

IMI2 GA853989 - ERA4TB

European Regimen Accelerator for Tuberculosis

WP8 – Management, Outreach and Sustainability

D8.4 Project communication plan and initial toolset

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2. Document History

Version	Date	Description
V0.1	11 06 2020	First Draft
V0.2	20 08 2020	Second Draft following Initial Comments
V0.3	29 09 2020	Third Draft addressing initial comments
V0.4	22 10 2020	Fourth Draft further content from collaborators included
V0.5	20 11 2020	Final Draft for approval
V1.0	09/12/2020	Final Version

3. Abstract

ERA4TB (European Regimen Accelerator For Tuberculosis) project is a public-private initiative devoted to accelerating the development of new treatment regimens for tuberculosis. The project aims to develop a European open platform to facilitate this development, to reflect the commitment of the European Commission, the private sector and other public and private research institutes to the global challenge described in the WHO End TB strategy. This will be achieved through the following actions:

- Implementation of state-of-the-art tools and capacities.
- Development of modelling and simulation tools and application of standard and new artificial intelligence (AI) techniques.
- Management of data generated by the project.
- Provision of a flexible and efficient management structure.
- Provide a sustainability plan that incorporates all the synergies and lessons learned.
- Define and execute an outreach, engagement, dissemination, and communication plan.

The four pillars of the overall ERA4TB communication strategy for successful communication are as follows:

- Definition of the communication objectives and priorities.
- Identification of target audiences.
- Description of the dissemination activities to be tackled.
- Identification of the specific tools and channels to be used to support communication.

Deliverable 8.4 describes the project communication plan and initial toolset for ERA4TB. This plan will be updated periodically as the project progresses, to reflect any changes or progress in communication requirements. Internal communication is required to inform and engage partners in collaboration; whereas external communication will raise awareness, build a community, inform, and engage external stakeholders.

1. Introduction

1.1. Who are ERA4TB?

ERA4TB (European Regimen Accelerator for Tuberculosis) project is a public-private initiative devoted to accelerating the development of new treatment regimens for tuberculosis.

ERA4TB is expected to revolutionise the way in which tuberculosis treatments are developed through its parallelised, multi-entry pipeline structure, analogue to a production line. This structure will allow systematic investigation of drugs and combination efficacy simultaneously, while facilitating entry of new molecules into the project pipeline at the research stage corresponding to the degree of knowledge on said candidate drugs gathered before the project.

The ERA4TB consortium predicts this approach will reduce the time required for the development of new tuberculosis treatment regimens by up to 25%.

The ERA4TB initiative incorporates more than thirty organisations from the EU and the US, including the main global actors in the fight against tuberculosis infection, namely eight prestigious academic institutions (UC3M, UNIZAR, UU, EPFL, UKÖ, UNIPD, UPV, LUND), four non-profit organizations (IPP, IPL, iM4TB, BAR), eight public research organizations (FZB, CNR, IDMIT, SERMAS, PHE, NICE, SCI, IOS) and five highly skilled small-medium enterprises (SYNAPSE, C-Path, IBT, QPS, GRIT42), together with three EFPIA members (GSK, EVT, JANSSEN), and three IMI2 Associated Partners (BMGF, TBA, DDU).

ERA4TB has started in 2020 and will last six years. At project close, the consortium expects to have developed at least two or more new combination regimens with treatment-shortening potential ready for Phase II clinical evaluation. The aim is to sustain the ERA4TB platform beyond the project duration.

1.2. Objectives

The main objective of ERA4TB is to create a European open platform to accelerate the development of new regimens for the treatment of tuberculosis. To reach this goal, the consortium has set the following specific objectives:

- Implementation of state-of-the-art tools and capacities into an open platform for the evaluation of TB drug candidates to efficiently advance compounds from early preclinical to clinical development and identify potential new Pan-tuberculosis (Pan-TB) regimens ready for Phase II clinical evaluation.
- Modelling and simulation tool development and application of standard and new artificial intelligence (AI) techniques for improved characterisation of pharmacokinetic-pharmacodynamic (PK/PD) relationships, clinical trial design optimisation, therapeutic dose range prediction and antibacterial activity in humans.
- Effective management of project-generated data, integrating additional data and knowledge from historical datasets available in reference databases and from previous and existing consortia and projects, to develop an evolving 'learning system' that allows refining the platform continuously.

