Project Number: *101057390*

Project Acronym: HappyMums

Project title:

Understanding, predicting, and treating depression in pregnancy to improve mothers and offspring mental health outcomes.

D9.2 Exploitation and Business Plan version1

Research and Innovation Action
HORIZON-HLTH-2021-STAYHLTH-01-02

Work Package:	
Due date of deliverable:	30/04/2024
Actual submission date:	30/04/2024
Lead beneficiary:	ABACUS
Contributors:	Maria Bulgheroni (ABACUS), Margherita La Gamba (ABACUS)
Reviewers:	Libera Cavaliere (UMIL), Annamaria Cattaneo (UMIL)

Disclaimer

The content of this deliverable does not reflect the official opinion of the European Union. Responsibility for the information and views expressed herein lies entirely with the author(s).

Version Log

Issue Date	Version	Involved	Comments
06/03/2024	V0.1	Maria Bulgheroni (ABACUS), Margherita La Gamba (ABACUS)	First draft
19/04/2024	V1.0	Maria Bulgheroni (ABACUS), Margherita La Gamba (ABACUS)	Final revision
22/04/2024	V1.1	Libera Cavaliere (UMIL)	Comments
24/04/2024	V1.2	Margherita La Gamba (ABACUS)	Final Draft
26/04/2024	V2.0	Libera Cavaliere (UMIL), Annamaria Cattaneo (UMIL)	Final Revision

Table of Contents

Acronyms

Abbreviation	Full term
AU	Aarhus University
CA	Consortium Agreement
DPO	Data Protection Officer
EMC	Erasmus Medical Center
EPO	European Patent Office
EU	European Union
FI	Finland
FtO	Freedom to Operate
GA	Grant Agreement
IRB	Internal Review Board
IPRs	Intellectual Property Rights
IT	Italy
KER	Key Exploitable Result
KCL	King's College London
OSR	Ospedale San Raffaele
PR	Project Reporting
RIA	Research and Innovation Action
TL	Task Leader
UB	University of Barcelona
UH	University of Helsinki
UMIL	University of Milan
WP	Work Package
WPL	Work package Leader

Acronyms

Executive Summary

This deliverable describes the initial ideas to build the future exploitation of the *HappyMums* project's results. These thoughts have been collected through brainstorming with the entire consortium to address the expected developments in the scientific, clinical and technological areas.

Expected Key Exploitable Results (KERs) have been further defined and related exploitation actions identified.

After some introductory notes in Chapter 1, Chapter 2 is dedicated to the full description of the selected KERs. Indeed, because of the wide spectrum of the project, including some basic research activities as well as technological developments quite close to the market, the growth paths for the KERs widely differ from one another.

Chapter 3 describes the overall exploitation strategy and recaps the criteria applied to identify and describe KERs.

Chapter 4 lists the categories of stakeholders that the project's partners aim to reach to push the exploitation of the results. When possible, some direct contacts have also been already identified.

Chapter 5 addresses the Intellectual Property Rights (IPRs) investigation. An initial analysis to assess the Freedom to Operate (FtO) for the selected KERs has been performed by searching the European Patent Office (EPO) database. No major competitors have been identified so far.

Chapter 6 introduces a slightly revised version of a brainstorming tool to elicit a value proposition description. The porting of these tools to a scientific environment requires some adaptations and open discussions. Results of the exercise have been reported for the KERs currently at a more advanced development level.

Chapter 7 wraps up the main activities carried on so far.

1   Introduction

1.1   Purpose of the Exploitation and Business Plan

This document aims to drive the exploitation-oriented activities of the *HappyMums* project. Given the high basic research content of the project, the results will follow different exploitation paths.

1.2   Users of the plan

This plan is designed for use by all consortium partners. In addition, as per the Grant Agreement, the plan is available to the European Commission.

1.3   Structure of the plan

The Exploitation and Business plan covers the following:

- The project's approach to exploitation, including the envisioned strategy and the activities performed in the first 18 months;
- The project's approach to Intellectual Property (IP), including protection and strategy;
- An evaluation of the potential economic impact of the project;
- Progress to date and future planned actions in the context of exploitation and protection.

2   Key Exploitable Results (KERs)

The main KERs of the *HappyMums* project, preliminarily identified at the start of the project and subsequently refined through meetings with the whole consortium, are described in Table 1.

KER	WP	Specification	Key Users and Beneficiaries	Benefit	Proposed Exploitation Strategy
Novel Biomarkers	WP3 & WP4	Biological markers and signatures in the mother associated with the risk for developing depression during pregnancy (risk and protective factors) or associated with the response to treatment. Biological markers in the exposed offspring associated with the transition toward negative mental outcomes, postnatal factors which can exacerbate or moderate the offspring's negative outcomes	Scientific community, National healthcare systems/ welfare systems/ insurance companies, Pharmaceutical companies, Healthcare professionals	More objective screening, risk detection, diagnosis, and better therapy assessment	Open access Publications; whenever possible, IP protection will be needed for any method developed for diagnostics
Novel Therapeutic Targets and Strategies	WP7	Targets for the development of novel pharmacological or non-pharmacological interventions for depressive-like conditions during pregnancy	Pharmaceutical companies, Scientific community, Technical researchers and technologists, National healthcare systems/ welfare systems/ insurance companies	More effective preventive and personalized strategies or therapies	Open access Publications; whenever possible, IP protection will be needed for any method developed for therapy
Risk Prediction Algorithm/Algorithm to generate a composite personalized score	WP8	An algorithm to generate a composite personalized score integrating different multimodal components (clinical, medical, lifestyle and AI-based, e.g. video analysis) for an early identification of depressive symptoms and for the prediction of the course of the symptomatology	Scientific community, Healthcare professionals, National healthcare systems/ welfare systems/ insurance companies	Patient/population stratification based on different score profiles	Open access Publications

Mobile App for Women	WP5 & WP8	Mobile App integrating passively collected data from smartphone sensors and actively collected data from voluntary activities (i.e., standardized tests and questionnaires, speech recording and text typing exercises)	Women, Healthcare professionals, Scientific community	Enabling data collection and (self-)monitoring of mental health and lifestyle	IP protection
Clinical Dashboard for Healthcare Professionals	WP5 & WP8	A clinical dashboard integrating data coming from the Mobile App and implementing a personalized Clinical Decision Support System (CDSS)	Healthcare professionals, Women, Scientific community	Remote and continuous monitoring of the women, clinical decision support	IP protection
Open Access Research Platform	WP2& WP8	Web-based platform to manage and share selected datasets, tools, protocols, and papers	Scientific community, Healthcare professionals, National healthcare systems/ welfare systems/ insurance companies, Pharmaceutical companies	Enabling exchange of information, tools, ideas, and technologies to support the development of spin-out products and processes from the *HappyMums* project	Open access
Updated Clinical Guidelines and Recommendations in Pregnancy	WP9	Provision of informative and evidence-based reports (e.g. best practices for diagnosis and treatment) to support revision and update of clinical guidelines	Public bodies and regulatory agencies, Healthcare professionals, General public, Women	Improvement of health and social care services and policies	Open access with proactive dissemination

Table 1 - HappyMums Key Exploitable Results (KERs)

