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D8.1 TopSpec Intellectual Property Protection Strategy

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* This Deliverable is Confidential (CO) and subject to Section 10 of the TopSpec Project Grant Agreement

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EXECUTIVE SUMMARY

This document provides an Intellectual Property (IP) protection strategy for the TopSpec project, funded by the European Commission under Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020), Grant Agreement number: 829157

TopSpec is a three-year project that started in January 2019. It aims to develop a ground-breaking TOP-down tandem mass SPECTrometry (MS/MS) platform to solve the challenge of unraveling the sequence repertoire of human antibodies and their respective antigens.

The TopSpec consortium comprises 8 participants from 7 countries who bring together a mix of stakeholder organisations and corresponding expertise. The participants include instrument manufacturers, technology SME's, universities, and research institutes.

The rules regarding the ownership and use of IP is governed by the Grant Agreement number 829157 governing the project and the consortium agreement signed by the TopSpec consortium.

In this document, which is a Deliverable in WP8 titled 'Dissemination, Communication & Exploitation', the principles concerning background IP, foreground IP and dissemination are provided. The role of WP Leader and other participants in WP8 is explored concerning their management responsibilities with respect to IP. As the project anticipates the inclusion of software and data from non-TopSpec consortium partners, the approach to third party interactions is explored as is an overview as to how IP assets will be recorded. Key aspects of the IP policy adopted by the TopSpec consortium include compliance with contractual obligations, considering protection of IP assets before disclosure and maintaining a register of both own and third party IP assets that are relied upon by the project.

This report contains Annexes that are indicative of how the strategy delineated in this document will be implemented. The Annexes will be treated as 'live' documents throughout the duration of the project to reflect the most up to date information.

CONTENTS

VERSION AND CONTROLS	1
EXECUTIVE SUMMARY	2
CONTENTS	3
1 Background	4
2 Introduction	4
3 Contracts Controlling IP	5
3.1 Background IP	5
3.2 Foreground IP	5
3.3 Dissemination	6
4 Management Responsibilities and Communications	6
5 Third Part Interactions	7
6 IP Audit	7
7 IP Strategy and Policy	8
8 Exploitation	9
9 Concluding Remarks	9
Annex 1	10
Annex 2	12

1 Background

TopSpec is a three-year project that started in January 2019. A major and growing challenge in the EU health system is the cost of drugs and targeted therapies. Reducing time taken to develop novel therapies will reduce costs to the health system. To address this grand challenge, it is imperative to better understand how the human organism defends itself against diseases. The biggest mystery is the human immune system; and, understanding this ultimately requires knowledge of the sequence repertoire of human antibodies and their respective antigens.

The purpose of the TopSpec project is to be the first in the world aiming to solve this challenge, opening up opportunities in medical research and drug development that are today only dreamt about. We will create a breakthrough technology that will revolutionize academic, clinical and industrial proteomics and dramatically advance the development of new generation antibody- and protein-based therapeutics.

This complex and ambitious project brings together 8 participants from 7 countries and funded by the European Commission under Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020), Grant Agreement number: 829157.

The Grant Agreement together with a consortium agreement provides the obligations relating to the treatment of intellectual property. This document outlines the intellectual property protection strategy for the project, its interface with governing contracts and guidance regarding key activities of the project that include the use of third party data and the dissemination of project results.

The protection of IP is an important activity in TopSpec as a number of consortium partners are required to share confidential information within the confines of the project, and the nature of the project itself is likely to lead to knowledge and insights which hold significant value.

2 Introduction

IP in its widest sense is knowledge, but the term is usually restricted to well-defined packages of knowledge. IP would include: ideas, techniques, data, know-how, results, inventions and creative works. Thus inventions, books, designs, software programs, logos, music, etc. are considered property – IP.

It is much easier for IP to be copied or re-used as compared to a physical property. There is usually no way to “physically” lock-up IP and in recognition of this there are legal tools in place to provide protection – IP rights (or IPRs).

There are six key types of protection available for IP are:

- Trade Secrets / Confidentiality;
- Patents;
- Design Rights;
- Database Rights;
- Copyright;
- Trade Marks.

These protections work in different ways to protect different aspects of IP. Sometimes more than one type of right may be needed to fully protect a product or service. Some IPRs can be registered, whilst others arise automatically or through contracts.

The consortium partners will consider all rights of protection when assessing their Foreground IP (“Results”) but will adopt confidentiality in the first instance (see 7. IP Policy) and will adhere to the contractual obligations concerning Background and Foreground IP (see 3. Contracts controlling IP). The consortium partners will keep each other aware of any IPRs they plan to progress concerning their own Foreground IP.

3 Contracts Controlling IP

The TopSpec Consortium Agreement governs the treatment of Background IP and Foreground IP and dissemination of the latter.

- *Background IP* is IP relevant to a project that existed before or is created concurrently but independently of the project.
- *Foreground IP* or Results is IP that is created during the project.

