D6.3 Project Handbook

777363 - DRIVE

Development of Robust and Innovative Vaccine Effectiveness

WP6 – Project Management, coordination and sustainability

Lead contributor	Elena del Rey, Susana Vaquero (5 – Synapse)
	edelrey@synapse-managers.com
Other contributors	Topi Turunen (1 – Fisabio)
	Margarita Riera (3 – P95)
	Laurence Pagnon, Nathalie Piton (12 – SP)
	Mendel Haag (14 – Seqirus)

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Document history

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Definitions

- Participants of the DRIVE Consortium are referred to herein according to the following codes:
  - **FISABIO.** Fundación para el fomento de la investigación sanitaria y biomédica de la Comunitat Valenciana (Spain)
  - **IRD.** Institut de recherche pour le developpement (France)
  - **P95.** P95 CVBA (Belgium)
  - **UNIFI.** Universitá degli studi di Firenze (Italy).
  - **SYNAPSE.** Synapse Research Management Partners S.L. (Spain)
  - **THL.** Terveyden Ja Hyvinvoinnin Laitos (Findland)
  - **ISS.** Istituto Superiore di Sanitá (Italy)
  - **SURREY.** University of Surrey (United Kingdom)
  - **CoMO.** Confederation of meningitis organizations Ltd (United Kingdom)
  - **UCBL.** Université Lyon 1 Claude Bernard (France)
  - **IABS-EU.** Association Internationale de Standardisation Biologique pour l' Europe (France)
  - **SP.** Sanofi Pasteur (France)
  - **ABBV.** ABBOTT BIOLOGICALS BV (Netherlands)
  - **SEQIRUS.** Seqirus UK Limited (United Kingdom)
  - **GSK Bio.** GlaxoSmithKline Biologicals S.A. (Belgium)
- **Consortium.** The DRIVE Consortium, comprising the above-mentioned legal entities.
- **Consortium Agreement.** Agreement concluded amongst DRIVE participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.
- **Deliverable review:** An evaluation procedure by one or more reviewers, which precedes the distribution of a deliverable (as defined in the Work plan) to the IMI JU.
- **Grant Agreement.** The agreement signed between the beneficiaries and the IMI JU for the undertaking of the DRIVE project (777363).
- **Project.** The sum of all activities carried out in the framework of the Grant Agreement.
- **Quality assurance:** All the planned and systematic activities implemented to provide adequate confidence that an entity will fulfil requirements for quality.
- **Quality policy:** A set of principles on which quality assurance procedures are based.
- **Risk:** Uncertainty that may have a significant impact on the execution or outcome of the project, and which effect may be negative – a threat risk - or positive – an opportunity risk.
- **Work package.** Group of specific tasks related to a part of the action to be carried out.
- **Work plan.** Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.

Abbreviations

- CFS. Certificate on Financial Statements.
- CT. Coordination Team
- DF. Drive Forum
- DoA. Description of Action.
- DRIVE. Development of Robust and Innovative Vaccine Effectiveness
- EAB. Ethics Advisory Board.
- ECDC. European Centre for Disease Prevention and Control
- EFPIA. European Federation of Pharmaceutical Industries and Associations.
- EC. Ethics Committee.
- EMA. European Medicines Association
- GA. General Assembly.
- IMI JU. Innovative Medicines Initiative Joint Undertaken
- ISC. Independent Scientific Committee
- NRAs. National Regulatory Authorities
- PMO. Project Management Office.
- QCAC. Quality Control and Audit Committee
- SC. Steering Committee.
- SP. Study Partner
- PP. Participant Portal.
- PPP. Public Private Partnership
- WHO. World Health Association
- WPL. Work Package Lead.
- WP. Work Packages.

Publishable Summary

The present document aims at providing an overview of the management and administrative procedures and principles that will ensure an efficient execution of the DRIVE project and thus contribute to the production of high quality project results.

The main objective of the Handbook is to make available to the project participants a quick reference ‘manual’ that points out, in an understandable way, the management structure, tasks, decision-making procedures, responsibilities and procedures on all levels of project execution. All the information and general principles in the Handbook are defined in the

Grant Agreement, the Description of Action and in the Consortium Agreement provisions, but it also draws from best practice, IMI2 rules and accepted project management standards.

This document specifically covers the following areas:

- General project management processes that ensure tight coordination of research and development activities resulting in high quality Deliverables.
- An internal communication strategy that ensures clear and effective communication between the Participants and that allows for the early escalation and the timely resolution of management and technical issues.
- An overview of the methods and procedures undertaken by the Consortium to identify, analyse, assess and monitor risks affecting the project or its results, and the development and monitoring of associated mitigation and contingency plans that aim at mitigating the potential negative effects and maximising the potential benefits of risks.
- Administrative project management processes that ensure accurate financial reporting and justification of the work being carried out.

Please note that this Handbook is circulated as a guidance document only. It should not be relied upon for making any legal assessments, for which Participants should always refer to the Grant Agreement (including its annexes) and the Consortium Agreement.

1. Introduction

1.1. Purpose, scope and structure

The present document aims at providing an overview of the management and administrative procedures and principles that will guarantee an efficient execution of the DRIVE project and thus contribute to the production of high quality project results. Special attention will be paid to ensure that the project results are delivered in due time, within budget and considering the formal quality standards developed for the project.

The established procedures are based mainly on the general principles and policies set up in the grant regulations and official guidelines under the IMI2 Programme (Grant Agreement and its annexes, Consortium Agreement). The procedures set up in this document should be understood as a starting point and may be adjusted as the project evolves.

The procedures and principles herein described refer to generic coordination and management tasks and follow best practices and principles for project management (PMBOK, Project Management Body of Knowledge) established by the internationally recognised Project Management Institute (PMI); thus, they can be supplemented at the level of technical Work Packages (WPs) or activities as needed. The activities described in this document will be mainly undertaken in the framework of Work Package 6 Project management, coordination and sustainability, but they may also belong or be related to other WPs.

The main areas considered are:

- Project coordination and management structure
- Progress reporting
- Quality assurance and project assessment
- Financial management
- Risk management
- Legal management

The strategy followed for selecting the procedures described in this document is based on the following guiding principles:

Adequacy – Appropriateness for the general characteristics of the DRIVE project and Consortium.

Attainability – Selected strategies must allow for implementation within a Consortium conformed by a variety of partners with different cultures, backgrounds, profiles, interests, levels of involvement, and degrees of expertise in management and quality issues. Since an active involvement of all participants is needed, the last factor is regarded as most crucial. Therefore, a progressive approach that allows for increasing complexity and refinement of procedures over the project duration is to be favoured whenever possible.

Efficiency – The effort and resources spent in learning, implementing and maintaining the selected procedures cannot overweight the benefits expected from their effectiveness

(understood as accuracy and completeness with which their goals are achieved). In particular, selected strategies cannot create bottlenecks that hamper the technical and scientific work they are intended to support or endanger the Grant Agreement fulfilment.

Flexibility – Although suited for the project as a whole, strategies must allow for adaptation to changing needs derived from the project's own development as well as changes in the environment.

Reliability – Strategies and procedures must be capable of maintaining a level of performance for a period of time. They should be compliant with international standards, documented, and tested by past experience of partners and/or previous projects whenever possible.

1.2. Precedence

The general principles for the project execution are defined in the Grant Agreement, the Description of Work and in the Consortium agreement provisions. This project handbook shall not replace any of the established agreements within the consortium or with the IMI JU, or any of the IMI JU guidelines for project implementation. Where there are any apparent or real inconsistencies between these documents the following order of precedence shall be applied:

1. Grant Agreement
2. Consortium agreement
3. Project Handbook

1.3. Basic project information

Project acronym: DRIVE

Project title: Development of Robust and Innovative Vaccine Effectiveness

Grant Agreement number: 777363

IMI call topic: Topic 6 of the IMI Call 9, entitled "Joint Influenza Vaccine Effectiveness Studies" (JIVES).

Project start date: 1st of July 2017

Project end date: 30th June 2022

Number of participants: 15

IMI project officer: Angela Wittelsberger

Total project budget: 9,999, 938 €

IMI JU 2 funding: 8,999,813 €

Total EFPIA in-kind contribution: 1,000,125 €[1]

[1] Additionally, EFPIA companies participating in DRIVE are making a €4,000,000 financial contribution to the IMI2 JU in support of this action.

2. Project coordination and management

2.1. Objectives

Work Package 6 (Project management, coordination and sustainability) aims at ensuring a proper execution of the project, particularly:

- To provide overall project leadership to optimally coordinate all project activities, promoting strategic direction, alignment and achievement of the project goals.
- To provide timely and efficient administrative and financial coordination of the project and compliance of the commitments with IMI.
- To assure a high level of collaboration and partnership among all organizations involved to establish and ensure the surveillance of the Project governance and procedures and enable an effective internal communication and work dynamics between the public-private partnership created to perform the project.
- To provide professional management to ensure the Project implementation, the management of resources, as well as procedures and tools to deliver the Project to plan, time and budget, including risk management and quality control procedures on deliverables.

2.2. Coordination and management structure: roles and composition

The overall structure of DRIVE and the related project governance is presented in Figure 1, which has been devised to respond to the particularities of the project, its size and complexity. It will both help steer the efforts optimally towards the desired results in the given time frame with limited resources, promote scientific discussion and consensus building and provide a structure for efficient decision-making. It has been developed to respond not only to the organizational needs of a public-private partnership, but also to absolutely ensure the scientific independence of the results and to create spaces for interaction with the relevant stakeholders in the field.

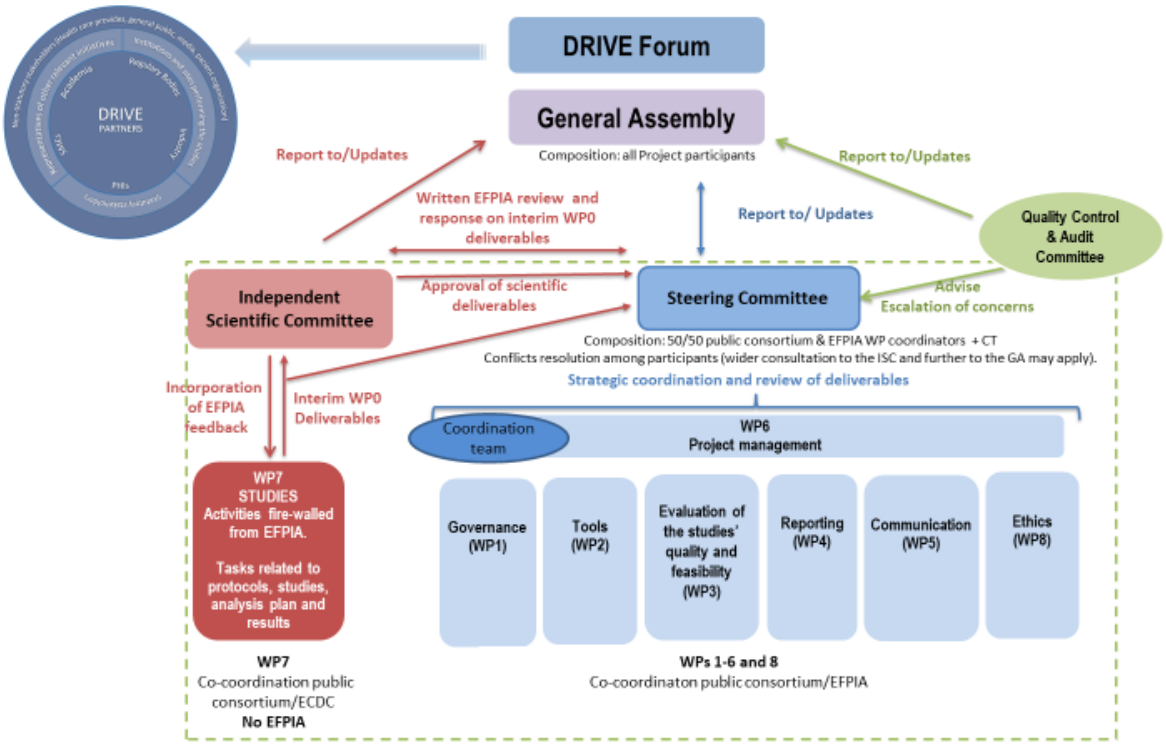


Figure 1. DRIVE Governance structure

DRIVE Forum: space for wide communication and public consultation. Channel for discussing project challenges & obtaining feedback from all stakeholders and facilitating community uptake of the project results. The DRIVE Forum has no decision-making power.

General Assembly: ultimate decision-making body in the project dealing with matters requiring unanimous decision and critical issues, such as major changes in the overall strategy.

Steering Committee: responsible for the project execution, with prerogatives regarding technical development decisions, minor work plan updates, and effort/budget re-assignment in pursue of optimal efficiency.

Coordination Team: responsible for the day-to-day operational aspects of the project. Prepares, supports, recommends decisions to the Steering Committee.

Independent Scientific Committee: consists from 5 up to 10 independent external experts (experts from organisations who are non-partners in DRIVE). The ISC's mandate is to evaluate and endorse the scientific deliverables of the DRIVE project developed by the Work Package 7 (WP7) and to provide advices on their review process and communication components. The contributions of the EFPIA consortium in reviewing scientific deliverables will only be made in writing to maintain independence and ensure transparency and traceability. For further information, please refer to D1.2 (Governance SOP).

Quality Control and Audit Committee: The QCAC will be tasked with the quality control and auditing of the overall project with a specific focus on compliance, quality and regulatory

aspects. This committee has an advisory role and it is composed of 3 independent external experts (experts from organisations who are non-partners in DRIVE) and 4 qualified EFPIA representatives. For further information, please refer to D1.2 (Governance SOP).

2.2.1. DRIVE Coordinator and Project Leader

DRIVE is co-led by a Coordinator (public lead partner) and a Project Leader (private lead partner) which are jointly responsible for the overall scientific progress of the project. Dr. Javier Díez Domingo represents FISABIO, the Coordinator of the Project. The Project Leader SANOFI is represented by Cédric Mahé.

Functions and responsibilities of the Coordinator and the Project Leader are described in the DRIVE Consortium Agreement, in section 11.

Project Coordinator	Javier Díez Domingo (FISABIO)
Project Leader	Cédric Mahé (SP)

Table 1. DRIVE co-leads

2.2.2. DRIVE Forum (DF)

The DRIVE Forum (DF) is composed of all Beneficiaries, the Associated Partners and all other external relevant stakeholders, statutory (EMA, NRAs, WHO, ECDC, etc.) or non-statutory (health care providers, patient organisations, media, etc.) and representatives of all other initiatives relevant for the Project topic and expressly invited by the Consortium. The aim of this body is to provide fruitful discussions and to ensure a long-lasting impact of DRIVE Project as it is not considered a decision-making body.

2.2.3. General Assembly (GA)

The DRIVE GA is the ultimate decision-making body in the project dealing with matters requiring unanimous decision and critical issues, such as major changes in the overall strategy. Full description of functions, meeting frequency and voting rights of the GA are described in the DRIVE Consortium Agreement, in section 11.3. Several members of each organization can participate in the GA, but only one vote per institution is allowed, which will serve for scientific discussion and follow up the general progress of the project.

The GA meets approximately every twelve months.