Abbreviations: **UC3M:** University Carlos III de Madrid; **UNIZAR:** Universidad de Zaragoza; **UU:** Uppsala Universitet; **EPFL:** Ecole Polytechnique Federale de Lausanne; **UKO:** University of Koln; **UNIPD:** Università Degli Studi di Padova; **UPV:** Università Degli Studi di Pavia; **LUND:** Lunds Universitet; **IPP:** Institut Pasteur; **IPL:** Institut Pasteur de Lille Foundation; **IM4TB:** Fondation Innovative Medicines for Tuberculosis; **BAR:** Bioaster Fondation de Cooperation Scientifique; **FZB:** Forschungszentrum Borstel; **CNR:** Consiglio Nazionale delle Ricerche; **IDMIT:** Infectious Disease Models for Innovative Therapies; **SERMAS:** Servicio Madrilenio de Salud; **PHE:** Public Health England; **NICE:** National Institute for Health and Care Excellence; **SCI:** Sciensano; **IOS:** Latvijas Organiskās Sintēzes Institūts; **SYNAPSE:** Synapse Research Management Partners SL; **C-Path:** Critical Path Institute LTD; **IBT:** Imabiotech SAS; **QPS:** QPS Netherlands BV; **GRIT:** Gritsystems AS; **GSK:** GlaxoSmithKline Investigacion y Desarrollo SL; **EVT:** Evotec International GMBH; **Janssen:** Janssen Pharmaceutica NV; **BMGF:** Bill & Melinda Gates Foundation; **TBA:** Global Alliance for TB Drug Development; **DDU:** University of Dundee

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- Provision of a flexible and efficient management structure able to adapt the capacity and resource allocation level required by each platform component at each stage of the project.
- Provide a sustainability plan that incorporates synergies and learning points within the project and secures sustainability of the ERA4TB platform beyond project close.
- Define and execute an outreach, engagement, dissemination, and communication plan in collaboration with regulatory authorities and other stakeholders, including patient organisations, to maximise the impact of the project.

1.3. ERA4TB's Ambition

In May 2015, The WHO End TB Strategy was unanimously endorsed by all Member States of WHO and the UN at the World Health Assembly and their adoption of the UN Sustainable Development Goals (SDGs).

The ERA4TB Consortium aims to reflect the commitment of the European Commission and the private sector (through the EFPIA companies), with the support of Associated Partners as key players in TB research, as well as other public and private research institutions in the EU, to respond to this global challenge.

The ambition of creating a novel world-class platform for acceleration of new anti-TB treatment options will be realised through ERA4TB. ERA4TB aims to build across Europe and consolidate globally a solid network of collaborations to achieve this.

This new sustainable platform will integrate, maintain, and further advance the drug development processes and tools needed for the effective acceleration of anti-TB drug combinations, including:

- Hollow fibre systems.
- Single cell time-lapse analysis.
- Imaging in animal models.
- New biomarkers and host/pathogen interactions and virulence approaches.
- Drug-disease modelling.
- Physiologically-based predictive modelling.
- Artificial intelligence data mining.
- Clinical trial simulation techniques.

1.4. Work Package 8: Management Outreach and Sustainability

Work Package 8 will provide scientific guidance and professional project management to ensure correct prioritisation between scope, time, quality, and cost to ensure adequate progress and successful completion of the Project. Additionally, this WP will aim at developing strategies for long-term sustainability of the ERA4TB platform.

Task 8.6 'Dissemination and outreach to key stakeholders' will focus on the development and implementation of a project communication plan and initial toolset (D8.4) for raising awareness about the project and its results among different stakeholders. This will mean:

- A consistent strategy that allows for maximising the impact of communication efforts will be designed.

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- A range of communication tools will be developed (such as a project image, website, newsletter, brochure, templates, etc.), that will serve as a basis for undertaking the actions and reaching the audiences established in the Communication Plan, in collaboration with the communication teams of the participating institutions.
- Policies will be developed for determining consistency across the Consortium in relation to the amount, form and content of any messages delivered to the target audiences. Special attention will be devoted to two key stakeholder groups: regulators/Health Technology Assessment (HTA) agencies (through partner NICE) and patients.

2. Overall Communications Strategy

A communications and dissemination strategy has been developed for ERA4TB to communicate the project results among different stakeholders, but also to liaise and establish synergies with neighbouring initiatives (especially with Pillars A and C of the AMR Accelerator Programme) and with the community as a whole.

A full communication strategy will also be developed, specific to the needs of ERA4TB, leveraging the expertise and resources available in the Consortium, and especially in the latter with regards to marketing and communications expertise of EFPIA and APs. This strategy will ensure alignment with key stakeholders in the Consortium, so that project activity and achievements are consistently portrayed independently of the specific partners involved.

This strategy will target a variety of audiences, including patients, researchers and regulators/HTA agencies, as well as related initiatives worldwide. It will assess, define, and characterise their needs and expectations from the project outset. Key messages will be tailored to the interest of those specific target audiences and the most appropriate dissemination actions will be identified and developed to meet their needs.

As developed in section 4.6.3, appropriate review procedures will be implemented to guarantee consistent communication delivery, while preserving the right of all partners to be adequately sighted on, participate in and be able to object to dissemination activities that may hamper their rights in terms of publication, disclosure of IP, etc.

Deliverable 8.4 “Project communication plan and initial toolset” devises a dissemination plan that includes the:

- Communication objectives.
- Target audiences.
- Activities to be carried out.
- Initial toolset for ensuring efficient communication.

3. Internal Communications Plan

3.1. Focus

Internal communications in large projects such as ERA4TB tend to generate a lot of documentation. It is mandatory to have strict guidelines and protocols to follow, and always communicate with efficiency under clear goals, using pre-established good practices and existing tools to avoid redundancies and non-optimal messages in all communication activities.

