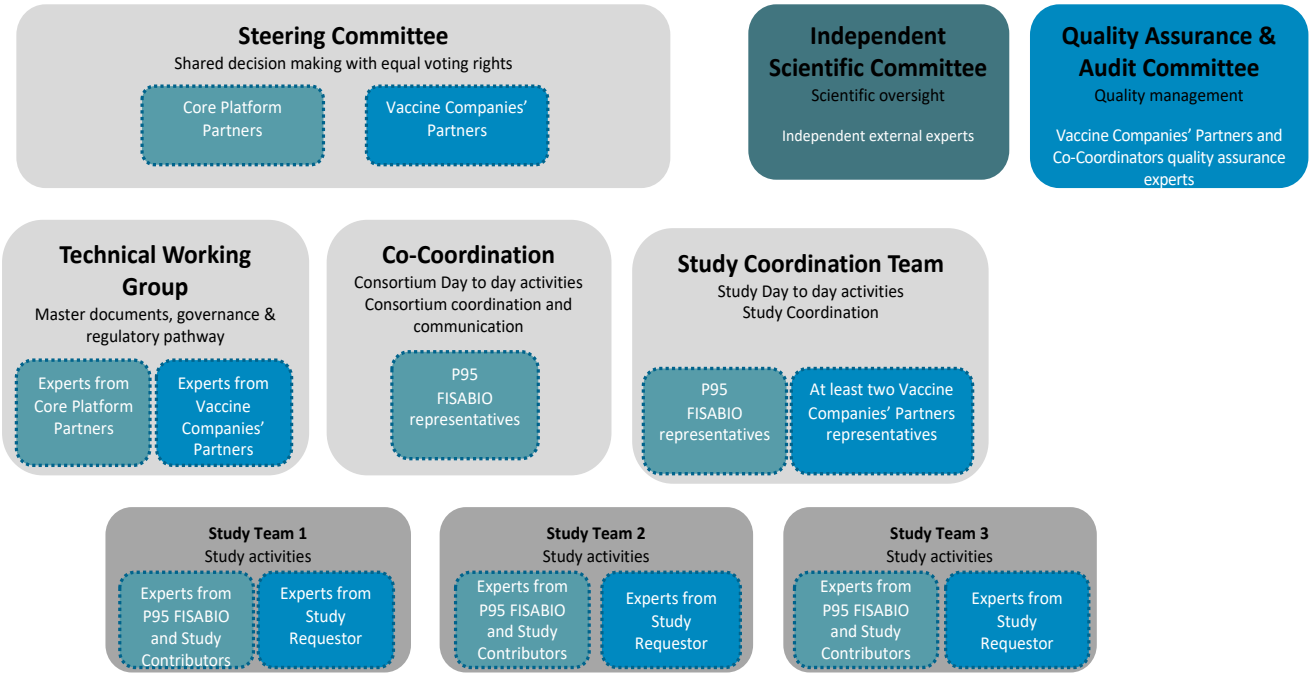


Figure 3. COVIDRIVE partnership: way of working

2.6 Steering Committee

Composition

Each COVIDRIVE Partner shall be represented in the SC; however, decision authority will be split equally between the two groups of the Core Platform Partners and the Vaccine Company Partners.

The SC meets regularly, through teleconferences and face-to-face when possible. The frequency of the meetings is adapted to the partnership needs.

Roles and responsibilities

The SC is responsible for the COVIDRIVE leadership including the following roles and responsibilities:

- ensures strategic direction of COVIDRIVE and alignment between activities,
- ensures alignment across all Partners and solving input-output relationships among them,
- endorses the allocation of funds and resources for the partnership (the management of the funds is ensured by P95),
- agrees on Study relevance for the partnership, in alignment with the scope of Studies within this partnership as described in Section 2.4, when a study request is made,
- mediates in conflict resolutions which are escalated from the Co-coordinators or individual Partners,
- agrees on new partners' involvement in COVIDRIVE (for new Study Contributors, endorses their involvement in the partnership), in alignment with objective, non-discriminatory criteria as described in Section 2.11,
- ensures external communication and advocacy for COVIDRIVE, and
- selects the ISC and QAAC members using a transparent and documented process justified by the member's expertise relevant to COVIDRIVE.

Decision-making process and voting rights

The SC will strive to make decision by consensus. However, voting can be requested by any member for any decision related to COVIDRIVE strategic direction, governance framework, allocation of funds and resources, partnership key activities, Study requests, new partners and Study Contributors' involvements, ISC and QAAC composition and external communication.

Voting occurs as described below:

- Voting rights are distributed equally between the two groups (Core Platform Partners and Vaccine Company Partners)
- A decision is approved if two-thirds or more of the entire membership of each of the two groups agree.

Any decision related to a new partner will be based on the criteria mentioned in Section 2.11 and the SC partners will pro forma vote in favour of a new partner request if those criteria are fulfilled. Assessment of potential new partners shall be timely. Decision on new partners joining COVIDRIVE may not be unnecessarily delayed.

Bearing in mind that the SC is the governance body to endorse the strategic direction of the Project, it is worth noting that the SC should not be the place to go into detailed discussions but only a place to get endorsement (or refusal) of concrete and strategic proposals. In this line, some specific measures to improve the efficiency of the SC meetings and dynamics are proposed:

Way of working

- The Co-coordinators filters and identifies key issues and common needs to be escalated to the SC for endorsement or alignment if they fall under the responsibilities of the SC. The SC is the ultimate level of escalation in case of disagreements between Partners (except when it concerns Study scientific documents for which escalation should go to the ISC).
- An agenda is circulated in advance of the SC meeting presenting the different items, their duration/speaker and expected outputs (discussion, endorsement…). The supporting materials are circulated by email as pre-reads or even to collect SC feedback before the meeting. This allows focusing the meeting discussion on the critical comments. The minutes of the SC meetings are circulated before the next meeting.

2.7 Co-Coordination

Composition

The Co-Coordination is composed of representatives of P95 and FISABIO as Co-Coordinators.

The Co-Coordination may be supported by external consultants/experts (endorsed by the SC) to undertake ad hoc activities and prepare related materials for SC decisions.

Roles and responsibilities

The Co-Coordination is responsible for the implementation and execution of the Consortium's Action.

The Co-Coordination:

- manages the day-to-day operational aspects, administrative tasks and ensures coordination between Partners at the Consortium and Study level,
- prepares, supports, recommends decisions and points of discussion to the SC,
- prepares the agenda and the content of the different working group meetings,
- Identification and escalation to the SC of conflicts or issues at the consortium level
- manages internal and external communication,
- coordinates the ISC and is taking charge of its scientific secretariat,
- coordinates the QAAC and communicates its recommendations to the Consortium,
- identifies potential conflicts and is the first point of contact in case of dispute.

P95 has the following additional roles and responsibilities:

- leads the legal and financial management of the Consortium and the Studies,
- develops and maintains the IT infrastructure (telecommunication tools, document sharing platforms, etc.)

- leads the development of the Master Scientific Documents.

Way of working

The Co-Coordination meets by teleconference weekly (and ad hoc meetings when issues are identified), and face-to-face when possible, to monitor the partnership progress, to address any issues that may arise and to identify what should be escalated to the SC level.

2.8 Study Team(s)

Roles and responsibilities

The ST(s) is (are) created to design and conduct the Studies to be performed by COVIDRIVE upon study request (**Figure 4**). The ST has the following roles and responsibilities:

- develops the Study Requestor-specific documents (protocols, SAP, mock report),
- evaluates and selects Study Contributors for participation in the Study,
- coordinates with participating Study Contributors, and
- writes the Study Requestor report following the process detailed in Section 5.2.

In addition, in its capacity as Study Sponsor of all Studies, P95 has the following roles and responsibilities:

- provides Study Contributors with the necessary information to conduct the Study,
- ensures proper monitoring of the Study,
- facilitates and follows-up that all required ethic review(s) and approval(s) are obtained,
- ensures that the Study is conducted in accordance with the applicable good "x" practice (GxP) requirements,
- ensures a proper vendor selection for study and consortium specific external services as per the COVIDRIVE vendor management plan.

Additionally, the Study Contributors should ensure good execution of the Studies as per COVIDRIVE Master Protocol and national requirements.

Composition and setup

The ST is progressively set up following endorsement of the Study request by the SC (refer to Figure 4).

The Full ST is composed of experts from P95 and FISABIO as Co-Coordinators, experts from the Study Requestor(s) and experts from participating Study Contributors.

The *Restricted Study Team* (Restricted ST) is composed of experts from P95, FISABIO and Study Contributors, i.e. not including participants from the Study Requestor(s).

It is expected that the ST will comprise several profiles, coming from the different stakeholders:

- From P95: Principal Investigator (PI), statistics lead, statistical programmers and data managers, study manager, medical writer
- From FISABIO: investigator, study manager
- From Study Contributors: investigators
- From Study Requestor: (pharmaco-)epidemiologist and statistician

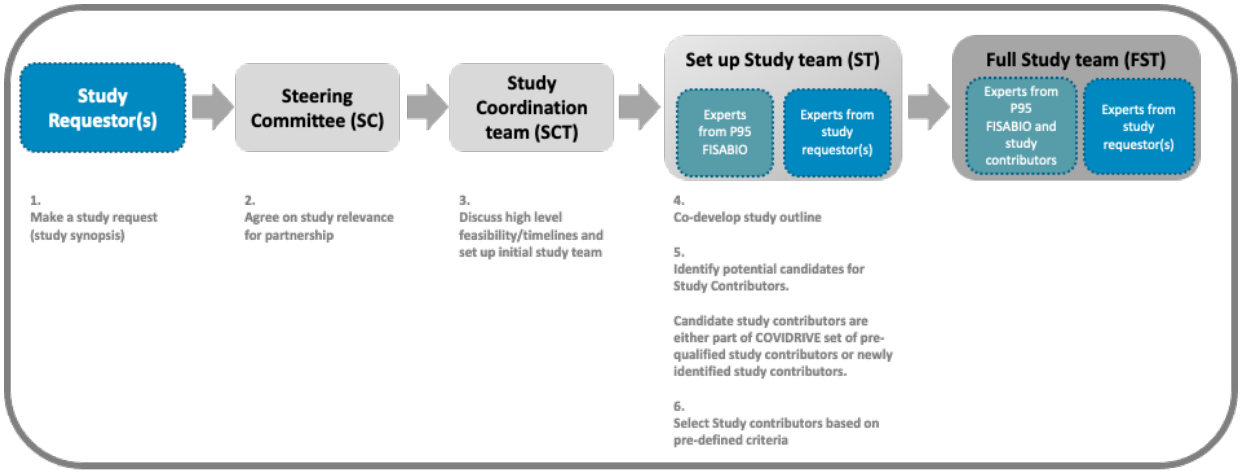


Figure 4. COVIDRIVE Study Team setup

The following steps take place when an ST is set up:

1. The Study Requestor(s) make(s) a Study request by submitting a study synopsis (or specifications to adapt the Master Protocol(s) to the Study Requestor needs) to the SC. Study Requestors can be any of the COVIDRIVE Partners (either Vaccine Company Partners or Core Platform Partners).
2. The study synopsis is reviewed by the SC who agrees on the relevance of the requested Study for COVIDRIVE based on the predefined scope described in Section 2.4.
3. The request is discussed by the Co-coordinators, who determine the high-level feasibility and timelines of the requested Study and who setup the ST.
4. The ST is progressively set up and starts its work by co-developing the Study outline from the synopsis.
5. The ST identifies potential candidates for the role as Study Contributor(s). Candidate Study Contributors are either selected from COVIDRIVE's list of pre-qualified Study Contributors or are newly identified Study Contributors (upon SC endorsement).
6. The ST selects the Study Contributors based on predefined criteria (refer to Section 4).
7. In the end, the Full ST is composed of experts from P95, FISABIO, participating Study Contributors and Study Requestor(s).