The GA is made up of one senior Representative nominated by each of the Participants:

PARTICIPANT	GA MEMBER
1. FISABIO	Javier Díez Domingo
2. IRD	François Simondon
3. P95	Margarita Riera

4. UNIFI	Paolo Bonanni
5. SYNAPSE	Elena del Rey
6.THL	Hanna Nohynek
7. ISS	Caterina Rizzo
8. SURREY	Simon de Lusignan
9. COMO	Sam Rosoman
10. UCBL	Bruno Lina
11. IABS-EU	Pieter Neels
12. SP	Cédric Mahé
13. ABBV	Jos Nauta
14. SEQIRUS	Mendel Haag
15. GSK Bio	Gaël dos Santos

Table 2. DRIVE GA Representatives

2.2.4. Steering Committee (SC)

Composed of the Project Leader, the Coordinator, the Work Package Leaders (WPLs) and the Coordination team members, the SC is the responsible for the determination of project policies, alignment across all Work Packages and solving input-output relationships among them. In order to keep a balance representation of public and private members, the official members of the SC are those included in table 3.

The SC will deal with amendments to the work plan and changes in budget allocation between WPs. It will approve project deliverables (except the deliverables of WP7, falling within the specific competences of the ISC), ensure that objectives and milestones are fulfilled with appropriate quality and decide on technical roadmaps with regards to the project.

The SC will meet as needed, through regular teleconferences, face-to-face and around GA meetings. Full description of functions and voting rights are described in the DRIVE Consortium Agreement, section 11.4.

In order to keep parity between public and private representatives, voting rights are provided to the SC members as reflected in table 3 below:

WORK PACKAGE	ACADEMIC LEAD	EFPIA LEAD

WP1	François Simondon - IRD	Cedric Mahé or Laurence Pagnon - SP
WP2	Javier Díez Domingo or Topi Turunen- FISABIO	Gaël dos Santos - GSK
WP3	Caterina Rizzo - ISS	Mendel Haag - SEQUIRUS
WP4	Margarita Riera - P95	Jos Nauta - ABBOTT
WP5	Hanna Nohynek - THL	Sharon MacHale - SEQIRUS
WP6	Elena del Rey - SYNAPSE	Cédric Mahé or Nathalie Piton-SP

Table 3. DRIVE SC members

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 have been proposed:

Better identification of the topics for the discussion

- In the framework of the scientific coordination tasks, the project coordinator and the PL will organize periodic bilateral TCs with the different WPs. This will allow to filter and identify key issues and common needs to be scaled up to the SC for endorsement or alignment.
- The CT will hold periodic[2] meetings where key issues of common interest for the whole consortium may be also identified to be tackled at the SC level.

Better preparation of the topics by those in charge

- Any proposal presented to the SC should be previously circulated by email to collect SC feedback before its discussion at SC meetings. This will allow focusing the discussion at the SC meeting only on the main critical comments raised by the SC in writing. In this exercise, the author of the proposal, should distinguish between critical comments and not-so-critical comments. Only critical comments need to be followed up and agreed upon at the SC. The number of critical comments everyone can have has to be limited.
- Proposals presented to the SC should be concrete and agreed with the corresponding collaborating partners. Alternative options may be available if needed.
- Inter-WPs consultations are highly recommended before presenting a proposal to the SC for approval. Those project documents dealing with external communication should follow the process described in section 5.

Delegation to smaller teams

- For certain tasks that are not clearly described in the project, or for those proposals that have not been endorsed after the corresponding discussion at a SC meeting, the SC could agree up front a sub-team with the right expertise and accountability (as per the DoA) to solve the issue. Then the sub-team must come to SC for final approval following the indications of point 2.

Strict meeting organization

- The purpose of each topic will be clearly stated in the agenda (decision making, endorsement, discussion, etc.)
- Each topic will have a specific duration stated in the agenda. In order not to affect the last points of the agenda, there will be a strict time keeping. If a team does not manage to have their topic resolved in their allocated time, the discussion will be resumed once the proposal will be reworked according to point 3.
- The agenda will be circulated at least 2 days in advance of the meeting together with the supporting materials of the topics to be discussed.
- The minutes of the SC meetings will be circulated before the next meeting. Minutes of the last SC meeting should be reviewed by the participants before the next meeting to better follow up the discussions and avoid reopening the issues.

2.2.5. Coordination Team (CT)

The CT is composed of a representative of the Coordinator, a representative of the Project Leader and the two representatives of the Project Management Office (but not restricted to those, as other partners interested are welcome to join). The CT is responsible for the day-to-day operational and technical aspects of the project. The CT will meet frequently (bi-weekly by teleconference) to monitor the project progress and to address any issues that may arise. Full description of functions and voting rights are described in the DRIVE Consortium Agreement, section 11.6.

ROLE	CT MEMBER
Coordinator	Javier Díez Domingo (FISABIO)
Project Leader	Cédric Mahé (SP)
Project Management Office	Elena del Rey (SYNAPSE), Nathalie Piton (SP)

Table 4. DRIVE CT members

2.2.6. Project Management Office (PMO)

The PMO is responsible for the project management and it is made up of the Project Manager of SYNAPSE and SP. The PMO is dealing with the day-to-day management of the project, supporting on the main areas regarding the management of the Project to the Project Leader and the Coordinator. The PMO performs the follow-up on activities and monitors compliance with the work plan, planned resources and time schedule, as well as coordinates fulfilment of all administrative milestones (including progress and financial reporting) according to IMI2 JU rules. Full detail on responsibilities of the PMO are described in the DRIVE Consortium Agreement, in section 11.10.

2.2.7. Ethics Advisory Board (EAB)

The EAB will be composed of three experts (non-partners in DRIVE) with detail knowledge of ethical policies at European level, representing various fields involved in the action. The EAB will be responsible of reviewing the proper application of the ethical rules by the Beneficiaries as well as to provide advice to the Beneficiaries, the General Assembly and the Steering Committee on the compliance of any European relevant ethical applicable laws, regulations and guidelines. The EAC meets upon request of the SC or the GA.

2.2.8. DRIVE Governance and decision-making bodies overview

The following table summarizes the different governance and decision-making bodies within DRIVE Project including their composition and how decisions are taken when applicable:

Table 5. DRIVE Governance bodies composition and decision-making.

2.3. How and when do the project partners meet?

The Coordinator and the Project Lead, supported by the Project Manager, are responsible for convening meetings of the management and scientific bodies at the DRIVE overall level (i.e. GA, SC and other committees), complying with the frequency of ordinary meetings as defined in the DRIVE Consortium Agreement. WPLs hold the responsibility of calling meetings within their respective WPs as needed.

According to the CA, the bodies of the DRIVE governance will have the following approximate meeting frequency:

Meeting Frequency	Project bodies
Regularly	Coordination Team (CT) - TC[2]
Quarterly (at least)	Steering Committee (SC) - TC[3]/F2F

	COMPOSITION	QUORUM	DECISIONS
DF	All beneficiaries+ APs+ other external stakeholders	-	DF shall not have any decision authority
GA	1 representative per partner	75%	Double majority 75% among EFPIA 75% among non-EFPIA
SC	WP Leads and WP Co-coordinators + CT	75%+ representatives of Project Leader and Coordinator	75% of attending members
CT	Project Leader+ Coordinator+ PMO	75%+representatives of the Project leader and the coordinator	Simple majority
PMO	2 Project Managers	-	PMO is not entitled to make decisions
QCAC	3 external experts+ 4 representatives of EFPIA	70%	Consensus
ISC	Up to 10 independent external experts	70%+observer	66% of attending members
EAB	3 external experts	-	EAB is not a decision-making body although provides decision making support

[2] CT Teleconferences have been scheduled biweekly, in principle
[3] SC Teleconferences have been scheduled biweekly, in principle.

Meeting Frequency	Project bodies
Every 6 months (at least)	Independent Scientific Committee (TC/F2F)
	Quality Control and Auditing Committee (TC/F2F)
Yearly	GA (F2F)
	DF (F2F)
	EAB (F2F)

Table 6. DRIVE governance meeting frequency

2.3.1. DRIVE Face-to-Face meetings organisation

2.3.1.1. General Assembly Meetings

We focus this subsection on General Assembly Meetings (GAM) because these meetings imply a strong logistic preparation. DRIVE partner institutions may volunteer to host DRIVE GAMs and other meetings related to the project[4].The list below is indicative and intended to help identify the commitments at both sides (it may vary slightly for each specific meeting):

Host responsibilities

Before the meeting:

- Identification, initial visits and initial negotiation with meeting venues (ideally 2-3 options). Venue requirements:
  - Reasonable cost (range to be confirmed) via a daily delegate rate
  - Availability of plenary room (for 50 people approximately), plus smaller break-out rooms (3-4 breakout rooms for 10-15 people)
  - Catering service
  - Audiovisual equipment / TC equipment (to be confirmed)
  - Audiovisual technician
- Identification, initial visits and negotiation with hotel (ideally the same as the meeting venue). Negotiation of special rate if possible. Pre-blocking of rooms if possible.
- Identification, initial visits and negotiation with restaurant for one project dinner (for practical reasons, it is recommended to have it in the same place as the venue if possible. If not, it is important that attendants can pay individually and get receipts for subsequent cost justification)
- Participate in meeting organisation TCs as needed
- Facilitate contact with provider to print the meeting material
- Participation in the press release

During the meeting:

- Provide support personnel during the meeting (for registration desk, audiovisual equipment and TC facilities tests, etc.) - desirable.

PMO´s responsibilities

Before the meeting:

[4] The SC agreed not to use EFPIA premises for the organization of DRIVE Forum meetings.

- Participate in the venue/hotel/restaurant selection, close negotiations with the venue/hotel/restaurant
- Drive the agenda configuration and produce the meeting logistics document (input will be requested from the host)
- Prepare and send meeting invitations and reminders to partners and invitees
- Set up attendants' registration and follow up of registrations
- Prepare the meeting documentation (support may be agreed with the host organisation if practical and available)
- Organise and chair meeting preparation TCs as needed

During the meeting:

- One person for meeting organisation support: gathering and uploading the presentations, dealing with logistic aspects of the meeting (catering, technician, etc.), registration desk.

After the meeting:

- Upload documents/information in SharePoint
- Coordinate minutes' production

2.3.1.2. Other meetings covered by other direct costs

Other meetings may be organised during the project at the WP or cross-WP level or when foreseen in the DoA (i.e. workshops, etc.). These meetings will be organized by the WPL or the corresponding partner leading the task/activity. The PMO may support the organization of meetings as needed.
For travel and subsistence costs related to project meetings please refer to section 7.2.3.

2.3.2. DRIVE meetings participation

2.3.2.1. DRIVE partners

Each DRIVE partner should book their travel, accommodation and pay his/her dinner costs and delegate rate (if applicable), which should be covered by themselves from their own project travel budget and then claimed directly to IMI at the time of the reporting.

2.3.2.2. DRIVE Associated Partners and external experts

For the DRIVE associated partners and external independent advisors (for example ISC and QCAC) a separate fund is allocated under FISABIO´s budget to their travels to meetings. FISABIO will take care of the costs generated according to the terms of the corresponding agreements to be formalized between FISABIO and the expert/Associated Partner.

2.4. How can Participants change their representatives to the GA?

The representatives of each of the Participants are supposed to be maintained throughout the project. Any representative in the GA may nominate a substitute to attend and vote at any meeting. In that respect, any change in a representative in the GA must be informed by

the original representative, in writing (by email), to the Chairs directly (Coordinator and/or Project Leader) or via the PMO at least 2 days before an ordinary meeting of the GA takes place, indicating the reason for substitution and identifying the new representative.

GA members can be accompanied by other representatives of their respective institutions at meetings, but only one vote per institution is allowed in the GA.

2.5. What are the main partners' responsibilities?

Beneficiaries must use all reasonable endeavours to perform and fulfil, promptly, and on time, all of their obligations under the Grant Agreement and the Consortium Agreement, to accomplish the purpose and objectives of the DRIVE project and act in cooperation and mutual trust. Beneficiaries shall also provide their respective contributions to deliverables, information, and reports as required by the WPLS, the GA, the SC, the CT, the PMO, and the Coordinator, so as to help these bodies to fulfil their obligations.

Beneficiaries shall promptly notify the Coordinator and the PMO through the appropriate WPL of any significant problem or delay likely to affect the success of the project.

In lay terms, each Participant must, essentially:

- Do the work assigned to it in the Description of Action, and any other detailed work plan derived from it, on time and with an appropriate level of quality.
- Collaborate with all other Participants as required by the tasks, including contributing to relevant deliverables.
- Not hinder the work of others or delay it unnecessarily.
- Attend meetings and teleconferences as required.
- Notify promptly the relevant governance body of any potential issue affecting performance. The normal chain of reporting would be, in this order: WPL -> PMO -> SC -> GA.
- Notify the PMO about any risk that may be detected in the course of the work, and that may affect future performance.
- Fulfil the administrative and financial reporting obligations according to IMI2 rules – spend the costs foreseen only for the work expected in DRIVE and report it faithfully.

2.6. How are internal conflicts resolved?

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

- Conflicts amongst partners in any given activity will be discussed at the Work Package (WP) level with the help of the respective Work Package Leads (WPLs).
- If unresolved, the issue will escalate to the CT, which with the help of the PMO will use mediation and expert and referent powers to objectively aim to solve the issue.

- The SC will mediate conflicts which cannot be handled within the work packages. The SC may also opt to refer the issue to the General Assembly (GA) for wider consultation if needed.

- Scientific issues can be escalated to the Independent Scientific Committee (ISC) if needed.

- Compliance Quality Control issues can be escalated to the QCAC if needed.

3. Key legal aspects

3.1. The Grant Agreement

The Grant Agreement is the main legal document underpinning the project's execution – effectively, a contract between the participants and the IMI2 JU. It is first signed by the IMI2 JU and the Coordinator. Each DRIVE beneficiary then accedes to the Grant Agreement by executing an accession form. The Grant Agreement mainly provides information on the grant (parties, duration, start date, budget, maximum funding, etc.), obligations of the beneficiaries towards the IMI2 JU (such as reporting requirements), as well as the intellectual property framework and other legal conditions. The Grant Agreement is dated 07/08/2017 and has number 777363.

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

- Annex I. Description of the action
- Annex II. Estimated budget for the action
- Annex Ill. Accession form for beneficiaries
- Annex IV. Financial statement
- Annex V. Model for the certificate on financial statements
- Annex VI. Model for the certificate on the methodology

The GA core document includes a standard text (i.e. it is essentially the same for any IMI2 project) describing the general rules and regulations governing IMI2 projects, including financial rules (e.g. which costs are acceptable, how payments are handled, etc.), Intellectual Property Rights (who owns the results, how access to such results is enabled, etc.) and other general conditions applicable to IMI2 projects. These generic provisions can be supplemented (but not contravened) with project-specific provisions via a Consortium Agreement (see section 3.3 below), which enables projects to set out their specific IPR detailed rules, governance mechanisms, etc.

The most extensive and important Annex to the Grant Agreement is the Description of Action (DoA), which comprises the technical description of the work to be undertaken in the project (work packages, tasks, deliverables, milestones), the description and roles of the different partners, allocated efforts in person-months, and budget details. The DoA is derived from the original proposal submitted to the IMI2 JU for evaluation and approval, and it is the benchmark against which project progress will be judged. Compared to the rest of the Grant Agreement and annexes, which are mostly model texts, the DoA is specific of each project. It is important to remember that the DoA is an integral part of the Grant Agreement, and therefore it is a contractual commitment of all participants.

The Grant Agreement and all its Annexes are available in the DRIVE Share Point.

3.2. Changes to the Grant Agreement

The Grant Agreement (GA) can and must be changed whenever any important project parameter changes: partnership, duration, budget, etc. Implementation of such changes

must follow a specific procedure called 'Grant Agreement Amendment'. Amendments should be performed when there are any changes related to any of the GA annexes or its terms and conditions Most changes that trigger Grant Agreement amendments relate to updates in the DoA (e.g. changes in tasks and deliverables, changes in efforts allocated, changes in partner's teams, etc.).

