TransBioLine
Translational Safety Biomarker Pipeline

821283 – TransBioLine

Translational Safety Biomarker Pipeline

WP11 - Communication, dissemination, sustainability

D11.1 Project communication plan and initial toolset

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Document History

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V1.0	12 Sep 2019	First Draft
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Definitions

Participants of the TransBioLine Consortium are referred to herein according to the following codes:

UZH. University of Zurich, Switzerland
UMA-IBIMA. Universidad de Málaga, Spain
ITTM. Information Technology for Translational Medicine, Luxembourg
Landspitali. Landspitali University Hospital. Iceland
KUM. Klinikum der Universität München. Germany
UNOTT. The University of Nottingham. United Kingdom
USAL. Universidad de Salamanca. Spain
IR-HSCSP-ICCC. Fundació Privada Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau. Spain
TAM. TAmiRNA GmbH. Austria
SIGNATOPE. SIGNATOPE GmbH. Germany
ABX-CRO. ABX-CRO Advanced Pharmaceutical Services Forschungsgesellschaft mbH. Germany
MetaHeps. MetaHeps GmbH. Germany
APHP. Assistance Publique - Hopitaux de Paris. France
SYNAPSE. Synapse Research Management Partners S.L. Spain
Charité. Charité - Universitätsmedizin Berlin. Germany
UNEW. University of Newcastle Upon Tyne. United Kingdom
ULIV. The University of Liverpool. United Kingdom
MLM. MLM Medical Labs GmbH. Germany
UL. University of Leiden. Netherlands
SAS. Servicio Andaluz de Salud. Spain
PFIZER. LTD PFIZER UK
MSD. Merck Sharp & Dohme Corp. USA & France
LLY. Eli Lilly. USA & UK
NOVARTIS. NOVARTIS Pharma AG. Switzerland
ROCHE. F. Hoffman-La Roche Ltd. Switzerland
Janssen. JANSSEN Pharmaceutica NV. Belgium; U.S.A.
SARD. SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT. France

Grant Agreement. The agreement signed between the beneficiaries and the IMI JU for the undertaking of the TransBioLine project (No 821283).
Project. The sum of all activities carried out in the framework of the Grant Agreement.
Consortium. The TransBioLine Consortium, comprising the above-mentioned legal entities.
Consortium Agreement. Agreement concluded amongst TransBioLine 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.

Publishable Summary

This document describes the Initial Communication Plan, including project branding and policies, as per deliverable D11.1 of the TransBioLine description of action (DoA) and determines the dissemination objectives, key audiences. All relevant information, outcomes, progress and future plans must be shared with the appropriate audiences. This document optimises the internal consortium communication between the TransBioLine partners as well as outside the consortium (IMI and other nonclinical or clinical safety related projects, scientific audience and academia, payers, policy-makers, regulators, patient community, etc.). For this purpose, appropriate tools and channels have been identified and are described in this document.

1. Introduction

The TransBioLine Communication Plan describes the strategy used to provide stakeholders with information about, the various activities and tools in which objectives will be accomplished and addressed to the target audience. Internal communication, especially in large, complex projects, is one of the key drivers of engagement for Consortium members adding significant value to organizations.

All identified dissemination activities will be reported to TransBioLine partners and relevant dissemination activities will be distributed externally including scientific audiences, policy makers, payers, research participants, and media. Implementation of the dissemination activities will be carried out through scientific or general seminars, newsletters, publications, etc. utilizing a range of communication tools (such as a logo, external website, newsletter, brochure, templates, etc.), that will serve as a basis for undertaking the actions and reaching key stakeholders.

Policies for external communication will be developed in order to ensure consistency across the consortium in relation to the amount, form and content of any messages delivered to target audiences. A password-protected Intranet facility (SharePoint) has been set up to support management activities, communication and exchange of information among Participants. Communication will also drive adequate work dynamics, helping to propel efforts by friendly peer-pressure, close follow-up of tasks and personal interaction.

This repository of all communication activities planned or carried out will be regularly updated, with the objective of giving proper visibility to all dissemination efforts undertaken and to facilitate reporting.

The Initial Communication Plan is organised in the following main areas:

- TransBioLine Communication strategy
- TransBioLine Dissemination objectives
- TransBioLine Communication audiences
- TransBioLine Dissemination activities
- TransBioLine Dissemination tools
- Communications guidelines
- Dissemination activities reporting

2. TransBioLine Communication Strategy

The ultimate goal of TransBioLine is to develop, qualify and/or validate markers for organ toxicity. In order to achieve this, microRNA liquid biopsy assays will be developed, as well as protein and small molecule assays capable of detecting organ toxicity in an early stage.

The communication strategy assesses, defines, and characterises stakeholders needs and expectations from the project outset. Key messages are tailored to the interest of those specific target audiences and the most appropriate dissemination actions are identified and developed to meet their needs.

The dissemination strategy will be adjusted during the project with continuous up-to-date information and all relevant news will be disseminated as widely as possible using the TransBioLine tools identified. TransBioLine communication plan will ensure that promotional materials, press releases, articles, posters, etc. will be disseminated as widely as possible.

The communication strategy will be developed using the IMI communication guidelines (see Annex 1).

The Communication Plan fully defines the four pillars of the TransBioLine communication strategy:

1. Definition of the communication objectives

2. Identification of target audiences to whom the communication activities should be addressed

3. Description of the dissemination activities to be tackled, and

4. Identification of the specific tools to be used/developed in order to support effective communication.

These four pillars are summarised in the table below:

Objectives	1. Convey rationale for TransBioLine project 2. Generate visibility of the project and its progress to all partners, stakeholders and other IMI projects 3. Raise awareness about the project among external stakeholders 4. Towards the end of the project: the outcome of TransBioLine may streamline drug development by increasing efficiency, reducing costs and developing safer medicines.
Target audiences	• TransBioLine Consortium • IMI JU • EFPIA/Industry • Related initiatives • Scientific audience Toxicology, Pharmacology, Translational researchers and drug developers • Health Policy-makers, Payers, Regulators, Health professionals, Patient Federations • General public • Media
Actions	• Internal communication • General communication • Scientific communication • TransBioLine meetings

	• Networking with related initiatives
Tools	• Bulletin • Logo • Project presentation template • Website • Poster • Press releases • Newsletter • Social Media • Flyers • Internal Interface • Scientific publications and posters

3. TransBioLine Dissemination objectives

Communication and dissemination activities address diverse purposes. The general aim is to promote the dissemination of information and knowledge generated by the project to relevant stakeholders.