The PI is responsible for the oversight of the CVE studies.

P95 and FISABIO ST members are responsible for coordinating the Study Contributor(s) selection process and for overseeing the ethics committee approval process, the contracting and the study budget consolidation.

Data collection, statistical analysis and preparation of the study report are under the responsibility of the Restricted ST members. That means that those Study-specific activities are firewalled from Vaccine Company Partners to avoid perception of undue influence on the Study Results.

When multiple Study Requestors are interested in the same study design and/or Sites, cost sharing principles apply (refer to Section 3.11).

2.9 Study Coordination Team (SCT)

Composition

The Study Coordination Team (SCT) is composed of P95 and FISABIO representatives as Co-Coordinators of COVIDRIVE and representatives from Study Requestors running a study with shared data collection. Through rotating roles, at least two Study Requestors are represented in the SCT. All Study Requestors involved in a study with shared data collection can participate to the SCT at all times during their time of data collection. The rotation frequency will be decided by the SC upon need.

Roles and responsibilities

The SCT is responsible for the implementation and oversight of the running Studies. The SCT has the following roles and responsibilities:

- Primarily, to identify and manage Study-specific issues in the common data collection and conduct of the ongoing Study
- Identification and escalation to the SC of conflicts or issues at the study level
- Prepares, supports, recommends Study-related decisions and points of discussion to the SC.
- Assist the Study Contributors with implementation of study processes.
- Identify anomalies in reported data and following up with Study Contributors to resolve.

Way of working

The SCT meets frequently by teleconference, and face-to-face when possible, to monitor the study progress, identify and manage risks and to address any issues that may arise and to identify what should be escalated to the SC level.

2.10 Independent Scientific Committee (ISC)

Composition

As a start, the ISC is composed of up to five independent external experts with good expertise/experience relevant for Studies. The ISC's composition can be extended depending on COVIDRIVE partnership and study needs.

It is important to stress that ISC members act on their own and do not represent their respective institutions when providing scientific recommendations to COVIDRIVE.

The Co-Coordinators provide the scientific secretariat of the ISC.

Roles and responsibilities

To increase the robustness and transparency of the scientific results produced by the partnership, the scientific leadership of COVIDRIVE is supported by an ISC.

The ISC's mandate is to, based on its members' extensive expertise in the field, review and provide recommendations on the Master Scientific Documents and Study-specific scientific documents. In exercising this role, the ISC shall consider the particular importance of scientific integrity of the CVE results interpretation and Study report.

The current COVIDRIVE ISC members list and a short biography can be accessed through the present link.

The roles and responsibilities of the ISC are the following:

- reviews and makes recommendations for Study documents (protocols and SAPs), and
- reviews and makes recommendations for Study reports. In this particular case, the ISC receives written comments from COVIDRIVE's stakeholders (any scientific expert outside the Restricted ST, including scientific experts from the Study Requestor) and formulates recommendations for integration of their comments to the ST experts from P95 and FISABIO.
- reviews and formulates recommendations for the Master Scientific Documents, which are co-developed by Partners to harmonise CVE methodology (e.g., protocols and analyses to assess severe COVID-19 disease, long-term effectiveness, SARS-CoV-2 infection or transmission).

Selection

The selection of potential ISC members is managed by the SC using a transparent and documented process. The COVIDRIVE partnership generates a list of potential candidates based on the following criteria:

- expertise in vaccine effectiveness surveillance (influenza/COVID-19 specific) and related vaccination implementation programmes (observational research) or COVID-19 vaccine development or influenza/COVID-19 clinical or virological expertise, and
- no recent employment by any of the current Partners or Study Contributors (recent is defined as 2 years prior to date of ISC member invitation by COVIDRIVE).

Preferably, the ISC is a mix of international experts coming from various stakeholder groups (public health institutes, regulatory authorities, research institutes and organisations).

The ISC is active from March 2021, with the official introduction meeting between ISC members and COVIDRIVE SC members, organised by FISABIO and P95.

Way of working

P95 and FISABIO, as Co-Coordinators of COVIDRIVE, coordinate the activities of the ISC.

The ISC meets as needed, through teleconference (or face-to-face occasionally when possible), to discuss their comments on the scientific documents, and provides recommendations to P95 and FISABIO experts.

Compensation

The ISC members sign an ISC Agreement with P95. The contract is established between P95 and either the expert's organisation or the expert directly. The contract is a one-year agreement with automatic renewal unless terminated by the member in writing with two months prior notice before the end of the term.

COVIDRIVE proposes compensations for experts/organisations. Payments are made by P95. The reviews, recommendations and comments given by ISC members will benefit all Partners and future Studies. Consequently, all payments to ISC members will come from the COVIDRIVE budget and will be earmarked as being provided by all Vaccine Company Partners that are all explicitly listed. Compensations follow fair market value rates[2] at national level and include:

- for all ISC members: reimbursement of expenses for travel and accommodation to attend COVIDRIVE meetings, and
- optional (up to each ISC member's consideration): compensation for time spent on scientific review and recommendations (time expenditure in hours to be estimated).

The ISC secretariat ensures the full transparency of payments to the ISC, including HCP payment reporting when applicable and according to EFPIA obligations.

2.11 Quality Assurance and Audit Committee (QAAC)

Composition

The QAAC is composed of one quality assurance expert of each Vaccine Company Partner and one quality assurance expert of the Co-coordinators. If needed, specific audit can be subcontracted to an external qualified consultant auditor. There is a QAAC working group composed of P95, FISABIO and the QAAC members that meets regularly (or ad hoc if any issues with the monitoring arise).

The Co-Coordinators provide the scientific secretariat of the QAAC.

[2] ECDC reference rates for remunerated external experts

Roles and Responsibilities

Since vaccine companies use COVIDRIVE to fulfil their regulatory obligations in conducting Stud(y)(ies), a **Quality Assurance and Audit Committee** (QAAC) is set up with quality assurance experts from the Partners. Its mission is to provide, at the partnership level, guidance on implementation, conduct, monitoring and quality assurance of the Studies, as well as to ensure that data quality is in line with the Study request and to, when necessary and to the extent possible, identify areas for improvement. The QAAC seeks to develop and sustain a reasonable and feasible mechanism to support quality management together with P95 as the Study Sponsor of the Studies.

The QAAC has the following roles and responsibilities:

- develops a quality management questionnaire for Study Contributors, which can be used upon Study Requestor needs,
- reviews the monitoring documentation and activities of the Studies and gives recommendations for both,
- provides quality management recommendations for Study Contributors and oversees any audit at the partnership level.

At the Study level, study monitoring and quality control is ensured by P95 as part of its responsibilities as a Study Sponsor.

There is a QAAC working group (including QAAC members and P95, FISABIO as Co-coordinators) that meets regularly (or ad hoc if any issues with the monitoring arise)

Compensation

Only external consultant auditors will be reimbursed (with fees for services and travel accommodations).

2.12 New partners and Study Contributors

The partnership considers that new partners and Study Contributors are welcome to join COVIDRIVE if they fulfil the following criteria:

- For Core Platform Partners: Any public institution, research institution or private party (incl. SME) considered by the partnership to be able to provide valuable and sustainable long-term expertise and workforce to the partnership development over time, can join. Note: When there is a need for ad hoc specific activities/expertise, subcontracting to a third party shall be considered rather than such a service provider becoming a partner in COVIDRIVE. The subcontracting of a third party requires SC endorsement.

- For Vaccine Company Partners: Any vaccine company having a COVID-19 vaccine candidate under development in phase 2 or later, and for which the company is targeting a marketing authorisation in the EU, can join.

- For Study Contributors: Any organisation, institution or network with interest and expertise/capacity to perform Studies in Europe, and which fulfils the evaluation criteria (refer to Section 4.3), can join.

Any new partner (Core Platform Partner or Vaccine Company Partner) shall agree to join the partnership following the pre-established terms and conditions. After execution of the Form of Accession to the Consortium Agreement, the new Partner will have the same rights and obligations as other Partners.

Any new Study Contributor will sign the Study Contributor Agreement.

3 COVIDRIVE LEGAL AND REGULATORY FRAMEWORK

3.1 The Consortium Agreement

The Consortium Agreement (CA) is entered into by the COVIDRIVE Partners. The CA includes provisions on governance, intellectual property, dissemination, and liability among others. Amendments to the CA, when needed, are handled separately by agreement of all Consortium Partners, under the coordination of the Co-Coordinators.

The COVIDRIVE partnership corresponds to a 2-year engagement (March 2021-2023).

The renewal of the CA should be discussed between the Consortium partners willing to pursue their collaboration for an expected renewal period which will cover at least the planned Study(ies).

A COVIDRIVE Partner who would decide to leave the Consortium (early termination or no participation to the renewal) shall not benefit anymore from the COVIDRIVE partnership (in particular, no possibility to conduct a Study through the partnership), except with regard to Secondary Data Use collected during the time prior to departure of such Partner, as per Section 8.

3.2 Study Requestors

Study Requestors shall be Partners.

Study Requestors can be either Vaccine company Partners or Core Platform Partners.

3.3 The agreement with Study Contributors

It is planned to leverage the DRIVE study network to identify Study Contributors/Sites with good capacity and experience to conduct Studies and to expand this network progressively, based on Study needs. Once selected, the Study Contributor/site signs a Study Contributor Agreement with P95.

3.4 Sponsorship of COVIDRIVE Studies

In COVIDRIVE, P95 is the Study Sponsor for all Studies**.** This means that the Study Requestor will not be the Study Sponsor. Instead, P95 signs a contractual agreement with the Study Requestor and takes responsibility for study planning, conduct and delivery, in line with regulatory requirements, when applicable. P95 also signs contractual agreements with Study Contributors for Study conduct and data sharing.

For a Vaccine Company Partner Study Requestor, the Study is conducted within a framework which is usually called a c*ollaboration study*.

3.5 Study conduct

Within COVIDRIVE, several Studies may be conducted in parallel to respond to various Study Requestors' needs. Some Studies may even be conducted with the same design, being issued from one Master Protocol. Indeed, Master Protocols are set up to harmonise Study methods and to ensure potential mutualisation of HCP/Site resources in primary data collection.

The Co-Coordinators should ensure a good coordination between Study Requestors and Study Contributors to enhance mutualisation/pooling of HCP/Site resources when relevant. This means ensuring that research methods (e.g. study objectives, patients' inclusion/exclusion criteria; case definitions, exposures/outcomes and collected data/variables) are aligned between Study protocols issued from one Master Protocol and that the budget requested by a Study Contributor is fairly shared between the Study Requestors when data can feed several Studies.