As consequence, the amended provisions become an integral part of the Grant Agreement, while all other provisions remain unchanged and have full effect. For further details on policy on amendments see Article 55 of the DRIVE Grant Agreement.

Amendments are requested usually before the end of the project (as stated in article 3 of the DRIVE GA) although in exceptional cases (if the bank account changes or the coordinator responsible for paying the balance is replaced) can be requested once the project is completed.

An amendment is necessary when one or several of the following changes applies:

- Changes involving beneficiaries and linked third parties
- Changes involving the coordinator/principal beneficiary
- Changes affecting the project or its implementation
- Changes involving the financial aspects of the grant

The Grant Agreement may be affected by other types of minor changes which do not constitute an amendment, but which must be communicated to the consortium or to the IMI2 JU through an information procedure. In any case, participants should contact the PMO to confirm the procedure to follow for any modification needed. Some example of changes which do not require an amendment process *per se are*:

- Certain budget transfers[5] (see Table 7.)
- If the name or address of a beneficiary, linked third party or coordinator changes
- If there is a change in the name of the bank or the address of the branch where the coordinator has an account, or in the name of the account holder.

Budget transfers and re-allocation	Amendment needed?
From one beneficiary to another	**NO**
From one budget category to another	**NO**
Addition/removal of tasks in Annex 1 Re-allocation of tasks in Annex 1	**YES**
Transfers between different forms of costs (actual costs, unit costs, etc.)	**YES** if no budget was foreseen for the 'form of cost' receiving the transfer
New subcontracts, new in-kind contributions	**YES** (strongly advised)

Table 7. Budget transfers that requires an amendment

[5] Budget categories are explained in sections 7.2.1. to 7.2.4 of this document,

An amendment request, can be proposed by the Consortium as well as by IMI. If an amendment is proposed by the Consortium, the coordinator must ensure that the Consortium has reached agreement through an internal decision-making process, following the rules set out in the DRIVE CA. In addition, the Project Legal Signatory (PLSIGN) of the Coordinator must electronically sign and submit the amendment/s on behalf of the Project Consortium.

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

1. The procedure is as follows:
2. The PMO will keep track of all needed amendments. Meetings and communications with the participants affected will enable to compile all the necessary information to support the changes.
3. The Coordinator will launch the amendment request.
4. The list of modifications will be circulated to the General Assembly for their information and approval.
5. The IMI officer responsible will be consulted.
6. The PMO will prepare a new version of the DoA with the modifications and/or other documents needed to request the modifications.
7. The PMO will circulate the amended documents to the Steering Committee for validation. The approval by the General Assembly will be required for any Amendment to the Grant Agreement, as defined in the Grant Agreement article 55.2 (Amendments to the Grant Agreement – Procedure).
8. The PLSIGN of the Coordinator will electronically sign and submit the request for amendment
9. IMI will assess the amendment request (IMI)
10. IMI will make a decision (acceptance or rejection of the amendment)

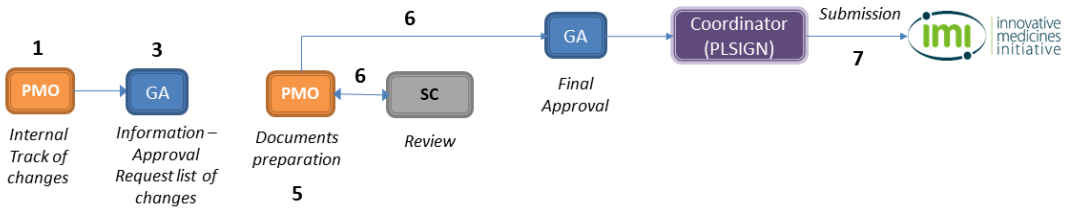


Figure 2. Grant Agreement Amendment process

3.3. The Consortium Agreement

The Consortium Agreement (CA) is concluded between the Participants aiming to provide a legal framework for their collaboration within the boundaries of the Grant Agreement. The CA includes provisions on governance, intellectual property, dissemination, and liability among others. The IMI2 JU is not a party to the CA. The signed version of the CA is accessible in Share Point.

Amendments to the CA may also be necessary during the project, sometimes purely because of Grant Agreement amendments. These CA amendments will be handled separately by agreement of all participants, under the coordination of the Coordinator and the Project Leader, with the support of the PMO.

3.4. Intellectual Property Rights

According to the Consortium Agreement (Articles 6 to 8), participants agree to respect their Individual Intellectual Property Rights and intend to cooperate with respect to the management of all matters relating to the protection and exploitation of all knowledge arising from the project and of the Intellectual Property Rights pertaining to such knowledge, with the view to promoting innovation.

3.4.1. Who owns the project results?

A project result (referred to as "Result" in the Grant Agreement and the Consortium agreement) is the property of the Participant that carries out the work that generates that result. The Participants remains free to transfer its ownership rights in Results.

3.4.2. What happens in case of joint ownership?

When several participants have generated a Result and where it is not possible to distinguish their respective shares therein, the participants (co-owners) will jointly own this result.

In case of joint ownership of Results, each Co-Owner may use the jointly owned Results without restriction for Research Use, including the right to grant non-exclusive sub-licenses to its Affiliated Entities and to Third Parties, subject to the following conditions[6]:

- At least 45 days prior notice must be given to the other co-owner(s); and
- Fair and reasonable compensation must be provided to the other Co-owners, to be decided on a case-by-case basis

3.4.3. How should project results be protected?

Project results are the property of the participant(s) carrying out the work leading to them. When the results can be industrially or commercially applied, its owner must provide for adequate protection by means of IP rights, with due regard for its own legitimate interests (and the interests of the other participants).

The Participants may also determine the action to take when the owner of an IP asset is not interested in formally protecting a Result.

In connection with the statements above, as long as the Results -which can be industrially or commercially applied- have not been protected, no dissemination activities may be carried out either by the owner or by other participants (otherwise access to IP rights protection may be seriously jeopardised).

[6] DRIVE Consortium agreement, article 7.2

3.4.4. What are access rights?

Access rights are the licences or authorisation rights that permit to use the information owned by a participant of the project.

Participants in a project generally arrive at the project with their own knowledge, data, know-how, etc. (the so-called “Background” in the Grant Agreement and the Consortium agreement). Some elements of this background may have to be shared with other participants in order to carry out the project. Reciprocally, participants are in contact with information held by other participants. In addition, the project itself will generate new results which, in some cases, might be exploitable only with the background of certain participants or with the foreground that will be the property of certain participants.

For detailed information on Access Rights, please refer to Article 8 of the Consortium agreement.

4. Deliverables elaboration and review

High quality standards are to be applied to all work undertaken throughout the project. Quality and its pursuit are regarded as important for every individual activity within the project. Criteria and standards by which the quality of both the results of the project and the processes involved in their production are detailed below.

The overall quality control of the project results includes the coordination of quality review for deliverables, prior to their submission to the IMI2 JU.It is crucial for the project to ensure that deliverables, as official results of the project, are reviewed and checked for quality. This may also apply to other outcomes of the project that are addressed to parties external to the project.

The present section focusses only on the general methods implemented to ensure quality of written materials delivered to the IMI2 JU. A document produced in a project generally aims to provide information concerning the work, its progress or the derived results. Each document should be carefully drafted with rich content, a clear structure and a professional presentation (see section 4.3, paragraph 2 for a link to the template repository). In DRIVE, the three basic aspects for building quality into project documents are content, appearance and timing. It is generally accepted that the relative importance of each document varies, and it is important that over-zealous quality criteria do not compromise timing if marginal benefit to the project is minimal.

4.1. Who generates project deliverables?

As official results of the project, deliverables deserve special attention and are generated and reviewed according to specific procedures (see section 4). As a general rule, the generation of deliverables is a responsibility of the corresponding WPLs, who need to gather contributions from WP participants as appropriate. Prior to submission to the IMI2 JU, deliverables will undergo an internal review process that is detailed hereunder.

In order to ensure homogeneity in the presentation and facilitate consolidation of contributions from different partners, the official IMI2 templates for reports and deliverables are available through Share Point.

With regards to naming convention for electronic files, it is strongly recommended to use a reference that allows an easy and rapid understanding.

Example: ACRONYM_Del#_Title_Version#.

(e.g. DRIVE_D6.3_ProjectHandbook_v1.0.pdf)

4.2. Deliverables follow-up: the traffic light system

To monitor the progress of DRIVE Project deliverables, a monitoring tool based on the traffic light system has been developed and will be monthly updated by the PMO (SP for this specific task) in close collaboration with the WPLs. The monitoring tool consists of a customized EXCEL file (see Annex I). This document contains a template sheet for WP in which all deliverables due along the 5 years duration of the project are marked. The traffic light system is used to declare the deliverable status according with the following criteria:

- Green. No problems: in time, in budget.
- Yellow. Slight delays. No action required yet, but closely monitoring required within WP.
- Red. Significant issue/delay. Full attention/mitigation plan required.

Monthly updates of this tool will be published in the DRIVE internal SharePoint and therefore it will be accessible to all DRIVE participants. This exercise is vital to understand and focus on the following issues:

- What challenges are arising?
- Who owns the challenges and needs to suggest and implement a solution?
- What is the impact on the deliverables?

The traffic light system is used to flag issues in a timely manner and it ensures transparent communication to the DRIVE Steering Committee. A WP sheet example of this tool (WP1) is shown as example in Annex I of this document while the entire EXCEL file is accessible in DRIVE Share Point.

4.3. How are project deliverables reviewed?

4.3.1. Quality criteria

The review process uses the following quality criteria as reference.

As regards to content:

- Completeness: Information provided in the deliverable report must address all aspects related to the purpose for which the information is produced. On the other hand, redundancy of information must be avoided, as it obscures the clarity of documents. All information used should be provided to the depth needed for the purpose of the document.

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

- Relevance: Information used in the document should be focused on the key issues and be written in a fashion that takes into consideration its target audience.

As regards to appearance and structure:

- Adherence to standards: it is important that documents are prepared with uniform appearance and structure so that, even if they are produced by different authors, they appear as originating from a single initiative. Therefore the IMI2 deliverable template available in SharePoint must be used.

4.3.2. Review processes

A) Internal review process for WP1-WP6 and WP8 deliverables

Within DRIVE, the review process is coordinated by the PMO[7] and can be described in six steps:

1. Five weeks before the submission deadline the PMO sends a reminder to the deliverable author to start the review process.
2. Four weeks before the submission deadline WPL/Author(s) sends a first draft outline[8] to the Coordination Team (CT), previously agreed with the WP collaborating partners.
3. Minimum three-weeks before the submission deadline the WPL/Authors shall generate the draft of the deliverable with the required contribution from the Collaborating Partners of the WP/task and comments of the CT to the draft outline. This draft of the deliverable shall be sent to the PMO.
4. The PMO sends the final draft to the SC. In order to avoid bottlenecks in the SC review, two members of the SC have been appointed for an in-depth review of each deliverable (Annex II). Within a period of two weeks SC's comments, if any, are gathered by PMO and forwarded to the Author to insert them properly.
5. At least two days before the submission deadline WPL/Author(s) sends the consolidated version to the PMO and the Coordinator submits it to IMI JU (via Participant Portal).
6. The PMO sends the final version to the GA for their reference and uploads it in Sharepoint.

A summary of the actions and timelines is included in the next table:

Step	Action	Time
1	PMO sends a reminder to the deliverable author	5 weeks before the submission deadline
2	WPL/Authors send draft outline to the CT	4 weeks before the submission deadline
3	WPL/Authors send the draft of the deliverable to the PMO to be forwarded to the SC	3 weeks before the submission deadline
4	SC's comments, if any, are gathered by PMO and forwarded to the Author to insert them properly	Until 1 week before the submission deadline maximum
5	WPL/Author(s) sends the consolidated version to the PMO and the Coordinator submits it to IMI JU	At least 2 days before the submission deadline

Table 8. DRIVE WP1-WP6 and WP8 deliverables review process.

[7] SYNAPSE will facilitate steps 1 to 4. FISABIO will ensure the official submission in step 5. SP will follow up monthly with the WPLs the status of the deliverables to be produced within the corresponding year using the traffic-light system.

[8] The draft outline is considered a table of contents of the deliverable to be produced, with the aim of allowing the CT to understand the structure and contents that will be developed.

The internal review process is depicted in the following diagram:

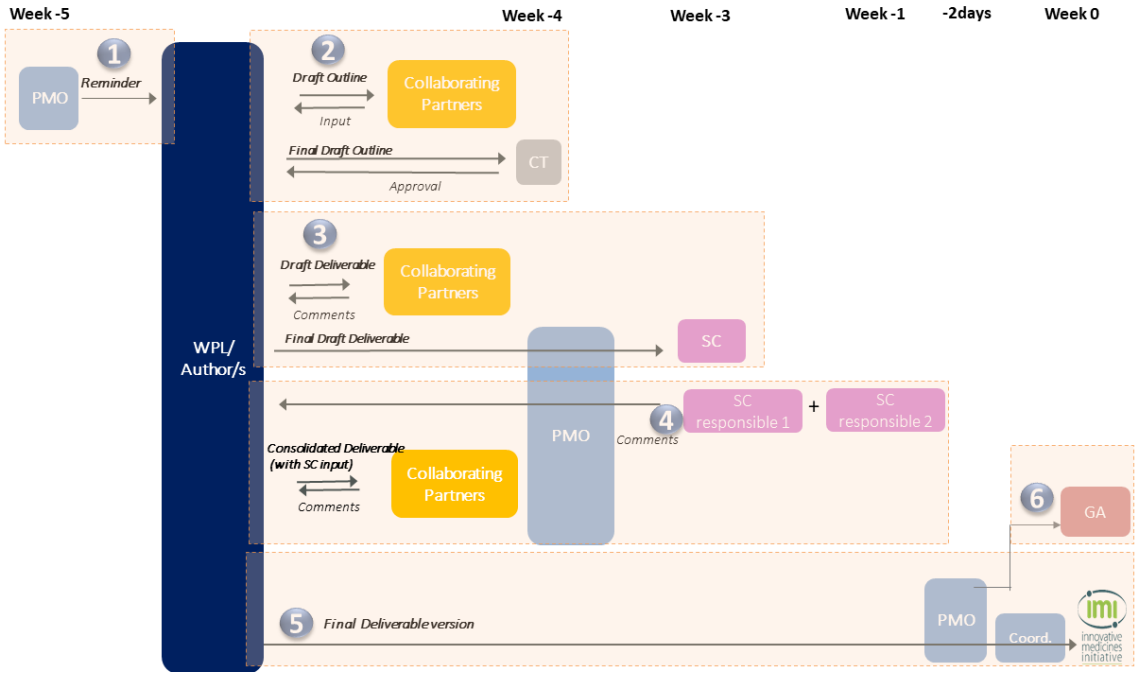


Figure 3. DRIVE internal review of WP1 to WP6 and WP8 deliverables

B) WP7 deliverables' review process

In the particular case of WP7 deliverables, the deliverable review process is different in order to ensure the scientific independence. EFPIA members are allowed to provide written comments to WP7 deliverables as members of the Consortium, although their inclusion or not is duly justified and assessed by the Independent Scientific Committee (ISC).