General good practices include:

- Communication should be based on needs, target audience, and feedback received.
- Coordinate communication with project milestones, events, activities, and results.
- Emails should not be overused but strategically used.
- Ensure that messages are sent in a timely manner.
- Take advantage of existing communication vehicles and opportunities.
- The usage of MS Office-compatible files for electronic exchange among participants (alternatively, PDF format is acceptable for files without edit needs).
- Label any communication with “ERA4TB” in the subject.
- Clarity in all messages with particular attention to key information such as deadlines and deliverables.
- Security and confidentiality care to guarantee the integrity and rights of all participants.

3.2. Internal target audiences

Staff members of the ERA4TB Partners, meaning the Public and Private Organisations officially listed in the [Grant Agreement](#)).

3.3. Internal communications objectives

- Develop a multilateral communication platform.
- Ensure efficient communications within the ERA4TB Consortium.
- Ensure re-evaluation of the communication strategy to ensure effectiveness.
- Development of collaboration tools to guarantee efficient work within the Consortium.

3.4. Initial tool kit for internal communications¹

- The electronic mail is the main tool for communication within the Consortium.
- Detailed documentation of discussions, agreements or meeting minutes will be made available to all

¹ See also section 5.2. “How should Participants communicate internally?” of the [Project Handbook](#)

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contacts through **SharePoint platform** (secure repository).

- Additionally, **22 distribution lists** will be used to update participants with relevant new information (one-direction communication, “reply to all” should not be encouraged by default). These mailing lists, associated to specific groups, will be carefully created and maintained by the PMO.
- Ad-hoc discussions, face-to-face team meetings, tele-conferences and video conferences; these should be documented with agenda and minutes.
- Official ERA4TB meetings.(see section 2.3 of the [Project Handbook](#) “How and when the project bodies meet”?)
- Project calendar and deliverable schedule (available on [Sharepoint](#))
- Dashboards for project pipeline progression (see section 3 of [D1.1 Full Pipeline specifications](#)).
- Participant portal for official communications between IMI and ERA4TB Consortium.
- A Project Bulletin addressed to the Consortium members is circulated bimonthly to provide remarkable updates on the project status and other relevant information related.

 <p>ERA4TB Bulletin October 2020, Issue 03</p> <hr/> <p>Main achievements</p> <ul style="list-style-type: none"> o Additional specific activities for molecules' progression through the pipeline have been sanctioned by the PDC, particularly: <ul style="list-style-type: none"> • The scientific relevance of in vitro activities (WP2) for the progression of molecules () has been endorsed by the PDC on 28 September. • A new Asset Progression Plan for molecule () has been endorsed by the PDC on 28 September. o 5 specific Asset Progression Plans (APPs) have been sanctioned by the SC at the meeting held on 19 of October: <ul style="list-style-type: none"> • APP1 (under the scope of WP6) of molecule () • APP1 (under the scope of WP6) of molecule () • APP2 (under the scope of WP2) of molecule () 	<p>Reference materials</p> <ul style="list-style-type: none"> o To recall the main working principles and internal procedures, please refer to the following documents: <ul style="list-style-type: none"> • Updated process to enter and manage a molecule into the pipeline • Updated overall working principles and procedures for compounds progression • Full pipeline modules' specifications, where the asset owner can check the technicalities and availability of the modules made available by the different WPs to progress the molecules through the pipeline. • Guidelines for budget configuration in the framework of specific APPs, including specific indications for subcontracting procedures according to IMI rules (draft version elaborated by the PMO available) • How to prepare and submit a project deliverable <p>Next meetings (Nov-Dec):</p> <p>16th and 23rd Nov. PDC Meeting (Session 1. Presentation, 16th Nov at 16:00 CEST/ Session 2. Voting, 23rd Nov at 16:00 CEST) – Bimonthly PDC meetings scheduled from Sept on 21st Dec. SC Meeting (16:00-18:00 CEST) - Bimonthly SC meetings scheduled from Oct on 12th Nov and 10th Dec. DIAT Meeting (15:00-16:30 CEST). 3rd Nov, 17th Nov, 1st Dec. Excom Meeting (16:30-17:30 CEST). For WP Meetings - please contact the corresponding WPL</p>
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For more information about internal communications tools and practices, see section 5 of [Deliverable 8.1: Project Handbook](#).

4. External Communications Plan

4.1. Focus

The main focus of the external communication plan is to spread awareness of the ERA4TB project and its activities, disseminate outputs, and communicate messages to external stakeholders as well as raising the profile of ERA4TB as a key player in the TB drug development area. The approach to achieving this will be based on reaching out to external target audience who represent the key stakeholders in the process of drug development and market access. The planned engagement and communication activities will take a staged approach starting with identifying these key stakeholders and establishing early engagement and develop as the project progresses to ensure continuation of this active engagement during the whole project life cycle.