3   Exploitation Strategy

The *HappyMums* exploitation strategy is being developed to maximize the use and benefit of the results of the project, with emphasis on long-term sustainability and clear revenue and benefit stream documentation for the stakeholders involved. This includes both commercial and non-commercial exploitation, depending on the nature of the results which may range from research findings to technological tools. The seven KERs, identified at the start of the project, underwent an initial characterization during months 9 to 18 through collaborative efforts by project partners, and will be further refined during dedicated meetings. It is possible to make direct associations between KERs and planned project deliverables, as detailed in Figure 1.
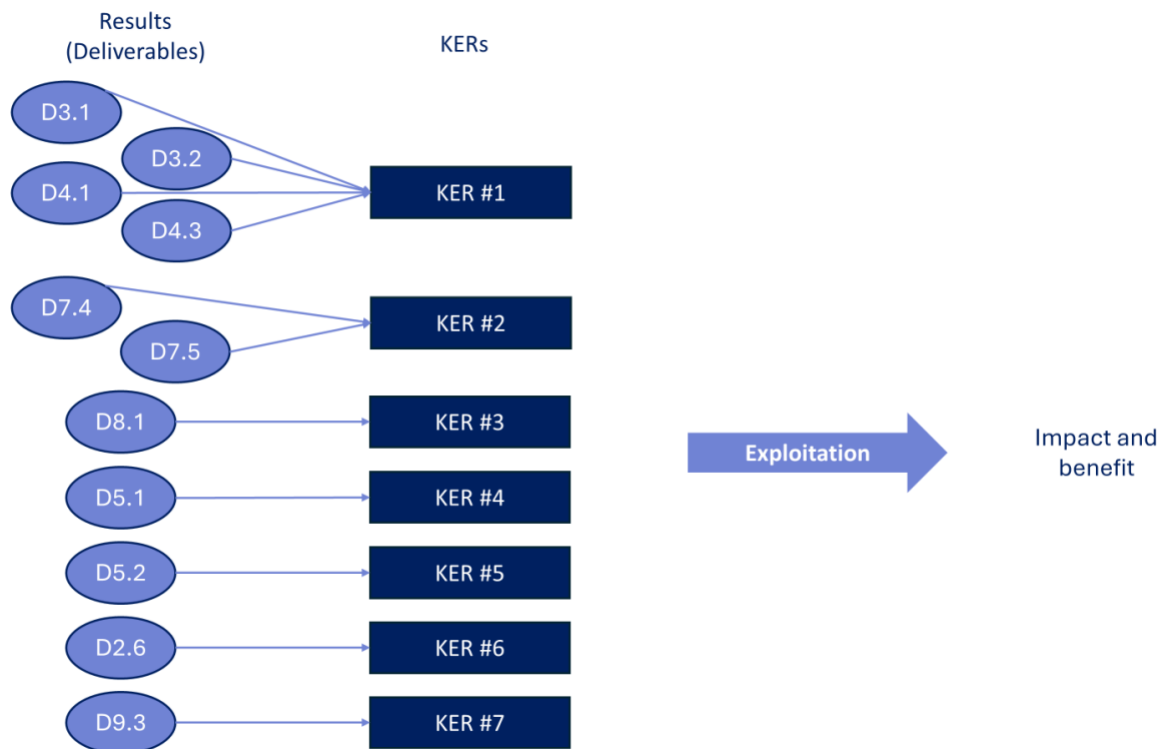

Figure 1 - Associations between KERs and Deliverables

The definition of an exploitation strategy for every identified KER and its successful pursuit will deliver considerable impact from the *HappyMums* project and is, therefore, a very relevant aspect of the project.

The initial criteria that have been applied for the characterization of the specific KERs in the early stages of the project (months 1 to 18) are specified in 2.

Criteria	Description	Rationale
KER specification	A description of the KER in the context of an asset arising from the project. In what form is the KER e.g. software, database, mobile or web application, research findings, or policy recommendation?	Explains what the KER consists of and will inform later criteria, e.g. IP protection.
Involved WPs	Project Work Packages that are mainly involved in the development of the KER.	Keeps track of the research groups targeting the KER development and states the project partners who will be first involved in further characterization work for the KER.
Key users and beneficiaries	A list of actors who will make direct use of the KER or who will indirectly benefit from the KER development and diffusion.	Develops an understanding of the target audience/ customers, in this document referred to as 'stakeholders', for the KER and if worthwhile exploiting.
Benefit	A description of the benefits the KER brings to its key users and beneficiaries and of the specific needs and opportunities the KER addresses.	Develops an understanding of the added value and impact that the KER brings and if worthwhile exploiting.
Proposed exploitation strategy	A description of the very preliminary envisioned plan for IP protection and exploitation.	Critical to understand and further define this aspect from the outset and manage expectations. Ensure the consortium is aware to avoid accidental disclosure.

Table 2 - Current KER characterization criteria

The priority for the next months is to undertake a more detailed characterization exercise for each KER, according to their individual stage of development, and develop an initial strategy for exploitation, which will then be updated and evolve through the project as concrete results are obtained.

4 Stakeholders

HappyMums is expected to raise significant interests across a wide range of stakeholders. Several key stakeholders have been identified and analyzed in order to create tangible benefits and impact from the project's outcomes.

4.1 Stakeholders' identification

The key groups of stakeholders have been identified as follows:

- Women
- Healthcare professionals
- National healthcare systems/welfare systems/insurance companies
- Technical researchers and technologists
- ICT SMEs and industries
- Pharmaceutical companies
- Public bodies and regulatory agencies
- Scientific community
- General public

Once stakeholders have been identified, an introductory Stakeholders Analysis has been conducted in order to assess the different stakeholders based on the level of interest/concern and the level of influence/power they have over the project. Results of such analysis are displayed in Figure 2.
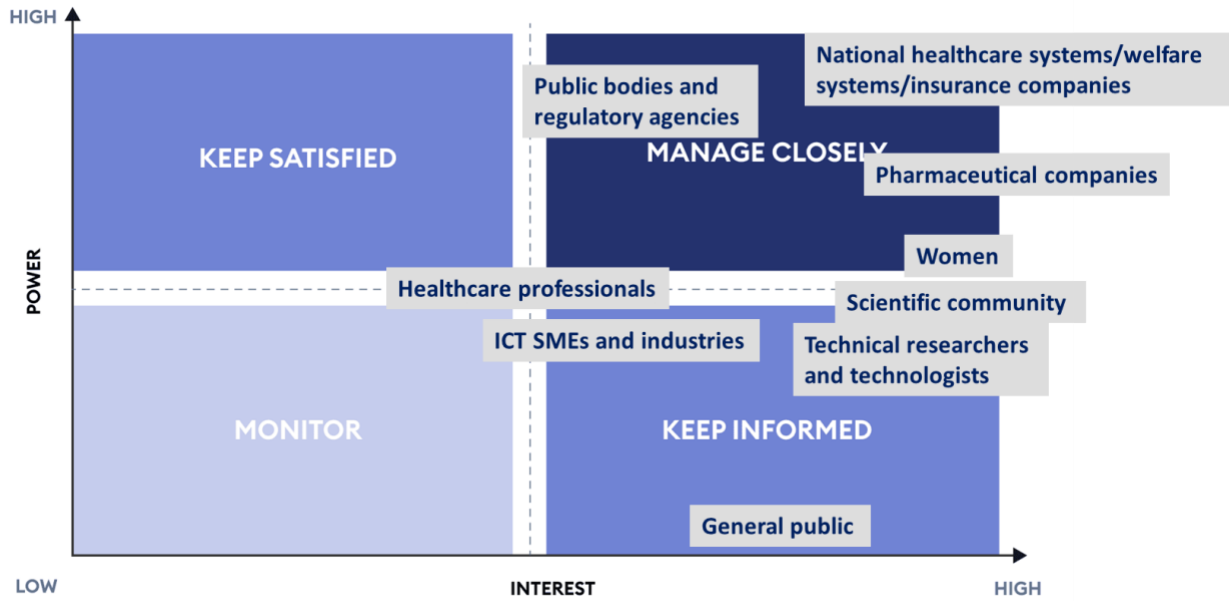
Figure 2 – Stakeholders Analysis: Power-Interest grid