Further details can be found in D1.2 "Governance Standard Operating Procedures (SOP)" but it can be summarized as follows:

1. A Brainstorming session is organized to discuss upfront key questions between EFPIA and WPL7 about the corresponding deliverable.
2. At least 6.5 weeks prior submission of the deliverable, WP7 Leader sends the draft deliverable to the Collaborating partners for their review
3. Once Collaborating´s partners comments are accommodated in the deliverable, the WP7 Leader sends the draft deliverable to the Independent Scientific Committee (ISC) and the private partners (EFPIA representatives of vaccine manufacturers) for their review.
4. Subsequently, private partners provide consolidated written comments to the project Coordinator (FISABIO as a Public Institution). The project Coordinator reviews and sends EFPIA's consolidated comments to the ISC.
5. Subsequently, the ISC reviews the deliverable, provides comments and marks for inclusion or exclusion EFPIA's comments. The ISC sends his feedback to the project Coordinator and public partners of WP7.

6. WP7 implements the comments according to the ISC's recommendation and shape the final version of the deliverable.
7. The Project Coordinator (or the PMO on his behalf) submits the **final deliverable**. The deliverable is published and submitted to IMI, EMA (in the case of the annual report) and other stakeholders.

A summary of the actions and timelines is included in the next table:
*Please note that the timelines are adjusted each season and agreed between all parties involved.

Step	Action	Time
1	Brainstorming session	Well in advance from submission deadline
2	WPL/Authors send draft deliverable to the Collaborating partners	6.5 weeks before the submission deadline
3	WP7 Leader sends the draft deliverable to the Independent Scientific Committee (ISC) and EFPIA for their review.	5 weeks before the submission deadline
4	EFPIA provides written consolidated comments to the Project Coordinator.	4 weeks before the submission deadline
5	The Project coordinator sends EFPIA consolidated comments to the ISC.	3 weeks before the deadline
6	ISC reviews the deliverable, provides comments and marks for inclusion or exclusion EFPIA's comments. The ISC sends his feedback to the project coordinator and WP7.	3 to 1 weeks before the deadline
7	WP7 implements the comments according to the ISC's recommendation and shape the final version of the deliverable.	1 week before the deadline
8	The Coordinator (or the PMO on his behalf) submits the final deliverable to IMI.	Submission deadline

The review process for WP7 deliverables is depicted in Figure 2.

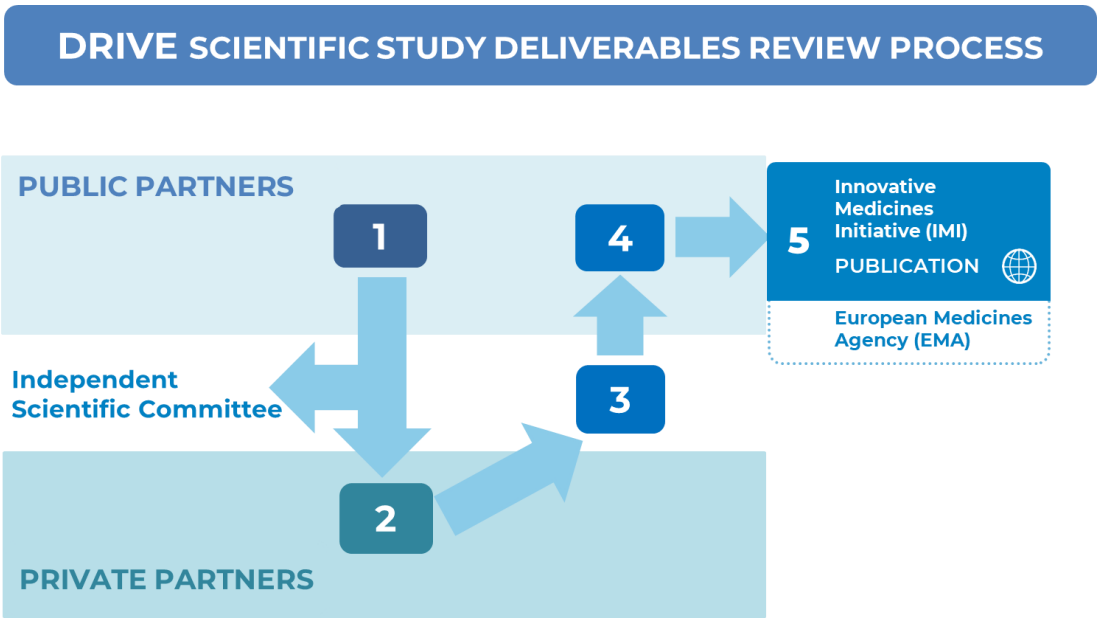


Figure 1. Review process for WP7 deliverables.

4.3.3. DRIVE deliverable dates

The deliverable due dates of the DRIVE project are expressed in the DoA as Project months, meaning that Project month 1 is the first month of the Project, 1st July 2017. The figure below shows the overview of the number of deliverables due per project month according to the DoA.

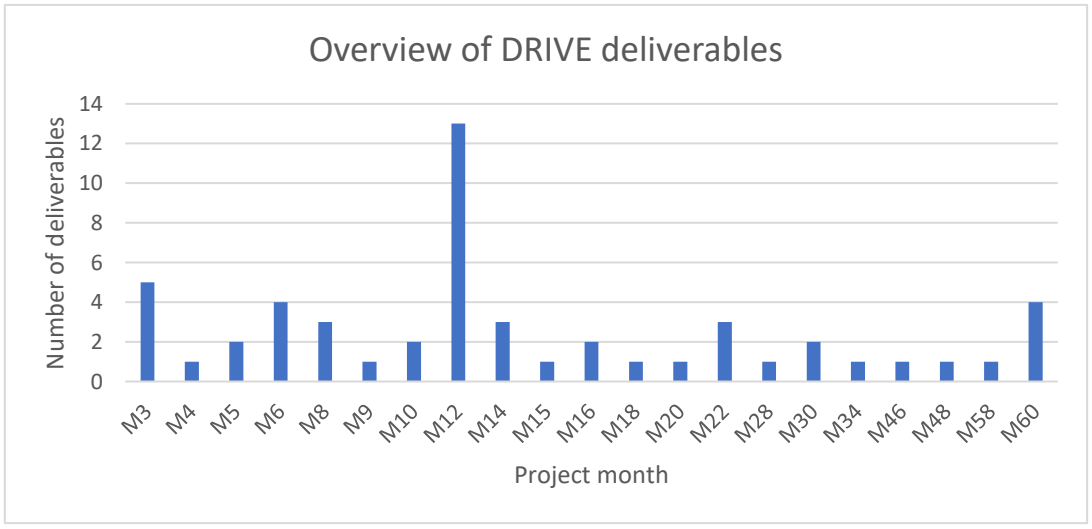


Figure 5. Number of deliverables due per project month.

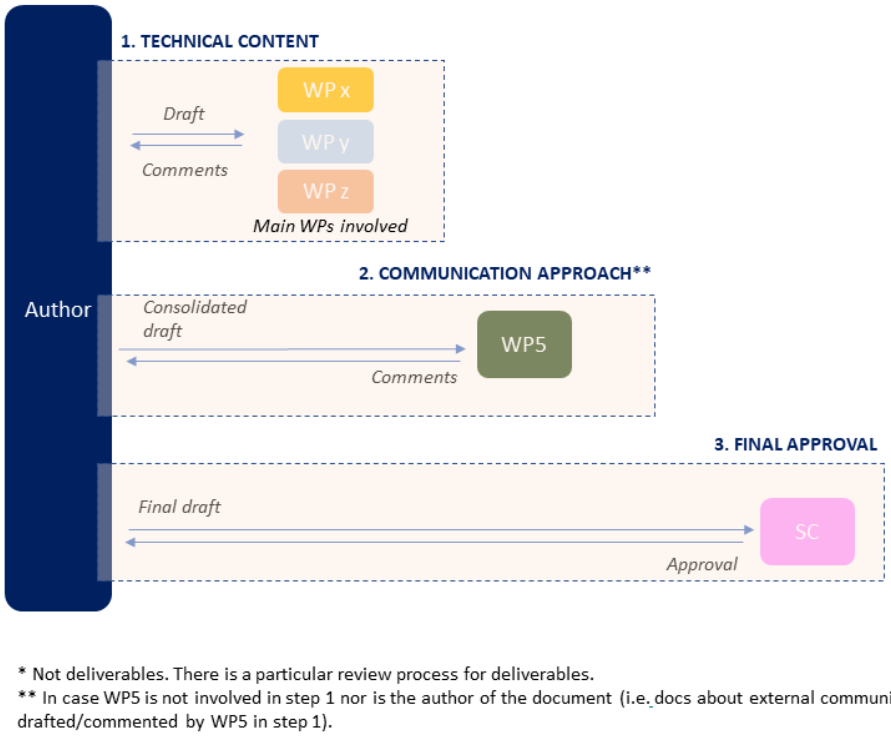
5. Internal documents review process (for external communication)

As many DRIVE documents (not necessarily deliverables) deal with external communication and/or diffusion, a separate procedure for the reviewing of these documents has been designed. The purpose of this procedure is to involve directly WP5 (Communication and dissemination of results) in the review flow regardless of their involvement, so that a final draft with the input of partners with communication expertise is presented to the SC for review.

Depending on the initial WP5 involvement in the production of the document, its action will be requested at different steps of the process, which can be described in 3 steps:

1. The author of the document sends a first draft to the main WPLs involved and the WPLs send their comments regarding the technical content of the document back to the author.
2. The author integrates the comments of the main WPs involved to produce a consolidated draft and sends it to the WP5. WP5 members review the document from a communication perspective and send their comments back to the author. In case WP5 is not involved in step 1 nor is the author of the document (i.e. docs about external communication) WP5 will provide comments in step 1.
3. The author integrates WP5 comments in the document and sends a final version to the SC for review which approves / rejects the final document.

The process of reviewing internal documents dealing with external communication is depicted in the following diagram:



* Not deliverables. There is a particular review process for deliverables.
** In case WP5 is not involved in step 1 nor is the author of the document (i.e. docs about external communication will be drafted/commented by WP5 in step 1).

Figure 6. DRIVE internal review of WP1 to WP6 and WP8 deliverables

For information regarding the process of producing communication material in DRIVE please refer to D5.2. Agreement on communications governance model.

6. Progress Reporting

6.1. Periodic reports

Throughout the entire project execution period (from 1st July 2017 until 30th June 2022), the Consortium will have to submit five periodic reports together with five cost justifications (financial statements) and a series of deliverables to the IMI2 JU, according to the following planning:

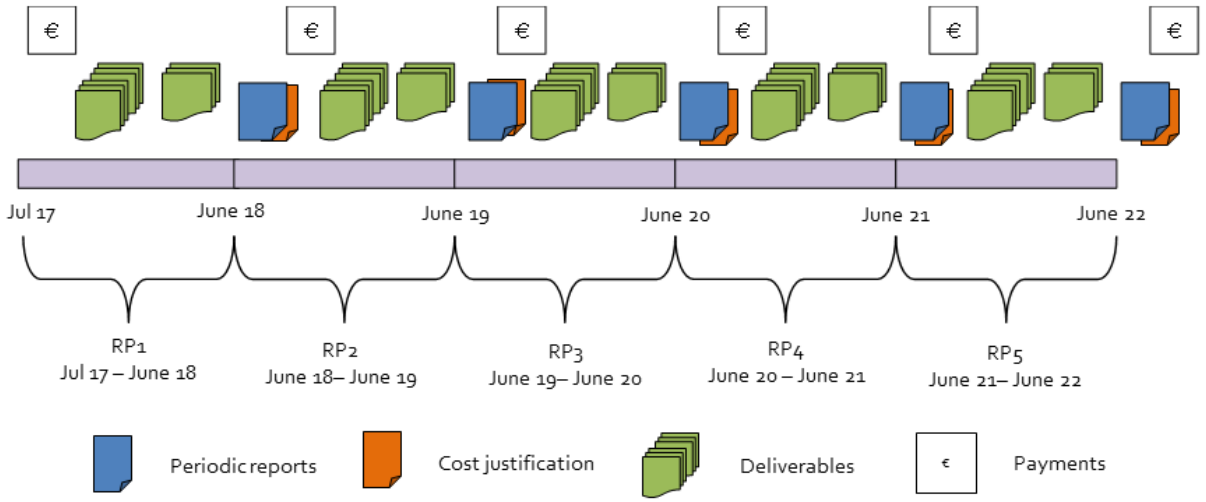


Figure 7. Periodic Reporting schedule

As depicted in the Figure 7, the project execution period is officially divided into 5 periods for both progress and financial reporting to the IMI2 JU:

- RP1: 1st July 2017 to 30th June 2018
- RP2: 1st July 2018 to 30th June 2019
- RP3: 1st July 2019 to 30th June 2020
- RP4: 1st July 2020 to 30th June 2021
- RP5: 1st July 2021 to 30th June 2022

Project deliverables are to be submitted at specific times stated in section 3.1 Project plan — Work packages, deliverables and milestones of the DoA. Deliverables reflect the results achieved during the lifetime of the project, and they are important documents to assess the progress achieved.

In compliance with the rules specified in clause 20.3 of the DRIVE Grant Agreement (Periodic reports — Requests for interim payments), periodic reports must be submitted to the IMI2 JU within 60 days after the end of each reporting period.

Periodic reports include detailed information on both scientific and financial aspects of the project for the covered reporting period, and must follow the template provided by the IMI2 JU, available in Share Point.

The scientific section of the report will contain:

- an explanation of the work carried out by the partners;
- an overview of the progress towards the objectives of the action, including milestones and
- deliverables identified in the DoA;
- an explanation justifying the differences between work expected to be carried out in accordance with Annex 1 and work actually carried out;
- a summary of the exploitation and dissemination of the project results;
- a summary for publication by the IMI;
- the answers to the 'questionnaire', covering issues related to the action implementation and the economic and societal impact, notably in the context of the key performance indicators and monitoring requirements of Horizon 2020 and the JU.

Each partner shall send, by e-mail, information about work performed and efforts devoted in the corresponding period to the PMO[9], within 30 calendar days after the end of the reporting period. Effort figures can however be requested by the PMO at any point in time during the project. For the purpose of accountability, participants are requested to keep track of their efforts at the task level. This facilitates the linkage between effort and progress when reporting to IMI JU.

All beneficiaries will be asked to complete their own Financial Statement and their contribution to the Technical Part of the Periodic Report through the Participant Portal.

The cost justifications (Financial Reporting), the type of costs and the costs that can be claimed for reimbursement are explained in section 7 (Financial Reporting) of the present Project Handbook.

6.2. Final report

Within 60 days after the end of the project, and in addition to the periodic report for the last reporting period and to D6.5 (Final Report and Sustainability plan, due in M60), the Consortium must also submit a final report to the IMI2 JU. This final report must include the following:

1) a 'final technical report' with a summary for publication containing:
   a) an overview of the results and their exploitation and dissemination;
   b) the conclusions on the action, and
   c) the socio-economic impact of the action.
2) a 'final financial report' containing:

[9] Specific additional tools/templates will be created and made available for the Consortium to facilitate the reporting.

a) a 'final summary financial statement'[10], created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the request for payment of the balance and

b) a 'certificate on the financial statements'[11] for each beneficiary, if it requests a total contribution of EUR 325,000 (excluding indirect costs) or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices[12].

This final report will be prepared by the PMO, with main input from the WPLs and also from the rest of the partners if needed

The PMO will also coordinate the elaboration of the final financial report that accompanies the technical report and in which reported figures from all participants throughout the project are consolidated.
At the time of issuing the Project Handbook, there is no IMI2 template available for the Final Report.

[10] See Annex IV to the Grant Agreement.
[11] See Annex V to the Grant Agreement
[12] See Article 5.2 and Article 6.2, Point A of the Grant Agreement.