Three main dissemination objectives have been established:

1. Convey the rationale of the TransBioLine project.
2. Generate visibility of the project and its project to all partners, stakeholders and other IMI projects.
3. Raise awareness about the project among external stakeholders.

3.1 Rationale of TransBioLine

Diverse communication activities will be addressed to highlight the rationale of the TransBioLine consortium, stressing the uniqueness of the project approach in the framework of the development of novel approaches to improve the safety of new medicines by developing novel safety biomarkers, with focus on kidney, liver, pancreas, vascular and central nervous systems.

3.2 Visibility of the project and its progress to all partners

The project must be visible by all partners and stakeholders. Dissemination activities will also reach audiences outside the TransBioLine consortium including academics and physicians, policymakers, health authorities, patients and the general population. Various dissemination activities and tools will be used to generate visibility of the project as well as its related events, results and findings. Milestones and deliverables will be identified to develop relevant internal and external communication.

3.3 Raising awareness among external stakeholders

Dissemination activities will also reach audience outside the consortium including toxicology, pharmacology, regulators, clinicians, policy-makers and the general population. Diverse dissemination activities and tools will be used to generate visibility of the project as well as its related results, findings and events.

Additional efforts will be devoted to establishing proactive and regular interactions with external key stakeholders, promoting interest and uptake of TransBioLine project results.

4. TransBioLine Communication Audiences

Defined target audiences are those having an interest in the TransBioLine project and outcomes. Messages will be adapted for each audience members role using suitable technical languages and the appropriate tools.

For a meaningful and appropriate communication, it is essential to identify all relevant target audiences and thus to determine the role of each one. The target audiences listed below is not exhaustive. Additional relevant stakeholders will be added during the development of the project.

- **TransBioLine Consortium members.** All internal partners will be kept informed about the development of the project, its outcomes and future.
- **IMI JU.** The TransBioLine project has received support and funding from IMI. The project needs to deliver its project progress, results and future plans to IMI. In addition, IMI can promote and communicate the objectives and results from the TransBioLine project through different ways (website, newsletter, press, brochures, events, etc.).
- **Related initiatives.** Ongoing IMI2 projects that share research interest or other initiatives active in the field of translational medicine will be identified during the project lifecycle and connections will be established looking for common interests. (TransQST, eTRANSAFE, PSTC, other biomarker consortia)
- **Scientific audience.** The scientific community will be reached, for instance, at international conferences or symposia (by networking, poster or oral communications) and using publications, allowing for awareness of the TransBioLine project goals and results.
- **Policy-makers, payers and regulators.** Will be reached by the TransBioLine website, the general media, and articles in specialised journals.
- **General audience.** TransBioLine community will reach the general audience to increase the general awareness of the project and to provide all relevant information about its outcomes and results using the media or other means.

5. TransBioLine Internal communications

Effective internal communication within the TransBioLine partners is mandatory. Each partner must be informed on the progress and future plans of the entire project.

Specific collaboration tools for the management will be established to guarantee efficient communication within the partners, which will include, among others, a library for document management and sharing (SharePoint service), forums for discussion, mailing lists, and other internet-based tools where appropriate.

To provide cohesion to the project and contribute to its success, tools and procedures for communication must comply with some essential principles:

- Ease of use
- Reliability
- Timeliness
- Efficiency
- Confidentiality
- Integrity

5.1 How should Beneficiaries communicate internally?

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

- 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 will include action items and people accountable), which should be made available through the SharePoint. Several **distributions lists** have been initially created which can be used by any beneficiary depending on the subject of the message. Additional lists may be created as the project evolves, if necessary. The PMO will be responsible for updating the above-mentioned lists with the information received from Beneficiaries. When a list is used, care needs to be taken by Beneficiaries to use the "reply to all" feature only when relevant;
- Creation and maintenance of **updated participants' contact information** with clear information of who is included in every mailing list mentioned above. The latest version of the TransBioLine contact list is available at the TransBioLine SharePoint;
- Use, when possible, of ***de facto* standards** based on MS Office-compatible files for electronic document exchange among beneficiaries. PDF format can alternatively be used to avoid excessive size of files when no editing is required;
- **Good practice** when using email is required. Beneficiaries must respond promptly in so far as feasible 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 preferably be labelled by default with "TransBioLine -" in the subject section and senders should add the particular subject of the message. When individual messages between beneficiaries are exchanged, use of the same tag is strongly encouraged (e.g. TransBioLine - GA meeting agenda). Below, some examples of descriptors to be used in the subject line for standardization purposes can be found:

  TransBioLine - For Review, comments due Oct 28th

  TransBioLine - For distribution, No Need to Reply

  TransBioLine - Input Requested by EOB Wednesday Oct 9th

  TransBioLine - Information sharing

  Flag urgent requests – TransBioLine -***Immediate request needed reply in 4 hours.

- **Messages need to be clear and short (max 2-3 paragraphs encouraged)**, especially when requests are made. Deadlines must be made explicit. Person accountable should be identified with clear expectations. No relevant issues for the work to be performed can remain unclear;
- **Security** of intra-Consortium emails 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.

Contact lists disclaimer: Synapse creates mailing lists to facilitate internal communications and avoid retyping of emails. Synapse will use best endeavours / reasonable endeavours to keep the mailing lists accurate and up to date. However, it is recommended that mailing lists are not used for private or sensitive discussions. If in doubt, please check the mailing list composition in SharePoint or expand to see members.

At the time of this deliverable preparation, diverse electronic mailing lists have been created to reach the appropriate people involved in the project. For instance, to send information to all partners one can address them by using all@transbioline.com mailing list.