For the main identified stakeholders, interest, influence, needs and expectations in relation to the *HappyMums* project and its outcomes have been defined and are still under investigation:

Stakeholders	Interest	Influence	Needs and Expectations
Women	High - (Self) management of mental health during pregnancy	Medium - Mobile app end-users, beneficiaries of improved mental health outcomes during perinatal period	Mobile app to effectively support (self-)management of mental health during pregnancy
Healthcare professionals	Medium - Screening, prevention, treatment, and monitoring of perinatal mental disorders	Medium - Clinical dashboard end-users, direct contact with women, responsible for perinatal care and support	Clinical tools and guidelines to support screening, prevention, treatment, and monitoring
National healthcare systems/ welfare system /insurance companies	High - Reduction of the impact of perinatal depression	High - Providers of healthcare (perinatal care and mental health services)	Strategies, tools, and guidelines to improve prevention and perinatal mental health care
Technical researchers and technologists	High - Development of new innovative tools for screening,	Medium - Lead the technological research	Knowledge about innovative technologies to

	prevention, treatment, and monitoring of perinatal depression	trend, providers of technology	enhance the tools they design or provide
ICT SMEs and industries	Medium - Deployment of new innovative tools for screening, prevention, treatment, and monitoring of perinatal depression	Medium - Providers of technology	Access to research, expertise and opportunities for product development, integration, or commercialization
Pharmaceutical companies	Medium to High - Development and production of new innovative pharmacological therapeutic interventions for perinatal depression	High - Providers of therapeutic intervention	Novel therapeutic targets for the development of pharmacological interventions
Public bodies and regulatory agencies	High - Reduction of the social and economic impact of perinatal depression	Medium to High - Establish policies and regulations	Scientific evidence and guidelines to base clinical regulations and preventive policies on
Scientific community	High - Progress scientific research on perinatal depression, related biomarkers, and interventions	Medium - Lead the scientific research trend	Novel mechanisms and biomarkers underlying the development of perinatal depression in women and of negative outcomes in the exposed offspring, novel therapeutic targets and interventions
General public	Medium to High - Reduction of the social burden linked to perinatal depression	Low - Diffusion of project findings, tools, and results	Initiatives, guidelines and tools to promote mental health awareness and the adoption of healthier lifestyles and behaviors preventing perinatal depression

Table 1 - Main stakeholders' description

A tentative assignment of potential stakeholders to the *HappyMums* partners that can reach them for engagement activities has been performed, as in Table 2.

	Women	Healthcare professionals	National healthcare systems/ welfare system /insurance companies	Technical researchers and technologists	ICT SMEs and industries	Pharmaceutical companies	Public bodies and regulatory agencies	Scientific community	General public
UMIL	X	X					X	X	X
ERASMUS MC	X	X					X	X	X
OSR	X	X					X	X	X
UB		X		X				X	X
AU								X	X
ABACUS		X		X	X			X	X
UH								X	X
CHARITE	X	X	X					X	X
MARCE	X	X						X	X
CUC	X	X						X	X
UvA								X	X
WU								X	X
COLUMBIA								X	X
SWPS	X	X	X					X	X
UZH								X	X
KCL	X	X	X	X		X		X	X
TOMMY'S		X						X	X

Table 2 - Tentative matching between HappyMums partners and stakeholder groups

Moreover, a list of relevant stakeholder names that the *HappyMums* partners can be able to communicate and connect with has been prepared for every stakeholder group after consulting all partners.

4.2   Women

Women, specifically those who are pregnant or planning to have a baby and are at risk for developing depressive symptoms, are the primary beneficiaries of the project, as they are the end-users of the mobile app and recipients of the mental health support and resources provided.

Pregnant women have a high interest in accessing effective tools for self-monitoring and managing their mental health during the perinatal period. They expect the mobile app to be user-friendly, accessible, inclusive, and capable of providing reliable information and support.

Their needs include access to mental health resources, privacy assurances, and effective self-monitoring tools to promote their well-being.

HappyMums partners MARCE and TOMMY's will lead the way for this target thanks to their already established connetions and channels (i.e comprehensive website, parents and pregnancy campaigns).

A preliminary list of stakeholders within the women group, as identified by *HappyMums* partners, includes:

- Centro PsicheDonna, a public outpatient center within the Macedonio-Melloni Hospital, specialized in the study, prevention and treatment of women psychological diseases and psychiatric disorders.

- Pregnancy and postpartum are the areas of choice.

- Participants from previous KCL studies who agreed to future contact

- Support groups on social networks (e.g., Facebook and Instagram) and chats (e.g., MamaChat)

- Frühe Hilfen

- Familienzelt

- Familie im Zentrum

- Familienplanungszentrum – BALANCE

- Feministisches Frauen Gesundheits Zentrum e.V.

- SWPS Polish NGO dedicated to supporting women who are pregnant and about to give birth

- Centre for Reproductive Mental Health (non-governmental organization led by Sandra Nakić Radoš and CUC team) – via social media and website

- "RODA" Parents in Action (NGO of parents, based in Zagreb)

- European Federation of Associations of Families of People with Mental Illness (EUFAMI) (link with FAMILY consortium)

4.3   Healthcare professionals

This group includes obstetricians, gynecologists, mental health specialists, and other healthcare providers responsible for delivering perinatal care and support. They are the clinical dashboard end-users and represent the direct contact between scientific and

technological researchers and women. They play a crucial role in screening, preventing, diagnosing, monitoring, and treating perinatal depression, as well as providing ongoing support to pregnant women and new mothers.

Healthcare professionals have a medium interest in technology solutions that enhance their ability to screen and monitor patients' mental health and intervene as needed. They expect the dashboard to be easy to use and to provide access to patient data, comprehensive data visualization, and analysis tools to optimize the clinical workflow and improve patient care and outcomes.

HappyMums partners MARCE and TOMMY's already involve professionals from all disciplines including: psychiatrists, psychologists, paediatricians, obstetricians, midwives, nurses, early childhood specialists.

Besides them, some healthcare professional groups that can be reached by the *HappyMums* consortium are:

- Family clinics and Gynbecology Departments within hospitals in Lombardy

- The Obstetric and Gynaecology Department EMC

- Medical staff (e.g. gynaecologists, obstetricians, GPs) at private medical healthcare company LuxMed

- Centre for Reproductive Mental Health

- Croatian Chamber of Midwives

- Croatian Association of Groups for Breastfeeding Support

- European Union of Medical Specialists, Section of Psychiatry (UEMS-Psychiatry)

- Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King's College London

- Psychiatrische Institutsambulanz der Charité

- Psychiatrische Institutsambulanz im Josefshaus

4.4   National healthcare systems/welfare systems/insurance companies

National healthcare systems represent the main providers of healthcare services during the perinatal period through their infrastructures (i.e., hospitals, clinics, …) and operators (i.e., health professionals). They are responsible for providing comprehensive care and support to pregnant women and new mothers.

Welfare systems represent the social services responsible for providing assistance and support to pregnant women, new mothers, and families in need, both at home and within municipalities.

Moreover, private healthcare providers play a significant role in supplementing public healthcare services, either providing specialized care and support for perinatal mental health issues, as in the case of private clinics, or providing coverage and reimbursement for such services, which is the case of insurance companies.

