PROMISE WORK PACKAGE 2

Rules of Collaboration

Version 21 October 2022

Background

The PROMISE partners aim to significantly advance the understanding of RSV to aid in the design of public health strategies as well as the development and use of vaccines and therapeutics in both children (including maternal vaccinations) and older people. More specifically, WP2 will foster a consensus and develop an operational plan for an expanded coordinated RSV surveillance, which will help prepare for decision making for introduction and post-licensure monitoring and evaluation of future products for RSV immunization across Europe.

PROMISE is built on the four IMI cornerstones: joint interest, shared decision-making process, joint funding, and transparent reporting. In addition, if PROMISE partners need to address any potential concerns over misalignment related to the involvement of EFPIA partners in WP2, the lessons learnt from the IMI-DRIVE project on brand-specific influenza vaccine effectiveness studies as a PPP initiative and platform, and its spin-off COVIDRIVE which also has established a PPP platform to study brand-specific COVID vaccine effectiveness, will be taken into consideration. The IMI-DRIVE project was implemented based on key fundamentals: transparency, clear roles and responsibilities of partners, mutual respect, and shared benefits.

The WP2 team has written these 'Rules of collaboration' to better define the collaborative framework of this WP and to clarify the roles of the public and private partners involved in the different tasks. In addition, this document aims to set these rules of engagement with full transparency to all external stakeholders involved or interested in being part of WP2 activities such as the WHO, ECDC, or public institutions. Our goal is to ensure that WP2 deliverables benefit all, especially citizens, and can be used more broadly, including by external stakeholders.

I. Collaboration rules

WP2 is composed of six tasks with their own objectives. By default, all partners involved in PROMISE have the willingness to collaborate and to contribute to the common objective to succeed on PROMISE goals. However, it is acknowledged that rules of collaborations between public and private partners could differ from one task to the other given the sensitivity to interact with non-PROMISE public institutions.

First, in the table below we define which and why some tasks within the WP2 are sensitive and then we propose solutions to overcome a potential hurdle that could hamper collaboration between public and private partners. We will also define how public and private partners will work together and who will be responsible for what. These rules of collaboration are further defined in section III.

Task	Objectives	Sensitive issues	Rules of collaboration
2.1	Surveillance platform	This task will request interaction with ECDC, WHO, external Public Health Institutions. Surveillance data generated by public institutions cannot be accessible to private partners.	▪ A firewall between private partners and external public partners ▪ Open communication between PROMISE public and private partners before and after meetings with external public partners with alignment on the core elements of the deliverables ▪ Private partners will not have access to raw data generated by public partners.
2.2	European Laboratory Network	This task will request interaction with ECDC, WHO, external Public Health Institutions.	▪ A firewall between Private partners and external public partners ▪ Open communication between PROMISE public and private partners before and after meetings with external public partners with alignment on the core elements of the deliverables
2.3	Effectiveness endpoints	This task will impact post-marketing evaluation of products developed by private partners	▪ Given the expertise of private partners on this topic especially when it refers to study designs/endpoints, active contribution of all partners is needed to achieve this objective.

			In case of misalignment between partners on scientific matters, a mechanism to on-board the ISAG/EAB to come to a resolution will be activated and will be ultimately documented by the PROMISE SC for transparency. Misalignment between partners on the way of working will follow the agreed rules defined within the PROMISE Consortium Agreement.
2.4	Safety endpoints	This task will impact post-marketing evaluation of products developed by private partners	▪ Given the expertise of private partners on this topic especially when it refers to study designs/endpoints, involvement of all partners is needed to achieve this objective. In case of misalignment between partners on scientific matters, a mechanism to on-board the ISAG/EAB to come to a resolution will be activated and will be ultimately documented by the PROMISE SC for transparency. Misalignment between partners on the way of working will follow the agreed rules defined within the PROMISE Consortium Agreement.
2.5	RSV vaccine policy	Engagement with EMA	▪ The PROMISE coordinator, in collaboration with PENTA, will facilitate communication with EMA. ▪ Given the expertise of private partners in interacting with EMA exemplified by the RESCEU experience, involvement of all partners is needed to achieve this objective. ▪ In case of misalignment between partners, there is a possibility to be supported by PROMISE committees and ISAG/EAB.