3.6 Data hierarchy and data flow

The validated electronic Data Capture System (eDC) server and COVIDRIVE Research Server CRS are the two server environments used for all Studies conducted by COVIDRIVE ensuring secured traceable data entry, data analysis and results output. The following data hierarchy is used for describing the data flow:

Level 1 – Raw patient-level data: This is the raw patient-level data prior to cleaning and pseudonymisation. This data remains local at the Study Contributors.

Level 2 – Cleaned pseudonymised Study Contributor's patient-level data ("Study Contributor Dataset"): This is the cleaned pseudonymised patient-level data. Pseudonymisation is done locally by the Study Contributor. The complete Study Contributor Dataset contains data on all patients collected by the Study Contributor. The Study Contributor Dataset may contain data of multiple vaccine brands depending on the study design used. A copy of the Study Contributor Dataset is transferred to the Study Sponsor (P95).

Level 3a – Cleaned pseudonymised patient-level data from all Study Contributors combined ("COVIDRIVE database"): The COVIDRIVE database combines all Study Contributor's Datasets (Level 2 data) transferred to the Study Sponsor (P95) under the Study Contributor Agreement(s). The COVIDRIVE database is the central database containing patient-level pseudonymised data. The COVIDRIVE database contains data of multiple vaccine brands based on the data collection to date (i.e. the Studies requested). The COVIDRIVE database will not be transferred out of the CRS.

Level 3b – Pseudonymised patient-level analytical dataset(s): The analytical datasets are subsets of the COVIDRIVE database. The analytical datasets contain only the data required for the analysis corresponding to the Study Requestor-specific protocol and SAP, for Primary Data Use and the Secondary Data Use requestor synopsis. The analytical dataset(s) only contain(s) the vaccine brand(s) of interest as specified by the requestor. Vaccine brands will not be identifiable when type-specific analysis will be performed. Thus, no vaccine brand will stand alone, and the proposed grouping by vaccine types shall be based on that principle. The analytical datasets will not be

transferred out of the COVIDRIVE Research Server for Primary Data Use and Secondary Data Use (CRS).

For Secondary Data Use, P95 may give a restricted access of the COVIDRIVE Research Server to either the Secondary Data Use Requestor or another entity than P95 (instructed by the Secondary Data Use Requestor) to conduct the analysis in the dataset prepared by P95 (refer to Section 8).

Level 4 – Tables/figures and listings presenting the study outputs: Tables/figures and listings as generated based on the Study Requestor-specific SAP for Primary Data Use. The tables/figures and listings will be transferred to the Study Requestor.

Level 5 – Anonymised aggregated analytical dataset(s): The anonymised aggregated analytical dataset(s) are aggregated dataset(s) that are generated based on the pseudonymised patient-level analytical dataset(s) (Level 3b), for Primary Data Use. The aggregated datasets do not contain patient-level data. The aggregated datasets will be transferred to the Study Requestor.

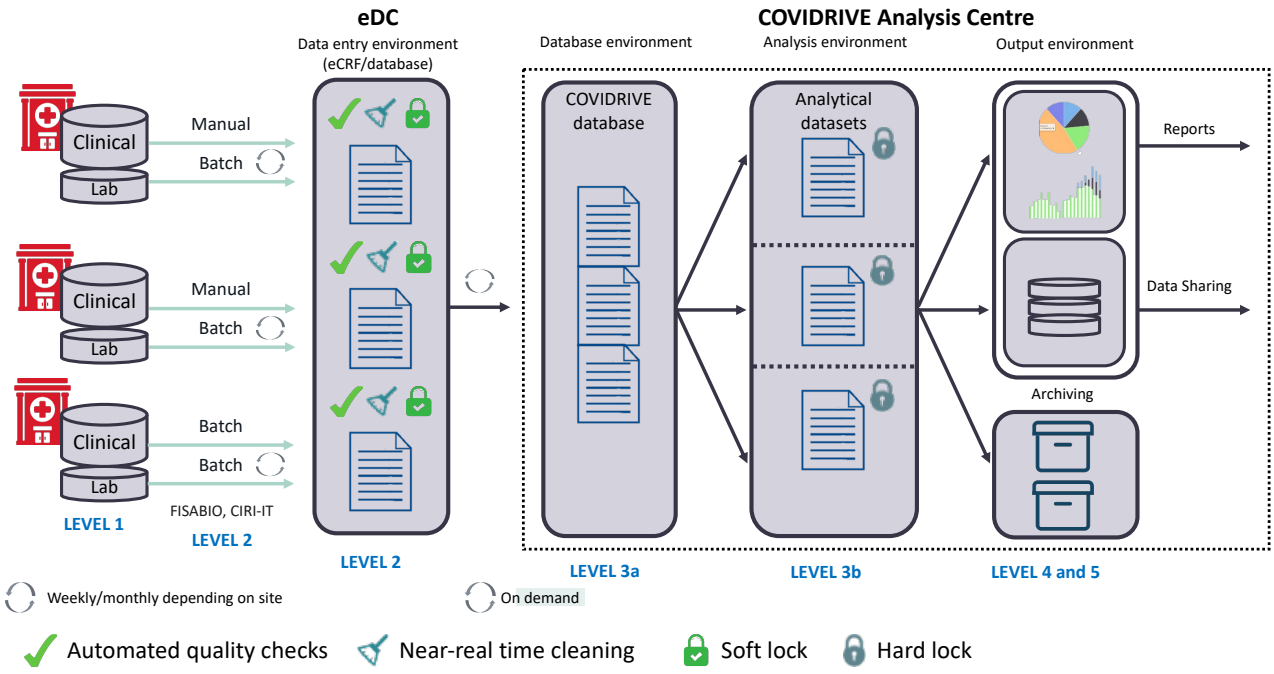


Figure 5. COVIDRIVE Research Server architecture

All personal data (Level 1 Data, Level 2 Data and Level 3 Data) is subject to GDPR considerations as defined in the Study Protocol and Informed Consent Form. The data flow from the Study Contributor to the CRS and extraction of results from the CRS is as follows (Figure 5):

- Step 1: Each Study Contributor creates a selection of the Level 1 database as per the protocol and SAP for the Study (moving from Level 1 data to Level 2 data).

- Step 2: The Study Contributor uploads a copy of the Level 2 data to the Data entry environment. Automated data quality checks are performed and queries are sent to the Study Contributor. When the necessary corrections are made or satisfactory answers provided, the query will be closed. Records on patients that are complete and without open queries will be soft locked.

- Step 3: The soft locked records are sent to the CRS on a regular basis. These records constitute the COVIDRIVE database (Level 3a), containing all data collected by all Study Contributors.

- Step 4: Starting from the COVIDRIVE database (Level 3a), Study Requestor-specific analytical datasets (Level 3b) are created as per Study Requestor-specific SAP, for Primary Data Use and per Secondary Data Use Requestor synopsis for Secondary Data Use. The analytical datasets only contain the information needed to perform the pre-specified analysis. The analytical dataset will not contain brand-specific information other than the vaccine brand of the Study Requestor. Other brand names will be appropriately blinded (e.g. mentioning vaccine platform instead of vaccine brand). Multiple analytical datasets will be created. Efforts will be made to avoid vaccine brands to be identifiable when type-specific analysis will be performed. Thus, no vaccine brand will stand alone, and the proposed grouping by vaccine types shall be based on that principle.

- Step 5: Starting from the Study Requestor-specific analytical datasets, data transformations on the analytical dataset will be performed to generate output results such as Tables and Figures (Level 4). Analytical datasets will be hard locked prior to any data transformation. When the data transformations are finalised, the P95 data analysts flag the resulting output files (Level 4) to the P95 system administrator for extraction out of the CRS. The system administrator checks the resulting output files flagged for extraction for compliance with the SAP.
    - If the check is satisfactory, the resulting files (Level 4 data) are extracted out of the CRS by the system administrator using a secure File Transfer Protocol (sFTP).
    - If the check is not satisfactory, the system administrator reports this to the data analyst and requests changes to get the Level 4 data into compliance with the SAP.

  After the Level 4 data files are extracted from the CRS, they can be used as the basis for reports, web applications and publications as per the Study specific SAP.

- Step 6: Starting from the Study Contributor-specific analytical datasets, aggregated datasets (Level 5) can be optionally created. The aggregated data do not contain individual-level records. The aggregated datasets can be extracted out of the CRS by the system administrator using sFTP. The aggregated data can be shared with the Study Requestors. Only the aggregated data derived from the analytical datasets corresponding to the SAP of a particular Study Requestor will be shared with that Study Requestor.

3.7 Data Control and access

Data Control considerations: Study Contributors remain the Controllers of their respective Raw patient-level data (Level 1 data) and cleaned pseudonymised patient-level data (Level 2 data). Study Contributors provide an automatic cost-free worldwide perpetual licence of their respective cleaned pseudonymised patient-level data (Level 2 data) to P95 for study analysis and for subsequent Secondary Data Use with the right to sublicence for Secondary Data Use to any Third Party under the Study Contributor Agreement(s) corresponding to the conditions as described in this Governance charter (refer to Section 8) and in compliance with the GDPR.

P95 Controls the Level 3 data and the COVIDRIVE Study Results (Level 4 data and Level 5 data). P95 provides:

i) an automatic, cost-free, perpetual, exclusive licence for any purpose for the Study Requestor of the specific Study to the tables/figures/listing and the study report (Level 4 data).

ii) an automatic, cost-free, perpetual, non-exclusive licence for any purpose for the Study Requestor of the specific Study to the anonymised aggregated analytical dataset (Level 5 Data) – this means that the Study Requestor is explicitly allowed to generate derivative data on the basis of Level 4 data.

Data access considerations: Access to data is controlled by P95 and will be restricted for any party other than parties having a right to use those data under the terms of the Consortium Agreement and of the Study Contributor Agreement(s) as described in this Governance Charter.

Data analysis considerations: In the frame of Primary Data Use, a minimum period of 6 months between the signature of the work order by a Study Requestor and its first data analysis shall be respected for data collected before the signature of the work order. If the data used in the first analysis was collected after the signature of the work order by the Study Requestor, this consideration will not apply.

Data access for secondary analysis is regulated by the guiding principles described in section 8.2.

3.8 Data retention

All data will be retained for a duration as stipulated in the Study protocol and in compliance with the GDPR. Level 1 data will be retained by the Study Contributor. Level 2, 3a, 3b, 4 and 5 data will be retained by P95 in its capacity as Study Sponsor. COVIDRIVE database (level 3a) retention is subject to the principles described in Section 3.9.

3.9 Consortium termination

Upon termination of the Consortium:

- In so far not already provided for in Section 8 of this Governance Charter, the Consortium Partners shall enter into good faith discussions on the possibilities to make the COVIDRIVE database (Level

3a data) available to the scientific community for future Secondary Data Use (including data hosting) after termination of the Consortium.

- The Study Requestors will receive a copy of the Level 4 and Level 5 data to which they have an automatic, cost-free, perpetual, licence for any purpose.

3.10 Adverse events reporting

The COVIDRIVE partnership conducts Studies, which may mix several sources of information provided by the various Study Contributors (primary data collection involving retrospective and/or prospective data collection).

All the Studies are non-interventional epidemiological studies for assessing the effectiveness of COVID-19 vaccination as per routine medical use. The Study Contributors who conduct the Studies should follow their local requirements in regard to the reporting of cases of suspected adverse reactions after vaccination to the competent authority in the country within the required timeframes.