TRANSBIOLINE All	all@transbioline.com
TRANSBIOLINE Communication	communication@transbioline.com
TRANSBIOLINE EFPIA Lead	EFPIAlead@transbioline.com
TRANSBIOLINE ExCom	excom@transbioline.com
TRANSBIOLINE Info	info@transbioline.com
TRANSBIOLINE Legal	legal@transbioline.com
TRANSBIOLINE Newsletter	newsletter@transbioline.com
TRANSBIOLINE PIs	PIs@transbioline.com
TRANSBIOLINE Statisticians	statisticians@transbioline.com
TRANSBIOLINE WP Leads	wpleads@transbioline.com
TRANSBIOLINE WP1	wp1@transbioline.com
TRANSBIOLINE WP10	wp10@transbioline.com
TRANSBIOLINE WP11	wp11@transbioline.com
TRANSBIOLINE WP2	wp2@transbioline.com
TRANSBIOLINE WP3	wp3@transbioline.com
TRANSBIOLINE WP4	wp4@transbioline.com
TRANSBIOLINE WP5	wp5@transbioline.com
TRANSBIOLINE WP6	wp6@transbioline.com
TRANSBIOLINE WP7	wp7@transbioline.com
TRANSBIOLINE WP8	wp8@transbioline.com
TRANSBIOLINE WP9	wp9@transbioline.com
TRANSBIOLINE WPx1	wpx1@transbioline.com
TRANSBIOLINE WPX2	wpx2@transbioline.com
TRANSBIOLINE WPx3	wpx3@transbioline.com

Figure 1. TransBioLine mailing lists

To ensure an efficient internal communication, different procedures have already been established.

5.2 Project Meetings

To ensure an efficient internal communication, with the intention of driving upstream, downstream and transversal communication, different regular/*ad hoc* meetings have been established, including:

- Regular team meetings within WP or WPs (regular teleconference calls – monthly on average).

- Meetings with the General Assembly (all partners) will meet at least one time per year.
- Meetings of the Steering Committee will be held bi-monthly and together with the GA (F2F).
- WP-specific workshops or trainings when needed.
- Weekly ExCom meetings.
- Ad-hoc SAB and EAB meetings

The key meetings organised for the consortium, such as the Consortium Meetings, workshops, trainings etc., will be announced officially through the email, and alternatively in the website and newsletter. The relevant outcomes will be reported, and the meeting minutes will be circulated and uploaded on the SharePoint.

5.3 TransBioLine SharePoint

The TransBioLine SharePoint contains:

- Project key documents, like DoA, Consortium and grant agreements, etc.
- All files related to the projects (deliverables, presentations, meetings minutes and related information, pictures)
- Completed milestones and deliverables
- Contact list, list of partners members names and e-addresses, and detail of information of mailing lists where they are registered
- An excel repository file has been created summarizing all the dissemination activities developed within the project. This document will be regularly updated
- EFPIA contributions
- Relevant points of contact for sample collection sites

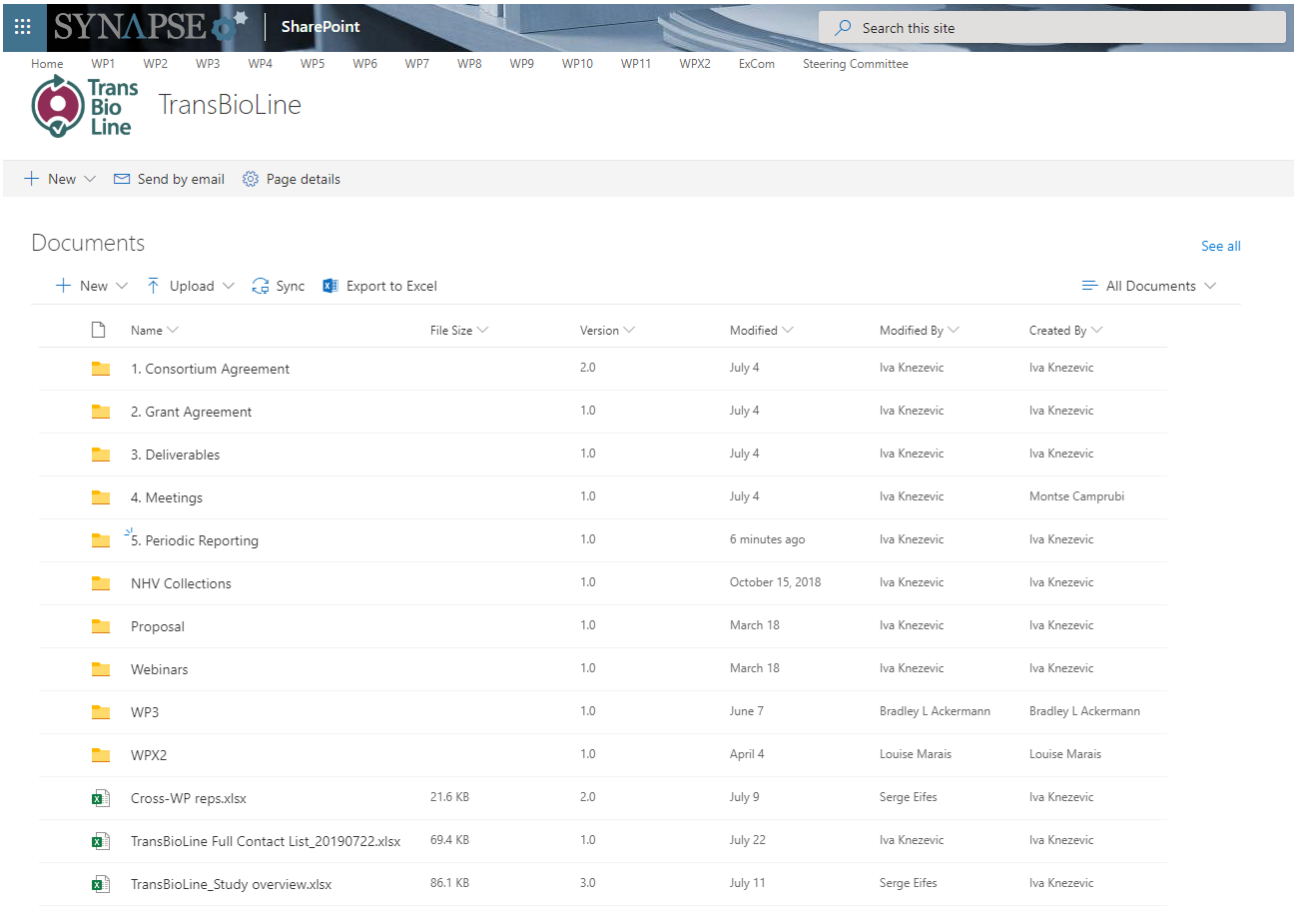


Figure 2. TransQBioLine SharePoint

5.4 Bulletin – Internal reports for all partners

- A bi-monthly Bulletin will be sent to all partners of the project. This internal release includes reporting on the effective news and disseminations activities, to keep consortium members informed on new, ongoing and already planned activities and documents of current interest (see Figure 3)