7. Financial Reporting

7.1. Basic documents and principles

As in any other IMI2 project, DRIVE's budgeting and financial flows are based on a few key concepts. Each participant has a budget, which comprises the estimated costs that will be incurred in due to the project. These costs can be covered with IMI2 funding, direct cash contributions from EFPIA partners, or both. Total funding received by a participant cannot exceed its costs (i.e. it cannot yield a profit derived from participation in the project). EFPIA participants have planned costs, but they receive no funding; all their costs are understood as in kind contribution to the project.

IMI funding follows IMI reimbursement rules, which imply in IMI2 a maximum 100% of the costs reimbursed for research and development activities. IMI2 funding is paid in several instalments: an advance payment (pre-financing) at the beginning of the project, several annual interim payments reimbursing the costs reported and accepted in each Periodic Report, and a final payment of 15% of the total funding. The following figure illustrates how the IMI2 funding is paid.

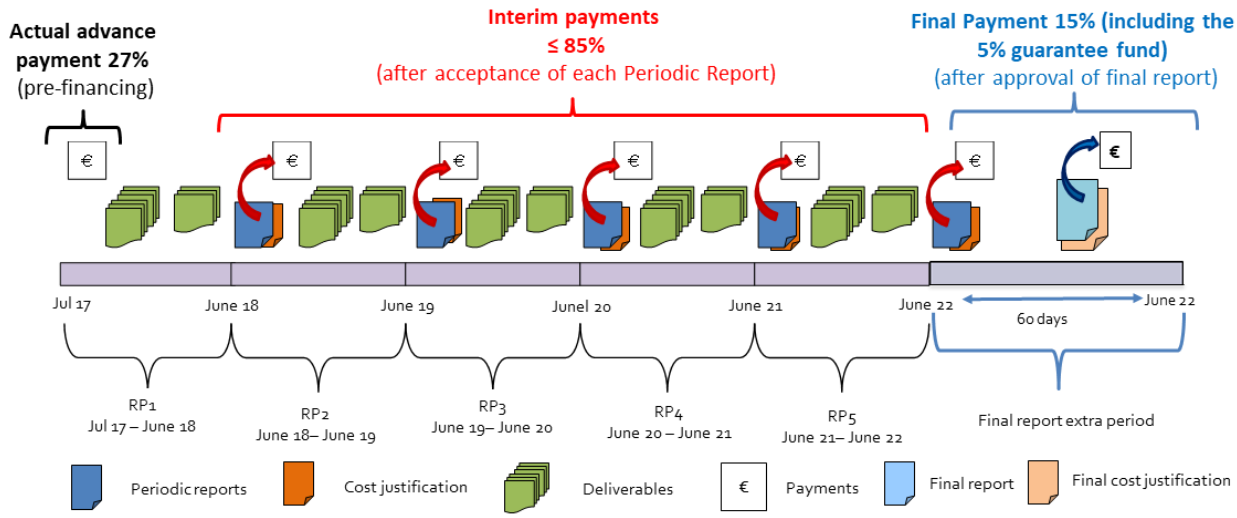


Figure 8. Reporting DRIVE schedule including the final report

Budgeting in DRIVE has been carried out by using a Responsibility Assignment Matrix (RAM), which is indispensable to understand the participants' costs and expected funding, and which can be found in the DRIVE SharePoint. Efforts and costs are also displayed in the DoA.

Budgets can be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment, if the action is implemented as described in DoA. In case of subcontracting, these costs should be included in the DoA (via Amendment if needed) to make sure they are accepted to IMI as costs claimed.

7.2. Costs that can be claimed for reimbursement / accounted for as in-kind contribution

In order to consider project costs as eligible and therefore to get them approved by the IMI JU, they must fulfil the following general conditions:

- Actual, economic and necessary for carrying out the project;
- Determined in accordance with the usual accounting principles of the participant;
- Incurred during the duration of the project, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report;
- Recorded in the participants' accounts;
- Comply with the applicable national law on taxes, and social security;
- Reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;
- Indicated in the estimated overall budget in the DoA.

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

- Need to be aware of their own budget distribution (please check DRIVE´s RAM for detailed budget information);
- Need to coordinate their financial flows: budget, funding, expenditure, justification, payments;
- Need to avoid inconsistencies between efforts spent in the project (recorded in time sheets) and personnel cost justification.

Beneficiaries should note that 'budget' means the costs that each partner is expected to incur, as declared in the DoA. The amount contributed by the IMI JU is called 'funding' or 'IMI JU contribution'. A participant has to justify its total budget in order to get the expected funding in full. The actual costs incurred during the project (the 'practical' implementation of the planned budget) are what we call 'expenditure'. The costs justified represent what we call 'justification', which is the core objective of financial reporting. Lastly, 'payments' refer to the actual amounts transferred to the partners' accounts during the project. These depend on the funding of each partner and the justification accepted by the IMI JU, and cannot exceed the total funding of each partner.

7.2.1. Direct Personnel costs

The IMI JU follows a policy of full cost justification for all partners. This means that the hours devoted by all of the personnel involved in a project can be justified, irrespective of them being newly hired for the project or permanent staff.

For the justification of personnel costs in the periodic financial statement, beneficiaries must take into account the efforts reported for the same period so that these are consistent with

the amounts justified. Personnel costs are understood to include salaries, social charges, etc. – all of the actual costs that the person represents for the institution.

The personnel costs are normally calculated by the hourly rate multiplied by the number of actual hours worked for the project.

The hourly rate (based on actual costs) can be calculated as: actual annual personnel costs, divided by number of annual productive hours. The number of annual productive hours that makes a person-month can vary between partners. All partners must calculate their specific productive hours according to the general practice in their organization. In case different categories of personnel have different working conditions, individual productive hours may be calculated. The productive hours per year should exclude annual leave, public holidays, training (if not project related) and sick leave.

In addition, for personnel costs, the beneficiaries must keep time records for the number of hours declared for all actual work performed for the project. The time records must be in writing and approved by the persons working for the action and their supervisors, at least monthly.

Time records should include (see template provided in Annex III):

- the title and number of the project, as specified in the GA;
- the participant's full name, as specified in the GA;
- the full name, date and signature of the person working for the action;
- the number of hours worked for the action in the period covered by the time record; the number of hours can be detailed either per day or per month. As an example, the template provided in Annex III is detailed per month.
- short description of the work carried out during the month;
- the supervisor's full name and signature.

As an exception, for persons working exclusively on the action, there is no need to keep time records, if the participant signs a declaration conforming that the persons have worked exclusively on the action. A template for this declaration is available on Sharepoint.

7.2.2. Subcontracting costs

Regarding subcontracting costs, it is very important that costs are explicitly mentioned in the DoA and foreseen in Annex II of the GA. Moreover, the DoA must include a specification that enables approval by IMI. The current DRIVE budget does not include cost for subcontracting.

Ground rule is that all partners must have the technical and financial resources needed to carry out the project themselves, but if it is necessary to implement the project, a participant may call upon subcontractors to implement "action tasks" described in the Grant Agreement ("Subcontracting"; art. 13 GA).

The costs for subcontracting (to develop project tasks) are eligible if the following criteria are met:

- Subcontracting may cover only a limited part of the action;

- Need for a subcontract must be substantiated, taking into account the specific characteristics of the action;
- Principles of “best price-quality ratio” or “lowest price”;
- Beneficiaries that are public bodies: compliance with national procurement rules;
- Avoid any conflict of interests;
- Tasks to be implemented and costs must be mentioned in the DoA; otherwise an amendment is required;
- Total estimated costs of subcontracting per participant must be set out in Annex 2 Estimated budget;
- Exceptionally: approval without formal amendment at IMI’s discretion.

Otherwise, if necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment (art. 11 GA), use of in-kind contributions provided by third parties free of charge (art. 12 GA) or linked third parties (art. 14 GA).

Third party with a legal link to a partner is any legal entity which has a legal link to the partner implying that collaboration is not limited to the action. This is different from direct contracts (art. 10 GA) which do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries.

The main differences between third parties linked to partners subcontrators and direct contracts are shown below:

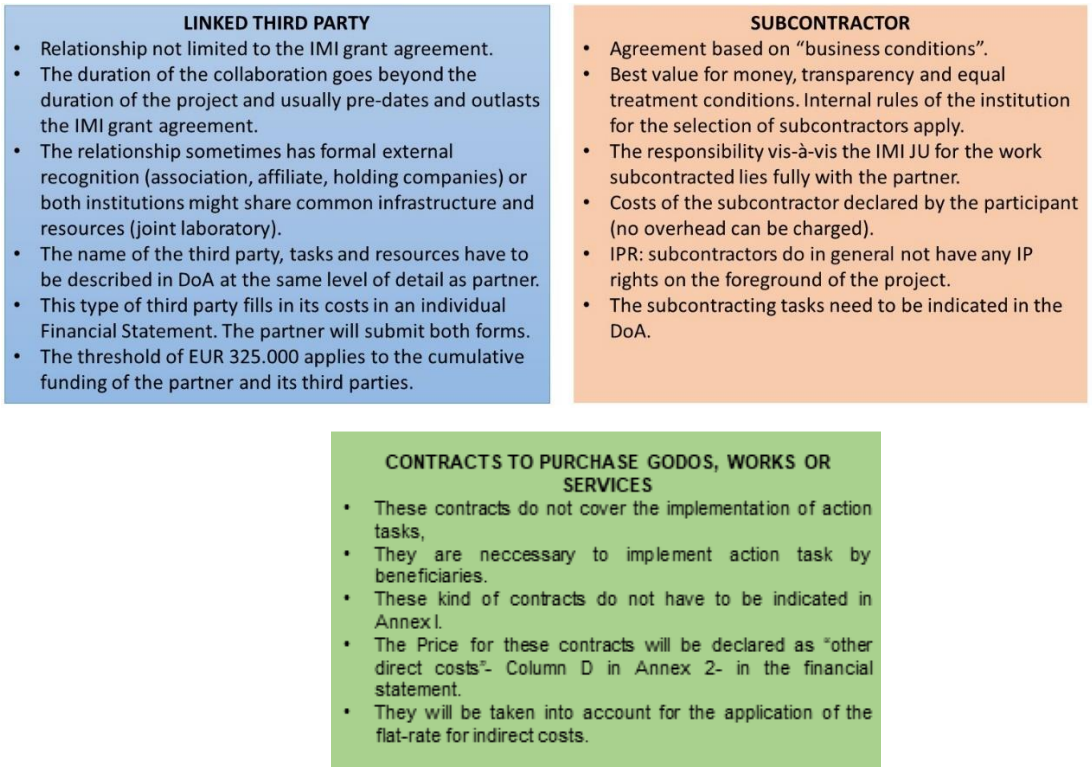


Figure 9. Third parties, subcontractors and direct contracts differences.

Figure 10 below shows a guidance overview how to determine a subcontractor, third party or in-house consultant.

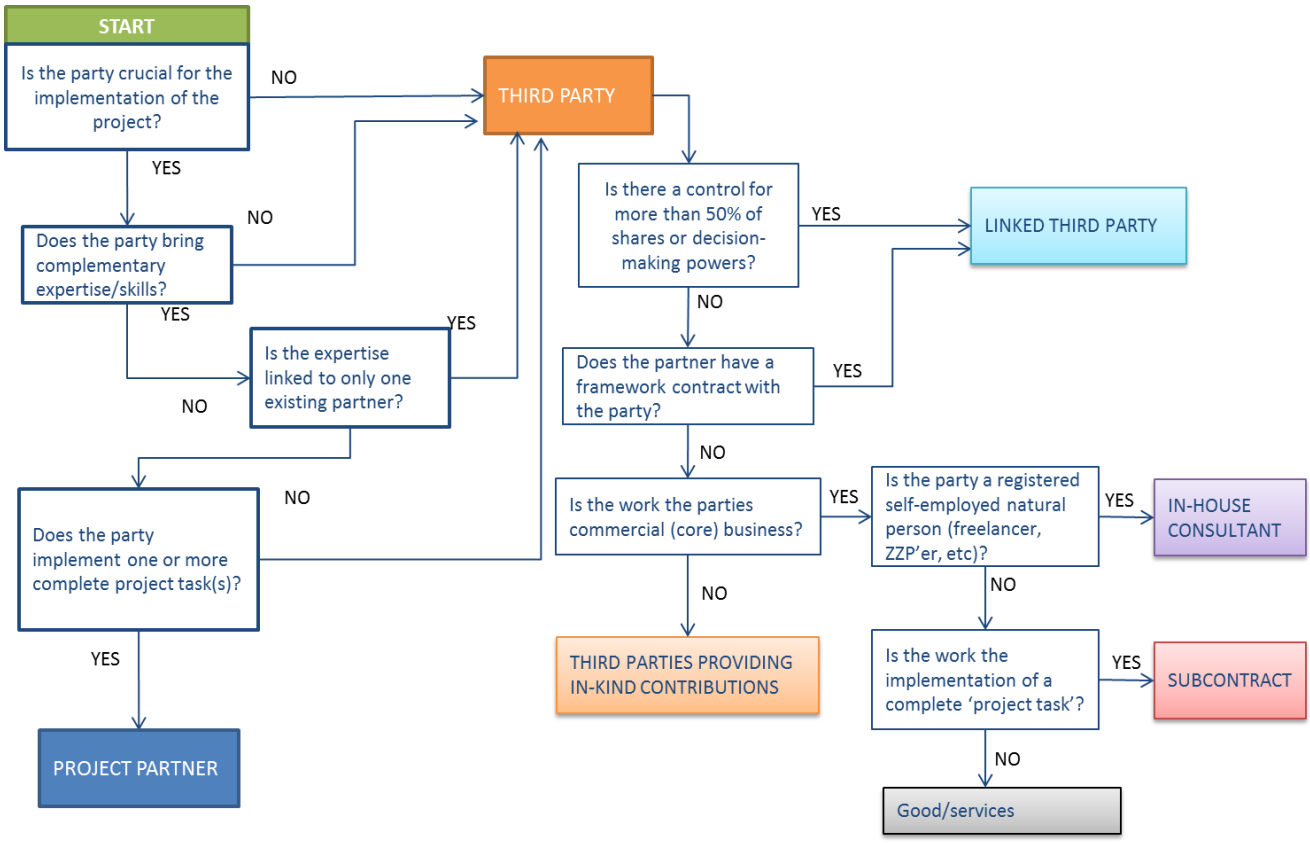


Figure 10. Third parties options

If you have planned to involve in the project activities a non-DRIVE organisation, please contact the DRIVE PMO to find the most optimal solution for this case, considering the current IMI2 rules.

The following costs are no longer considered as subcontracting under IMI2, they are instead considered as: "contracts to purchase goods, works or services":

- They might not be indicated in the DoA;
- Costs reported as other direct costs;
- Price may contain profit;
- Flat rate of 25% (indirect costs) eligible;
- Examples works & services: audit certificate, website creation, employment agency.

7.2.3. Other Direct Costs

Travel and subsistence costs have been identified in the DRIVE Project.

- As a general rule, General Assembly Meetings global expenses (caterings (lunch/coffee-tea), meeting rooms, technical equipment, etc.) will be justified in the corresponding

reporting period as “other direct costs” category. Alternatively, for any expenses covered by the meeting host directly, the amount paid by the host will be increased in the budget of the host partner.

- Travel costs must be needed for the work in the project, or for activities related to it (e.g. presentation of a paper explaining the results of the project in a conference). Travel costs related to a conference where no specific project-related work will be performed or presented by the participant would not be eligible. Travel costs should be limited to the necessity for the project; any extension of the travel for other professional or private reasons is not an eligible cost.
- Each partner must apply the travel rules of their own organisation (i.e. some organisations reimburse a flat rate allowance for meal expenses, others reimburse the actual costs).
- Travel costs and related subsistence allowances should be in line with the partner’s usual practises (keep boarding passes and other proof).