		Engagement with ECDC Engagement with NITAGs	▪ ▪ ECDC engagement is the sole responsibility of public partners, EFPIA partners may be invited to hearings but stay detached from these negotiations ▪ NITAGs engagement will be led by public partners, private partners will be informed and may be invited to hearings but stay detached from these interactions.
2.6	Patient Engagement	Some sensitivity	▪ Patient engagement will be led by public partners, otherwise as per usual process, defined in the consortium agreements and the PROMISE handbook

II. Management of WP2

To ease the day-to-day activities of the different tasks, tasks co-leads have been identified (one from the public partners and one form the EFPIA partners). They will oversee the work plan of each task, will ensure open collaboration between partners, and will make sure the rules of collaboration are well followed.

Regular task-specific meetings will be organized by Task Leads and Co-Leads. **During these meetings, all partners identified in the Description of Action (DoA) from the PROMISE Grant Agreement will be invited**. Objectives of these meetings will be to review the advancement of the tasks and the preparation of future meetings with PROMISE partners or external partners.

Task Co-Leads:
- Task 2.1 - Surveillance platform: John Paget, Nivel
- Task 2.2 - European Laboratory Network: Adam Meijer/Lance Presser, RIVM
- Task 2.3 - Effectiveness endpoints for product effectiveness: Topi Turunen, THL; Elisabeth Begier, Pfizer
- Task 2.4 - Safety endpoints for post-marketing evaluation: Anders Hviid, SSI; Lydie Marcelon, Sanofi
- Task 2.5 - Support science for RSV vaccine policy: Hanna Nohynek, THL; Gaël Dos Santos, GSK
- Task 2.6 - Patient Engagement Activities: Lies Kriek, ReSViNET; Charlotte Vernhes, Sanofi

In addition to these regular Task meetings, **monthly management meetings related to WP2 will be organized**. **All Task Co-Leads will be invited**. These meetings will be chaired by Hanna Nohynek (and Anne Teirlinck), with assistance from Tin Tin Myint, (and Rolf Kramer).

Objectives of these meetings will be to update the WP2 management team on the progress of the different tasks and to identify any risks, especially on deliverable delays, that may happen during the course of the PROMISE project. These meetings will cover all tasks, but especially focus on Task 2.1 and Task 2.2 where no EFPIA partners are identified as Co-Leads.

III. Rules of collaboration

Task 2.1 and Task 2.2 Surveillance platform and European Laboratory Network

Data Access: surveillance data from National Public Health Institutes and Labs
PROMISE partners are going to work with case-based RSV surveillance data which could include personal information reported by National Public Health Institutes and Laboratories. It is critical that these data are shared in a highly secure and confidential manner.

The raw data whether case based or aggregate will be held on a secure data platform managed by RIVM. The data will remain the property of the institute that has provided the data and can manage their data on the secure data platform. Only Nivel and RIVM will have access to all raw data and this will be only to submit scripts to prepare the RSV Bulletin (e.g., Maps, Tables, and Figures).

Data Transfer Agreements will be prepared with each country to clarify this point in writing. Details on WP2 data management processes will be integrated within Deliverables 5.3 and 5.6

A firewall is put in place to avoid PROMISE partners and third parties having access to the raw data collected via the PROMISE project.

Design of the European RSV Bulletin
The design of the European RSV Bulletin will be led by the Task Leads. It will be based on a survey, virtual workshops, and discussions/feedback from WP2 PROMISE partners and non-PROMISE public health institutes that participate in the RSV surveillance network.
Survey, workshops, and discussions **will be prepared** by the leads from the public health institutes, with input (e.g. the design of the RSV surveillance bulletins and providing comments when the initial bulletins are developed and shared within the consortium) from all PROMISE partners and participating non-PROMISE public health institutes involved in Tasks 2.1 and 2.2; public leads will be in charge to perform and to organize these activities.

Writing the bulletin text will be carried out by the Tasks 2.1 and 2.2 public partners.

In accordance with the firewall proposed, industry partners will not be involved in writing the European RSV Bulletin text.