TransBioLine Bulletin – November - December 2019

TransBioLine Studies RECRUITMENT STATUS	WP1	
	WP2	
	WP3	
	WP4	
	WP5	
	WP6	
ASSAYS	WP7	
DATA MANAGEMENT	WP8	
PROJECT MANAGEMENT	WP9	
REGULATORY INTERACTIONS	WP10	
DELIVERABLES		
CALENDAR		*Please inform SYNAPSE of your planned activities and their progress for a full record of TransBioLine dissemination activity*
Teleconferences		November ExCom: WP leaders: WP1: WP2: WP3: WP4: WP5: WP6: WP7: WP8: WP10: WP11: WPX2: December ExCom: WP leaders: WP1: WP2: WP3: WP4: WP5: WP6: WP7: WP8: WP10: WP11: WPX2:
Upcoming F2F		
DISSEMINATION		
Activities		
COMMUNICATION		
Contact List		*Please check the excel file to verify your details and to know to whichmailing lists you are registered, and if you have access permissions to the SharePoint. To create a customized list or to get more information, please contact ecallado@synapse-managers.com.*
Bulletins Archive at SharePoint		

Please contact ecallado@synapse-managers.com for further information.

Figure 3. TransBioLine bi-montly Bulletin

6. TransBioLine Dissemination Activities

The Consortium Agreement in Appendix 12 refers to the communication guidelines of external dissemination activities of participants in the TransBioLine project (See Annex 1 of the present document).

6.1 General communications

The results generated within the TransBioLine project will be shared with the general audience during the project's life cycle and closely after its ending. Partners will promote the project through general communications ways, such as:

- **General conferences**. General communication could be presented at general conferences in order to introduce the project and its outcomes by means of a poster or PowerPoint slides.
- **Partners' websites**. All relevant information about the project will be encouraged to be published on partners' websites.
- **Newsletter**
- **IMI events.** In addition, an overview of the TransBioLine project can also be provided at IMI events.

A series of relevant events where the project could be presented will be identified and listed in Table below. TransBioLine members are encouraged to disseminate the project and their results in wider audience events.

Event	Partner	Work Package	Date	Location

6.2 Scientific communication

Scientific papers are the most recognised form of scientific dissemination. The publication of TransBioLine results in scientific articles is recommended in high-impact scientific journals. Publications should be done with open access policy (by submitting the manuscripts to open access journals or by paying for this option in other journals). The main way for disseminating results and outcomes of TransBioLine will be through peer-reviewed high impact publications and user-accessible databases.

As mentioned in the General communications, partners will disseminate the TransBioLine project at relevant scientific events, which also constitute a key action to make an impact on the scientific community. Oral and poster presentations are also be encouraged to promote the project.

6.3 TransBioLine meetings

Through the website and newsletter, key meetings (i.e., General Assembly meetings, workshops) organized within the consortium framework will be announced and the relevant outcomes will be reported.

6.4 Networking with related initiatives

Dissemination activities will primarily entail scientific interactions that will include collaboration with other consortia, networks or initiatives. Specific activities will be carried out within WP11 (Task 11.2 Synergy with other initiatives) to develop networking and relationship with other projects and initiatives to promote synergies of efforts and mutual leverage of results.

7. TransBioLine Dissemination tools

In support of **general communication** addressed to the different stakeholders and to maximize the dissemination activities planned, a varied portfolio of communication tools is developed.

Target stakeholder	What	When	Responsible	Which format
TransBioLine Consortium	Project news -External events -Internal meetings -Summary of ongoing work/achievements per WP -Upcoming milestones/deliverables	Bi-Monthly	SYNAPSE (with the input from WP leaders)	PDF Bulletin sent by email
Related initiatives	Project News -Major achievements -Interviews of collaborators -News and Events	Twice-yearly	SYNAPSE	Newsletter Website Twitter
Scientific audience and academia (including clinicians)	Scientific communication	When relevant	WP leaders All partners	Scientific publications Presentations (oral/poster)
Policy-makers, payers, regulators	Project News -Major achievements -Interviews of collaborators -Events -Regulatory interactions	When relevant	WP1-WP5, WP10	Newsletter Website LOI, Briefing Books
General Audience	General communication -Presentation of the project -Major achievements	When relevant	SYNAPSE	Flyer Press releases Newsletter sent by email

	-Project News and Events			Website

7.1 The logo

To ensure a unified project image the TransBioLine logo will be used in all communications related to the project (both internal and external) such as meetings minutes, deliverables, bulletins, posters and slideshows to facilitate presentations at events.

The different formats of the TransBioLine logo and documents templates for the communication activities are available at SharePoint.

Figure 4. Different TransBioLine Logo designs

7.1 Project templates

Different project templates have been produced for the communication activities. All these templates are available for partners on TransBioLine SharePoint and are listened below:

- PowerPoint presentation through slideshows to support individual meetings and facilitate presentation at international events. The project partners will develop their own targeted posters once results become available to be presented in conferences or symposia.
- Letters
- Deliverable document
- Poster template

7.2 The website

A website will be accessible through a public Internet network and will contain information on project related topics. The use of TransBioLine website https://transbioline.com/ will support:

- Increasing the awareness of the project
- Reaching and informing efficiently the target audiences and additional relevant audiences
- Provision of relevant information
- Reinforcing the rest of the dissemination activities.