The depreciation costs of equipment, infrastructure or other assets (new or second hand) as recorded in the participant’s accounts are eligible, if they are purchased and written off in accordance with the participant’s usual accounting principles. The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purpose of the action.

Costs of other goods and services (consumables, supplies, dissemination, protection of results, certificates on the financial statements, certificates on the methodology, translations, publications, etc.) are reported as other direct cost category.

Please note IMI2 rules allow partners to report as eligible costs the non-deductible VAT according to specific methods of calculations. In case of doubts, please contact the PMO for further information.

7.2.4. Indirect costs

Indirect costs or overheads (e.g. heating, lighting, security, office supplies, etc.), which represent a fair apportionment of the overall overheads of the institution, are to be added to the above-mentioned categories. As they are indirect, these costs are not justified using invoices, etc., but simply stated in the Financial Statement, generally as a percentage of the direct costs explained above. They are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs, excluding their direct eligible costs for subcontracting and the costs of resources made available by third parties which are not used on the premises of the participant. EFPIA companies might include their indirect costs in the fully loaded FTE (full time equivalents) rate.

If any doubt arises with respect to project expenses or cost justification during the project life, participants are strongly encouraged to raise the issue to the PMO for guidance.

7.3. Costs that cannot be claimed for reimbursement

Some costs cannot be considered as eligible and therefore their justification in the financial cost statement is not allowed, in particular:

- Costs related to return on capital.
- Debt and service debt charges.
- Provisions for possible future losses or charges.
- Interest owed.
- Doubtful debts.
- Currency exchange losses.
- Bank costs charged by the partner's bank for transfers from the JU.
- Excessive or reckless expenditure.
- Deductible VAT.
- Costs incurred during suspension of the implementation of the action.
- Costs declared, incurred or reimbursed in respect of another EU or IMI project.
- Any cost which does not meet the conditions established in the previous section.

7.4. How must financial statements be signed and submitted?

Financial statements are specific documents in which each Participant declares all the costs incurred during each reporting period and the funding requested to the IMI2 JU when applicable.

The justification of costs is done through the Participant Portal by using the Periodic Reporting Module. The costs must be filled by each Consortium participant through the system, which uses the Financial Statement model provided in the Annex IV of the GA (see Annex IV of this document). EFPIA will not use this model but will report costs by submitting annually a financial report at company level for all IMI2 projects on 31 of January.

In addition, participants receiving IMI funding[13] will be also asked to provide an explanation of the costs in a use of resources table (see Table 10) that is included in the Part A of the Periodic technical report document (Finance cost section). Moreover, information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each participant and from each linked third party, for the reporting period concerned, should be also provided.

Beneficiary [insert beneficiary number] - [insert beneficiary name]			
Direct personnel costs declared as actual costs			
Persons months per WP			
Person months		Associated WP	
[insert number pm]		[insert WP number]	
Use of in kind contribution from third party			
Costs	Third Party name	Type	Foreseen in Annex 1

[13] This additional explanation excludes EFPIA, since they are not receiving IMI funding. However, since they must implement the action tasks attributed to them in Annex 1 they have to be included in the scientific report.

	(Explanations)		
[insert amount in EUR]	[insert comment]		*[*YES*]* *[*NO*]*
Direct costs of subcontracting			
Costs	Explanation	Foreseen in Annex 1	
[insert amount in EUR]	[insert comment]	*[*YES*]* *[*NO*]*	
Financial support to third parties			
Costs	Explanation		
[insert amount in EUR]	[insert comment]		

Other direct costs: explanation of major cost items if the amount exceeds 15% of personnel costs				
Costs	Short description	Category	Associated WP	Explanation (if not included in Annex 1)
[insert amount in EUR]	[insert comment]	[Travel] [Equipment] [Other goods & services]	[insert WP number]	[insert comment]

Use of in kind contribution from third party				
Costs	Short description	Category	Associated WP	Explanation (if not included in Annex 1)
[insert amount in EUR]	[insert comment]	[Travel] [Equipment] [Other goods & services]	[insert WP number]	[insert comment]

Specific costs	
Costs	Short Description (as per Annex 1)
[insert amount in EUR]	[insert comment]
Receipts (Article 5.3.3 of the GA) including financial contribution received from an EFPIA company/IMI2 associated partner [column (k) of the financial statement]	
Costs	Please indicate type of receipt or name of organisation providing the in-kind/financial contribution
[insert amount in EUR]	[insert Name/comment]

Table 10. Resources table included inside the Periodic Report template.

Specific guidelines for accessing the IMI Reporting tool will also be provided by the PMO in DRIVE. These guidelines will include complete instructions and recommendations for adequate reporting.

Cost must be filled in the Participant Portal within 60 calendar days after the end of the reporting period together with the use of resources explanation in the cost table. It is wise of

participants to prepare in advance for reporting and liaise with any relevant financial or administrative department in their respective institutions at least one month in advance of the end of the reporting period.

Once all the information is completed, each beneficiary shall electronically sign the Financial Statement. Only users with the role of Project Financial Signatory (PFSIGN) can perform this action through the Participant Portal. The signature action is simple and can be done with a simple click. Original wet ink copies are not needed since within the Participant Portal all signatures are electronic.

Once all Financial Statements have been signed by all beneficiaries (including the coordinator), the coordinator shall check that all information included is correct and include and re-do some steps if needed.

Finally, the Coordinator will be in charge of approving both the elements of the periodic report and the financial statements, submitting to the EU Services all the information electronically in a single step.

7.4.1. EFPIA Reporting

Under the IMI2 framework, EFPIA in kind contribution to IMI2 projects and SGG (Strategic Governance Groups) is to be reported by each company on an annual basis and on a portfolio level, independently of the project deadlines set in the Grant Agreement.

When reporting actuals in-kind contribution, costs shall be:

- determined in accordance with the usual accounting practices, to the applicable International Accounting Standards (IAS) and International Financial Reporting Standards (IFRS);
- Connected to the Action (project) as described in Annex 1 (DoA);
- Reasonable, necessary, justified, identifiable and verifiable;

The value of the contribution should be detailed at the level of each action (project), including both in kind (in kind EU/non-EU) and direct financial contributions.

In addition, total contributions to SGGs (Strategic Governance Group) where a company is involved should be reported. For Strategic Governance Group in kind contribution, costs shall normally be made of personnel costs and meetings travel costs, where representatives from EFPIA company have participated/contributed.

The contributions reported should be actuals or estimates (if actuals are not available).

Financial statements must be reported by 31 January for the period running since the start date of the activity until 31 December. Indeed, the yearly report has to be submitted to the IMI2 JU Programme Office no later than 31st of January of each year (n), together with adjustments to previous years, if applicable. The information on the contributions to be submitted by 31 January may be indicative/estimates (e.g. can be reported under personnel (regardless of the category), if the breakdown per categories is not yet known). The actual costs including explanation of use of resources as outlined above should be submitted and

certified annually at the latest by 30 April. Costs certified at a later date will be considered as such in the following year's exercise. There is no threshold for certification of costs.

7.5. Who needs to submit an audit certificate?

A certificate on the financial statement (CFS), also called audit certificate, is a statement from a competent auditor in which the correctness and compliance with IMI JU rules of a cost justification is certified.

CFS should be provided by participants once the threshold in the IMI Grant Agreement of EUR 325,000 of funding/in-kind has been claimed at the end of the project. This certificate will cover all reporting periods.

Auditors eligible to deliver audit certificates must be “external auditors” or “public competent officers” who are “independent” and “qualified to carry out statutory audits of accounting documents”. It is highly recommended to determine an adequate auditor well before the end of the reporting period to ensure his/her availability for a timely generation of the audit certificate.

As a guideline, Annex 5 of the Grant Agreement includes the terms of reference and independent report of factual findings for the certificate of financial statements.

The project coordinator must send the CFSs to IMI, with the final report, within 60 days of the end of the last reporting period

7.6. IMI JU funding payments

The IMI JU funding is paid to the Project Coordinator of the IMI JU funding account (FISABIO), who distributes it to the partners without unjustified delay.

Some general rules apply with respect to the payments:

- The IMI JU has paid a pre-financing at the project start of 27% of the total funding;
- Interim payments will be depending on costs justified and accepted after each reporting period, and distributed after receipt from the IMI JU;
- A final payment will be released by the IMI JU corresponding to the costs accepted for the last reporting period plus any adjustment needed.

Total payments during the project cannot exceed 85% of the total funding. 15% of the funding will only be paid after final reports are approved. The most important notion for participants to bear in mind is that payments follow costs reported – and costs reported follow work done for the project. The Coordinator has the right to reject costs reported by any participant if they are not in line with the work performed. The following Figure illustrates the reporting dates including the maximun date for payment for the first reporting period.

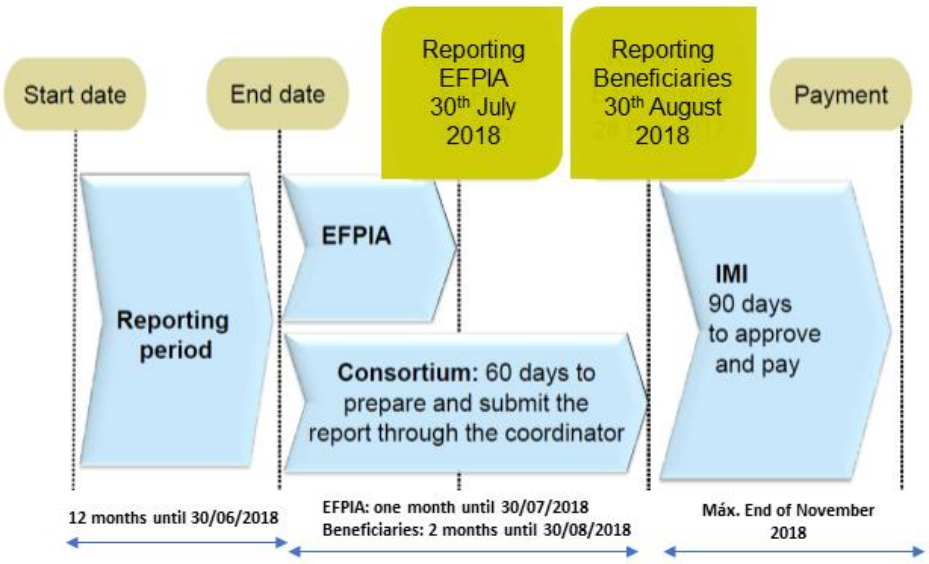


Figure 11. Timelines for reporting and IMI JU payments for the first DRIVE reporting period.

7.7. Receipts of the project

The receipts (in lay terms, 'income received due to the project') of the project are:

- **Financial contributions to the beneficiaries made by EFPIA companies and/or their affiliated** entities or made by participants that are neither a participant nor an EFPIA company. The financial contribution received by the participant from EFPIA companies must be declared by the participant as a 'financial contribution', in the Financial Statement. The EFPIA company must declare those costs in its Financial statement, when reporting yearly to IMI.
- Resources **made available by third parties to the partner** by means of financial transfers or contributions in kind which are free of charge:
  a. Shall be considered a receipt of the project if they have been contributed by the third party specifically to be used on the project.
  b. Shall not be considered a receipt of the project if their use is at the discretion of the participant's management.
- **Income generated by the project**:
  c. Shall be considered a receipt for the participant when generated by actions undertaken in carrying out the project and from the sale of assets purchased under the grant agreement up to the value of the cost initially charged to the project by the participant;
  d. Shall not be considered a receipt for the participant when generated from the research use or direct exploitation of foreground resulting from the project

7.8. Adjustments to previous periods

Any adjustment (retroactive modification of costs submitted in previous periods) requires the submission of a supplementary Financial statement for the period, where the details of that adjustment will appear.

Together with the new Financial statement, the details and justification for the adjustment must be provided by the participant in the periodic report.

Therefore, for correction of financial statements submitted in previous reporting periods, the following need to be submitted:

- One Financial statement for the current period;
- One separate Financial statement for every previous period where adjustments are needed, which will include those adjusted (negative/positive) costs of that specific previous period.

If these costs need to be covered by a Certificate on Financial Statements (CFS), they could be supported within the CFS for the current period but with a specific indication by the auditor certifying both the supplementary costs incurred in previous periods and those claimed in the current one.

8. Risk Management

8.1. Why is risk management necessary?

Risks are inherent in any activity, especially when it is unique, as is the case of a project. The presence of risk increases dramatically when projects include a significant research component, due to its inherently exploratory nature and uncertain outcome. The inevitability of risks does not imply however the inability to recognise and manage risks to minimise the potential negative consequences while taking advantage of the opportunities for improving performance and results that may arise. Risk management in the DRIVE project is the process that commences with the identification of risks and links this through to the resolution of individual risks. It encompasses the methods and procedures undertaken by the Consortium in order to identify, analyse, assess and monitor risks affecting the project or its results, and the development and monitoring of associated mitigation and contingency plans that aim at minimising the potential negative effects (for *threat* risks) and maximising the potential benefits (for *opportunity* risks).

8.1.1. Main objectives

The main objectives of the risk management task in DRIVE are the following:

- To provide visibility and raise awareness of uncertainties that may affect the project development and/or results through a structured mechanism that ensures that both completeness and accuracy will be achieved in the process;
- To allow the project to focus on major risks by appropriate assessment and prioritisation according to risk exposure, a value that results of combining the estimated probability and impact values for any given risk;
- To proactively manage uncertainties that can affect the project performance, time schedule and/or budget, with proper feedback channels to project management, allowing for the development of contingency plans, mitigation and/or risk avoidance strategies.
- To continuously monitor the evolution of risks throughout the project, providing a framework to incorporate them in the work plan (as risks become issues) or disregard them (risks becoming pure concerns);
- To document risks, activities and decisions made so as to allow for capitalisation of the knowledge acquired with a view on facilitating planning and development of the post-project phase and future projects.

8.1.2. Risk management procedures

The risk management procedures in DRIVE have been adapted from lessons learnt in past projects by the Consortium members, from guidelines produced by international standards bodies, and by recognised institutions such as the Project Management Institute (PMI).

Responsible for risk management within the project is the PMO. It facilitates straight forward and timely communication with the SC. However, risk management activities certainly benefit from the active participation of all involved actors, therefore an open structure that allows for contributions from all project partners is promoted. Taking into account the characteristics of

the DRIVE project, only the most appropriate procedures have been selected, giving priority to a pragmatic approach that focuses on the project success and the fulfilment of the Grant Agreement. As a consequence, the accent is put on risk identification processes that raise awareness on uncertainties and also on risk avoidance strategies. Qualitative analysis of risks is prioritized.

