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Finding Endometriosis using Machine Learning

FEMaLe

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Legislation

Legislation H2020 Framework Programme – Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ 347, 20.12.2013, p. 104).

Euratom Research and Training Programme (2014-2018) – Council Regulation (Euratom) No 1314/2013 of 16 December 2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 – The Framework Programme for Research and Innovation (OJ L 347, 20.12.2013, p. 948).

H2020 Specific Programme – Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme Implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p. 965).

Rules for Participation (RfP) – Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 of December 2013 laying down the rules for the participation and dissemination in Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013, p.81).

Financial Regulation (FR) – Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the European Union (OJ L 298, 26.10.2012, p.1).

Rules of Application (RAP) – Commission Regulation (EC, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of 1 Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 298, 26.10.2012, p.1).

1. Abbreviations and definitions

1.1. Abbreviations and acronyms

Abbreviation	Meaning
IP	Intellectual property
IPR	Intellectual Property Rights
FEMaLE	Finding Endometriosis using Machine Learning
IAAB	Innovation Action Advisory Board
WP	Work package
PMO	Project Management Office
IMP	Innovation Management Plan

Partner number	Participant organisation name	Referred as	Country
1 Coordinator)	Aarhus University	AU	Denmark
2	Aarhus University Hospital	AUH	Denmark
3	European Society for Quality and Safety in General Practice	EQUIP	Denmark
4	Semmelweis University, Dept. of Gynaecology and Obstetrics	SWU	Hungary
5	The Chancellor, Masters, and Scholars of the University of Oxford, Nuffield Department of Women's & Reproductive Health	UOXF	UK
6	SurgAR	SURG	France
7	Rigas Tehniska Universitate	RTU	Latvia
8	Kungliga Tekniska Högskolan	KTH	Sweden
9	Istanbul Avrupa Arastimalari Dernegi	IAAD	Turkey
10	PrecisionLife Ltd.	PREL	UK
11	Yourcode Lab Kft	YLK	Hungary
12	The University of Aberdeen	UNAB	UK

13	Correlate AS	CORR	Norway
14	Web Bay Solutions	WBS	Serbia
15	'Together it's easier' For Women's Health Foundation	TIEF	Hungary
16	The University of Edinburgh	UNED	UK
17	Aalborg University	AAU	Denmark

1.2. Definitions

'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.³

“Foreground” means all the knowledge produced within the collaborative venture or open innovation project during the project’s tenure.⁴

“Access rights” means rights to use results or background under the terms and conditions laid down in the Consortium Agreement.⁵

2. Introduction

The Finding Endometriosis using Machine Learning (FEMaLe) project want to bring the cohesion of state-of-the-art technologies, genetics, and biomarker testing together to personalise the early risk prediction of endometriosis with an aim to ensure individualised intervention, and to build knowledge for prognostic prevention by the identification of subtypes of endometriosis.

This project has the potential for several healthcare innovations and innovative results, and that is why the convergence between public research partners and healthcare industry partners should be defined in a precise IP framework.

Considering this development, the present deliverable is defining and detailing the guidelines for Intellectual Property Rights (IPR) management as pre-described in the FEMaLe Grant Agreement and Consortium Agreement. A procedure is presented covering identification of potential innovations, documentation, tracking and protection of Intellectual Property (IP) derived from the FEMaLe project. This deliverable will define FEMaLe's Innovation Management Plan (IMP) as well as provide the first monitoring report of the project:

³ From the FEMaLe Consortium Agreement.

⁴ From 'The Challenge of Closing Open Innovation', Ove Granstrand and Marcus Holgersson, 2014. DOI: 10.5437/08956308X5705258.

⁵ From the FEMaLe Consortium Agreement.

The IMP will:

- Provide guidelines for the project on valorisation of IP produced within FEMaLe.
- Define a favourable ground for optimal IP development within the project and between partners.

The first monitoring report will encompass:

- The first check on the innovations being developed by FEMaLe’s partners.
- If needed, necessary actions taken to ensure that claimed innovations are being developed.

2.1. Purpose and scope

The FEMaLE project will rely on a Scalable Multi-Omics Platform (SMOP) to convert multi-omics person population datasets into a personalised predictive model.

The goal is to improve intervention along the continuum of care for people with endometriosis. The project will also rely on participatory processes, advanced computer sciences, state-of-the-art technologies, and patient-shared data to deliver:

- A mobile health app for people with endometriosis.
- Three clinical decision support tools for targeted healthcare providers (risk stratification tool for general practitioners, multi-marker signature tool for gynaecologists, and non-invasive diagnostic tool for radiologist).
- Computer vision-based software tools for real time augmented reality guided surgery of endometriosis.

The implementation of these solutions would help to improve life quality of patients and to reduce healthcare costs. From these solutions arose numerous possibilities of exploitation of the underlying technologies and knowledge developed within the time frame of the project. Especially considering the diversity of partners from different scientific backgrounds, exploitation could include, but are not limited to, patents, publications, software, and databases.

Within FEMaLe, the WPs mostly involved in innovation activities are:

Table 1: List of WP associated with innovation action.