These actors are highly interested in reducing the impact of perinatal depression, both from an economic and social point of view. From the project they expect innovative strategies, technological solutions, and guidelines to promote mental well-being during pregnancy and support prevention, screening, treatment, and monitoring of perinatal depression, thus enhancing service quality and improving patient outcomes while reducing costs and burden on healthcare and welfare services.

Stakeholders within this group include:

- private medical healthcare company LuxMed
- senior decision makers in the NHS such as Dr. Trudi Seneviratne
- Kassenärztliche Vereinigung Berlin
- Sozialpsychiatrischer Dienst Berlin

4.5   Technical researchers and technologists

This group includes developers and providers of technology solutions, including mobile apps, data analytics platforms, and digital health tools, with a specific focus on those designed to support perinatal mental health monitoring and management.

They are highly interested in creating innovative solutions that support prevention, remote monitoring, and intervention relative to perinatal mental health issues, improve access to mental health resources, and enhance patient and carer engagement and outcomes. Their needs and expectations include opportunities for collaboration and knowledge about innovative technologies that could be employed or further developed to enhance the tools they design or provide, mainly linked to healthcare technological innovation.

A list of stakeholders that can be reached by consortium members is:

- Politecnico di Milano

- Università di Padova

- Università Politecnica delle Marche

- École Polytechnique Fédérale de Lausanne (EPFL)

- University of Manchester

- University College Dublin

4.6 ICT SMEs and industries

This stakeholder group includes small and medium-sized companies, larger corporations, and industry associations relevant to technology provision.

They have a medium interest in developing and deploying technological solutions, such as mobile apps, webapps, and digital platforms, that support perinatal mental health monitoring and management. They may also be interested in enlarging the applicability of such solutions to various and heterogeneous environments, thus expanding their market reach. The main expectations of ICT SMEs and industries are to access research, expertise, and opportunities for new product development, integration, or commercialization or for the application of existing products to new fields, in order to respond to unmet market needs.

Potentially interested SMEs and industries project partners are in contact with include:

- PAL Robotics

- MADE Competence Center

- Confindustria Dispositivi Medici

- Comftech

4.7 Pharmaceutical companies

These companies are involved in the development, manufacturing, and provision of pharmaceutical products, including medications and treatments for perinatal depression.

Pharmaceutical companies have a medium interest in collaborating on research and developing and producing new innovative therapeutic interventions for perinatal depression, with the aim of bringing new treatments to market and addressing unmet medical needs. Their needs and expectations consist of novel therapeutic targets for the development of novel pharmacological interventions.

Preliminary list of potentially interested pharmaceutical companies:

- Pharmaceutical companies working on Brexanolone

4.8 Public bodies and regulatory agencies

These entities include government departments, public health agencies, and regulatory bodies responsible for establishing policies, regulations, and guidelines related to perinatal mental health.

Public bodies and regulatory agencies have a high interest in reducing the social and economic impact of perinatal depression by implementing policies and regulations aimed at improving prevention, screening, and treatment efforts. Their needs and expectations correspond to scientific evidence, evidence-based practices, and guidelines to inform clinical regulations and preventive policies.

Preliminary examples of potentially interested public bodies are:

- Rotterdam Municipality
- Regione Lombardia
- Comune di Milano

4.9 Scientific community

This group comprises basic and clinical researchers, as well as scholars and professionals, involved in scientific and academic endeavors related to perinatal depression and mental health. They contribute to the project by conducting research, publishing findings, advancing knowledge in the field, and, most importantly, leading the scientific research trend.

The scientific community is highly interested in contributing to and progressing research on perinatal depression, related biomarkers, and interventions. They expect opportunities for collaboration and access to research data about novel mechanisms and biomarkers underlying the development of perinatal depression in women and of negative outcomes in the exposed offspring, and novel therapeutic targets and interventions.

Preliminary list of scientific community stakeholders as identified by consortium partners are:

- European College of Neuropsychopharmacology (ECNP) – A. Cattaneo (UMIL), the *Happymums* coordinator, has founded and is leading an ECNP Thematic Working Group on Perinatal Psychiatry and many other partners are members.

- International Association for Psychoneuroendocrinology (ISPNE)- C. Pariante (KCL) is the past president and many partners are members

- American Society of Human Genetics (ASHG- J. Lahti (UH) is member

- European Society of Human Genetics (ESHG)- J. Lahti (UH) is member

- Society for Biological Psychiatry (SOBP)- R. Grassi-Oliveira (AU) is part of the Program Committee and A. Cattaneo (UMIL) of the Advancing Women in Leadership Committee and many partners are members

- Society for Reproductive and Infant Psychology (SRIP) – Sandra Nakić Radoš (CUC) is a member of the SRIP Committee and co-editor in the SRIP official journal *Journal of Reproductive and Infant Psychology*

- COST Action *Maternal Perinatal Stress and Adverse Outcomes in the Offspring: Maximising Infants' Development* (TREASURE) (2023–2027) – S. Nakić Radoš (CUC) is a Management Committee member, M. Žutić (CUC) is a Gender-Balance and Young Researchers Coordinator

- American College of Neuropsychopharmacology (ACNP)- C. Anaker (COLUMBIA) is associate member and other partners are members

- International Society for Developmental Psychobiology- C. Monk (COLUMBIA) is member

- Society for Research in Child Development International- C. Monk (COLUMBIA) is member

- Academy of Behavioral Medicine Research (ABMR)- C. Buss and S. Entringer (CHARITÉ) are members

- Collegium Internationale Neuro-Psychopharmacologicum- many partners are members

- Society for Neuroscience (SfN)- many partners are members

- International Society for Neuroimaging in Psychiatry (ISNIP)- F. Benedetti (OSR) is Secretary

- Pediatric Academic Societies (PAS)- K. Raikkonnen is member

- European Brain and Behaviour Society (EBBS)- A. Korosi is member

- The Medical Image Computing and Computer Assisted Intervention Society (MICCAI), where K. Lekadir (UB) is General Chair 2024

- European Molecular Biology Organization (EMBO)- I. Mansuy (UZH) is member.

4.10 General public

The general public includes individuals, families, and communities affected by perinatal depression, as well as those with an interest in maternal and child health. They are stakeholders in the project as beneficiaries of improved mental health services and increased awareness and support for perinatal mental health issues. They represent the most important way for the diffusion of project findings, tools, and results also outside the group of people considered for the design of the system, in this way increasing the expected impacts of the project in different application areas.

The general public is interested in reducing the social burden linked to perinatal depression through access to reliable information and resources, reduced stigma surrounding mental illness, and improved access to mental health care services. They expect initiatives that promote mental health awareness, reduce barriers to care, and enhance support for individuals and families affected by perinatal depression.

Preliminary list of stakeholders that can be referred to as general public:

- Montessori school in Rotterdam

- European Federation of Associations of Families of People with Mental Illness (EUFAMI) (link with FAMILY consortium)

- Global Alliance of Mental Illness Advocacy Networks Europe (GAMIAN)

- Journal club ("psychotherapy in science")

- Centre for Reproductive Mental Health - non-governmental organization led by Sandra Nakić Radoš and CUC team

- Itaca

- BGScienza

- Online magazine 'InSPIre the Mind'

- Stiftung Hilfe für die Familie

- Familienportal des Bundes

5 Intellectual Property (IP) Rights and Strategy

The *HappyMums* project results will be disseminated as swiftly as possible, always in a way that is compatible with the protection of the intellectual property rights (IPRs), confidentiality obligations, and legitimate interests of the owners. IP within *HappyMums* shall be governed by the rules outlined in the Grant Agreement (GA) and the Consortium Agreement (CA).