Four main steps conform the risk management process, which are depicted in the following Figure:

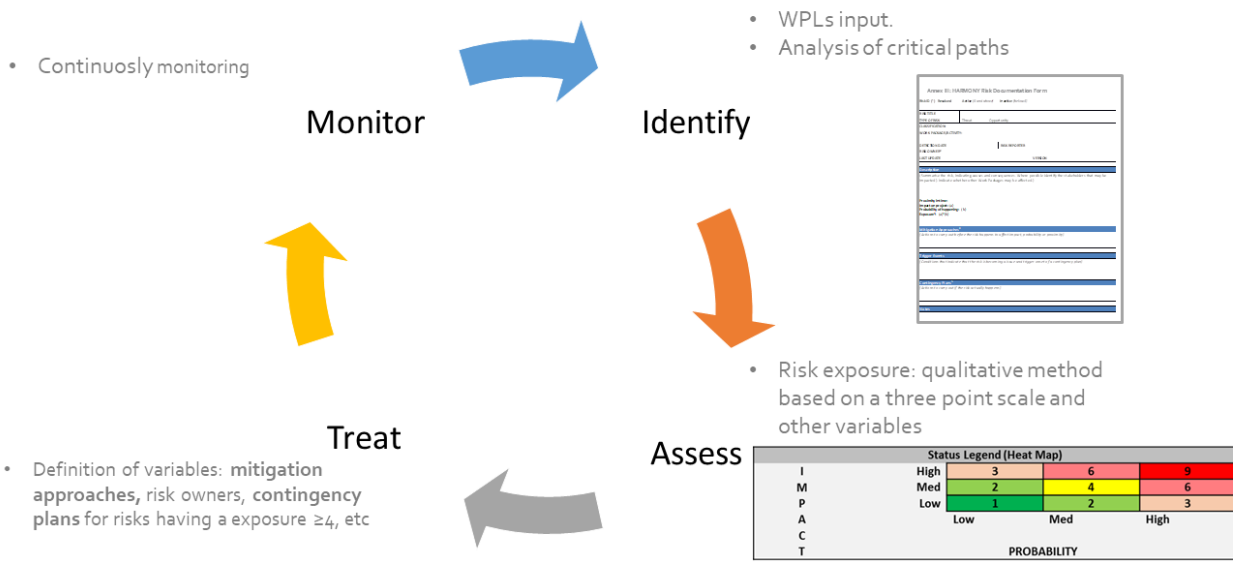


Figure 12. Risk management steps.

After the end of the project, a fifth step related to capitalisation of lessons learnt will be implemented by each partner in their respective organisations according to their own strategies. The project management will make documentation available for this purpose upon request. Importantly, in a project like DRIVE where sustainability in the long term is a core objective, and where the project activities serve to 'pilot' future ongoing activity, lessons learnt from managing risks during the project are of special importance.

8.2. Risk Identification

Before risks can be managed, they must be identified. Identification raises awareness of risks before they become problems and adversely affect the project. The first phase of the risk management process deals with systematic research for threats to the successful achievement of the project objectives, or for opportunities that may be hidden therein, and their appropriate classification. This process relies heavily on the encouragement of project personnel to raise concerns and issues for subsequent analysis, as past experience has demonstrated that most risks are usually known by the personnel, who usually experience them as uneasy feelings, concerns or doubts about aspects of the project that wouldn't be defined as risks per se and thus remain hidden. The Risk Identification process must create

and sustain a non-judgmental and non-attributive risk elicitation environment so that tentative or controversial views are not discouraged.

8.2.1. Activities for risk identification

In the DRIVE project the following activities will be considered for risk identification:

- Structured and facilitated brainstorming sessions. These can be normally organised taking advantage of SC meetings to ensure availability of participants, management involvement and face-to-face interaction[14]. However, these sessions are susceptible of being dominated by the stronger personalities, therefore complementary procedures such as online risk identification forms that can be freely submitted to the PMO are recommended.
- Structured interviewing. This method will normally be used to clarify details of risks, investigate new risks or for checking areas of the project that have been re-planned. One-on-one interviews or group meetings will be used depending on the issues to be discussed.
- Unstructured interview and informal reporting (at meetings, etc).
- Analysis of formal reporting by participants in the Interim and Periodic Progress reports.
- Analysis of critical path and WP interdependencies by the PMO and WP participants.

The outcome of the risk identification process will be the creation of a Risk Documentation Form (see template provided in Annex V of this document) for each identified risk. A Risk Registry composed of the regularly updated Risk Documentation Forms will be maintained by the PMO.

Both opportunity and threat risks will be identified in the same way.

8.3. Risk Assessment

An initial risk assessment is normally carried out as a natural consequence of the identification process. Assessment turns risk data into risk decision-making information, and provides the basis for the Project Managers to work on the "right" risks. It aims at estimating the likelihood (probability) of a risk becoming a problem, the estimated impact ("damage" or "severity" in relation to the project objectives fulfilment) and an associated risk exposure, which is a consequence of the two former variables. In DRIVE, a qualitative method will be initially used for estimation, ranking both probability and impact on a three-point scale (high, medium or low). In this simple scheme, risks having at least one dimension graded as "high" are always to be closely examined. However, quantification of the risk exposure is done by multiplying the numerical values ascribed to each grade in the scale as follows:

[14] Note that some risks, such as those related to the Consortium (e.g. underperformance of one partner) may need to be managed privately by the PMO and the CT.

	Impact	Low	Medium	High
Probability	*Values*	*1*	*2*	*3*
Low	*1*	**1**	**2**	**3**
Medium	*2*	**2**	**4**	**6**
High	*3*	**3**	**6**	**9**

Table 11. Risk exposure

Opportunity and threat risks are assessed in the same way, but threat risks have always priority over opportunity risks. Additionally, proximity in time is used to prioritize among risks with equal exposure.

Alternatively, probability could be estimated on a scale ranging from 0.1 (highly improbable) to 1.0 (certain to happen) while impact could be estimated on a scale from 1 (extremely reduced impact) to 10 (huge impact), in which case prioritisation will be derived from the risk exposure factor (result of multiplying the probability and impact factors). However, estimating in these longer scales is known to have caused difficulties in past projects and resulted in arbitrary prioritisation due to bias of the risk owners, therefore the simpler three-level scale will be initially used in the project. If needed, the method will be refined according to this alternative method to allow for more precise prioritisation of the top ranked risks.

It is important to take into account that interaction and inter-dependence between risks can occur, and that in some cases these complex situations should be treated as independent risks in themselves.

Risk assessment encompasses therefore a prioritisation of the risks that can be made according to exposure but that can also be filtered according to risk category or imminence in time. This phase also comprises a specification of the Risk Owner, understood as the partner in the best position to recommend mitigation strategies for the risk, develop and document a contingency plan and monitor the status of the risk. This normally corresponds to the partner responsible of the activity/WP to which the risk is ascribed. The partner being Risk Owner is responsible of closely following up the risk and report to the PMO, which acts as Risk Manager.

8.4. Risk registry and action plan

On the basis of the previous assessment, the planning phase turns risk information into decisions and actions (both present and future) to address individual risks. This phase comprises the definition of mitigation approaches (strategies to control, avoid, minimise or otherwise mitigate the risk, addressed to reduce risk probability and/or impact for threat risks, and the opposite for opportunity risks), identification of trigger events (conditions that indicate that the risk is turning into an issue) and configuration of contingency plans (actions to be taken to deal with the situation if the risk actually becomes a problem). All threat risks with "high" or "medium" probability or impact should have a mitigation strategy that must be immediately tackled and all risks having an exposure equal or greater than 4 must have a contingency plan prepared in DRIVE. Additionally, a mitigation plan is required to be

produced for all risks that can be easily mitigated, or that the PMO wishes to mitigate for strategic reasons. A mitigation strategy contains a plan for controlling either or both of the following:

- The risk cause/cause-impact relationship with the aim to reduce the impact probability of occurrence.
- The impact itself and/or its effect on the project.

Implementation of a mitigation approach is a responsibility of the Risk Owner, who will be supported by the Risk Management in the PMO when other partners are involved.

Contingency plans should identify the proposed management activity or alternative path to be taken should the risk give clear indications (understood as occurrence of trigger events) that it cannot be avoided. Contingency plans implementation are Project Management issues and often have to be agreed in DRIVE with the IMI JU services to be entered into the work plan. Contingency plans and responsibilities for their implementation are agreed upon at SC level.

In summary, mitigation actions are what one does before the risk happens; once trigger events are detected, the risk becomes an issue and contingency plans are activated. If mitigation is successful, trigger events are de-activated and the risk is managed out, or becomes irrelevant.

In all cases, risk avoidance strategies (which normally imply taking a lower risk path) have to be carefully considered provided that they do not endanger the Grant Agreement fulfilment.

9. Internal Communication

9.1. How should Participants communicate internally?

To ensure that communication within the project complies with the principles listed above, the Consortium will adopt the following approach in that respect:

- Use of electronic mail as the main tool for communication within the Consortium.
- Documentation of discussions, agreements and decisions made by phone is encouraged. Specifically, phone conferences should always have agenda and minutes, which should be made available through the DRIVE SharePoint.
- Several distributions lists have been initially created which can be used by any participant depending on the subject of the message. Additional lists may be created as the project evolves, if necessary. Synapse will be responsible for updating the above-mentioned lists with the information received from Participants. When a list is used, care should be taken by Participants to use the “reply to all” feature only when relevant. The table below shows the distribution lists created by the time of publishing this Handbook:

DISTRIBUTION LIST	RECIPIENTS
all@drive-eu.org	All DRIVE partners
sc@drive-eu.org	DRIVE Steering Committee
legal@drive-eu.org	DRIVE Legal
info@drive-eu.org	PMO
coordination@drive-eu.org	DRIVE Coordination Team
wp1@drive-eu.org	Work Package 1 Participants
wp2@drive-eu.org	Work Package 2 Participants
wp3@drive-eu.org	Work Package 3 Participants
wp4@drive-eu.org	Work Package 4 Participants
wp5@drive-eu.org	Work Package 5 Participants
wp6@drive-eu.org	Work Package 6 Participants
wp7@drive-eu.org	Work Package 7 Participants

Table 12. DRIVE mailing lists

- A Share point space has been created for DRIVE to be used as a repository of relevant information and files which facilitates the exchange of documents within the Consortium (i.e. meeting minutes, documents in progress, final versions and other relevant reports or announcements). The SharePoint platform also provides the possibility of discussion between participants through messages, maintenance of a calendar of meetings and events, upload of files, and tracking of important milestones and events at both the Project and WP level.
- The latest version of the DRIVE contact list is uploaded on SharePoint, in the Mailing lists section. The up-to-date participants' contact information with clear information of who is included in every mailing list mentioned above can be found.
- The use of *de facto* standards based on MS Office-compatible files for electronic document exchange among participants is required when possible. PDF format can alternatively be used to avoid excessive size of files when no editing is required.
- 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 should be labelled by default with “DRIVE” in the subject section and senders should add the subject of the

message. When individual messages between participants are exchanged, use of the same tag is strongly encouraged (e.g. DRIVE SC meeting agenda).

- Messages need to be clear, especially when requests are made. Deadlines must be made explicit. No relevant issues for the work to be performed should remain unclear.
- Security of intra-Consortium emails and SharePoint may be reinforced by appropriate means as the project unfolds to ensure confidentiality and integrity of information exchanged, especially if specific, potentially sensitive data is to be exchanged.

9.2. Participant Portal system

In addition to the conventional communication channels already in place, the IMI JU will communicate with the Consortium through the Participant Portal, an internet tool within the Horizon 2020 Program with the aim of becoming over time the main channel of interaction between IMI projects' Participants and the IMI JU, covering the stages of the project life cycle from proposal submission to project completion.

9.3 How to collect and share internally the external feedback received on DRIVE?

With the aim of sharing the feedback received and to following-up the status of the communications with DRIVE external stakeholders, such as possible candidates for the Independent Scientific Committee, Quality Control and Audit Committee or Public Health Institutes interested in joining DRIVE, an External Feedback registry has been created (Figure 13) and it is available on SharePoint.

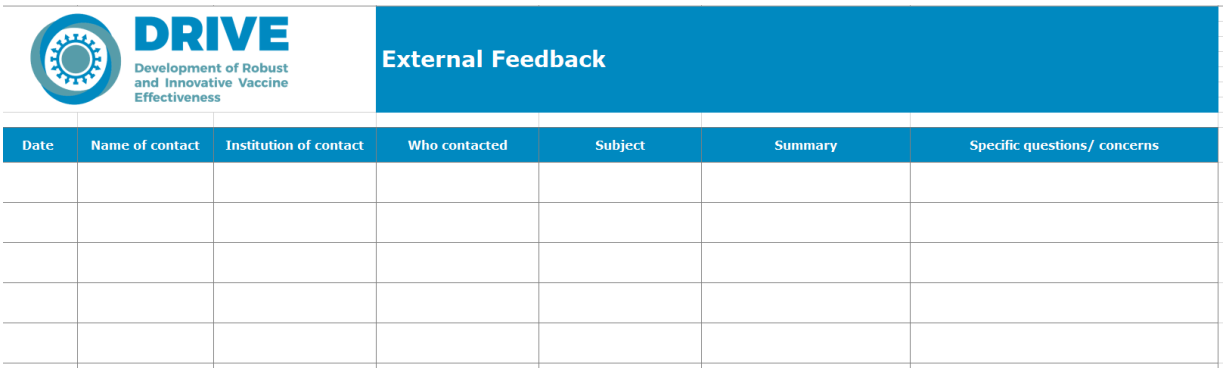


Figure 13. External feedback registry

The aim of this registry is to make all partners aware about the actions performed to contact external stakeholders (date of contacting, who contacted, person contacted, subject) and the feedback obtained from them (summary, specific questions/concerns). At the same time, keeping the registry updated will enable more efficient communication actions with DRIVE stakeholders.

10. Dissemination

10.1. DRIVE logo

The logo of the DRIVE project is depicted below:

Figure 14. DRIVE logo

Several versions of the logo have been deployed and are included in the Style Guidelines generated for DRIVE. The logo versions are available to all the DRIVE participants on SharePoint. To keep a consistent project image, the DRIVE logo available versions cannot be modified (font type or size, colours, etc.). The final visual image chosen is formed by the influenza virus surrounded by two rings which intends to reflect the robustness concept.

10.2. DRIVE website

The temporary DRIVE website address is *www.drive-eu.org*. The final DRIVE webpage will display public information about the project, the involved participants, contact information, deliverables and related articles and news. In addition, a link to the SharePoint will be available from the webpage. Additional features may be added if needed as the project evolves.

10.3. Other dissemination tools

Other dissemination tools will be developed within WP5 to support effective communication according to the project needs (video, poster, power point templates, etc.). For further information see D5.4: Communication plan

Moreover, a project slide deck and a collection of all presentations generated within the project will be also made available on SharePoint, including generic presentation templates that anyone can use and include in their own presentations. People should reference the creator or author of each presentation.

Participants will send their slides to the PMO, which will be in charge of the curation of the library of slides in order to help the entire consortium to promote DRIVE and also to standardise the messages given about the project.

10.4. How are dissemination activities tracked and reported?

WP5 will keep track of the project's dissemination activities for the purpose of IMI JU reporting. Participants will be asked regularly (quarterly) to provide information about any dissemination activity related to DRIVE they are involved in. Partners will be requested to fill in an EXCEL template with the details of both dissemination activities and scientific publications.

. The template, available on SharePoint and shown below (Figure 15) will be used to report and track the project's dissemination activities and scientific publications. This template can also be used by participants for their internal tracking.