The following sections consider ownership and access rights (licenses or user rights to IP) to Background IP and Foreground IP. This applies to all IP including software.

3.1 Background IP

For Background IP (section 9 of the Consortium Agreement), the key obligations are summarised as follows:

- Background IP remains in the full ownership and control of the owning party;
- Background IP and access rights should be identified by each consortium partner in Attachment 1 of the Consortium Agreement. This can and will be updated throughout the project;
- A consortium partner can get access rights to another consortium partner’s Background IP if they need it in order to deliver their part of the project. This will be free of charge unless otherwise agreed;
- A consortium partner can have access rights to another consortium partner’s Background IP if they need it to exploit their Foreground IP. This will be on fair and reasonable terms so a fee can be charged noting that use for internal research is free-of-charge;
- If a consortium partner leaves the project, access rights to Background IP are subject to the conditions as stipulated in section 9.7.2 of the Consortium Agreement.

3.2 Foreground IP

For Foreground IP (section 8 and 9 of the Consortium Agreement), the key obligations are summarised as follows:

- Foreground IP is owned by the consortium partner who generates it;
- If Foreground IP is jointly generated by two or more consortium partners they can agree on how to deal with it or they can choose to use the option given in the Consortium Agreement (See section 8.1 of the Consortium Agreement) where each owner can use it free of charge for non-commercial research but for commercial exploitation, or to offer sub-licences, compensation must be paid to the other owner(s);
- A consortium partner can transfer their Foreground IP but must ensure that the access rights of the consortium partners are maintained;

- A consortium partners is allowed to grant an exclusive licence if the other consortium partners waive their access rights.

3.3 Dissemination

Dissemination of Foreground IP is covered under section 8.3 of the Consortium Agreement and the key principles are summarised as follows:

The consortium partners will:

- Disseminate their Foreground IP as soon as possible as long it is does not go against its legitimate interests;
- Ensure they consider IP protection, confidentiality, security and data protection in any publication;
- Not disseminate the Foreground IP from another consortium partner unless written permission is received;
- Use the EC logo and disclaimer (see articles 29.4 and 29.5 of the Grant Agreement) in all TopSpec publications;
- Provide the proposed publication to all consortium partners 30 days before its planned release;
- Comment on any proposed publication directly to the consortium partner proposing the dissemination or to the Coordinator within 30 days of provision of the proposed publication;
- Where a licence or other permission is required to use information in the proposed publication, the consortium partner owning said information shall provide a paragraph outlining how such permission is obtained and applicable contact information. It is the responsibility of the consortium partner owning said information to maintain this contact information up-to-date and to progress any and all enquiries received.

If no objection is received to any proposed publication within 30 days of the notification and provision of the proposed publication, the publication is permitted.

The consortium partners will inform and work with the Work Package (WP) Leader of WP8 (Dissemination, Communication & Exploitation) concerning all dissemination activities.

Deliverables that are confidential to the project partners (identified Confidential (CO)) are subject to Section 3 of the TopSpec Project Grant Agreement No. 829157 and thus should be maintained as confidential by all consortium partners. The reporting template for such deliverables includes a statement in this respect.

4 Management Responsibilities and Communications

The Steering Committee oversees the direction and management of the project. Its chair, the Co-ordinator, is responsible for, amongst other things, the progression of planned publications to which objections have been raised.

The WP Leader of WP8 is overall responsible for the co-ordination of reports and activities on the project concerning dissemination, business plan, exploitation and software training. MS is responsible for this report (D8.1: TopSpec Intellectual Property Protection Strategy due in M3).

Matters concerning IP will be addressed in Task 8.2 that MS leads. MS will consult other participants of Task 8.2 as and when required. Any IP issue will first be sought to be solved by the Task participants. Matters that cannot be resolved will be elevated to the Steering Committee for resolution.

Any updates to the TopSpec Asset Register (see section 6. IP Audit) will be provided to the Co-ordinator who will make necessary amendments to Attachment 1 of the Consortium Agreement and provide to WP8 Leader.

5 Third Part Interactions

The consortium partners will ensure they have the appropriate agreement in place with their employees, students, agents or any other third parties who will be engaged in the delivery of some, or all, of the project on their behalf.

Confidentiality Agreements or Non-disclosure Agreements are documents that contractually bind one or both parties to the agreement to keep information disclosed confidential, thus limiting the possibility of the information being released to the market before an IPR patent or trade mark application has been made. They should be used if a consortium partner wants to disclose its Foreground IP outside of the consortium partners (the consortium partners have signed a confidential obligation in the Consortium Agreement).

The project anticipates the use of software and hardware (prototype, commercial, freeware, open source, etc) and data from third parties. To enable project delivery and exploitation of TopSpec outputs (see 8. Exploitation), the access rights to any IP assets owned by third parties needs to be established and logged into the third party IP asset register (see section 6. IP Audit).

Similarly with data, the source and access rights to data from third parties need to be identified and recorded for each scenario. From this, a database will be established and the details recorded in the third party IP asset register (see section 6. IP Audit).