The TransBioLine website will contain:

- Information about the project objectives, project structure and workpackages goals
- List of TransBioLine partners, links to their websites and a short description of their expertise contribution
- A publication section including the projects publications (ie., articles) and the press releases
- A section reporting all TransBioLine new updates (latest news, events, newsletter, etc.
- A Contact information page
- A link to the IMI website.
  A direct access to social media networks. The website will integrate Social media plugins which let you share the content by Email, Facebook, Twitter, LinkedIn, Google+.

The website will be enriched regularly, particularly the news section, which is one of the most important sections of the website. In addition, relevant information and achievements of the project will be progressively updated. People taking care of the website will be those in close contact with all project partners to ensure an updated communication.

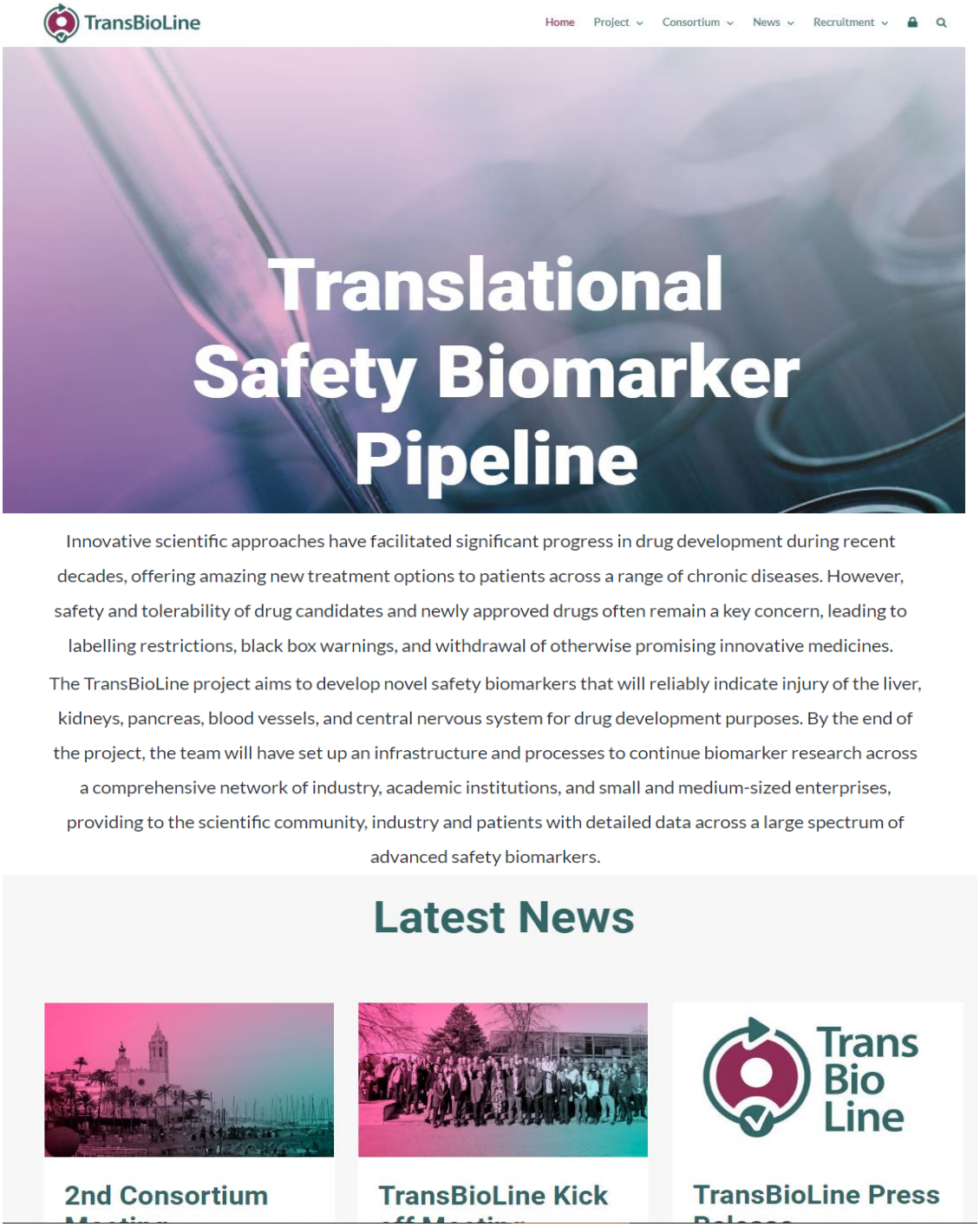


Figure 5. Snapshot of the TransBioLine homepage

7.3 Press release

The first TransBioLine press release, issued in April 2019, announced the official start and the main objectives of the project to the general public. Several TransBioLine partners made dissemination of the official start of the project.

During the project's life, when applicable, new press releases will be published for dissemination of public milestones.

7.4 Newsletter

The development of the TransBioLine newsletter is ongoing and the issues will be prepared twice yearly, starting from February 2020. The newsletter issues will be accessible on the TransBioLine website.

The newsletter will be sent to all the TransBioLine consortium members because it will include interesting contents for our partners and to other external stakeholders.

People subscribing to the newsletter on the TransBioLine website will directly receive it to their Email address.

The newsletter will contain different sections to highlight the relevant novel information of the project, like major achievements, news and events. Different sections could be added when appropriate to allow better and comprehensive dissemination.

7.5 Social Media

Social media create highly interactive platforms and users can share and discuss about specific topics. Social networks have increased the way to interact with interested people and are able to connect with thousands of people all over the world.

The TransBioLine Twitter account has been set up, and it will be used to disseminate relevant information about the project and its results.

7.6 Flyer

At the time of this deliverable preparation TransBioLine flyers or leaflets have not yet been developed. They will be prepared to further increase the awareness of the project and to reach efficiently known and additional relevant audiences. A flyer could be used to support oral and poster presentations at scientific and general events (conference, meeting, etc.) facilitating networking of project goals and results.

8. Communication Guidelines

8.1 Open Access philosophy (IMI2)

According to article 29.2 of the TransBioLine Grant Agreement, publications should be open access. Scientific papers could be submitted to open access journals or by paying for this option in journals. Furthermore, scientists should ensure open access to the

disposed publication if an electronic version is available for free via the publisher or within six months of publication.

More details about the open access philosophy can be found in the Annexes section 11.2.