3.11 Partners contribution, cost sharing principles and financial flow

3.11.1 Partners contribution:

Core Platform Partners and Vaccine Company Partners are jointly engaged in the co-development of COVIDRIVE for mutual benefit. Partners should commit to the following and to what is detailed in Section 2.3:

- Core Platform Partners will provide the workforce, expertise and will lead and coordinate deliverables development.
- Vaccine Company Partners will provide the workforce, expertise to contribute to the co-development of COVIDRIVE and related deliverables. It is expected that each Vaccine Company Partner will provide at least 0,2 FTE per year for in kind contribution to support the COVIDRIVE (independent of the time spent by Vaccine Company Partners' experts as part of the Study Team).

3.11.2 COVIDRIVE cost sharing principles:

- Vaccine Company Partners pay an equal share of the total COVIDRIVE costs, for a given time period, irrespective of when they joined. These costs are referred to as the Consortium Fee.
- Vaccine Company Partners that joined after the start of the Action in November 2020 will not be able to revisit prior discussions/decisions unless the Consortium agrees.
- The COVIDRIVE costs should remain the same for a given time period irrespective of the number of Vaccine Company Partners. When a new Vaccine Company Partner joins, a rebate of the last invoice will be applicable in case of overcharging for the other Vaccine Company Partners.
- Some cost adjustments may be needed to account for additional activities for a given time Study Period upon agreed by the SC. This additional amount will be shared equally by the Vaccine Company Partners and the payment schedule will be modified accordingly.

3.11.3 Study cost sharing principles:

- Study cost sharing principles apply when several Study Requestors will benefit of mutualising resources by conducting Studies using Study Sites in common, under the same Master Study Documents (Based on the Master Scientific Documents Templates developed at partnership level). The Master Study Documents are developed to perform the Study with a common study design and a common data collection.

- Study budget consists of two parts:

    - **A Study Requestor-specific part**, which will not be shared among the different Study Requestors. It includes the Study Requestor's specific activities/tasks, such as Study Requestor-specific Study Documents (based on Master Scientific Document Templates). Examples of Study Requestor-Specific Study Documents are, the Study Requestor-Specific Protocol, Study Requestor-Specific SAP, Study Requestor-Specific Progress Report, Study Requestor-Specific Study Report. Examples of Study Requestor-Specific activities are Study Requestor-Specific data analysis, Study Requestor-Specific generation of Study report and attendance at Study Requestor-specific meetings.
    - **The common part,** which will be divided among the Study Requestors according to the sharing principles detailed below.
      It includes activities/tasks conducted by Core Platform Partners and Study Contributors linked to a given Master protocol, such as study project management, Study Set up, Operation and Close Out activities, Study Data Management activities, Study Operations document development, filing and archiving including Study quality document development. It also contains costs related to Study Contributor start-up, and Study Contributor monitoring, and Study Contributor close out activities. For the sake of clarity, the Study Documents and Master Study activities listed in this bullet point are documents and activities for the benefit of all study requestors and will not overlap with activities budgeted in the study Requestor-Specific Part.

- A **Study** is divided in three stages: **Start-up, Running and Close out**. The Start-up stage and Close out stage do not require further subdivision. The running stage is further divided into Study Periods. Each Study Period will cover 3 consecutive calendar months with fixed calendar dates (periodic milestones). A period starts on the first day of the respective calendar month (starting 1st of September 2021), and ends 3 months later at the last day of the month. Therefore, the first study period started 01 September 2021 and ended 30 November 2021, the second study period started on 01 December 2021, and subsequently. The running stage shall last for **at least one year (4 Study Periods) for each Study Requestor**. During each stage, 3 types of costs are applicable. First, the working costs, an overarching Study cost not directly influenced by the number of Study Contributors or Study Requestors. Second, the P95 Site Related costs, which are fees for work done by P95 to activate, run or close a Study Contributor/Site. And third, the Study Contributor costs, which are costs payable to the Study Contributor for their internal work required to collect data according to the protocol.

    - **Working costs**

- The working costs of starting up the Study (not directly influenced by the number of Study Contributors) will be shared equally by all Study Requestors joining the Study, regardless of the start date. Study Requestors that become Study Requestors prior to the activation of the first site (Original Study Requestors) will initially pay the full amount. When/if a new Study Requestor becomes a Study Requestor after activation of the first Site, the working costs will be redivided equally among all Study Requestors. In the situation of a new Study Requestor joining, the initial Study Requestor(s) will receive a credit against future payments.

- The working costs to run the Study will be shared equally amongst the Study Requestors with any site active during that particular Study Period. Each Study Requestor joining the Study is required to join for a minimum of 12 months (4 Study Periods). The notice period for Study Requestors to end data collection from a given Site is 6 months (the six months start counting from the start of the next Study Period). Study Requestors will not be responsible for any working costs to run the Study after such data collection end date.

- The working costs to close the Master Study are to be shared equally among all Study Requestors joining the Master Study, regardless of the end date.

- **P95 Site related costs:**

  - The P95 site-related costs are fees payable to P95 to activate one Study Contributor/Site, to run one Study Contributor/Site during **one** Study Period (cost per 3 months) and to close down one Study Contributor/Site.
  - The P95-related Site start-up Costs will be shared equally among the Study Requestors that initially activate any Study Contributor/Site.
    - If a Study Requestor contributes to a Site that has already been activated by another Study Requestor, the Site start-up costs will not be redivided among the Study Requestors active at that Site, unless if the Study Requestor would desire primary data access to the data collected prior to the decision to contribute to this site. In this case the new Study Requestor will contribute to the start-up costs, using the debit against future payments principles. Note: access to data collected prior to initial work order signature will be frozen as per data access principles set out in Section 3.7.
  - The Study Contributor running costs will be shared equally among all Study Requestors that have requested P95 to actively collect data from that Study Contributor/Site during each Study Period.
    - The Study Requestor must contribute to the prospective data collection at this Study Contributor/Site for at least 12 months (4 Study Periods).
    - Study Requestors must notify P95 of their intent to discontinue data collection from a Study Contributor/Site ("Site Data Collection End Date") a minimum of two (2) Study Periods (6 months) prior to such discontinuation.

- The Site Data Collection End Date must align with the predetermined Study 3-monthly Study Periods.
- The P95-related Site Close out costs will be shared equally amongst Study Requestors participating in the data collection at a given Site in the final Study Period of Site data collection. If a Study Requestor discontinues data collection prior to the Site Close out, then the Study Requestor is not responsible for close out costs.

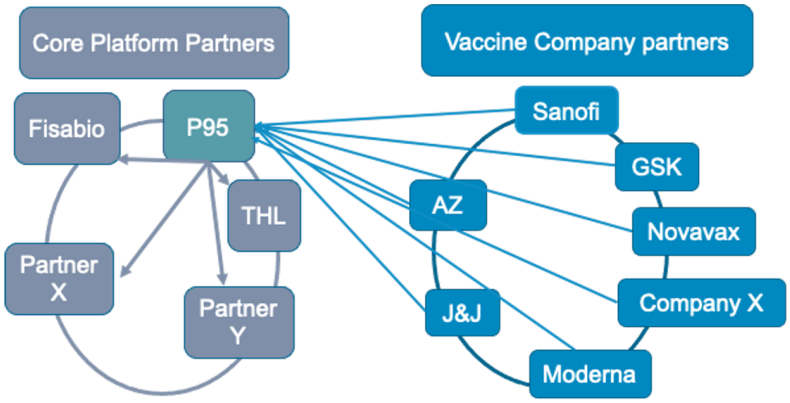
- Study Contributor-specific costs or Site-specific costs:

The site-specific costs follow the same sharing principles as the P95 Site Related Costs.

3.11.4 Financial flow

P95 is responsible for managing the financial activities of COVIDRIVE. Thus, P95 receives the financial contributions from the Vaccine Company Partners and distributes the funds among the Core Platform Partners and Study Contributors following the agreed-upon budget for the partnership and agreed-upon budget for the Study (Figure 6).

a)



b)

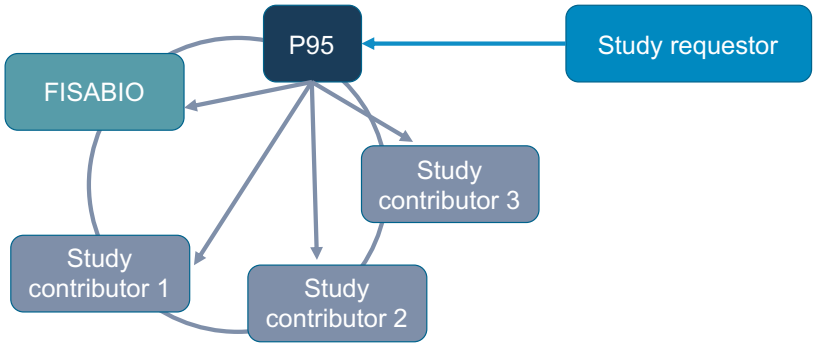


Figure 6. COVIDRIVE financial flow.

a) Financial flow at the partnership level and b) for a specific Study.

3.12 Regulatory pathway

Each Vaccine Company Partner engages in direct discussions with EMA or any other relevant competent authority regarding its Risk Management Plan (RMP) even if it includes a Study conducted by COVIDRIVE.

COVIDRIVE engages in discussions with EMA to seek advice on the Master Scientific Documents and discuss any Consortium level topic, as needed. However, the regulatory obligation to include the Study protocol in the EMA RMP remains for each Vaccine Company Partner, as does the obligation to submit the interim and/or final Study report to EMA.

The regulatory pathway may be adjusted based on discussions with EMA and national regulatory authorities.

4 STUDY CONTRIBUTORS

4.1 Study Contributors Selection process

- Upon Study request and setup of the ST, relevant Study Contributors/Sites are identified from COVIDRIVE's set of pre-qualified Study Contributors/Sites by the ST. According to specific Study needs, new Sites can be added to the set of pre-qualified Study Contributors (any new Site will have to be endorsed by the SC) and become eligible for participation in any of COVIDRIVE's Studies.

- The Study Requestors, advised by P95 and FISABIO, select the Study Contributors based on predefined criteria (section 4.3). P95/FISABIO organise the Study start-up (Study implementation, ethics requirements, allocation of the Study budget, contracting, …).

The Study Contributor/Site selection process is summarised in Figure 7.

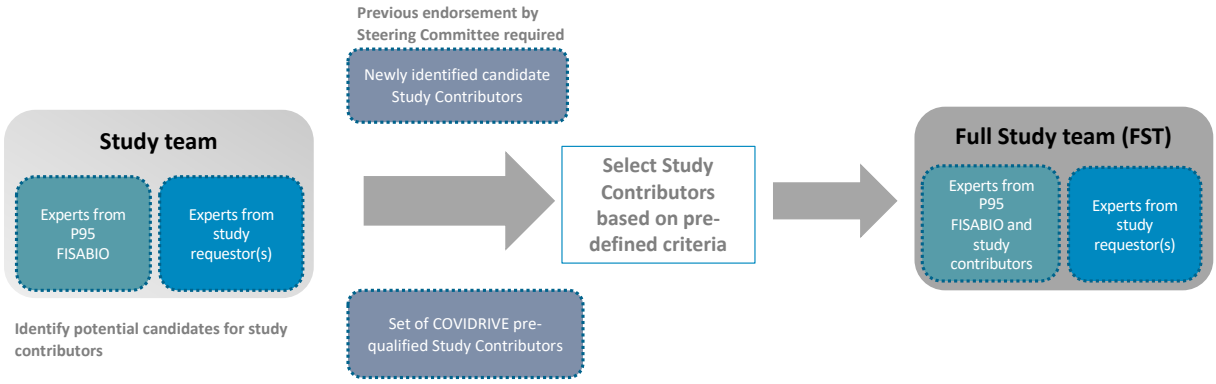


Figure 7. Workflow of the Study Contributors selection process for Study(ies).