5.1   Background Intellectual Property

Any result generated before the effective starting date of the *HappyMums* project (Background) will remain with the respective partner bringing such background to the project. After conducting a comprehensive search in the European Patent Office (EPO) database, no patents directly relevant to the topics and technologies being addressed by the HappuMums project were found. The search encompassed keywords and phrases related to perinatal mental health biomarkers, monitoring and associated mobile applications, web applications, and other technologies. The absence of patents in these areas indicates a potential opportunity for our project to innovate and develop novel solutions without significant concerns regarding existing patent rights. However, it is important to note that while no patents were identified through this search, there may still be relevant patents or patent applications in other jurisdictions or databases that were not covered in our investigation. Therefore, ongoing monitoring of the patent landscape and periodic searches will be further detailed as the project progresses.

5.2   Foreground Intellectual Property

All results generated by individual partners during and within the scope of the project, whether they qualify for IPR protection, will vest in the partner that generated them. Jointly generated results will be jointly owned by the partners who contributed to their development. In case of a new IP (Foreground) being generated, an exploitation agreement will be set up to ensure that the new IP is managed and protected adequately and correctly. In case no party takes ownership and valuable Foreground is unprotected, the European Commission will be informed (at least 45 days prior to any dissemination act) and may assume the ownership.

5.3   Intellectual Property Strategy

In order to ensure the effective exploitation of the results of the *HappyMums* project, all partners have the responsibility to share with the whole consortium the results they may obtain during the project. This allows all consortium members to be updated about potential interesting findings to disseminate and/or exploit. Before making any specific results public, all partners need to be notified about planned contents and timing of the dissemination and

needed protections (patents) need to be secured. Partners will have the possibility to object to (elements of) the intended dissemination in a reasonable timeframe.

The project Intellectual Property strategy emphasizes collaboration and openness while ensuring the protection of valuable IP assets. The project Consortium Agreement (CA) sets a legal framework for the project and outlining the terms and conditions for collaboration and IP management. When CA provisions prove not sufficient, the Project Coordinator will collaborate with the IPR departments of the partners involved, building on the experience of previous projects. In addition, specific advice from SESAB members will be sought. If needed, we will consult the IPR Helpdesk of the European Commission.

6   Potential economic impact

6.1   Value proposition

This chapter presents an initial analysis of the *HappyMums* project value proposition, i.e., the unique promise of value that the project offers to its stakeholders. Since the range of potential stakeholders (commonly referred to as 'customers' within standard value proposition templates) that were identified for the project is extremely wide, it must be noted that the value proposition may vary for some of them.
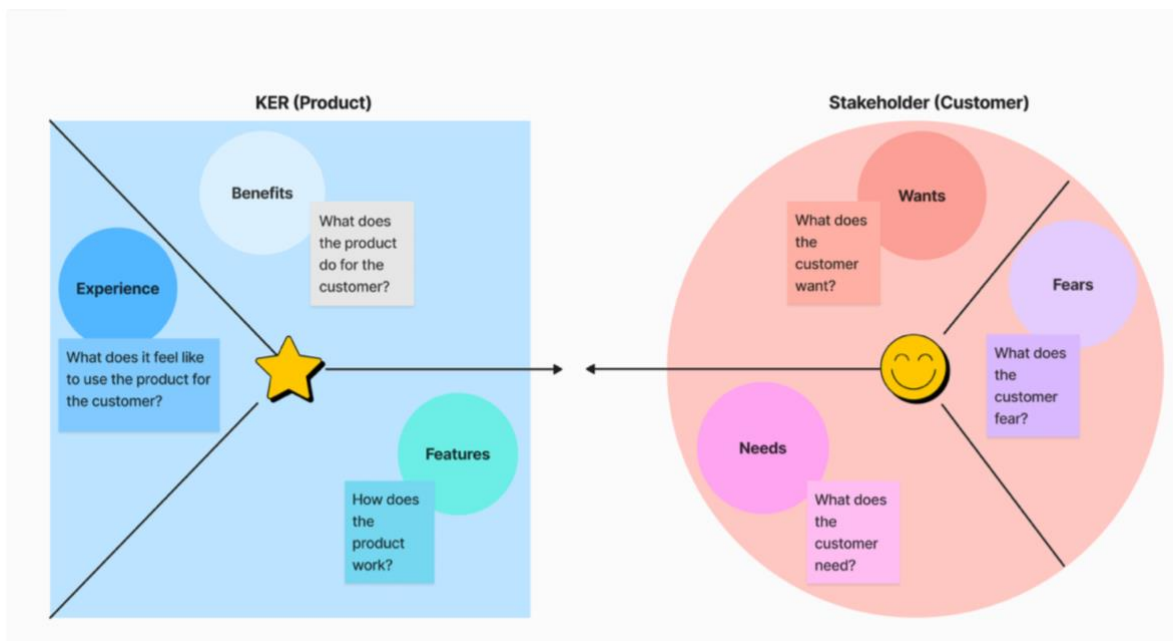

Figure 3 - Value proposition canvas

Figure 3 displays the standardized canvas on which we based the definition of an initial value proposition. This is a strategic tool originally used by businesses and organizations to better understand their customers' needs and preferences and to ensure to effectively meet those needs.

The basic workflow idea consisted of applying such canvas to every identified KER and every potential stakeholder/customer of the *HappyMums* system, therefore it was possible to identify several different value propositions.