8.2 IMI Acknowledgement

In line with the TransBioLine Grant Agreement, all scientific publications and presentations at international events must specify that the results have been funded by the IMI2/EU and the EFPIA. Indeed, all the TransBioLine dissemination activities (articles, presentations, posters, flyers, press-releases, website, etc.) must include the following acknowledgement stating that the project have been funded by the IMI2/EU and the EFPIA:

"This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 821283. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA".

This following statement is also allowed in case of restricted character count:

"This work has received support from the EU-EFPIA Innovative Medicines Initiatives 2 Joint Undertaking (grant No 821283)."

These statements should be translated into the language of the communication product.

8.3 IMI Communication Guidelines

In addition, communications should include a link to the IMI website http://www.imi.europa.eu/ as well as the IMI, EFPIA and EU logos. Respective entire and original forms of each logos should be used. In case of specific communications activities with space constraints (not allowing logos and web addresses), the acknowledgement phrase alone is sufficient. These logos are available in SharePoint to all TransBioLine members.

All the TransBioLine communications products (e.g. website) must be sent to the IMI Communications Team for review, at least two working days before publication or release at the following Email address: communications@imi.europa.eu. The aim of this review is the validation of the communication activity by IMI in term of rules correctly applied and misunderstandings prevented.

8.4 Consortium Agreement

The Consortium Agreement has installed a review and approval process responsible for reviewing every proposal for publication that contains findings, data or other interpretations of data, which contain or describe results.

Authors must submit the proposed dissemination to the other beneficiaries by written notice at least 45 days before the envisaged dissemination and then beneficiaries will evaluate the proposed dissemination within 45 days of its receipt. A dissemination

workflow has been defined and approved for regular planned activities but also to cover a fast-track need as, for instance, in case of abstract submission or short notice invitation for Oral communications in conferences or similar events.

If an objection is made, the publishing Beneficiary will extend the review period and delay the proposed publication.

More details on the review and approval process can be found in the Annex 3.

8.5 Authorship policy

Authors should be informed about their responsibilities for the published work and therefore all principles of authorship policy. They must also avoid conflicts of interest. Therefore, the project's authorship policy will follow the generally accepted rules for academic publication.

9. Dissemination activities reporting

Evaluation of the dissemination results is a very important way to improve communication processes. The evaluation of the communication plan will help the TransBioLine consortium to adjust their communications strategy and activities.

9.1 Internal track by WP11

In order to ensure a full report of all the dissemination activities, WP11 will monitor other WP activities. TransBioLine partners will be asked regularly to provide any dissemination activities related to the project, in which they are involved. A repository of all the dissemination activities and communications related to each activity will be available on the TransBioLine SharePoint. This list will be regularly updated. Partners will be asked to check the repository, in order to ensure the accuracy of each dissemination activity.

TransBioLine

Last update 09/09/2019
Updated by Iva Knezevic

ID	Title	Date (dd/mm/year)	Year	Location	Partners Involved	Responsible Partner	Status	Contact person	Type of Activity	Audience
Please, do not modify	Include here full title; if it's a scientific paper please use Vancouver's style.	Include only start date.		City, Country	Partner (s) (acronyms).			Responsible contact in case we need to keep track of this activity, specially if it is a scientific paper.		If possible include estimation of targeted audience.
001	Innovative Medicines Initiative launches Translational Safety Biomarker Pipeline Project	15/04/2019	2019		UZH	UZH	Done	Michael Merz	Press Release	General
002	Joint session at SOT 2020	15/03/2020	2020	Anaheim, US	Signatope	Signatope	Planned	Oliver Pötz	Presentation	Scientific
003	Biobanking for Precision Medicine	08/10/2019	2019	Lubeck, Germany	Charité	Charité	Submitted	Dana Briesemeister	Presentation	Scientific
004	MicroRNAs and toxicology: A love marriage	23/09/2019	2019	Barcelona, Spain	TAmiRNA	TAmiRNA	Done	Matthias Hackl	Presentation	Scientific

Figure 6. Snapshot of the TransBioLine Dissemination Tracker

9.2. Internal procedure for Publications review

Prior to release of a Publication (meaning the dissemination of Foreground for instance by means of an abstract, thesis, article or paper in a journal or a presentation of the same at a conference or seminar), Participants need to submit the proposed Publication

in writing to the ExCom and Steering Committee following the recommended internal review process:

Step 1: Author sends article/abstract/presentation/poster, etc., to ExCom & SC through PMO

Step 2: ExCom & SC review the communication material

Step 3: If no objections are received, PMO sends it back to the author

Step 4: Author submits the communication

Step 5: PMO uploads the communication to the TransBioLine SharePoint resource.

Step 6: PMO uploads the communication to the Participant Portal

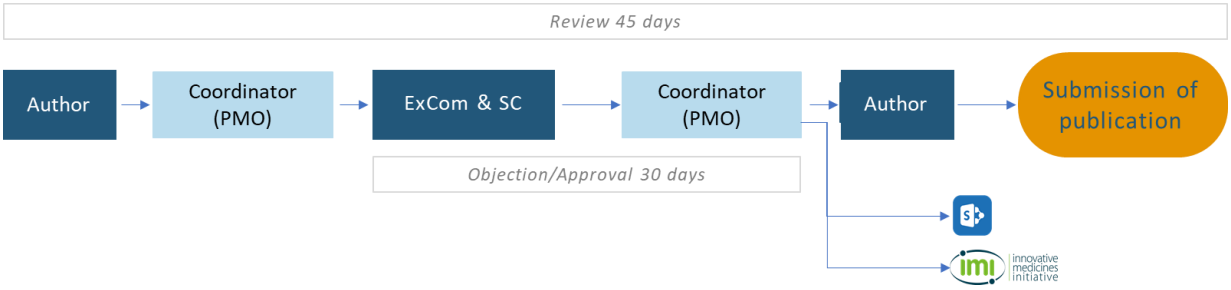


Figure 7: Dissemination workflow

In the case of short communications (abstracts, posters or presentations for conferences), the review/approval procedure may be simplified (fast-track review process). Due to the usual time constraints that apply to these cases, the response should arrive within 1 week; the deadline for both review and submission must be clearly stated by the author.