However, **it is the responsibility of Task Leads to gather inputs every time when there is a major change in the content or design in the bulletin. The frequency of this will most likely vary, and may be more in the beginning and fewer at a later more mature stage. Input will be sought from all partners identified in the DoA of the PROMISE Grant Agreement on the content and the design of the European RSV bulletin**. EFPIA partners will have the ability to provide inputs on the European RSV Bulletin at this step.

Technical Surveillance Group
We will create a Task 2.1 and Task 2.2 Technical Surveillance Group, consisting of people from public health institutes, ECDC, and WHO, which will actively participate and advise Task 2.1 and Task 2.2.

To align with PROMISE external partners agreement, private partners will not be involved in the Technical Surveillance Group of Tasks 2.1 and 2.2.

It is, however, the responsibility of Task Leads to involve each partner identified in the DoA of the PROMISE Grant Agreement in the preparation of the Technical Surveillance Group meetings and to share the meeting objectives and the minutes of those meeting conveying the key highlights and important elements. Those minutes should be shared in a reasonable timeframe (1 week post meeting ideally but no longer than 2 weeks after them).

Task 2.3 and Task 2.4 Effectiveness and safety endpoints for post-marketing evaluation

Tasks 2.3 and 2.4 will benefit from feedback from all partners given the complementary expertise from public and private partners.
A work plan including the different activities to be performed will be developed by Task Co-Leads and then circulated among all partners identified within the DoA of the PROMISE Grant Agreement.
One objective of Tasks 2.3 and 2.4 is to develop study protocols for post-marketing safety and effectiveness (test-negative design studies and phase IV RCT studies). Private partners will not take the lead on this activity rather this is a co-working responsibility; all PROMISE partners are looking to develop protocols that will be validated and used for post-marketing evaluation applicable both for EMA´s requirements and the requirements of public health institutes advising governments in their countries on vaccine introduction and evaluation. Optimally a workshop meeting should be organized by the task leads to align on the framework and key elements for the protocols.
The first draft of these protocols will be written by public partners, then will be circulated to EFPIA partners for input.

Any input may only be provided in written form, and a spreadsheet with all received comments and the authors' response will be kept for transparency. The spreadsheet (with the commentors' name and organization omitted) may be made available on the project website or on request.

Task 2.5 Support science for RSV policy

In this task, the overall leadership remains with the public partners. One objective (T 2.5.1) will be to liaise with EMA, ECDC and National Immunization Technical Groups (NITAGs)/Regional Immunization Technical Groups (RITAG) on regulatory and policy guidance on post-licensure requirements and the other (T 2.5.2) will be to perform a living systematic review of RSV burden and product trial outputs to aid national decision making.

For both of these, private partners have the relevant knowledge and expertise to contribute. Similar to what was done in RESCEU, private partners will be limited or excluded from meetings with NITAGs stakeholders but will be involved in the preparation of those meetings in collaboration with public partners, will receive feedback from the discussion, and will actively contribute to the deliverables.

More specifically and given the expertise of private partners in interacting with EMA, involvement of all partners is needed to achieve T2.5.1 objectives however PENTA foundation or the PROMISE coordinator will facilitate communication with EMA.

NITAGs engagement will be led by public partners, private partners will be informed and invited to these meetings when necessary but otherwise will not be involved in the process.