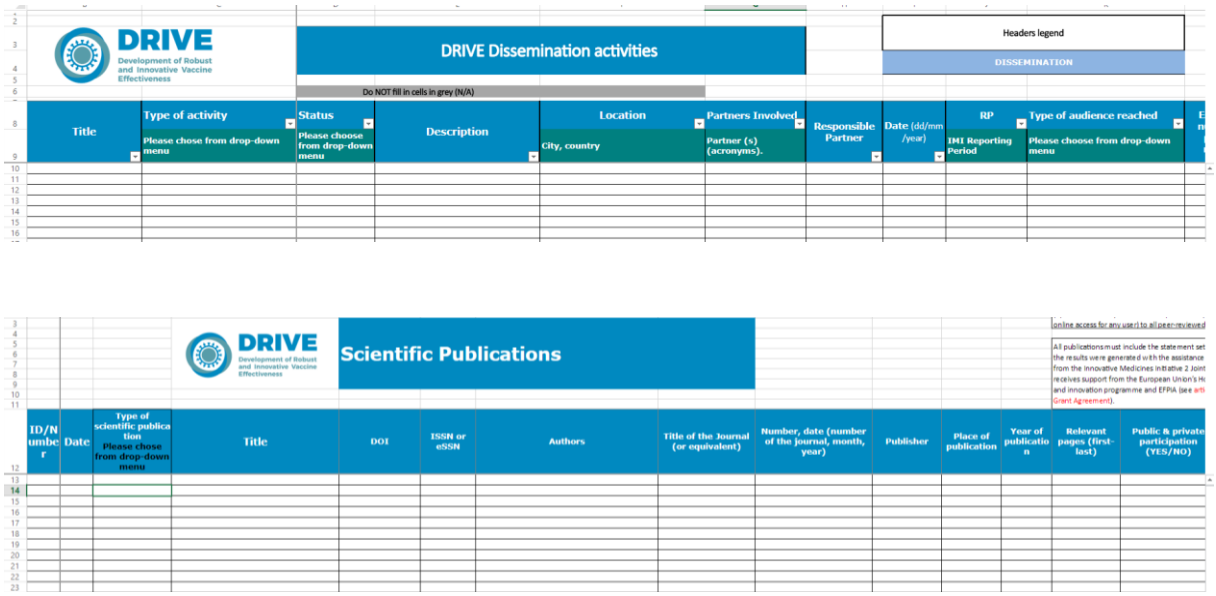


Figure 15. Screenshot of dissemination activities and scientific publications tracker

10.5. Acknowledgement

In line with the IMI DRIVE Grant Agreement, all dissemination activities related to the DRIVE Project (manuscripts, press articles, project websites, presentations, flyers, press releases, patents, etc.) must include the following elements:

1. The following phrase referring to the IMI/EU funding and the EFPIA contribution:

   "DRIVE has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 77736. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA".

2. A disclaimer for external presentations
3. A link to the IMI website: http://www.imi.europa.eu
4. The IMI logo, the European emblem and the EFPIA logo, as stated in the IMI Communication Guideline available in Sharepoint.
5. Some communication formats (e.g. short communications in peer reviewed scientific journals) may not allow the inclusion of logos and web addresses. In these cases, the acknowledgement phrase will suffice.

11. ANNEXES

Annex I: Deliverables follow-up: The traffic light system

MONITORING OF WORK PROGRESS
DRIVE JIVES / WP 1

- no problems: in time, in budget
- slight issues/delays - no action needed yet but close monitoring required within WP
- significant issue/delay - full attention/mitigation plan required

♦ Deliverable to be completed DoA

				YEAR 1 (2017/2018)												YEAR 2 (2018/2019)												YEAR 3 (2019/2020)												YEAR 4 (2020/2021)												YEAR 5 (2021/2022)											
				M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38	M39	M40	M41	M42	M43	M44	M45	M46	M47	M48	M49	M50	M51	M52	M53	M54	M55	M56	M57	M58	M59	M60
	Deliverables	Comment on progress	When	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June
D1.1	Multi-stakeholder research agenda (updated plans annually)												♦												♦												♦												♦												♦		
D1.2	Governance Standard Operating Procedures (SOP)					♦																																																									
D1.3	Report on the SOP implementation												♦												♦												♦												♦												♦		
D1.4	Final report on governance and principles																																																												♦
D1.5	Generic post authorisation development plan on effectiveness of vaccines																																																											♦

Annex II: SC members appointed for an in-depth review of the deliverables

Nr.	Title	Due delivery date (as per the DoA)	Updated delivery date	Lead	Co-lead(s)	Reviewer 1 (No-EFPIA)	Reviewer 2 (EFPIA exc. WP7)
D1.1	Multi-stakeholder research agenda *(updated plans annually)*	M10 (30/04/2018)		IRD	SP	FISABIO	ABBOTT
D1.2	Governance Standard Operating Procedures (SOP)	M3 (30 /09/2017)	M5 (31/11/2017)	SP	IRD	P95	SEQIRUS
D1.3	Report on the SOP implementation	M60 (30/06/2022)		SP	IRD	P95	GSK
D1.4	Final report on governance and principles	M60 (30/06/2022)		IRD	SP	SYNAPSE	SEQIRUS
D1.5	Generic post authorisation development plan on effectiveness of vaccines	M22 (30/04/2019)		IRD	SP	THL	SEQIRUS
D2.1	Standard Operating Procedures (SOPs) and templates (annual updates)	M8 (28/02/2018)		SURREY	GSK	ISS	SP
D2.2	Report of the results of a systematic analysis on existing initiatives, tools, and/or study protocols for determining IVE and results of a systematic review of the literature to identify and analyse the main confounding factors in IVE studies	M12 (30/06/2018)		GSK Bio	FISABIO	IRD	SP

D2.3	Electronic study support application	M12 (30/06/2018)		P95	FISABIO, GSK	SYNAPSE	SP
D2.4	Guideline for the identification of vaccine status and vaccine used in study sites *(periodic updates)*	M16 (31/10/2018)		GSK Bio	FISABIO	THL	ABBOTT
D2.5	Annual tenders for influenza vaccine effectiveness study conduct	M16 (31/10/2018)		FISABIO	GSK	SYNAPSE	ABBOTT
D2.6	Recommendations for virological analysis of samples of the studies	M30 (31/12/2019)		UCBL	SEQIRUS	P95	GSK
D3.1	Report on the sources for usage of specific influenza vaccine brands and accessibility *(periodic updates)*	M6 (31/12/2017)		P95	SEQIRUS	FISABIO	GSK
D3.2	SWOT analysis plan and list of quality management components	M8 (28/02/2018)		ISS	SEQIRUS	IRD	SP
D3.3	Report on the brand availability and usage of specific influenza vaccine brands *(periodic updates)*	M12 (30/06/2018)		ISS	SEQIRUS	P95	ABBOTT
D3.4	Report on the comparison of adapted local protocols and Ethical Committee evaluation in each study site (**periodic updates)**	M12 (30/06/2018)		UNIFI	SEQIRUS	P95	GSK
D3.5	Written report on quality and feasibility evaluation *(periodic updates)*	M14 (31/08/2018)		ISS	SEQIRUS	FISABIO	ABBOTT

D4.1	Methodology guidelines for concerted analysis of data and control of confounding factors - M4 1st version, M55 final version	M4 (31/10/2017)	M12 (30/06/2018)	P95	ABBOTT	THL	SEQIRUS
D4.2	Generic DMP - M6 1st version	M6 (31/12/2017)		P95	ABBOTT	ISS	SEQIRUS
D4.3	Report templates - M6 1st version, M15/M27/M39 annual review, M59 final version	M8 (28/02/2018)		ISS	ABBOTT	FISABIO	SEQIRUS
D4.4	Generic SAP	M9 (31/03/2018)		P95	ABBOTT	IRD	GSK
D4.5	IT infrastructure to receive and analyse the data	M12 (30/06/2018)		P95	-	ISS	ABBOTT
D4.6	Points to consider document on the interpretation of VE results (updates annually)	M12 (30/06/2018)		FISABIO	P95, ABBOTT	SYNAPSE	SEQIRUS
D4.7	Evaluation reports of how the vaccine effectiveness results could fulfil the new regulatory requirements (updates annually)	M15 (30/09/2018)		IABS-EU	SEQIRUS	FISABIO	ABBOTT
D4.8	Mid-Term DMP	M30 (31/12/2019)		P95	ABBOTT	IRD	SEQIRUS
D4.9	Final DMP	M60 (30/06/2022)		P95	ABBOTT	ISS	GSK
D5.1	Communication of a detailed stakeholder map for the DRIVE project, including the identification, grouping and layering of all stakeholders	M3 (30 /09/2017)	M6 (31/12/2017)	THL	SEQIRUS	SYNAPSE	SP
D5.2	Agreement on communications governance model	M5 (30/11/2017)		THL	SEQIRUS	ISS	ABBOTT

D5.3	Web-based survey amongst layer 1 stakeholders	M6 (31/12/2017)		THL	SEQIRUS	P95	GSK
D5.4	Development of communications plan *(revised periodically)*	M12 (30/06/2018)	M5 (31/11/2017)	THL	SEQIRUS	FISABIO	SP
D5.5	Report on the collected feed-back from “layer 1” stakeholders how DRIVE succeeded in meeting their expectations in communication and *thereafter as needed until end of the project*	M14 (31/08/2018)		THL	SEQIRUS	IRD	ABBOTT
D5.6	Periodical back-to-back Forum of key stakeholders to review major scientific and process building results and plan for the remaining duration of the project to secure sustainability of the platform once project time period is over *(annual review)*	M14 (31/08/2018)		IABS-EU	THL	P95	SEQIRUS
D5.7	Report on synergies identified and collaborations developed with other initiatives	M18 (31/12/2018)		IRD	-	THL	SEQIRUS
D5.8	Tailored, timely seasonal summaries of VE results for different stakeholder/clients in layer 1 and 2	M10 (30/04/2018)	M12 (30/06/2018)	THL	-	ISS	GSK
D5.9	Communication report of the study milestones arising from WP7 for the use of “layer 1” stakeholders (i.e. study approach, progress	M20 (28/02/2019)		THL	-	FISABIO	SEQIRUS

	and findings influenza season)						
D5.10	Report on knowledge gaps needing future R&D efforts in IVE studies	M48 (30/06/2021)		THL	-	IRD	ABBOTT
D6.1	Templates for monitoring the work progress aligned and distributed	M3 (30 /09/2017)	M6 (31/12/2017) Merged with D6.3	SP		-	-
D6.2	Report with the definition of the ethics policies handbooks collection (good practices in all aspects of the project)	M5 (30/11/2017)		FISABIO	SYNAPSE	THL	GSK
D6.3	Project Handbook	M6 (31/12/2017)		SYNAPSE	-	P95	SP
D6.4	Project assessment	M28 (31/10/2019)		SP	-	SYNAPSE	SP
D6.5	Final Report and Sustainability Plan	M60 (30/06/2022)		FISABIO	-	THL	SP
D7.1	Updated and developed protocol for type- and brand-specific influenza vaccine effectiveness studies (field-based studies)	M3 (30 /09/2017)	M7 (31/01/ 2018)	ISS	-	P95	THL
D7.2	Updated protocol for type- and brand- specific influenza vaccine effectiveness studies (population-based database studies)	M3 (30 /09/2017)	M7 (31/01/ 2018)	THL	-	FISABIO	ISS

D7.3	Report on feasible novel and innovative approaches for measuring influenza VE *(periodic updates)*	M12 (30/06/2018)		P95	-	THL	IRD
D7.4	First seasonal final report of conducted studies	M12 (30/06/2018)		P95	-	SYNAPSE	FISABIO
D7.5	Report on feasibility study for influenza virus characterization, molecular epidemiology studies related to influenza related disease in vaccinated and unvaccinated subjects *(updates if needed)*	M22 (30/04/2019)		UCBL	-	ISS	P95
D7.6	Second seasonal final report of conducted studies	M22 (30/04/2019)		P95	-	FISABIO	SYNAPSE
D7.7	Third seasonal final report of conducted studies	M34 (30/04/2020)		P95	-	IRD	THL
D7.8	Fourth seasonal final report of conducted studies	M46 (30/04/2021)		P95	-	SYNAPSE	IRD
D7.9	Fifth seasonal final report of conducted studies	M58 (30/04/2022)		P95	-	IRD	ISS
D8.1	HCT - Requirement No. 2	M12 (30/06/2018)		FISABIO	-	P95	SP
D8.2	POPD - Requirement No. 3	M12 (30/06/2018)		FISABIO	-	SYNAPSE	GSK
D8.3	POPD - Requirement No. 5	M12 (30/06/2018)		FISABIO	-	THL	SP
D8.4	POPD - Requirement No. 6	M12 (30/06/2018)		FISABIO	-	ISS	ABBOTT

Annex III. DRIVE Time Sheet Template

Title of the action (acronym):		Grant Agreement No:	
Beneficiary's/linked third party's name			
Name of the person working on the action:		Type of personnel (see Art. 6.2.A Grant Agreement)	

	[Month / Year]	[Month / Year]	[Month / Year]	[Month / Year]	[Month / Year]	[Month / Year]		Total
Number of hours								
Work packages to which the person has contributed by the reported hours								
Date and signature of the person working for the action								
Name, date and signature of the superior								

Annex IV: Financial Statement Template

ANNEX 4

FINANCIAL STATEMENT FOR REPORTING PERIOD 1

	Eligible[1] costs (per budget category)												Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	[C. Direct costs of fin. support]	D. Other direct costs		E. Indirect costs[2]	[F. Costs of …]		Total costs	Receipts	Reimbursement rate %	Maximum JU contribution[3]	Requested EU contribution	Information for indirect costs :
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons [A.6 Personnel for providing access to research infrastructure]	A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary					D.1 Travel D.2 Equipment D.3 Other goods and services	[D.4 Costs of large research infrastructure]		[F.1 Costs of …]	[F.2 Costs of …]		Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs[4]	Actual	Unit	Unit		Actual	Actual	Actual	Actual	Flat-rate[5]	Unit	Unit						
			XX EUR/hour						25%	XX EUR/unit							
	a	Total b	No hours	Total c	d	[e]	f	[g]	h=0,25 x (a+b+ c+f+[g] + [i1][6] +[i2][6] - o)	No units	Total [i1]	Total [i2]	j = a+b+c+d+[e] +f + [g] +h+[i1] +[i2]	k	l	m	n	o
[Partner]									-				-			-	-	

The beneficiary/linked third party hereby confirms that:

The information provided is complete, reliable and true.

The costs declared are eligible (see Article 6).

The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).

For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be

[1] See Article 6 for the eligibility conditions

[2] The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim any indirect costs.

[3] This is the *theoretical* amount of JU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may have to be less (e.g. if you and the other beneficiaries are above budget, if the 90% limit (see Article 21) is reached, etc).

[4] See Article 5 for the form of costs

[5] Flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)

[6] Only specific unit costs that do not include indirect costs

Annex V: DRIVE Risk Documentation Form

Risk ID ([15]) **Resolved** ☐ **Active** *(4 and above)* ☐ **Inactive** *(below 4)* ☐

RISK TITLE				
TYPE OF RISK	Threat ☒	Opportunity ☐		
CLASSIFICATION:				
WORK PACKAGE/ACTIVITY:				
DETECTION DATE		**RISK REPORTER**		
RISK OWNER[16]				
LAST UPDATE		**VERSION**		

Description

(Summarise the risk, indicating causes and consequences. Where possible identify the stakeholders that may be impacted). Indicate whether other Work Packages may be affected.)

Proximity in time:
Impact on project: (a)
Probability of happening: (b)
Exposure[17]: (a)*(b)

Mitigation Approaches[18]

(Actions to carry out before the risk happens to affect impact, probability or proximity)

Trigger Events

(Conditions that indicate that the risk is becoming a issue and trigger onset of a contingency plan)

Contingency Plans[19]

(Actions to carry out if the risk actually happens)

Notes

[15] Risk ID codes are completed by the PMO.
[16] The Risk Owner is the partner in the best position to recommend mitigation strategies, develop contingency plans and monitor the status of the risk.
[17] Exposure is the result of the impact multiplied by the probability (a*b)
[18] All threat risks with medium or high probability or impact should have a mitigation strategy.
[19] All risks having an exposure equal or greater than 4 should have a contingency plan in advance.