The set of COVIDRIVE pre-qualified Study Contributors is composed of several former and non-former DRIVE sites, whose CVE capacity is assessed in COVIDRIVE's Feasibility Report (through sites survey and individual feasibility assessment meetings) and endorsed by the SC. The Feasibility Report provides an overview of sites' capacity to conduct Studies. P95 and FISABIO will update the Feasibility Report in a timely manner (within 1 month of any added Sites or updates of information regarding included Sites). This network of capable Study Contributors/Sites is planned to increase progressively based on study needs. The newly identified candidate Study Contributors should be assessed and their involvement in the partnership endorsed by the SC.

4.2 Eligibility and exclusion criteria

Eligibility criteria

Any organisation, institution, hospital or hospital/general practitioner network with interest and capacity to collect relevant data to perform brand-specific Studies, as defined per Master Protocol

and/or study outline (study objectives, setting, targeted population and countries), can be considered for Studies as a Study Contributor.

To fulfil the eligibility requirements, the Study Contributor should:

- be located in the EU/EEA or the United Kingdom,
- pass the feasibility assessment performed by P95/FISABIO, and
- sign the COVIDRIVE Confidentiality Disclosure Agreement (CDA) attached as Appendix 4 to the Consortium Agreement.

4.3 Study Contributor evaluation criteria

The ST assesses the relevance of the application forms in the following way:

- The Study Contributor should propose to perform data collection according to the COVIDRIVE Master Protocol (ensuring maximum possible adherence). If a local protocol is developed by the Site, this will be shared with COVIDRIVE's ST (version in English) and the differences with the COVIDRIVE Master Protocol will be described in the "COVIDRIVE Local protocol tracker".
- The COVIDRIVE Feasibility Report provides site-specific details on the study setting, the catchment population, the anticipated sample size, including age distribution, COVID-19 vaccine coverage, and laboratory methods used to detect SARS-CoV-2.
- Country-specific information regarding national COVID-19 vaccination policies, coverage, and evolution of the epidemiologic situation is collected by the ST, in order to support the decision-making.

The qualitative evaluation of the site proposals is done by the ST based on the key criteria:

- previous experience in studies relevant for CVE,
- scientific relevance (adherence to study protocol, reliable brand-specific information available for potential participants, laboratory testing and characterization capacity),
- estimated sample size and vaccine coverage of targeted populations in the country/region, COVID-19 vaccine recommendations in the country,
- Availability of retrospective vaccine exposure and outcome information for patients eligible to be included in Master Studies, and
- cost-effectiveness of the proposal and the level of co-funding.

4.4 Study Contributors: local protocols

COVIDRIVE Study Contributors may conduct data collection for COVIDRIVE nested into a broader research programme or surveillance scheme. This implies (Figure 8):

1. The Site integrates the COVIDRIVE Master Protocol (objectives, case, outcome and exposure definitions, covariates…) in a wider study protocol scheme (a "**local protocol"**). Thus, several adaptations are foreseen in the local protocols, namely:

- language adaptation (but English versions are foreseen to be available too)
- other case definitions for inclusion in the research programme/surveillance scheme (but COVIDRIVE patients will always fulfil the COVIDRIVE case definition)
- Description of the patient screening at the site level and study inclusion algorithms
- additional testing, for example subtyping influenza; respiratory PCR panels…
- collection of additional variables

2. The research programme/surveillance scheme is partly funded by COVIDRIVE, but might also receive additional funding (e.g. government, ministry of health, public health foundations, other study platforms…) for other objectives not included in COVIDRIVE protocols, under the following conditions:

- COVIDRIVE budget will be used only for COVIDRIVE patients' inclusion, data collection, SARS-CoV-2 testing and sequencing.
- COVIDRIVE budget will not be used for data collection beyond COVIDRIVE studies.
- However, the additional budget coming from other sources could also benefit COVIDRIVE studies, e.g. contributing to the laboratory testing of additional controls or the collection of extra variables not included in COVIDRIVE protocols. These data could be of added value in case of changes in the COVIDRIVE protocol or an additional study request (under the condition that the Study Contributor is allowed to share that additional data with COVIDRIVE).

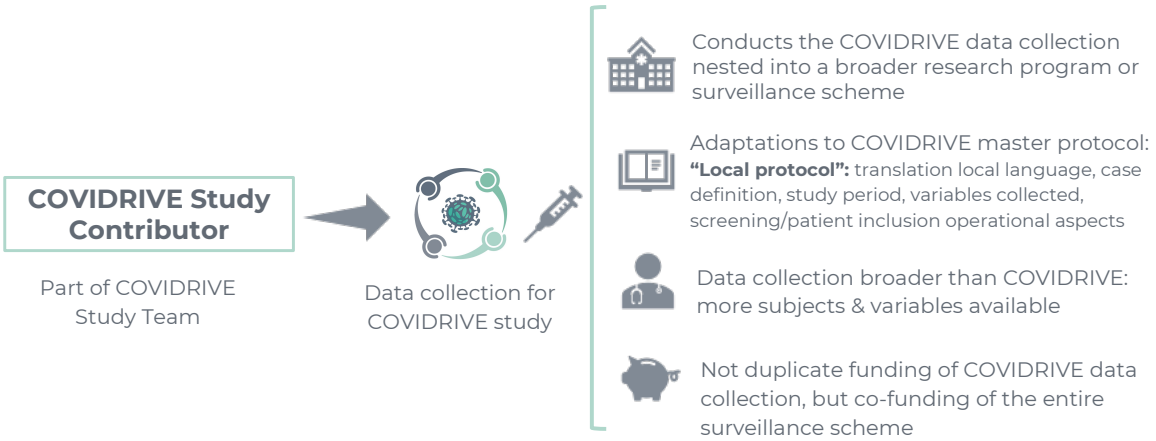


Figure 8. COVIDRIVE Study Contributors way of working.

For compliance with COVIDRIVE standards and full transparency, Study Contributors will share their local protocols (translated into English). Moreover, Study Contributors shall report all the modifications with respect to COVIDRIVE Master Protocol in the "COVIDRIVE Local protocol tracker". This tracker will be updated yearly or when major amendments of the local protocol are implemented by the Study Contributors (e.g. because of a COVIDRIVE Master Protocol amendment).

5 SCIENTIFIC DOCUMENTS DEVELOPMENT AND REVIEW PROCESS

One of the COVIDRIVE partnership objectives is to leverage scientific discussions and exchanges between the different stakeholders (Core Platform Partners, Study Contributors/Sites and Vaccine Company Partners) and with the external scientific community. However, some activities are considered more sensitive, such as the data collection/analysis and writing of the study report, which includes interpretation of the CVE results. Those activities are led by the Co-coordinators and overseen by the ISC.

5.1 Master Scientific Documents

The Technical Working Group (WG), which includes scientific experts from COVIDRIVE Core Platform Partners and Vaccine Company Partners, co-develop Master Scientific Documents with the objective to harmonise CVE methodology (e.g. protocols and analyses to assess severe COVID-19 disease, long-term vaccine effectiveness and SARS-CoV-2 infection or transmission). The ISC is consulted to review and provide recommendations to the Technical WG.

The final version of the Master Scientific Documents are posted on the COVIDRIVE website, as well as the EU PAS register, upon agreement by the SC.

5.2 Study scientific documents (protocols, statistical analysis plans, study reports)

The most restrictive case, when the Study Requestor is a COVIDRIVE Vaccine Company Partner, is presented in Figures 9 and 10:

a. Upon study request, the Full ST co-develops the **Study Requestor-specific protocol and SAP,** based on the Master Scientific Documents, when available. Next, the ISC reviews and provides recommendations to the Full ST. Several rounds of review may occur if needed following the same process. Then, if considered necessary, a collaborative session (teleconference) is organised by the Full ST to consolidate the final version of the protocol and the SAP.

Figure 9. Development and review process of the Study protocol and SAP.

b. The Restricted ST prepares the **Study reports** (whether it is a progress report, interim report or final Study report) containing Level 5 data, based on the master mock report, when available.

The draft Study report presenting the CVE results is shared in parallel with the ISC and with the ST experts from the Vaccine Company Partner Study Requestor. The ST experts and any other scientific experts from the Vaccine Company Partner Study Requestor review and provide written comments. A reasonable review period is defined (e.g. 7-14 days).

The ISC reviews the report and the comments provided by the reviewers. The ISC provides comments on the Study report and recommendations for the integration of other reviewers' comments (including the ones from the vaccine company Study Requestor).

The Restricted ST develops and provides a point-by-point response to all the comments within a reasonable time period (e.g. 7-14 days).

The Restricted ST prepares the final version of the Study report or organises a discussion point or another round of reviews if needed.

Several rounds of review may occur if needed following the same process

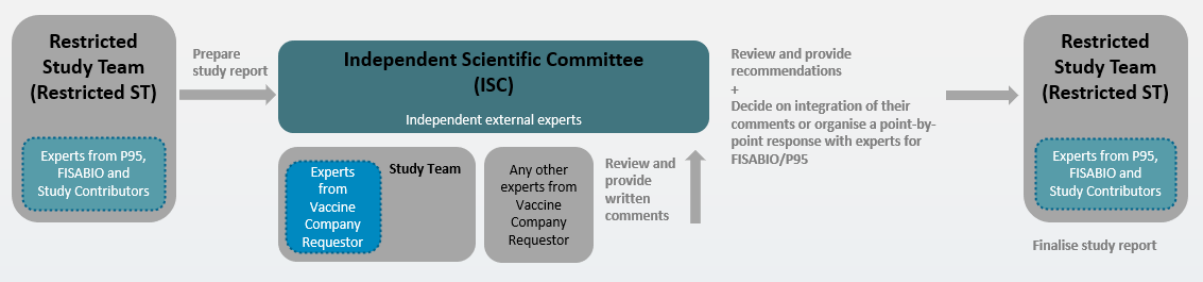


Figure 10. Development and review process of the Study report

5.3 COVIDRIVE Study Results Scientific Primary Publications

Principles of Study Results Scientific Primary Publication and its communication

- The ST should work collectively to define the publication plan related to the Study report, which includes primary publication and other publications.
- Every ST must disseminate its Study Results as soon as possible after submission of the Study report to EMA and in line with the timing requirements of the internal Study Requestor.
- The Study Results Scientific Primary Publications should be based on the Study report content.
- Sources of funding should always be disclosed in all Study Results Scientific Primary Publications (peer-reviewed journal publications, oral or written presentation…) using a predefined statement.

- The ST should ensure open access (free of charge, online access for any user) to its peer-reviewed scientific publication. The cost of the primary scientific publication is covered by the Study budget.