4.2. External target audiences

The key stakeholders within the TB drug development eco-system has been identified in deliverable 8.2 (Stakeholder and interdependencies mapping and engagement plan. TB Ecosystem). These have been categorized into the following 4 main categories:

- Early Drug Discovery initiatives or alternative candidate sources: initiatives include earlier R&D stages (prior to entering ERA4TB) and which will bring assets into the ERA4TB pipeline for further development.
- Parallel initiatives: initiatives which focus on the same R&D phases as ERA4TB and possibly run concurrently.
- Successive initiatives: initiatives which focus on later R&D phases past ERA4TB; these initiatives have the potential to further develop “ERA4TB assets” which successfully meet the ERA4TB Phase 2a stage gate criteria.
- Other initiatives: initiatives which focus on different aspects of TB R&D; engagement with these initiatives can promote transparency on ongoing TB R&D activities.

Other stakeholders who represent the key players in the drug development and use space will also be targeted. These include the following:

- Regulators (e.g. EMA, MHRA, FDA): regulatory agencies and their scientific advice teams will be key target audience to engage given the ongoing work at these agencies on antimicrobials and the evolving regulatory landscape in terms of evidence requirements for registration of the assets included in the ERA4TB pipeline. Sharing information on progress of ERA4TB and its deliverables will also be relevant to these agencies’ horizon scanning activities.
- Health Technology Assessment (HTA) agencies (e.g. ZIN, TLV, GBA, HAS, EUNetHTA): HTA agencies will be one of ERA4TB target audience groups given their role in the decision-making process around market access of new drugs in European countries. Similar to regulators, being aware of the progress of ERA4TB, its pipeline, outputs and deliverables will be beneficial for their horizon scanning activities and their involvement with the project from its early stages will help shape the evidence generation activities in the clinical phase of asset development.
- Payers and commissioners: payer organisations and commissioners of health technologies are increasingly becoming closely involved in the process
- Patient groups: patients are key stakeholders in the TB drug development process. Raising patient awareness

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of ERA4TB work and its outputs and their involvement in shaping it will be a central part of the project external communication plan. Information specifically tailored for and directed to patient groups will be provided through the different project media outlets including newsletters, website and social media feeds.

- Researchers: academic and applied researchers working in the area of TB drug development as well as those who are working in related fields (e.g. pharmaceutical, biomedical, epidemiological and health economics-related disciplines) will be one of the key stakeholder groups, particularly those with direct interest in the area of antimicrobials, their development and use.
- Pharmaceutical and biomedical Industry/companies: in addition to companies that will have assets in the ERA4TB pipeline, other major companies working in the field of antimicrobial development in general will be included in the stakeholders targeted by ERA4TB external communications to raise awareness of its activities. Other interested pharmaceutical and biomedical companies can sign up to receive our external communication products and
- Non-governmental organisations: organisations that are non-governmental will be included as a key stakeholder group that will be targeted by ERA4TB external communication activities including regular updates on activities and outputs.
- General public: Informing the general public about ERA4TB aims, activities and outputs will be facilitated through publicly available platforms e.g. the project website and social media channels. Tailored information that is accessible for various abilities and levels will be made available on these platforms to facilitate public engagement and raise awareness. Additionally, own communication channel strategies of the partners (and specially of the asset owners) can be used to leverage project achievements and relevant information of the project particularly to lay persons, life science journalists and general media.

4.3. External communications objectives

The key objectives of the external communication activities are to:

- Identify the right stakeholder contacts from categories listed above.
- Establish early engagement to build effective relationships, and ensure new findings are shared and insight obtained and explored.
- Build the ERA4TB Community for discussion and development of the project and its results.
- Maintain productive working relationships throughout the project and with AMR Accelerator (see Deliverable 8.3: framework for collaboration within the AMR Accelerator).
- Develop a regularly updated repository of all communication activities planned or carried out.

External communication activities, other than scientific publications, will be governed by the Communication Guidelines detailed in Appendix 11 of the Consortium Agreement (Included in the Appendix, below)

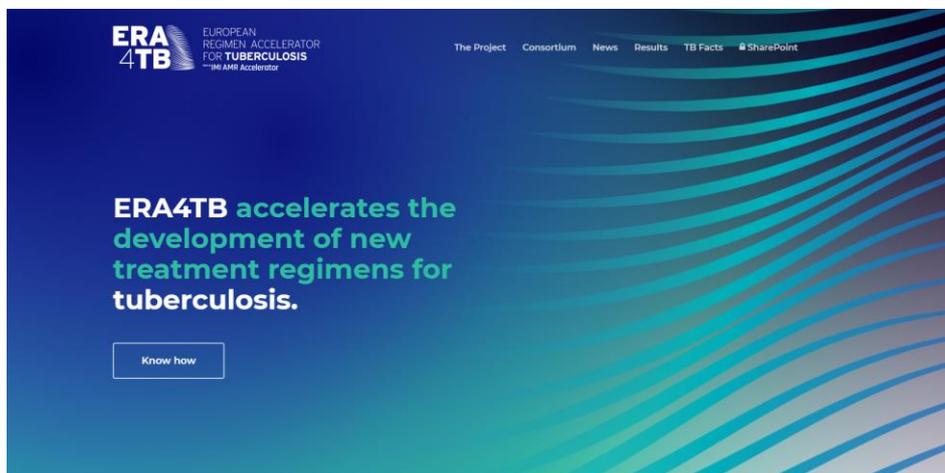
4.4. Initial tool kit for external communications

External communications need an easy access to the different resources (visual assets, templates, etc. available on SharePoint/Home) plus a style guide or specific indications for its correct implementation in all dissemination and promotional materials. The main activities and tools of external communication during ERA4TB project are:

- **Corporate Image and Logo:** Available versions of the logo are stored on [SharePoint](#). It is recommended the use of the standard version by default (squared) and to respect the style considerations (margins, etc.). Alternatively, there are other variants available for specific needs: rectangular distribution, black or negative.