The following figures represent the initial value propositions which were identified through co-creation with project partners for different KERs: KER #4 Mobile App for Women, KER #5 Clinical Dashboard for Healthcare Professionals and KER #3 Risk Prediction Algorithm, respectively.
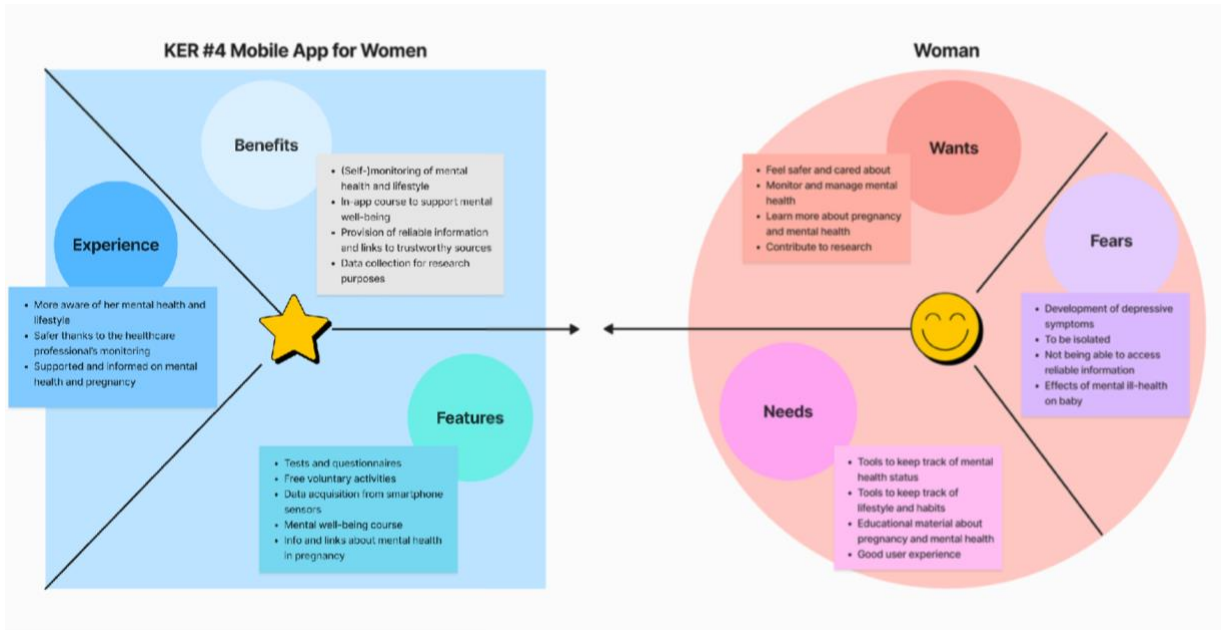
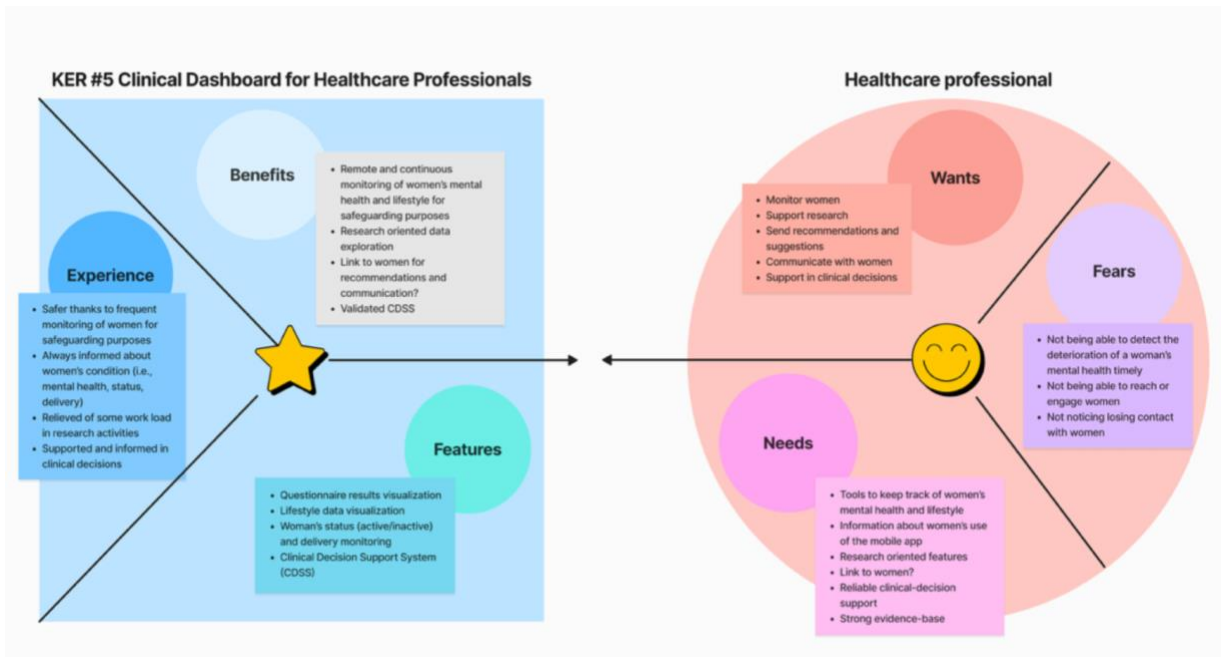*Figure 4 - Value proposition for KER #4 Mobile App for Women*

Figure 5 - Value proposition for KER #5 Clinical Dashboard for Healthcare Professionals
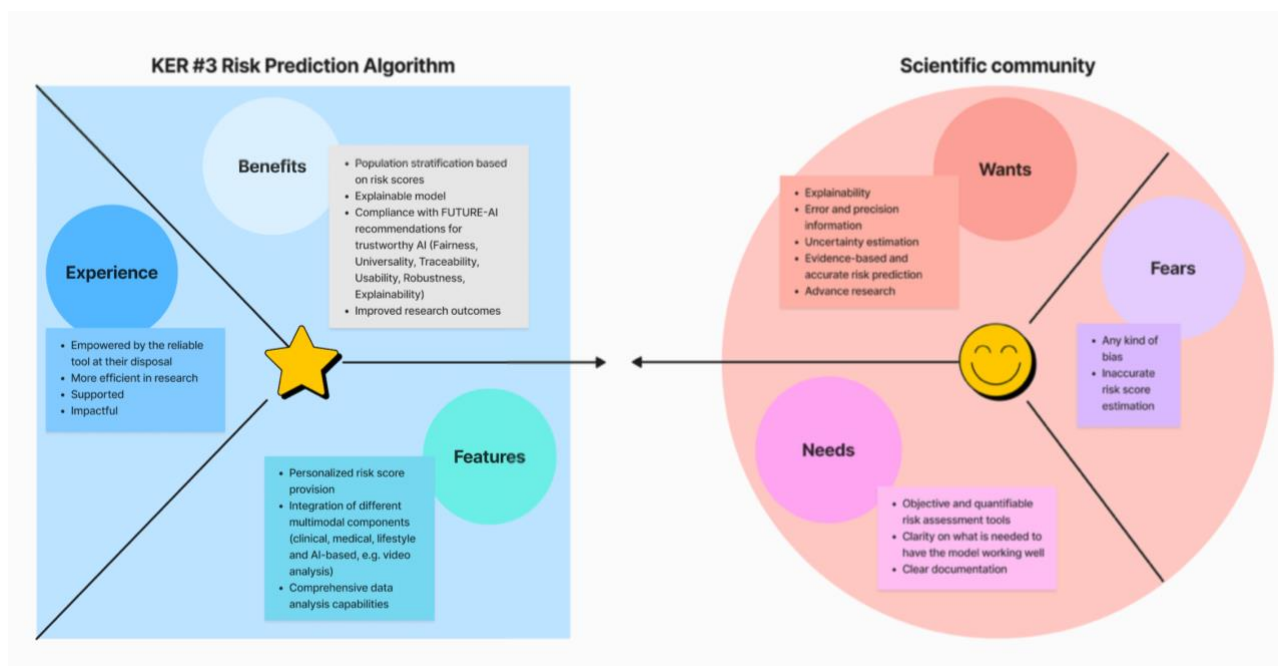
Figure 6 - Value proposition for KER #3 Risk Prediction Algorithm

6.2 Initial market analysis

6.2.1 Current situation and opportunities

Perinatal mental health, referring to the period between conception and the end of the first postnatal year, is a critical aspect of maternal and infant well-being. It encompasses a range of conditions, including prenatal depression, postpartum depression, anxiety disorders, and postpartum psychosis.

According to the World Health Organization (WHO), worldwide an estimated 10% of pregnant women and 13% of women who have just given birth experience a mental disorder, primarily depression[1]. If we consider that 3.88 million babies were born in the European Union in 2022[2], more than 500.000 women likely experienced depression in the perinatal period. In developing countries, these values are even higher, i.e. 15.6% of women experience a mental disorder during pregnancy and 19.8% after childbirth. Globally, maternal mental health issues are, therefore, considered a major public health challenge. In fact, the worsening of a woman's mental health during the perinatal period may affect her well-being, as well as that

---

[1] World Health Organization. Maternal mental health. Retrieved from https://www.who.int/teams/mental-health-and-substance-use/promotion-prevention/maternal-mental-health

[2] Eurostat. Fertility Statistics 2022. Retrieved from https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Fertility_statistics

of her infant and family. Poor mental health is associated with higher risks of obstetric complications (e.g., pre-eclampsia, hemorrhage, premature delivery, and stillbirth) and suicide[3], but also poor birth outcomes, such as low infant weight, and greater risks for physical illnesses and emotional and behavioral difficulties in the offspring[4]. Several studies demonstrated a 70% increase in the odds of adolescent and adult depression among offspring of mothers who suffered from perinatal depression[5], with about 40-50% of offspring who are exposed to maternal depression in pregnancy already developing negative mental outcomes during childhood or adolescence.