Authorship of Study Results Scientific Primary Publications

- Authorship on COVIDRIVE scientific publications must comply with the ICMJE authorship criteria.

  The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion 2 or 3. Therefore, all individuals who meet the first criterion (being part of the respective ST) should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

  Thus, all ST members (including scientific experts from the Study Requestor, potentially a Vaccine Company Partner) should be co-authors, if they meet the ICMJE criteria.

  With regard to the co-authorship of the Study Contributors in the Study Results Scientific Primary Publications, one co-author per Study Contributor (generally the local PI) will be included, ensuring compliance with the ICMJE authorship criteria. The rest of the members of the Study Contributor's team will be included in the acknowledgements section.

Review process of Study Results Scientific Primary Publications

The review process of the Study Results Scientific Primary Publications is the following (Figure 11):

1. The full Study Team prepares a first draft of the publication.
   - Timeline for preparation of first draft (manuscript): 1-2 months
   - Timeline for preparation of first draft (abstract or oral presentation): 1-2 weeks
   - Timeline for preparation of conference presentation / poster: 2 weeks
2. The first draft will be sent to the COVIDRIVE ISC and other relevant reviewers nominated by the Full ST, to review and share their comments regarding the content of the manuscript or conference abstract. In parallel, the draft will also be reviewed by the Study Requestor to check for internal compliance and to provide scientific feedback.
   - Timeline for review: 2-3 weeks
3. The ISC provides recommendations on the integration of the comments received from the reviewers (including scientific experts from Vaccine Company Partner) and the full ST implements the reviewers' comments, as well as providing a point-by-point response to the comments.
   - Timeline for implementation of comments: 2 weeks

4. The full ST proceeds with the finalisation the publication and the submission of the manuscript to the targeted journal, upon final internal clearance by the Study Requestor. Several rounds of review may occur if needed following the same process
    - Timeline: 3 weeks

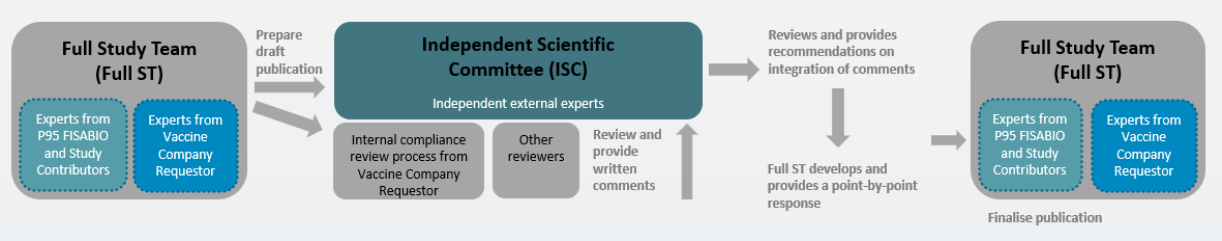


Figure 11. Development and review process of the Study Results' Scientific Primary Publications.

Timelines can be adapted depending on the type of publication to review (paper, abstract, oral/poster presentation) and the Vaccine Company Partner(s)-specific internal review and clearance procedures. For example, a faster process could be proposed exceptionally if a scientific abstract is to be submitted to a conference with short timelines and all parties involved in the review agree (ST, ISC, Study Requestor clearance).

The **COVIDRIVE Publication and Communications plan** contains more detailed information on the COVIDRIVE Publication plan and an annual Publication Roadmap which is updated yearly based on the publication needs.

Acknowledgement section of <u>Study Results Scientific Primary Publications</u>

The "Acknowledgements" section of COVIDRIVE Study Results Scientific Primary Publications shall include two statements acknowledging:

- the contribution and efforts of the Partners involved in the set-up of the Consortium. A proposed statement: "The authors/We thank the COVIDRIVE Consortium Partners [list the Consortium Partners] for their key contribution to setting up the platform to conduct the present study. The authors also thank FISABIO, P95, THL, Sanofi and GSK for their early contribution in the genesis of the COVIDRIVE Consortium".

- the contribution and efforts of the Vaccine Company Partners who contributed to the Master Study for the given Study Contributors/Sites and time period. A proposed statement: "The authors/We thank the COVIDRIVE Vaccine Company Partners (AstraZeneca and Janssen) for their contribution to the initial primary data collection and efforts in setting up the framework of the first COVIDRIVE study."

5.4 Study Contributors Publications policy

Definition

The Study Contributors Publications policy applies to any scientific publications (abstract/oral-poster presentation to congress or peer-reviewed journal publication) generated at the Site level (or across different Sites), which include COVIDRIVE patients and/or analyse COVIDRIVE data (Levels 1 and 2).

Guiding principles

Study Contributors shall comply with the following guiding principles and publications policy:

- Study Contributors / Principal Investigators are members of the Study Team and therefore engaged in the primary scientific publication of the Study. Thus, PIs will be considered co-authors a priori, if ICMJE authorship criteria are met. See section 5.3.
- The contents of the Study Contributor's scientific publication can include, but is not limited to:
    - Site/country CVE estimates on vaccine brand,
    - scientific outputs, at the Site level, beyond brand-specific CVE (e.g. epidemiological studies, burden of disease…)
- Study Contributors shall inform the Study Team of any planned scientific publication at the Site level, which contains (partly or totally) data collected in COVIDRIVE and/or include data from a patient included in a Study.
- Thus, Study Contributors shall send the first draft of the scientific publication to the Study Team in advance to its submission to a journal or scientific conference. The draft shall be evaluated by COVIDRIVE following two different review processes:
    - If data do not account for any of COVIDRIVE's brands of interest, the Study Team shall send the final draft of the Study Contributor's scientific publication to the SC and ISC for a parallel review (non-binding comments). The timeline for the SC and the ISC review will be 2 weeks.
    - If data does account for (a) brand(s) of interest, the Study Team shall send the final draft of the Study Contributor's scientific publication to the experts from the Vaccine Company Partner(s) concerned and the ISC. The ISC should review and provide recommendations for integration of comments of experts from the Vaccine Company Partner(s) to the Study Contributor (as in Section 5.3). The timeline for the review will be 2 weeks.
    - Sources of funding should always be disclosed in all Study Contributors' publications using a predefined statement acknowledging COVIDRIVE.
- Study Contributors shall share in advance the manuscript version approved for submission and inform the ST when the submission is completed and the manuscript approved for publication.

- Timing: the first publication of the Study Results (brand-specific CVE) should be done by the Study Team (based on interim or final Study report – as per Study Results Primary Publications definition and guiding principles). Therefore, any Study Contributor Publication should be submitted once the first Study Results Primary Publications have been submitted to a journal published by the Study Team.

5.5 Study Master File Considerations

5.5.1 Regulations and guidelines

The COVIDRIVE partnership conducts non-interventional epidemiological studies (collecting real-world data) which are not defined as clinical trials and therefore fall out of the scope of the European Directive 2001/20/EC and International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines.

5.5.2 Study Master File Structure

The Trial Master File Reference Model provides a standardised taxonomy structure for Trial Master File. The TMF Reference Model was developed under the auspices of the Drug Information Association (DIA) Document and Records Management Community and is now affiliated to the Clinical Data Interchange Standards Consortium (CDISC) and is commonly accepted across multiple pharma companies, CRO organisations and eTMF software applications.

The structure of the Trial Master File has been simplified for real-world evidence studies by the TMF Reference Model association following the taxonomy of the Trial Master File used for Clinical trials. This "Real-world studies Document Index" has been used as the basis to set up the COVIDRIVE Study Master File.

The Core and Recommended sections of the Real-World study index can be consulted on the website: https://tmfrefmodel.com/resources-

The core documents will be collected and filed as applicable. For the recommended documents, the Co-coordinators will carefully assess the added value of these documents and file the documents accordingly.

5.5.3 Study Master File responsibilities

P95, in its role as Study Sponsor of all COVIDRIVE Studies, should ensure filing and oversight of the Study documents. The QAAC will provide quality recommendations concerning the contents of the Study Master File.

5.5.4 Sharing of Study Master File contents

5.5.4.1 Non-Study Contributor level documents

(Master) Scientific and operational Study documents should be made available to the COVIDRIVE Partners through the Veeva Vault software application. The Partners will receive a read-only access to

the documents and will be able to download any Master Scientific and operational study documents for internal filing.

5.5.4.2 Study Contributor level documents

The Vaccine Company Partners can receive access to the Study Contributor level documents (such as CVs, Site specific protocols, etc.) of the Study Contributors of Interest (i.e. the Study Contributors covered in the Vaccine Company Work Order) on the condition that all members of the Study Contributor staff have a signed Data Privacy Agreement in place.

6 COVIDRIVE Non-Study Results Publications

6.1 Definition

Publications (in peer review journals, poster/oral presentation at scientific conference), which do not contain Study Results, include:

- publications on COVIDRIVE partnership,
- scientific methodological publications,
- presentations of the COVIDRIVE partnership and methodologies at scientific/institutional fora,

6.2 Principles of non-Study Results Publication and its communication

- Sources of funding should always be disclosed in all non-Study Results publications using a predefined statement.
- COVIDRIVE should ensure open access (free of charge, online access for any user) to its peer-reviewed publications (as part of the Consortium budget).

6.3 Authorship

Please refer to the paragraph about authorship in Section 5.3.

6.4 Review process of non-Study Results publications

Initially, one or several Partners prepare an outline (as stipulated in the Publications roadmap or ad hoc) and communicate it to the Co-Coordinators. The Co-Coordinators will share it with the SC, in order to welcome relevant collaborators/experts wiling to contribute to the publication. Next, the

review process of the non-Study Results publications ("other publications) consists of the following steps (Figure 12):

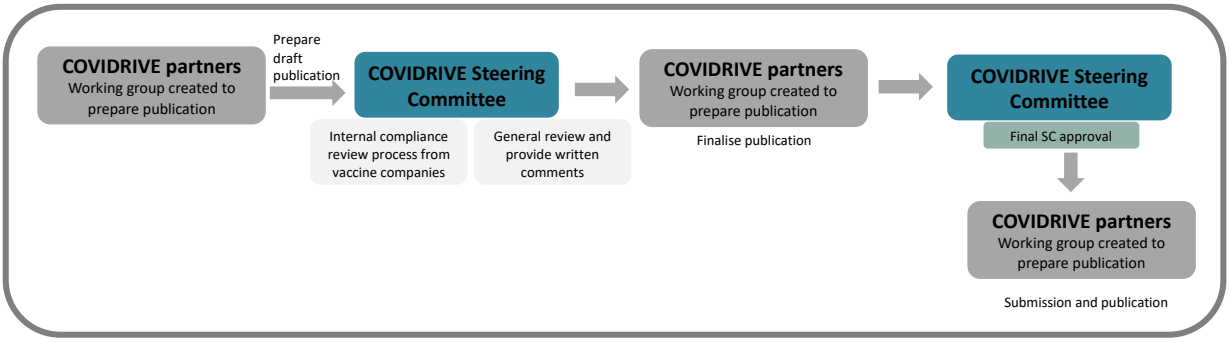


Figure 12. Development and review process of the COVIDRIVE publications not containing Study Results.