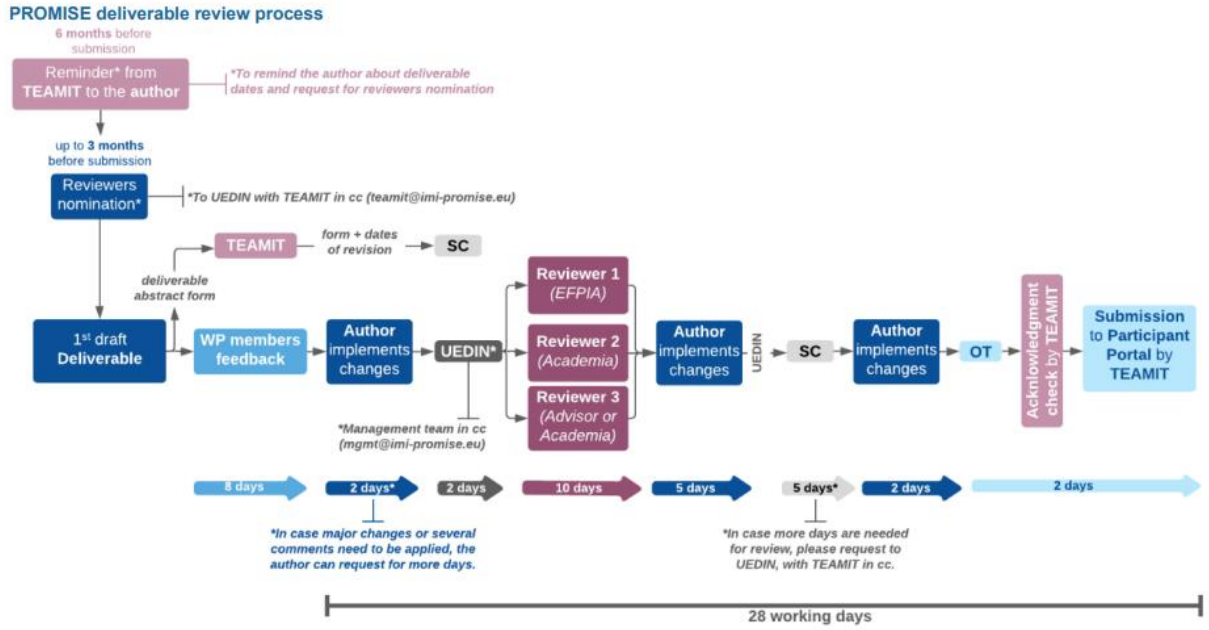
In case of misalignment between partners, there is a possibility to be supported by PROMISE committees and ISAG/EAB.

Task 2.6 Patient engagement activities

There is some sensitivity identified with Task 2.6 activities which focuses on raising RSV awareness and understanding barriers to immunisation. It will be the accountability of the task lead/co-lead to organise the meetings to gather the inputs from the different partners. The task leads can define the different situations where industry partners can provide input or rather serve as observers.

IV. WP2 Deliverables/Publication review

All WP2 deliverables and publications will follow the same process as other PROMISE outputs with 3 reviewers (one each from a public partner, a private partner, and ISAG).
See below, the review process per the PROMISE Handbook.



In case of disagreements between partners, a consultation will be organized with the Steering Committee (SC) and, ultimately, with the ISAG who will formulate recommendation for integration of PROMISE partner comments to deliverables.

V. WP2 Communications

WP2 Website

As part of WP2 activities, we will use the PROMISE website to share updates on relevant literature and laboratory methods used in WP2.2. This site could be used, for instance, to publish the European RSV Bulletin when it comes publicly available. In the first year, the bulletin will not be publicly available, but will be shared with all PROMISE partners, including the EFPIA partners.

Access to WP2 documents

As part of WP2, we will have a library of documents related to our different activities within the private PROMISE SharePoint site, which is managed by Team-IT.

By default, all information will be available to PROMISE partners and third parties, e.g., WHO, ECDC involved in PROMISE. However, access to certain information might be restricted, e.g., National Public Health Institute contact names and details from public partners external to PROMISE

Scientific publications

We are planning a number of WP2 publications, including the European RSV Bulletin, and it is sensitive for most public partners external to PROMISE to be associated with private partners.

For all tasks, publications that only include the PROMISE partners, we will use the PROMISE Project Handbook (D5.1) and this uses the International Committee of Medical Journal Editors (ICMJE) recommendations.

For publications of task 2.1 and 2.2 that focus on surveillance data of public health institutes, as well as for publications that focus on recommendations regarding prevention and control measures (e.g. vaccination and use of monoclonal antibodies, Task 2.5), industry partners may not be included as co-authors, but will have the opportunity to provide suggestions/ comments according to the internal peer review process. Authors may choose not to incorporate certain suggestions/comments, however, for major comments, a written justification would be expected for transparency purposes.

References on all publications

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