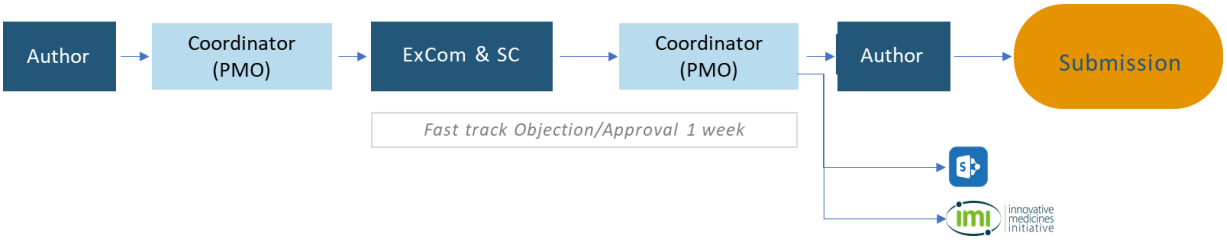


Figure 8: Dissemination workflow for short communications

All content included in deliverables that are labelled as "public" will not require any specific approval to be disseminated by Beneficiaries.

In this context, "Dissemination" means any public disclosure by a Beneficiary of its Results by any appropriate means (other than public disclosure arising from protecting or exploiting such Results), including but not limited to by means of scientific publication (in any medium), press release, on a website, or by presentation at a scientific conference.

9.2 Yearly reporting to IMI

An official report of the project must be sent every year to IMI, following the corresponding IMI2 rules and guidelines. These periodic reports include the risk management and the project assessment and must be sent at months 12, 24, 36 and 48 respectively. In addition, a final periodic report must be sent at the end of the project at 60 months. The deliverables D2.3 will report an Interim and Final report on dissemination activities in M30 and M60, respectively.

The dissemination results will be reported to IMI according to the IMI table template for dissemination activities (Table below).

Number	Type of dissemination and communication activities	Type of audience reached In the context of all dissemination & communication activities ('multiple choices' is possible)	Estimated Number of persons reached
	*[*Organisation of a Conference*]* *[*Organisation of a workshop*]* *[*Press release*]* *[*Non-scientific and non-peer reviewed publications (popularised publications)*]* *[*Exhibition*]* *[*Flyers training*]* *[*Social media*]* *[*Web-site*]* *[*Communication campaign (e.g radio, TV)*]* *[*Participation to a conference*]* *[*Participation to a workshop*]* *[*Participation to an event other than a conference or workshop*]* *[*Video/film*]* *[*Pitch event*]* *[*Participation in activities organised jointly with other H2020 project(s)*]* *[*Other*]*	Scientific Community (higher education, Research)*]* *[*Industry*]* *[*Civil Society*]* *[*General Public*]* *[*Policy makers*]* *[*Social media*]* *[*Medias*]* *[*Investors*]* *[*Other*]*	

9.3 Evaluation of dissemination results

Evaluation of dissemination results is an ongoing process and should be planned directly at the beginning of the project through measurable indicators.

In addition, evaluating the communications plan provides the opportunity to obtain feedback and constructive suggestions of target audiences (formally or informally). For example, we could suggest obtaining feedback for the dissemination tools and activities by TransBioLine partners through a survey.

a. Evaluation of the communication tools

Indicators to evaluate the communication tools should be minimalist and automated using for example free online tools generating detailed statistics.

- Evaluating the website: GoogleTM Analytics reporting TransBioLine website audience information (Number of visitors. Time spent on the website. Sections/pages most visited).
- Evaluating the newsletter: Number of subscriptions. Number of downloads on the website.
- Evaluating flyers: Number of flyers/leaflets distributed.

b. Evaluation of the dissemination activities

Finally, the dissemination activities will be evaluated through:

- Scientific communication: Number of scientific publications, oral and poster presentations. Total of citations of articles published.
- General communication: Number of general communications.
- Press release: Number of downloads on the website.

Annexes

Annex 1 TransBioLine Consortium Agreement: Appendix 12. 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. * 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
K. General chats about Project
L. [Enrolment announcements]
M. Links to caregiver support groups and other similar resources, unless permission to link is required
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
17. Any language that promotes drugs or alcohol, predation of minors, illegal or inappropriate activities or dangerous behaviour 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. Personal 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.
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.

Annex 2 TransBioLine Grant Agreement: Article 29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge online access for any user) to all

peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications; Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences

and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms "Innovative Medicines Initiative 2 Joint Undertaking", "European Union

(EU)", "Horizon 2020" and "EFPIA";

- the name of the action, acronym and grant number;

- the publication date, and length of embargo period if applicable, and

- a persistent identifier.

Annex 3 TransBioLine Consortium Agreement: 7.5 Dissemination of Results

7.5.1 General commitment on Dissemination

7.5.1.1 Each Beneficiary shall Disseminate its Results as soon as possible, unless such Dissemination goes against its legitimate interests (for instance, because the

Results have not yet been protected, the Results concern trade secrets, or disclosing the Results would infringe on applicable Personal Data protection, security related, or other applicable obligations).

7.5.1.2 A Beneficiary may not Disseminate Results generated by another Beneficiary or any Background or Confidential Information of such other Beneficiary, even if such Results, Background or Confidential Information are amalgamated with such Beneficiary's Results, without the other Beneficiary's prior written approval.

7.5.2 Review and Approval Process

7.5.2.1 A Beneficiary may only Disseminate any Results if it has circulated the proposed Dissemination to the other Beneficiaries by written notice at least thirty (30) Days prior to such Dissemination, and the below procedure has been followed.

7.5.2.2 Any Beneficiary may object to such a proposed Dissemination within thirty (30) Days of notification, if it can show its legitimate interest in relation to the Results would be significantly harmed for the reasons as detailed here below:

a) where protection of the objecting Beneficiaries' own Results or Background would be adversely affected by the proposed Dissemination;

b) where the proposed Dissemination contains Confidential Information from the objecting Beneficiary; or

c) where other legitimate interests of the objecting Beneficiary are significantly harmed..