- **Website:** this communication tool has a double purpose. On one side, the main project website (era4tb.org) will promote the general knowledge of ERA4TB, its activities and results, having a marketing standpoint. Secondly, the website data will help an ongoing contribution towards shared website for AMR Accelerator (amr-accelerator.eu), which is currently a non-autonomous process (see D8.3). Aside from the sections available to anonymous public, the website enables a password-protected direct access to Sharepoint repository to participants.



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The screenshot shows the 'The Project' page of the ERA4TB website. At the top left is the ERA4TB logo. The navigation menu includes 'The Project', 'Consortium', 'News', 'Results', 'TB Facts', and 'SharePoint'. The main heading is 'The Project'. Below it are links for 'About', 'Objectives', 'Ambition', and 'Structure'. The 'About' section is active, with the text: 'ERA4TB (European Accelerator of Tuberculosis Regime) project is a public-private initiative devoted to accelerate the development of new treatment regimens for tuberculosis.'

The screenshot shows the 'Objectives' page of the ERA4TB website. The navigation menu is the same as the previous page. The main heading is 'Objectives'. The text states: 'The main objective of ERA4TB is to create a European open platform to accelerate the development of new regimens for the treatment of tuberculosis.' Below this, it says: 'The main objective of ERA4TB is to create a European open platform to accelerate the development of new regimens for the treatment of tuberculosis. To reach this goal, the consortium has set the following specific objectives.' Two columns of objectives are listed, each with a circular icon: 1. 'Implementation of state-of-the-art tools and capacities into an open platform for the evaluation of TB drug candidates to effectively progress compounds from early preclinical to clinical development and identify potential new Pan-tuberculosis (Pan-TB) regimens ready for Phase II clinical evaluation.' 2. 'Development of modelling and simulation tools and application of standard and new artificial intelligence (AI) techniques for better characterization of pharmacokinetic-pharmacodynamic (PK/PD) relationships (concentration-effect or exposure-response relationships depending on the trial), optimization of clinical trial design, prediction of therapeutic dose range and antibacterial activity in humans.'

The screenshot shows the 'News' page of the ERA4TB website. The navigation menu includes 'The Project', 'Consortium', 'News', 'Results', 'TB Facts', and 'SharePoint'. A search bar is visible. Two news items are featured: 1. 'The potential impact of the Covid-19 response on tuberculosis in high-burden countries: a modelling analysis' (May 20, 2020), with a thumbnail image of pink virus particles. 2. 'ERA4TB Press Release' (January 29, 2020), with a thumbnail image of a woman and a man in a lab. On the right, there are sections for 'RECENT POSTS', 'CATEGORIES' (Event, Press), and 'TWITTER' with a 'Follow' button for @IMLERA4TB.

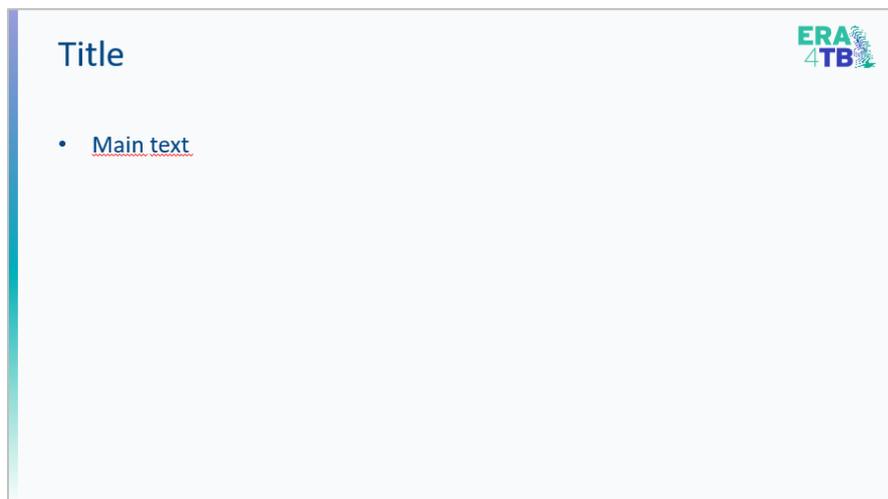
- **Social media:** quick dissemination of the project progress and achievements. The main platform will be [Twitter](#) (@IMI_ERA4TB). Hashtags used and general tone needs to be defined in the respective section on the general style guide for external communications.