1. COVIDRIVE Partners (in particular, a working group created ad hoc for the preparation of the publication) prepare a first draft of the manuscript/abstract.
    - Timeline for the preparation of the first draft: 1-2 months
2. The first draft will be sent to the SC (and potentially to other COVIDRIVE working groups or the ISC, if necessary), to review and share their comments regarding the content of the document. The draft will also be reviewed by the Vaccine Company Partners concerned to check for internal compliance.
    - Timeline for review: 2 weeks
3. The COVIDRIVE Partners of the publication working group concerned implement the comments received from the SC and finalise the publication.
    - Timeline for implementation of comments: 2 weeks
4. The final version of the publication is sent to the SC for final approval before being submitted to the target journal / conference by the COVIDRIVE Partners of the publication working group for publication.
    - Timelines for approval: 2.5 weeks maximum

Timelines can be adapted depending on the type of publication to review (paper, abstract, oral/poster presentation) and the Vaccine Company Partner-specific internal review and clearance procedures.

6.5 Acknowledgement section of non-Study Results publications

The "Acknowledgements" section of COVIDRIVE non-Study Results publications should include a statement acknowledging the contribution and efforts of the Partners who initiated the Consortium. A proposed statement: "The authors/We would like to thank the early COVIDRIVE Consortium Partners [include list of Partners] for their key contribution to setting up the COVIDRIVE platform. The authors also thank FISABIO, P95, THL, Sanofi and GSK for their early contribution in the genesis of the COVIDRIVE Consortium".

7 EXTERNAL COMMUNICATIONS PLAN

The **COVIDRIVE Publication and Communications plan** contains more detailed information on the COVIDRIVE communication goals, channels and tools. An external communication roadmap is updated yearly and includes the communications monitoring specifications.

7.1 Definition and scope

COVIDRIVE's Communications plan applies to "large media" external communications, such as website posts, press releases, social media posts and multimedia content. It is not applicable to the publications included in Sections 5 & 6 and 8 of the present Governance Charter.

7.2 Review process

The review process that will be applied to external communications, such as website posts, press releases, and other potential dissemination content (e.g. videos, infographics) consists of four steps and is depicted in Figure 13:

1. The Co-Coordination team (in particular, the subgroup devoted to communication and dissemination), as per the communication roadmap timelines (or upon receiving a request for an external communication from any COVIDRIVE Partner) prepares a first draft.
    - Timeline for preparation of a first draft: 1 week
2. The first draft is shared first with the COVIDRIVE Partners mainly involved in the content, to review and share their comments regarding the technical content of the communication. The Co-Coordinators integrate the comments to produce a consolidated draft.
    - Timeline for review and consolidation: 2 weeks
3. The Co-Coordinators send a final version to the SC for review and internal review and clearance of the contents. The SC approves or rejects the final communication to be published.
    - Timeline for SC review: 2 weeks
    - Timeline for edits after SC review: 1 extra week (only if needed)
4. Once the SC approves the content of the communication, the Co-coordinators proceed with the publication according to a specific dissemination plan.

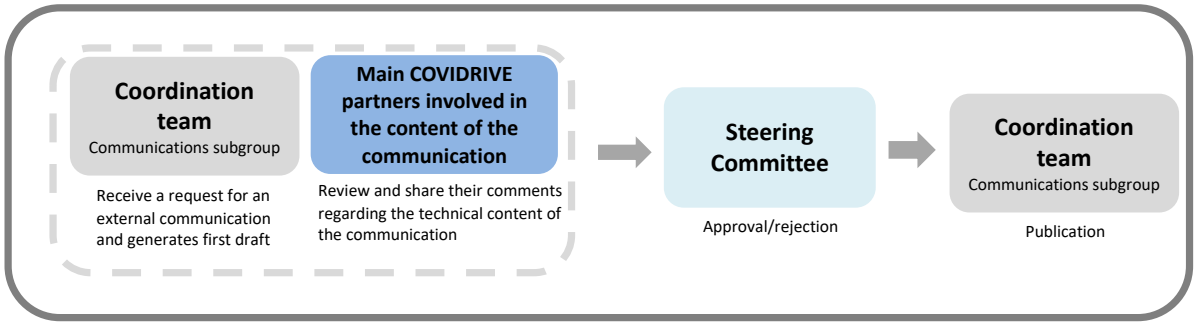


Figure 13. Review process of external communications.

7.3 COVIDRIVE website

A website was created to display public information about the partnership and ensure full transparency of its CVE results and governance. More details on the COVIDRIVE website can be found in the COVIDRIVE Communications and Publication plan document.

COVIDRIVE website address: http://covidrive.eu

8 ACCESS FOR SECONDARY USE

8.1 Rationale

The first COVIDRIVE Studies started in September 2021, with AstraZeneca (UK) and Janssen (Belgium) as the first Vaccine Company Partners to monitor the effectiveness of their respective vaccines. Several other Vaccine Company Partners are expected to join the ongoing Studies or set up new ones in 2022. Therefore, the COVIDRIVE database is expected to gradually grow in the coming years collecting epidemiological data (clinical data, virus testing and vaccination information) from patients included in any of the COVIDRIVE studies.

The COVIDRIVE database could be leveraged and further utilised for various purposes:

- To advance the knowledge in COVID-19 disease beyond brand-specific vaccine effectiveness,
- To promote research collaboration between COVIDRIVE Sites, Partners, and Third Parties,
- To attract more Sites in COVIDRIVE and enable robust brand-specific CVE with a larger pool of data,
- To value COVIDRIVE Site data through scientific publications,
- To contribute to the worldwide efforts to enhance the global surveillance network for respiratory viruses and associated diseases and monitor related vaccines performance and foster collaborations with external stakeholders.

Therefore, COVIDRIVE Partners have predefined some guiding principles and governance process to address potential future requests for Secondary Data Use from COVIDRIVE Partners or Third Parties.

8.2 Guiding principles

1. Scope and relevance	
1.1	A request for Secondary Data Use shall be based on a scientific rationale aiming to answer a specific research question in a public health perspective advancing knowledge in COVID-19 disease and related vaccines.

1.2	A request for Secondary Data Use can only be assessed based on a synopsis with detailed rationale, objectives, a detailed description of the data from the COVIDRIVE database required, planned analyses and foreseen dissemination of the results. For every Secondary Data Use request, the corresponding analytical dataset (Level 3b data) will be created.
1.3	Scientific publications must be foreseen for Secondary Data Use or at least disclosure of the outcomes in the public domain within maximum 6 months.
1.4	Collaborations with COVIDRIVE Partners and Sites shall be encouraged for Secondary Data Use especially with the aim of sharing data knowledge. Any detrimental impact on the collaboration spirit promoted by COVIDRIVE should be forbidden.
1.5	A request to get access to brand-specific data (vaccine brand name) for Secondary Data Use shall be possible only for the COVIDRIVE Vaccine Company Partner owner of the brand and being contributor to the primary data collection. Otherwise, only non-brand-specific information shall be accessible (such as dates of vaccination, number of doses and vaccine types). Former COVIDRIVE Vaccine Company Partners shall have access to their own brand-specific data only for the period for which they have been contributing to the primary data collection. In addition, measures will be taken to ensure that brands cannot be identified when type-specific analysis will be performed. Thus, no vaccine brand will stand alone, and the proposed grouping by vaccine types shall be based on that principle.
2. Governance	
2.1	P95 is the data custodian of the COVIDRIVE database (Level 3a data).
2.2	FISABIO and P95, as COVIDRIVE Co-Coordinators, shall manage Secondary Data Use requests and ensure coordination between the COVIDRIVE governance bodies, Partners, and Sites on review of Secondary Data Use requests where the SC deems it necessary. If the request for Secondary Data Use comes from the Consortium, it shall follow the same process as if the requestor represents a COVIDRIVE partner, Site or Third Party.
2.3	Before deciding on a request, the SC shall first consult the Co-Coordinators who shall assess the technical feasibility of providing data to fulfil the request for Secondary Data Use and then the ISC who shall assess the scientific & ethical relevance of the Secondary Data Use requests.
2.4	The COVIDRIVE SC shall provide final approval for requests for Secondary Data Use.

	The Steering Committee shall approve the requests unless there is an objective justification for dismissing the request, such as a negative advice from the ISC, a negative advice from the Co-Coordinators, the fact that there is a risk that data will be transferred outside the EU/EEA, or a potential legal issue.
2.5	P95 shall be responsible to provide appropriate restricted access to the IT infrastructure (COVIDRIVE Research Server). Access will be given for the reasonable period of time necessary to perform the actions detailed in the request. This period of time for access will be determined by P95.
2.6	P95 shall ensure that patients' privacy is protected in the processes of preparing and making data available for Secondary Data Use requests.
3. Sites-patients control of data	
3.1	Informed consent at Sites level shall include an authorisation to use Level 3 data for Secondary Data Use (to leverage knowledge on COVID-19 disease and related vaccines). This authorisation shall entail the right to access an analytical dataset for Secondary Data Uses as described in the Master Protocols.
4. Requesting and accessing data for Secondary Data Use	
4.1	Any entity (public or private) can request access to the COVIDRIVE database for Secondary Data Use. The Secondary Data Use Requestor can be either a COVIDRIVE Partner, the COVIDRIVE Consortium, a Site or a Third Party, knowing that pseudonymised patients level data shall not be transferred outside of the EU/EEA. Only aggregated data which does not contain pseudonymised patient-level data can be transferred outside of the EU/EEA.
4.2	The Co-Coordinators shall ensure that any data made available is of sufficient quality and minimum sample size to expect that the objectives of the Secondary Data Use can be achieved.
4.3	If the Secondary Data Use Requestor decides to instruct another entity than P95 to conduct the analysis in the dataset prepared by P95 on the basis of the COVIDRIVE Database (Level 3a data), P95 will ensure that this other entity has no possibility to export Level 3a data and that the access given is compliant with the GDPR. P95 will also ensure that the Secondary Data Use Requestor only gets access to the parts of the COVIDRIVE database (level 3a data) that are necessary in the frame of the projected Secondary Data Use.

4.4	Access to aggregated data shall be primarily proposed when adequate for secondary use.
4.5	Prior to data being released, P95 shall require the Secondary Data Use Requestor to sign the agreement set to detail the conditions for Secondary Data Use.
4.6	Access to COVIDRIVE database for Secondary Data Use shall only be given when the relevant dataset is locked for a given site. Periodic 6-monthly 'data releases' (data cut-off, cleaned, hard lock) shall be planned by P95 based on a fixed calendar time.

8.3 Data control and access for Secondary use

Access to the COVIDRIVE database is controlled by P95. For Secondary Data Use, P95 may give a restricted access to the COVIDRIVE Research Server to either the Secondary Data Use Requestor or another entity than P95 (instructed by the Secondary Data Use Requestor) to conduct the analysis in the dataset prepared by P95.

The Secondary Data Use Requestor will control its Secondary Data Use analysis results:

- Tables/figures and listings presenting the Secondary Data Use analysis outputs: Tables/figures and listings as generated based on the Secondary Use Requestor synopsis;
- Anonymised aggregated analytical dataset(s): The anonymised aggregated analytical dataset(s) are aggregated dataset(s) that are generated based on the pseudonymised patient-level analytical dataset(s) (Level 3b), for Secondary Data Use.