If such objection is made, the publishing Beneficiary will:

(i) in case of a) extend the review period and to not unduly delay the proposed publication for a period of at least six (6) months but up to a maximum of twelve (12) months from the date of the proposed Dissemination was circulated to the other Beneficiaries to allow the objecting Beneficiary to evaluate the patentability and/or to file a patent application for the objecting Beneficiary's Results or Background; and/or otherwise modify the publication as requested for scientific or patent reasons;

(ii) in case of b) to not unduly delay the Dissemination until the objecting Beneficiary's Confidential Information is removed from the proposed Dissemination

(iii) in case of c) enter into good faith discussions with the objecting Beneficiary on how to address the legitimate interests of the objecting Beneficiary, as the case may be, by amending the proposed Dissemination.

7.5.2.3 If no objection is received in writing within the thirty (30) Days' period mentioned above, the Beneficiary seeking Dissemination will be free to proceed with the Dissemination as submitted to the other Beneficiaries to the extent such Dissemination does not include or refer to Results or any Confidential Information of any other Beneficiary.

7.5.2.4 Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Beneficiaries or any of their logos or trademarks without their prior written approval.

7.5.2.5 Details of any publication and an electronic copy of the published version must be provided to the IMI2 JU within two (2) months following publication.

Notwithstanding the provisions of this Clause, nothing in this Agreement shall prevent a student from submitting for a degree of the Beneficiary university a thesis based on the Results obtained during the course of work undertaken as part of the Project, the examination of such a thesis by examiners appointed by the Beneficiary university, or the deposit of such a thesis in a library of the university in accordance with the relevant procedures of the Beneficiary university. The Steering Committee will be informed on an on-going basis regarding the proposed contents of any thesis to be submitted to the Beneficiary university and the final draft shall be submitted to the Steering Committee for review prior to submission to the Beneficiary university. Other Beneficiaries may comment on the contents of the thesis within sixty (60) Days of receipt of the thesis in accordance with Clause 7.5.2. All appropriate measures ensuring confidentiality must be taken by the Beneficiary with which the student is associated to ensure protection of Confidential Information and/or patent protection of the other Beneficiaries, which shall, where appropriate, require examiners external to the Beneficiary university to sign an agreement of non-disclosure prior to receipt of the thesis and comply with any other applicable requirement under Appendix 2, as the case may be.

7.5.3 Open access to scientific publications

Where Dissemination concerns a peer-reviewed scientific publication, each publishing Beneficiary shall comply with Article 29.2 of the Grant Agreement.

7.5.4 Mandatory Messaging in connection with Dissemination

Unless the IMI2 JU requests or agrees otherwise or unless it is impossible, any type of Dissemination that shall arise from the Action shall include the logos, emblems, and text provided for in Article 29.4 of the Grant Agreement.

Annex 4: SharePoint for Beginners

Introduction to Sharepoint

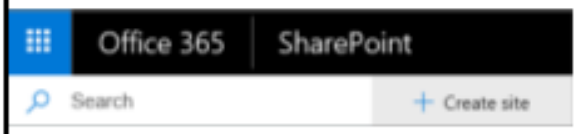
SharePoint is a cloud-based service that helps organizations share and collaborate with colleagues. With SharePoint, you can access internal documents and other information from anywhere. In a SharePoint document library, create a new file, upload your own, and then share it with others.

Sign in to Sharepoint

You will receive an invitation to join Sharepoint via email. Follow the instructions to obtain access to Sharepoint. You don't need to install any software to use SharePoint Online. Instead, just connect through your web browser.

Search for something

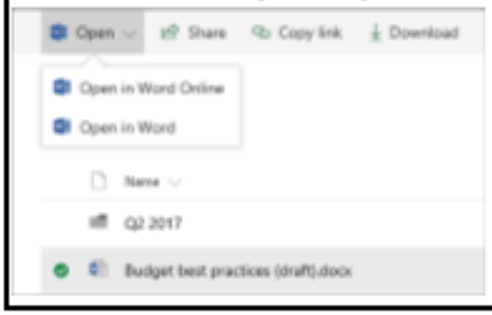
1. Type into the Search box in the top left under the app launcher.
2. Filter your results by type, for example Sites, People, or Files.



Open a document from a document library

1. Go to the SharePoint site.
2. Open the document library.
3. Do any of the following:

- Select **Open** and select to edit in Office Online.
- If you have the desktop app installed on your computer and want to use it, select a file and then select **Open** > **Open in**



Share a document

1 Select the document you want to share.
2 Select **Share**.
3 You have 3 options:

- Type the names or email addresses of the people you want to share the document with and add a message if you'd like. When you're ready, select **Send**.
- Select **Copy Link** to create a direct link to the file that can be shared in an email or IM.
- Select **Outlook** to open Outlook on the web and add a link to the file in a new email.

Work with others on the same document, at the same time

With SharePoint, multiple people can work together on a Word document, Excel spreadsheet, or PowerPoint presentation. Open the document for editing in Office Online. The number of people currently editing the document appears at the top of the document in Office Online.

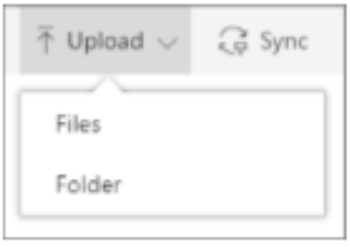
Upload a folder or files to a document library

You can upload files to a document library in SharePoint by just dragging them from your computer and dropping them into the document library. With most browsers, you can also upload folders and the files they contain.

Important:

- Before you can upload or create files in a document library, your admin must give you permission to contribute to the library.
- You can use Microsoft Edge, Mozilla FireFox, or Google Chrome to upload folders from your computer to a SharePoint Online document library. Internet Explorer 11 does not support uploading folders.

1. Open the document library where you want to upload a folder or files.
2. On your computer, click **Start** , type file explorer, and then click **File Explorer**. Navigate to the folder or files that you want to upload.
3. Select files or folders in **File Explorer** and drag and drop the folder or files onto the document library page. When you upload a folder to a document library, all files contained in the folder are automatically uploaded as well.
4. You can also select **Upload** from the main document library menu, and then select **Files** or if your browser supports



*If your browser doesn't support folders, when you click **Upload**, the **Choose File to Upload** page opens where you can select one or more files*