- **Newsletter:** bulletins will be sent periodically to external stakeholders to provide remarkable updates on the project status and other relevant information related. These bulletins will use standardized templates created for this project specifically. The tool to create and distribute these electronic bulletins will be Mailchimp. An alternative online HTML version of these newsletters will be created as well, which will be pushed (when no sensitive data needs to be protected) to the public website in the 'Newsletter' section. the course of the project for cohesive electronic communications to all participants.
- **Presentations (PPT) and other templates:** Project templates as different types of slides have been designed and will be used systematically in all presentations during the course of the project. The templates conform with the IMI requirements (see below) including the inclusion of the funding information. It will also be designed to be aligned with the general project branding and corporate image in terms of colors, fonts and formatting. Information relating to the project contact detail and social media platforms.

Available templates are stored on [Sharepoint](#).

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- **Scientific publications:** dissemination of ERA4TB outputs in the form of scientific publications such as journal articles and submissions to conferences for presentation as posters or orals will be subject to the publication policy as outlined in section 4.6.
- Position/white papers.
- **Press-releases:** they will be published on project website along with the standard distribution to scientific press and ERA4TB Consortium. All press releases will include the respective acknowledgement with logos, disclaimer and main contacts.

Example: <https://era4tb.org/era4tb-press-release/>

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Press

ERA4TB Press Release

January 29, 2020

ERA4TB, an international consortium to accelerate the development of comprehensive treatments against tuberculosis

More than 30 partners from 13 countries participate in the ERA4TB project

The ERA4TB (European Regimen Accelerator for Tuberculosis) project is a public-private initiative dedicated to the development of drugs against tuberculosis. With a team of more than thirty organizations and a budget of over 200 million euros ERA4TB will focus on developing a new, improved tuberculosis treatment. The partners will share their expertise, knowledge and resources to rapidly progress new candidate drugs into clinical trials.

Tuberculosis is the leading cause of death by an infectious disease worldwide. According to the World Health Organization (WHO), an estimated 10 million people became ill with tuberculosis in 2018, and 1.6 million died. Even though the incidence of tuberculosis is declining, the drug-resistant form constitutes a growing threat to the safety of the world population. It is in this spirit that the UN has pledged to end the tuberculosis epidemic by 2030 through joint action of its member states.

Acknowledgement

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853989. The JU receives support from the European Union's Horizon 2020 research and innovation programme, and in-kind support from EFPIA, TB Alliance, Bill & Melinda Gates Foundation and University of Dundee.


Innovative medicines initiative


EUROPEAN UNION


European Federation of Pharmaceutical Industries and Associations


TB Alliance


BILL & MELINDA GATES foundation


University of Dundee

Disclaimer

This communication reflects the views of the ERA4TB Consortium and neither IMI nor the European Union and EFPIA are liable for any use that may be made of the information contained herein.

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Scientific Leader: Stewart Cole <stewart.cole@pasteur.fr>

- Formal meetings with TB initiatives for communication and information exchange (see D8.2).
- Advisory and communication board for collaboration within the AMR Accelerator (see D8.3), facilitated by communication champions from each AMR pillar/project.
- Knowledge platform for sharing of information between projects (see D8.3).

4.5. IMI requirements for communication activities

In line with the Grant Agreement, all communication activities and products of IMI projects (articles, presentations, flyers, press releases, social media etc.) must include the following elements:

- A link to the IMI website: www.imi.europa.eu
- The ERA4TB logo.
- The IMI JU logo, the logo of EFPIA and of and Global Alliance for TB Drug Development Non-Profit Organisation, Bill & Melinda Gates Foundation, University of Dundee.
- The EU emblem and the following text:

“This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853989. The JU receives support from the European Union’s Horizon 2020 Research and

Innovation Programme and EFPIA and Global Alliance for TB Drug Development Non-Profit Organisation, Bill & Melinda Gates Foundation, University of Dundee”.

4.6. Scientific Publications

4.6.1. Project’s authorship policy

The project’s authorship policy will follow the generally accepted rules for academic publication (www.icmje.org). Participants are encouraged to give visibility to all contributing authors, especially junior researchers.

In the case of very general publications (i.e. those merely introducing ERA4TB and its general objectives and/or work plan), and/or on which authorship may be difficult to discern, articles can be signed with the names of the Principal Investigators of each institution followed by “The ERA4TB Consortium”.

4.6.2. Reporting scientific communications

ERA4TB participants will be requested by the PMO to provide regular updates on the publication plans or dissemination activities. Once updated, this information will be made available on SharePoint.

4.6.3. What is the internal procedure for Publications review?

At least 45 days prior to release of a Publication (meaning the dissemination of Results for instance by means of a thesis, article or paper in a journal, including manuscripts being deposited in open archives), Participants need to submit the proposed Publication in writing to the ExCom (via the PMO), which will mainly assess whether:

- Confidential information from other participants is included.
- Other participants may consider that their IP can be adversely affected.