The third party IP asset register will change as the project progresses.

6 IP Audit

The IP assets of the collaboration partners require identification in addition to key IP assets of third parties that will be relied upon to deliver the TopSpec product(s). IP assets are registered patents, trademarks, copyrights or designs. Through conducting this IP review or audit the partners will also identify any relevant licenses to third parties by the IP asset owning collaboration partner and any licenses from third parties, including cross-licenses that will be, or are likely to be, relied upon by the collaboration partner to deliver their work under the project and/or to utilise the TopSpec product(s).

A TopSpec Consortium Partner IP Asset Register, showing the identified IP assets of the TopSpec consortium partners that may or will be relied upon for the TopSpec product, has been compiled (see Annex 2) and will be maintained by the partners throughout the project. Further an IP Asset Register for IP assets owned or controlled by third parties i.e. non-TopSpec consortium partners has been created (see Annex 3) and will be populated by the partners during the project.

Task Leaders of Task 9.2 will monitor activities in order to periodically review and update the IP Asset Register.

Note that Annexes are subject to change as the project progresses.

7 IP Strategy and Policy

The IP strategy consists of the following:

Legal measures:

- Carry out patent and trade mark searches in order to be certain that trade marks or patent applications will not infringe any existing rights held by other parties or to determine the novelty of your invention.
- Register intellectual property.
- Check the markets and consistently pursue infringements by third parties.
- Have providers, distributors or other business partners sign non-disclosure agreements.

Organisational measures:

- Ensure that confidential information is protected at all consortium partners.
- Distribute sensitive technological know-how among several employees so that there is no concentration of risk if someone leaves.

Technical measures:

- If it is technically possible, elements that can't be reproduced easily by reverse engineering will be integrated (known as 'black boxes'), without which the product cannot work.

The following IP policy is adopted by the consortium partners to enable Foreground IP protection and exploitation.

The consortium partners will:

- Own, protect, licence and disseminate their Foreground IP in compliance with the contractual obligations of the project written in the Consortium Agreement including obligation to including EC logo and disclaimer;
- Keep Foreground IP secret until a decision is made on if and how to protect it;
- Record all research data and information accurately and clearly and will keep all such data secure and in a permanent and retrievable form;
- Follow all guidelines concerning the protection of communications between the consortium partners;
- Identify access rights to both own and third party IP assets, review and update the TopSpec IP Asset Registers (consortium partner and third party, see section 6, IP Audit) at regular intervals. All updates are to be provided to the WP8 Leader;
- Provide proposed project-related publications to the consortium partners at the earliest possible opportunity and no less than 30 days before the planned publication date; and where applicable include permission and contact information for any information incorporated by the consortium partner that is subject to access rights (see section 3.3, Dissemination);
- Inform the Co-ordinator of any infringement or alleged infringement of third party IPRs that comes to it notice. Work on the project affected by such will cease and the Co-ordinator will inform the Steering Committee who will decide next steps concerning the project;
- Use Confidentiality Agreements if you want to disclose your Foreground IP outside of the consortium partners.

8 Exploitation

The objective of TopSpec project is to develop a ground-breaking top-down tandem mass spectrometry platform to solve the challenge of unraveling the sequence repertoire of human antibodies and their respective antigens. Thus, the activities within the project will require tools to be developed by the participants and/or third parties and then integrated into a comprehensive and customised platform.

The partners will develop a Plan for Exploitation and Dissemination of Results (PEDR) in WP8 which will provide guidelines for exploitation activities, both during and post project, and the route to market for the platform constituents developed.

9 Concluding Remarks

This Deliverable provides the principles concerning background IP, foreground IP and dissemination with WP9 of TopSpec. The role of WP Leader and other participants in WP8 is explored concerning their management responsibilities with respect to IP. As the project anticipates the inclusion of software and data from non-TopSpec consortium partners, the approach to third party interactions is explored as is an overview as to how IP assets will be recorded. Key aspects of the IP policy adopted by the TopSpec consortium include compliance with contractual obligations, considering protection of IP assets before disclosure and maintaining registers of both own and third party IP assets that are relied upon by the project.

This report contains Annexes that are indicative of how the strategy delineated in this document will be implemented. The Annexes will be treated as 'live' documents throughout the duration of the project to reflect the most up-to-date information.

Annex 1

TopSpec Consortium Partner IP Asset Register (To be kept updated)

Collaboration Partner	Type of asset (also record if prototype (P) or commercial (C) available)	Name	Extent of use	Incorporated into TopSpec final product(s) Y/N	If Y, details	Access Rights (during project)	Access Rights (post project/for exploitation)



Annex 2
TopSpec Third Party IP Asset Register
(To be kept updated)

Third Party	Type of asset	Name/details	Incorporated into TopSpec final product(s) Y/N	If Y, details	Access Rights (during project)	Access Rights (post project/for exploitation)