8.4 Data Access Fees for Secondary Use

Secondary Data Use Requestors shall receive access to data for secondary use upon payment of the applicable fees (stipulated in clauses 8.3.1 to 8.3.3), if the request for secondary use of data is approved by the SC. The fees to be paid for access to the COVIDRIVE database take into consideration the involvement of the Secondary Data Use Requestor in the primary data collection process and the involvement of the Secondary Data Use Requestor in COVIDRIVE. The fees for data access paid by the Secondary Data Use Requestors will be injected into the Consortium budget, managed by P95. For the sake of clarity, the fees detailed below are proportionate to the costs for getting access to the data.

Additionally, the Secondary Data Use Requestor will pay for the costs of coordinating the review and approval of the request (described in section 8.5), and the legal, administrative and data management activities (if applicable) of its Secondary Data Use request. These costs will be paid to the Co-coordinators based on not for profit rates. If support for additional statistical analysis by P95 is requested, the Secondary Data Use Requestor will pay an additional fee, at P95 commercial rates.

8.4.1. Free of charge access to data for Secondary Use

Secondary Data Use Requestors that are Vaccine Company Partners that contributed to a Study by activating one or multiple Study Sites shall receive “free of charge” access to data for Secondary Data Use.

In this case the “free of charge access to data for Secondary Data Use” is restricted to a one-year period for one Study Contributor/Site for each activated Site. The “one-year period” can be divided in two periods of six months. The one-year period can be applied for either the activated Study Contributor/Site, after the Vaccine Company Partner has ended its contribution to the Study Contributor/Site or, the one-year period can be used to receive data from Study Contributors/Sites for which the Vaccine Company Partner joined the existing effort (in other words, the site was activated by another Partner). In this case the one-year period can be used before or after the contribution period. Finally, the one-year period can also be applied to another equivalent Site the Vaccine Company Partner did not contribute but activated during the same period that the vaccine Company Partner contributed to the Study.

Other Secondary Data Use Requestors than Vaccine Companies shall also have free of charge access to data for Secondary Data Use if they contribute to the COVIDRIVE Studies by collecting and providing data. Thus, other Secondary Data Use Requestors than Vaccine Companies that contribute to the Study by sharing data can receive data collected by another equivalent Study Contributor/Sites. The data is limited to a one-year period.

The SC shall take a decision with regards to the Study Contributor equivalence.

8.4.2 Limited fees for access to data for Secondary Data Use

A limited fee for access to data for Secondary Data Use will be applicable for Vaccine Company Partners that contributed to the Study but have not contributed to the activation of any Study Contributors/Sites and for COVIDRIVE DRIVE Partners other than Vaccine Company.

8.4.3 Regular fees for access to data for Secondary Use

For Third Parties access to data for Secondary Data Use can be provided based on predefined regular fee

Secondary Data Use Requestor	Type of data access	Fees for data access - Free of charge	Fees for data access - Limited fees	Fees for data access - Regular fees
COVIDRIVE Partner – Vaccine Companies Taking part to the Master Study Having initiated a Site	Brand-specific information (vaccine brand name) on its own vaccine during the period of primary data collection contribution Non brand-specific information	Free of charge restricted to a one-year period for one Study Contributor/Site for each activated Site - the one-year period can be divided in two periods of six months - the one-year period can be applied to the initiated Site or another Site (whatever the Partner is contributing or not)		
COVIDRIVE Partner – other than Vaccine Companies Taking part to the Master Study Having shared data	Non brand-specific information	Free of charge restricted to a one-year period for another equivalent Site		
COVIDRIVE Partner – Vaccine Companies Taking part to the Master Study	Brand-specific information (vaccine brand name) on its own vaccine during the period of primary data collection contribution Non brand-specific information		Limited fees (reduction based on Partnership and Master Study contribution) restricted to a one-year period for one Study Contributor/Site for each activated Site - the one-year period can be divided in two periods of six months	

			- the one-year period can be applied to the initiated Site or another Site (whatever the Partner is contributing or not)	
COVIDRIVE Partner – other than Vaccine Companies Taking part to the Master Study	Non brand-specific information		Limited fees (reduction based on Partnership and Master Study contribution)	
COVIDRIVE Partner – other than Vaccine Companies	Non brand-specific information		Limited fees (reduction based on Partnership contribution)	
COVIDRIVE former Partner – Vaccine Companies	Brand-specific information (vaccine brand name) on its own vaccine during the period of primary data collection contribution Non brand-specific information		Limited fees (reduction based on Partnership and Master Study contribution) restricted to a one-year period for one Study Contributor/Site for each activated Site - the one-year period can be divided in two periods of six months - the one-year period can be applied to the initiated Site or another Site (whatever the Partner is contributing or not)	
Third Party	Non brand-specific information			Regular fees

Table 1. Summary of the contents of sections 8.2 and 8.4

8.5 Process

Several processes shall be needed to consider, determine, monitor, and report on a request to use COVIDRIVE data for secondary purposes. Processes and the roles and responsibilities of the parties involved are presented in a stepwise approach below and in Figure 14.

Step	Description of process	Responsibility
1	Make an application for Secondary Data Use by completing the Request form, provide a synopsis (see above)	The Secondary Data Use Requestor
2	Seek for recommendations about the application	P95-FISABIO
2.1	Assess application in terms of intended use & required Privacy Authorizations (Data Privacy Authorities Authorisation for the data requestor, Data Protection Impact Assessment, Reference Methodology if any)	SC with support of external law expert
2.2	Assess the technical feasibility of the Secondary Data Use, considering overlap with other data requests or previously published analysis	P95-FISABIO
2.3	Assess the scientific relevance and ethical compliance of the Secondary Data Use	COVIDRIVE Independent Scientific Committee
3	Provide final approval for Secondary Data Use	SC
4	Inform and liaise with COVIDRIVE Partners and Sites to foster collaboration	P95-FISABIO
4.1	Set the conditions for Secondary Data Use in an agreement with the data requestor	P95

4.2	Sign the agreement governing the Secondary Data Use	P95 and the Secondary Data Use Requestor
4.3	Ensure proper information of Secondary Data Use requests and associated research projects is included on COVIDRIVE website, for transparency purposes.	Co-Coordination
4.4	Provide specific restricted access to data for Secondary Data Use purpose	P95
4.5	Leverage COVIDRIVE network for collaboration in the Secondary Data Use project	The Secondary Data Use Requestor
4.6	Provide feedback about Secondary Data Use outcomes /scientific publication to COVIDRIVE Steering Committee	The Secondary Data Use Requestor

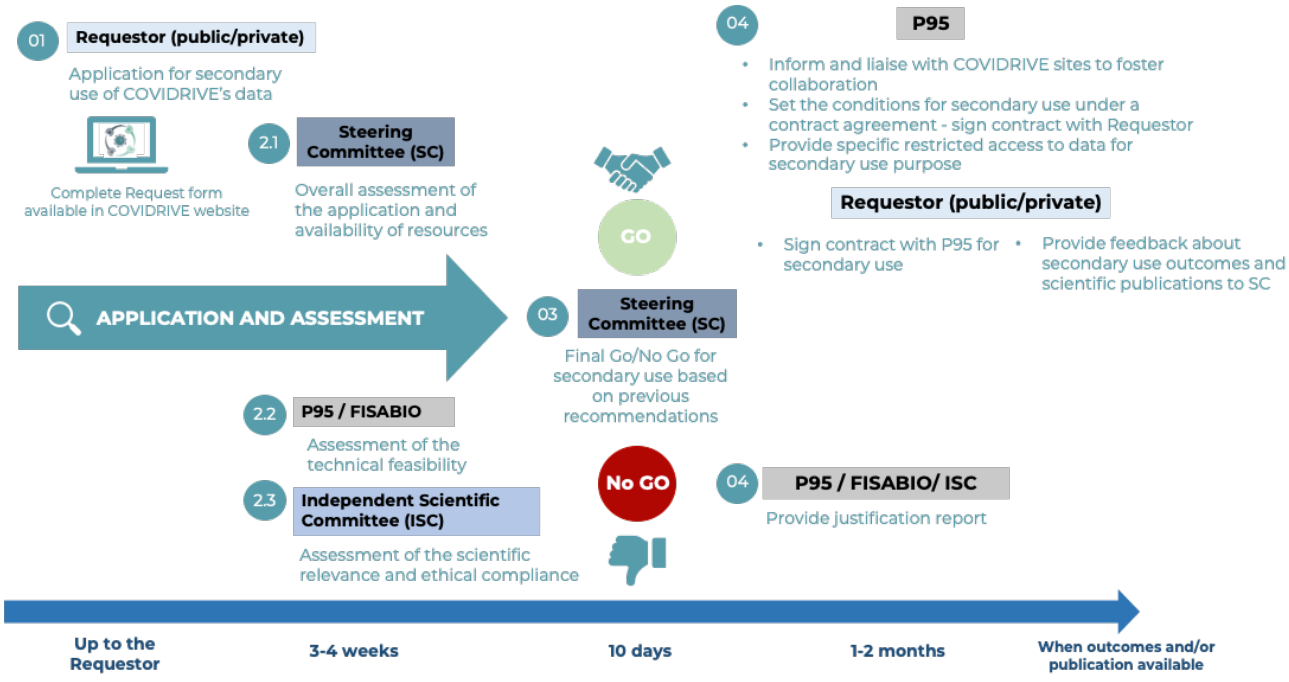


Figure 14. Process for assessing requests for use of secondary data.

9 Internal communication and conflict resolution

9.1 How participants should communicate internally

To ensure a compliant and effective communication flow within COVIDRIVE, the partnership will adopt the following approach:

- All communication will be in line with the competition law guidelines.
- All communication will be in English.
- Electronic mail is used as the main tool for communication within the partnership.
- Documentation of discussions, agreements and decisions made by phone is mandatory. Specifically, phone conferences should always have an agenda and minutes, which should be made available to COVIDRIVE Partners through the COVIDRIVE Microsoft SharePoint.
- Several email distribution lists are created which can be used by any participant depending on the subject of the message. Additional lists may be created if necessary. P95 is responsible for updating the above-mentioned lists with the information received from the Partners.
- Veeva Vault electronic Study Master File (eSMF) has been created as a repository of relevant information and files. It facilitates the exchange of documents within the partnership (i.e. meeting minutes, documents in progress, final versions and other relevant reports or announcements) and the COVIDRIVE Studies.
    - Link to Veeva: https://login.veevavault.com/
    - Access to Veeva for Consortium Partners will be provided after training.

- The use of *de facto* standards based on Microsoft Office-compatible files for electronic document exchange among Partners is required when possible. PDF format can alternatively be used to avoid excessive size of files when no editing is required.
- Good practice when using email is essential. 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. Carefully consider whether “reply to all” is required. All emails sent to any of the mailing lists created so far are labelled by default with “COVIDRIVE” in the subject line and senders add the subject of the message.

9.2 How internal conflicts are resolved

In the event that an internal conflict arises at a given time, the following process applies:

Conflicts amongst Partners in any given activity are discussed at the WG or ST level.

- If unresolved, the issue is escalated to the CT, which uses mediation to objectively aim to solve the issue.
- The SC mediates conflicts which cannot be handled at the CT level.
- Scientific issues are escalated to the ISC if needed.
- Compliance quality assurance issues are escalated to the QAAC if needed.

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