If the ExCom considers unanimously that there are no issues, the publication submission will be approved. If issues are raised by the ExCom, the green box of the diagram below will be followed.

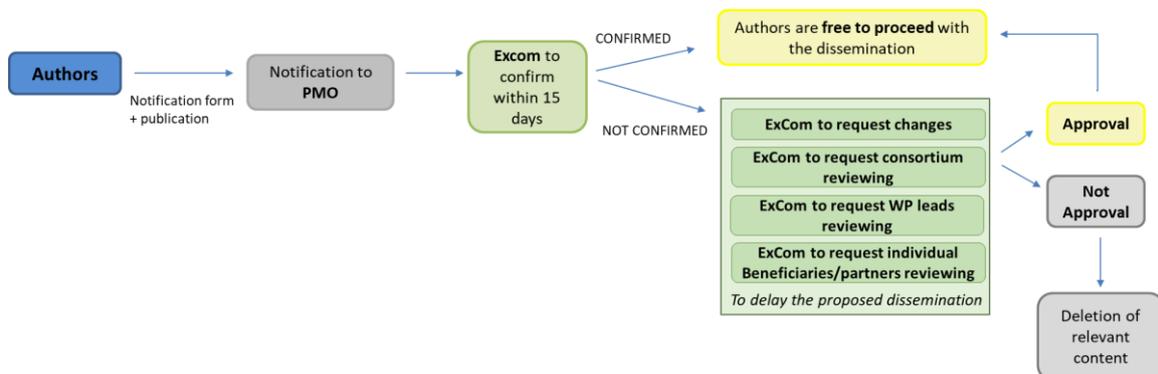


Figure 1: Publication approval process

For communications other than Publications, please refer to Appendix 11 of the Consortium Agreement for the communication guidelines of external dissemination activities of participants in the ERA4TB project (Included in the Appendix below).

- In the case of short communications (abstracts, posters or presentations for conferences), the review procedure may be simplified. Due to the usual time constraints that apply to these cases, the response from the SC should arrive within one (1) week.

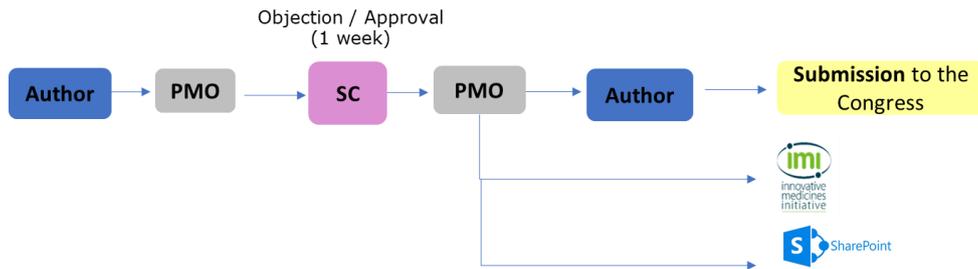


Figure 2: Short communications approval process

However, partners should be aware that if the communication includes information about compounds of an asset owner, it will need to go through the internal process of the corresponding asset owner for publications approval as well, so the review process of the short communication may be delayed. Therefore, it's strongly recommended to involve the asset owner in the elaboration of the material from the very beginning to avoid further delays.

5. Appendix

5.1. Communication Guidelines

Appendix 11: COMMUNICATION GUIDELINES

This Appendix governs Communication, by means other than Dissemination, by or on behalf of Beneficiaries. It is intended to cover, for example, the use of social media where the Project is associated with such Communication, e.g., a tweet that includes a reference to the Project, the Project twitter handle, “[XX]”, or the like. The use of social media, e.g., Twitter, Facebook, Instagram, Linked-In, blogs, and the like, is generally encouraged to build awareness of and publicize the Project and its progress. It is within this spirit that the following binding guidelines are provided. These guidelines cover Communications related to the Project that do not contain Results or Background, including by means of newsletters, blogs, and websites of patient groups, caregiver organizations, and the like.

Any activity listed as “Permitted Communications” below can be undertaken. Activities that are listed as “Prohibited Activities” below list may be permissible, but are subject to the terms of the Consortium Agreement, including those on Dissemination and Confidential Information.

Permitted Communications *

* To the extent not including any Results of any Beneficiary or any Background or Confidential Information of another Beneficiary and to the extent applicable confidentiality obligations are respected.

- A. Announcements regarding upcoming Project presentations
- B. Links to web pages containing news coverage of Project, and any web-based content, e.g., journal articles and abstracts.* But see “Links Guidelines” below
- C. Information raising awareness about the need to treat, prevent, or diagnose of [XX], but statements in a tweet that include health statistics and scientific content must include a link to a credible independent site that supports the information
- D. Information about the IMI2 JU’s values and the IMI2 JU’s commitment in society
- E. Information about partnership/collaboration with patients’ associations/charitable associations and foundations
- F. Information aimed at involving and engaging people in a future IMI2 JU or Project event directed to general public
- G. Information about the launch of the Project website or a Project app open to general public
- H. Information about new EU health policies/regulations
- I. Information that may refer to healthy living tips
- J. Information about the Project’s press releases that have been approved

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- K. General chats about Project
- L. XX. [Enrollment announcements]
- M. LLLLLLLLL. Links to caregiver support groups and other similar resources, unless permission to link is required
- N. N. Links to general news regarding [XX], treatments, screening, biomarkers, and diagnostics developed outside of the Project.