Considering the impact these issues have on public health, the market for perinatal mental health services and solutions is a relevant component of the broader mental health sector. It is currently growing and is expected to continue growing as societal awareness of perinatal mental health issues increases, leading to greater demand for screening, diagnosis, and treatment services.

Key market trends in the field include:

- Focus on early detection and intervention: There is a growing emphasis on early detection and intervention for perinatal mental health issues to prevent adverse outcomes for both mothers and infants. Healthcare providers are increasingly integrating mental health screening into routine prenatal and postpartum care[6].

- Telehealth and digital solutions: The COVID-19 pandemic has accelerated the adoption of telehealth and digital solutions for perinatal mental health care. Telepsychiatry, online support groups, and mobile applications are becoming more prevalent, offering convenient and accessible resources for individuals seeking support[7].

- Holistic approach to care: There is a shift towards a holistic approach to perinatal mental health care, recognizing the interconnectedness of physical, emotional, and

---

[3]Howard LM, Khalifeh H. Perinatal mental health: A review of progress and challenges. World Psychiatry. 2020;19(3):313–27.

[4] Field T, Diego M, Hernandez-Reif M. Prenatal depression effects and interventions: A review. Infant Behav Dev. 2010;33(4):409–18.

[5] Tirumalaraju V, Suchting R, Evans J, et al. Risk of Depression in the Adolescent and Adult Offspring of Mothers With Perinatal Depression: A Systematic Review and Meta-analysis. JAMA Netw Open. 2020;3(6):e208783. Published 2020 Jun 1.

[6] Gavin, N. I., Gaynes, B. N., Lohr, K. N., Meltzer-Brody, S., Gartlehner, G., & Swinson, T. (2020). Perinatal depression: a systematic review of prevalence and incidence. Obstetrics & Gynecology, 106(5), 1071-1083.

[7] Choi, K. R., Records, K., Low, L. K., Alhusen, J. L., Kenner, C., & Bloch, J. R. (2021). Promotion of Maternal Perinatal Health: A Mixed-Methods Study on the Perspectives of Mothers and Healthcare Providers. Journal of Perinatal & Neonatal Nursing, 35(2), 97-106.

social factors. Integrated care models that address both mental health and maternal health outcomes are gaining traction[8].

- Demand for Evidence-Based Interventions: There is increasing demand for evidence-based interventions and therapies for perinatal mental health issues. Healthcare providers and policymakers are prioritizing interventions with demonstrated efficacy and safety profiles[9].

Together with emerging trends, however, this field of the mental health market faces several challenges that need to be addressed. Some of the most relevant ones are:

- Stigma and barriers to care: Stigma surrounding mental health issues, particularly during pregnancy and the postpartum period, remains a significant barrier to seeking care. Many individuals may hesitate to disclose their symptoms or seek treatment due to fear of judgment or discrimination[10].

- Access disparities: Disparities in access to perinatal mental health care persist, particularly among underserved populations such as low-income individuals, minorities, and rural communities. Limited access to mental health providers, lack of insurance coverage, and social determinants of health contribute to these disparities[11].

- Workforce shortages: Shortages of mental health providers trained in perinatal mental health care pose a challenge to meeting the growing demand for services and providing comprehensive and timely support to women in need. Efforts to expand training programs and increase the number of perinatal mental health specialists are underway but may take time to address[12].

---

[8] Goodman, J. H., Guarino, A., Chenausky, K., Klein, L., Prager, J., Petersen, R., & Forget, A. (2016). CALM Pregnancy: results of a pilot study of mindfulness-based cognitive therapy for perinatal anxiety. Archives of Women's Mental Health, 19(2), 373-381.

[9] Molyneaux, E., Howard, L. M., McGeown, H. R., Karia, A. M., Trevillion, K., & Antepartum, A. (2018). Antidepressant treatment for postnatal depression. Cochrane Database of Systematic Reviews, (8).

[10] Sword, W., Busser, D., Ganann, R., McMillan, T., Swinton, M., & Women's Health Office, M. O. H. (2018). Women's care-seeking experiences after referral for postpartum depression. Qualitative Health Research, 18(9), 1161-1173.

[11] Satcher, D., Chester, F. M., Conlon, C. M., Davis, D. M., & Travis, E. L. (2019). A policy framework for public health uses of electronic health data. Public Health Reports, 133(4), 429-434.

[12] Byatt, N., Biebel, K., Friedman, L., Debordes-Jackson, G., Ziedonis, D. (2018). Women's perspectives on postpartum depression screening in pediatric settings: a preliminary study. Archives of Women's Mental Health, 21(3), 365-375.

While progress has been made in recognizing the importance of perinatal mental health and integrating support services into maternal healthcare programs in various European countries, collaborative efforts between healthcare providers, researchers, policymakers, and advocacy groups are essential for addressing gaps in perinatal mental health care and promoting awareness and access to services and opportunities exist for innovative solutions that can help address these challenges and improve outcomes for individuals, as well as society.

6.2.2   Status for every KER

KER	Current status of development
#1 Novel biomarkers	This KER represents one of the key pillars of the project aimed at investigating the risk of developing depression during pregnancy. Together with the ones relative to mothers, also biological markers describing potential negative outcomes in the exposed offspring will be investigated. These results will be available at the very end of the project and their characterization still needs time.
#2 Novel Therapeutic Targets and Strategies	This KER is strictly correlated to the previous one and shares the same paths of development. Indication for therapies and care paths will be consolidated later on in the project's life.
#3 Risk Prediction Algorithm/Algorithm to generate a composite personalized score	The next path for this KER is clearer than the previous two. The harmonization of data coming from the different historical cohorts, as well as the integration of the new data collected during the *HappyMums* clinical trial, is already on the way and the expected result is quite well identified in terms of an AI model able to compute scores associated to the risk of developing depression in pregnancy.
#4 Mobile App for Women	The first version of the mobile app to collect data during pregnancy is already available to the clinical centers and will be employed in the clinical trial in the next months.
#5 Clinical Dashboard for Healthcare Professionals	In parallel to the mobile app for women, a dashboard devoted to clinical and research personnel has been developed to allow monitoring of the trial.
#6 Open Access Research Platform	This platform will be developed in the next phases of the project to collect the main results of the research and make them available to the public within the constraints set by GDPR.
#7 Updated Clinical Guidelines and Recommendations in Pregnancy	Guidelines and recommendations will be the last result developed by the project and will summarize the results of the previous KERs to contribute to the advancement of care in the area.

Table 3 - Current status of development for the identified KERs

7   Progress to Date

Table 4 below displays the progress to date within WP9, Task 9.5 Exploitation and Business Planning. The task focuses on planning and implementing exploitation activities for the *HappyMums* project to maximize exploitation outcomes while minimizing exploitation risks.

Activity	Impact/Outputs
Exploitation Introduction	An introductory presentation on planned exploitation activities was given. During the session, an orientation was provided to project partners on the exploitation process and two meetings were scheduled to start discussing the topic.
Identification of Key Exploitable Results (KERs) survey	A survey was shared with *HappyMums* consortium partners in order to identify and understand the potential Key Exploitable Results (KERs) of the project linked to each partner's work.
Exploitation Meeting #1	An online meeting was held to finalize the Key Exploitable Results (KERs) and the stakeholder groups for the project that were previously identified based on the DoA and the answers provided to the survey. During the meeting, different working groups for the specific KERs were set up for future meetings and partners were assigned to each group after voluntary consent.
Exploitation Meeting #2	An online meeting was held to perform the assignment of stakeholder groups to project partners for exploitation and dissemination activities and to define some initial value propositions. *HappyMums* project partners were able to successfully cover all envisioned stakeholder groups and four? Initial value propositions were defined and detailed.