WP	Title	Lead
4	OMICS: risk classifier and biological subtypes	UOXF
5	BIG DATA: digital health monitoring and the Lucy App	SWU
6	DIAGNOSIS: surgical phenotyping using machine learning	RTU
7	VISUAL: augmented reality to improve laparoscopic surgery	SURG
8	DIGITAL: self-management program	YLK

3. Innovation Solutions and Related Technology Levels

Before the project, several innovations were already detailed in the project description and new ones were identified since the beginning of the project. Along the FEMaLe project, the developed innovation will gain maturity and their Technical Readiness Level (TRL) will increase.

Table 2: List of WP associated innovation / technology and their corresponding and expected TRL at this time point of the project.

WP	Technology / Innovation	TRL Now	Expected TRL
WP4	2 prototypes of CDS tools: a) the risk stratification tool, and b) the multi-marker signature tool.	2	5
WP5	Lucy app	7	9
WP5	Prototypes of two dietary and lifestyle Lucy app modules.	4	7
WP5	A prototype of a global risk profile.	1	5
WP6	Software implementing a machine learning-based algorithm for the detection and scoring of endometrioses.	3	5
WP7	Software implementing a machine learning-based algorithm for the suggestion of endometriotic resection zone.	2	4
WP8	Implementation of the MY-ENDO program into the Lucy app.	4	6

The TRL scale used for the table above is the one from the Annex G of Horizon 2020 – Work Programme 2014-2015⁶:

- TRL 1 – basic principles observed.
- TRL 2 – technology concept formulated.
- TRL 3 – experimental proof of concept.
- TRL 4 – technology validated in lab.
- TRL 5 – technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies).
- TRL 6 – technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies).
- TRL 7 – system prototype demonstration in operational environment.
- TRL 8 – system complete and qualified.
- TRL 9 – actual system proven in an operational environment (competitive manufacturing in the case of key enabling technologies; or in space).

The strategy is to follow the exploitation of the innovation solutions and check that the indicated TRL's are correct. In case some innovation solutions are resulting from the FEMaLe project, they will also be added to the table in the following reports. The evolution of the TRL for each solution will be monitored and will be reported on the upcoming innovation reporting.

WPI IMPACT: LEAN, AGILE AND RESULT-DRIVEN PRODUCTION APPROACH is all about monitoring and assessing impact in the FEMaLe project. To secure a structured and systematic approach to innovation and intellectual property management, we will embed WP9 Task 9.4 activities into the Impact Solution Design process. For this reason, we will ensure that innovation and intellectual property management is being monitored and tracked as an integrated part of FEMaLe's impact monitoring and assessment system; each WP leader will identify and track KPIs related to innovation and intellectual property management for a 6-month period.

3.1.1. Innovation Management Process

FEMaLe partners will follow these general steps regarding exploitation of the project's results:

- **Identification of the innovation / technology:** IP assets resulting from FEMaLe's associated foreground and that could be exploited by one/several partners internal or external to the consortium.
- **Determination of ownership:** depending on the partners involved in the foreground, ownership and access rights will be discussed and defined between them. If need be, an agreement will be set up between involved partners under the management of this WP.
- **Protection of the foreground:** the involved partners will determine the most appropriate IP protection approach or tools for the foreground.

⁶ https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf

- **Use of foreground:**
 - There will be direct use when the involved partners will industrially or commercially exploit the foreground.
 - There will be indirect use, when involved partners will transfer the foreground to other project partners or third parties, in line with the specific agreement and FEMaLe consortium agreement.
 - Use could also consist in the utilisation of foreground in further research activities for further enhancement of the developed foreground.
- **Dissemination of results:** whenever possible, results will be communicated openly with appropriate means (e.g.: scientific articles or reviews, web site posts, conferences, data open access, etc...) in accordance with the conditions defined in IP agreement and FEMaLe's consortium agreement to ensure confidentiality.

4. Innovation monitoring and exploitation plan

4.1. Key Performance Indicators

Innovation is a key activity with multiple synergies between the 10 work packages and tasks across the FEMaLe project. We will ensure a strong coordination across the consortium regarding innovation development as well as their exploitation during the project and afterward (when foreseeable). The valorisation and dissemination activities are being monitored (see section 4.2).

The Key Performance Indicators (KPIs), which have been set to assess the progress of the FEMaLe innovation efforts are indicated in the proposal. They have been defined and updated in accordance with the project deliverables and are addressing project exploitation respectively.

4.2. Exploitation plan

The exploitation plan will follow the terms of the Grant Agreement and Consortium Agreement ensuring there is an efficient exploitation of project outputs. Each of the WPs involved in innovation activities will have a specific exploitation strategy depending on the produced innovation/ technology. It is important that the dissemination and communication activities of all WPs are listed for the first periodic report at M18, and they will be monitored in the framework of IP rights plan.

5. Conclusions

Task 9.4 will monitor the protection of IPR in terms of GA and CA, and the protection of innovation will be discussed in FEMaLe project meetings to identify the needs of both commercial and public partners.

This task is aimed at creating a favourable environment for respecting IP rights and guaranteeing a logical approach during the project. The IP-related management structure, and workflows will be designed to be able to satisfy IP rights objectives (for instance, to balance the need to protect IP assets, and to facilitate the way to release as many innovative outcomes as possible).