Prohibited Activities*

* May be permissible by applying the relevant provisions concerning Confidential Information and Dissemination.

1. Communications including Results of any Beneficiary or any Background or Confidential Information of another Beneficiary
2. Dosage amounts/timing
3. Photos and video of people (unless prior written permission has been obtained)
4. Any post/comment regarding a Beneficiary's products or compounds, including compound names, off-label or inappropriate use, making claims that are false or unsubstantiated, and making claims about another Beneficiary's products
5. Promotion of products (considered identifiable or viewable), promotional text regarding specific product or comparison of products
6. Attempts to diagnose a condition, recommend a treatment, or address other topics more appropriately reserved to healthcare professionals
7. Disclosure of Confidential Information or Background of another Beneficiary
8. Financial disclosures about a Beneficiary and predictions of its future performance
9. Commentary regarding ongoing litigation or other dispute resolution matters
10. Commentary regarding any crisis situation, adverse events, side effects resulting from the Project
11. Any harassing, threatening, derogatory, defamatory, discriminatory, abusive, hateful, violent, inciteful, or obscene language or material
12. Any reference to personal information of another, including name or information that may be used to identify or locate an individual (including last name, e-mail address, phone number, age or geographical location) or that could otherwise be deemed to constitute invasion of another's privacy
13. Libel, slander or defamation of the character of anyone
14. Any direct use (not linked) of third party copyrighted materials without prior permission
15. Any illegal statements, material, or content
16. Any political or religious content or propaganda

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17. Any language that promotes drugs or alcohol, predation of minors, illegal or inappropriate activities or dangerous behavior that may result in harm to anyone reading the tweet or any linked content.

LINKS GUIDELINES

- A. Links must be to non-product promotional websites/content only
- B. The content of the Communication with a link must be consistent with and supported by the content found in the link. Such a supporting link should be to a credible and appropriate independent source
- C. Linked content must not include statements that the Beneficiary making the Communication cannot communicate itself
- D. Ensure the linked content is credible and appropriate, and aligns with the IMI2 JU and the Project's values, tone & objectives
- E. Make it clear that the linked content belongs to a Third Party by including an appropriate citation or link back to the original source
- F. Ensure there is no implication that linked non-sponsored third party content is affiliated with or endorsed by the IMI2 JU, the Project or the Beneficiaries.
- G. Do not alter Third Party content
- H. Links to Third Party websites are permissible, provided the website content is approved taking into account these guidelines. Review of content linked to the Third Party website hosting the article linked to the Communication is not required unless there is some indication that the linked content may contain unsubstantiated statements or promotional claims.

THIRD PARTY PERMISSION GUIDELINES

- A. Third Party content is generally copyright protected. Obtain or ensure that permission to use or a copyright license is in place prior to communicating content as use of copyright protected content without a copyright licence / written permission could lead to a claim for copyright infringement.
- B. Personally identifiable information of living individuals is protected by data protection legislation, and the individual's written consent to use this is generally required. However, other legal basis may apply according to Applicable Legislation.
- C. It is permissible to retweet a link that a Third Party content owner has already tweeted, provided the content is approved under these guidelines for this use.
- D. It is also permissible to retweet a retweet of content, provided that the original source can be verified and has social sharing for Twitter enabled, and the content has been approved for this use.

FOR THIRD PARTY CONTENT FROM ORGANISATIONS (E.G. MEDIA, PARTICIPANTS, ASSOCIATIONS, ETC.)

- A. Photographs of trademarked content (e.g. magazine covers or articles) should not be posted without the express written permission from the publisher.

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B. No content from an image or stock photography warehouse should be used without first obtaining a proper licence. No content that says “courtesy of” a stock photography warehouse, even if it has social sharing functionality, should be used without obtaining a proper license.

FOR THIRD PARTY CONTENT FROM INDIVIDUALS

A. Photos and/or videos depicting individuals may not be taken (and posted) without the express written consent of each of the depicted individuals (right of self-image and personal data protection right if the images are identifiable information) and the photographer (intellectual property rights).

B. Names and other personally identifiable information of individuals may not be publicly posted without the individual’s express written consent as a general rule. However, other legal basis may apply according to the Applicable Legislation.

C. Quotations and sayings from living individuals or individuals that have been deceased less than 75 years (or any other applicable period during which authorship is protected under the relevant applicable law) should not be used without written permission from the individual or their estate. Whether copyright rules apply to the relevant individuals’ saying must be first assessed.

D. Content from minors should be accompanied or replaced, as the case may be, by the parents/guardian consent. In any event, information on minors should not be posted publicly or retweeted.

E. Third Party tweets should not be used on other social media platforms or for offline uses (e.g., in printed materials) without first obtaining the individual’s express written permission, unless permitted by the Applicable Legislation.