Table 4 - Summary of performed Exploitation activities

The Identification of KERs survey was created on Google form and shared with all project partners by email. The survey is reported in Annexes 1 – Survey: Identification of Key Exploitable Results (KERs) for the *HappyMums* project.

During Exploitation Meeting #1 and #2, after recognizing the need for a versatile platform that would enable efficient brainstorming, visualization, and collaboration, we decided to employ FigJam, an online collaborative whiteboarding tool. The use of the online board brought various advantages, including:

- Real-time collaboration: FigJam facilitated seamless collaboration among various partners, regardless of geographical locations, fostering a dynamic exchange of ideas and perspectives.

- Visual representation: The visual nature of FigJam allowed us to conceptualize complex concepts, relationships, and strategies, enhancing comprehension and alignment among partners.

- Iterative refinement: The flexibility of FigJam enabled us to iteratively refine our ideas, swiftly adapting to evolving project requirements and partner feedback.

- Accessibility and documentation: FigJam's cloud-based platform ensured accessibility to project artifacts beyond the duration of the meetings, serving as a centralized repository for documentation and reference.

FigJam boards resulting from these meetings are displayed in Annexes 2 – Exploitation Meetings: FigJam boards.

8 Conclusions

This document sets the framework for explotoiting *HappyMums* results to targeted stakeholders. It is a live document that will be updated periodically during the project, led by ABACUS but in constant collaboration with all consortium partners. A new updated version is expected at the end of the project (M48) where the results of the project will be fully developed and available.

Annexes 1 – Survey: Identification of Key Exploitable Results (KERs) for the *HappyMums* project

Identification of Key Exploitable Results (KERs) for the HappyMums project

The following questions are thought to better understand the potential exploitable results of the project for each HappyMums partner. Exploitable results are not only results that are expected to reach the market, but also results that are expected to contribute to new phases and activities within the scientific research community itself.

1. What is your institution?

    _____

    1. **Introduction to specific research area**

    2. **Research area overview**: Can you describe the specific area of the project you are responsible for?

        _____
        _____
        _____
        _____
        _____

    2. **Initial findings and objectives**

    3. **Overview of your research area**: What are the initial objectives and expected outcomes for your specific area within the project?

        _____
        _____
        _____
        _____
        _____

    3. **Potential impact and applications**

4. **Scientific potential**: Based on your findings so far, what scientific questions or areas do you think your research could impact significantly?

---

5. **Potential applications and implications**: What are the potential scientific applications or broader implications of your research findings?

---

4. Intellectual contributions and future directions

6. **Intellectual Property and publications**: Are your findings leading to any publications, patents, or other forms of intellectual contributions?

---

7. **Future scientific directions**: What are the next steps in your research, and how do you plan to build on your current findings?

---

8. **Long-term goals**: How do you envision the long-term impact and sustainability of your area's contributions to the project and the broader field?

_____

_____

_____

_____

_____

9. **Early commercial potential**: Do you see any early indications of commercial potential for your research outcomes?

_____

_____

_____

_____

_____

Questi contenuti non sono creati né avallati da Google.

Google Moduli

Annexes 2 – Exploitation Meetings: FigJam boards

Exploitation Meeting #1

Key Exploitable Results (KERs)

KERs	WPs	Specification	Key users and Beneficiaries	Benefit	Proposed Exploitation Strategy
#1 Novel Biomarkers	WP3 & WP4	Biological markers and signatures in the mother associated with the risk for developing depression during pregnancy (risk and protective factors) or associated with the response to treatment. Biological markers in the exposed offspring associated with the transition toward negative mental outcomes, postnatal factors which can exacerbate or moderate the offspring negative outcomes	• Scientific community • National healthcare systems/ welfare systems/insurance companies • Pharmaceutical companies • Healthcare professionals	More objective screening, risk detection, diagnosis and better therapy assessment	Publications are open access whenever possible, IP protection will be needed for any method developed for diagnostics
#2 Novel Therapeutic Targets and Strategies	WP7	Targets for the development of novel pharmacological or non-pharmacological interventions for depressive-like conditions during pregnancy	• Pharmaceutical companies • Scientific community • Technical researchers and technologists • National healthcare systems/ welfare systems/insurance companies	More effective preventive and personalized strategies or therapies	Open access? IP protection?
#3 Risk Prediction Algorithm/Algorithm to generate a composite personalized score	WP8	An algorithm to generate a composite personalized score integrating different multimodal components (clinical, medical, lifestyle and AI-based, e.g. video analysis) for an early identification of depressive symptoms and for the prediction of the course of the symptomatology	• Scientific community • Healthcare professionals • National healthcare systems/ welfare systems/insurance companies	Patient/population stratification based on different score profiles	Open access?
#4 Mobile App for Women	WP5 & WP8	Mobile App integrating passively collected data from smartphone sensors and actively collected data from voluntary activities (i.e., standardized tests and questionnaires, speech recording and text typing exercises)	• Women • Healthcare professionals • Scientific community	Enabling data collection and (self-)monitoring of mental health and lifestyle	IP protection
#5 Clinical Dashboard for Healthcare Professionals	WP5 & WP8	A clinical dashboard integrating data coming from the Mobile App and implementing a personalized Clinical Decision Support System (CDSS)	• Healthcare professionals • Women • Scientific community	Remote and continuous monitoring of the women, clinical decision support	IP protection
#6 Open Access Research Platform	WP8	Web-based platform to manage and share selected datasets, tools, protocols and papers	• Scientific community • Healthcare professionals • National healthcare systems/ welfare systems/insurance companies • Pharmaceutical companies	Enabling exchange of information, tools, ideas and technologies to support the development of spin-out products and processes from the HappyMums project	Open access
#7 Updated Clinical Guidelines and Recommendations in Pregnancy	WP9	Provision of informative and evidence-based reports (e.g. best practices for diagnosis and treatment) to support revision and update of clinical guidelines	• Public bodies and regulatory agencies • Healthcare professionals • General public • Women	Improvement of health and social care services and policies	Open access with proactive dissemination

Exploitation Meeting #2

Stakeholders

- Women
- Healthcare professionals
- National healthcare systems/welfare systems/insurance companies
- Technical researchers and technologists
- ICT SMEs and industries
- Pharmaceutical companies
- Public bodies and regulatory agencies
- Scientific community
- General public

Matching between stakeholders and partners

	Women	Healthcare professionals	National healthcare systems/ welfare system /insurance companies	Technical researchers and technologists	ICT SMEs and industries	Pharmaceutical companies	Public bodies and regulatory agencies	Scientific community	General public
UMIL	Yellow	Yellow						Yellow	Yellow
ERASMUS MC	Green	Green					Green	Green	Green
OSR	Green	Green					Green	Green	Green
UB		Green		Green				Green	Green
AU							Yellow	Yellow	Yellow
ABACUS		Green		Green	Green			Green	Green
UH	Yellow	Yellow	Yellow					Yellow	Yellow
CHARITE	Green	Green	Green					Green	Green
MARCE	Yellow	Yellow	Yellow				Yellow	Yellow	Yellow
CUC	Green	Green						Green	Green
UvA								Green	Green
WU								Green	Green
COLUMBIA								Green	Green
SWPS	Green	Green	Green					Green	Green
UZH						Yellow		Green	Green
KCL	Green	Green	Green			Green		Green	Green
TOMMY'S	Green	Green						Green	Green