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Abbreviations	
AI	Artificial Intelligence
B2B	Business To Business
B2C	Business to Consumer
CA	Consortium Agreement
DSS	Decision Support System
EC	European Commission
EU	European Union
GA	Grant Agreement
GDPR	General Data Protection Regulation
iOS	iPhone Operating System
IP	Intellectual Property
IPR	Intellectual Property Rights
KER	Key Exploitable Result
NGO	Non-Governmental Organisation
SME	Small Medium Sized Enterprise
SN	Specific Needs
WP	Work Package

Table of Contents

Table of Contents.....	5
List of Tables.....	6
List of Figures.....	6
Executive Summary.....	8
Introduction.....	9
Objectives of T8.3 and T8.4.....	9
Link with other WPs.....	9
Structure of deliverable.....	9
Methodological note.....	10
Strategic Context of Exploitation.....	11
Key concepts overview.....	11
SMILE Key Exploitable Results.....	12
Market and Ecosystem Landscape.....	14
Market study.....	14
Key Targeted Customer Segments.....	16
Unmet Customer Needs analysis.....	16
PESTLE analysis.....	17
Intellectual Property and Value Protection.....	24
IP Protection Landscape.....	24
Applicable IP Protection Methods.....	25
SMILE IP Mapping Process.....	26
SMILE's Background IP.....	26
SMILE Exploitation Framework.....	28
Exploitation Strategy Overview.....	28
Exploitation and Innovation Analysis by KER.....	30
KER 1. SMILE Game.....	30
KER 2. Self-Assessment and Monitoring Framework (SAMF).....	33
KER 3. SMILE KM-EP.....	38
KER 4. COPEN APP & KER 13. WebAPP.....	41
KER 6. SMILE eXplainable Decision Support System.....	46
KER 7. Exploitation, branding, and business strategies.....	50

KER 8. SMILE Data Models.....	54
KER 9. SAPL Policy Engine.....	58
KER 10. EU Tracker.....	62
KER 11. Open SMILE Dataset.....	67
KER 14. FHIR server.....	70
74	
KER 15. SMILE API.....	74
77	
KER 16. ESM Sigma.....	77
Dissemination Plan per KER.....	81
Sustainability, Risks, and Next steps.....	82
Transferability and Replication Potential.....	82
Exploitation Risks and Mitigation Measures.....	82
Conclusion.....	84
References.....	85
Annex.....	87
Contact.....	99

List of Tables

.....	12
Tableau 2: SMILE EU-level PESTEL analysis.....	17
Tableau 3: SMILE Background IP.....	26
Tableau 4: SMILE Exploitation Risks and Mitigation strategies.....	82

List of Figures

.....	28
Figure 2: Exploitation Pathways (KER 1: Game).....	32
Figure 3: Exploitation Pathways (KER 2: SAMF).....	37
Figure 4: Exploitation Pathways (KER 3: KM-EP).....	40
Figure 5: Exploitation Pathways (KER 4: COPEN & KER 13: WebApp).....	45
Figure 6: Exploitation Pathways (KER 6: xDSS).....	49
Figure 7: Exploitation Pathways (KER 7: Exploitation, branding, and business strategies).....	53

Figure 8: Exploitation Pathways (KER 8: Data Models).....	57
Figure 9: Exploitation Pathways (KER 9: SAPL).....	61
Figure 10: Exploitation Pathways (KER 10: EUTRACKER).....	66
Figure 11: Exploitation Pathways (KER 11: Open SMILE Datasets).....	69
Figure 12: Exploitation Pathways (KER 14: FHIR).....	73
Figure 13: Exploitation Pathways (KER 5: SMILE API).....	76
Figure 14: Exploitation Pathways (KER 16: ESM Sigma).....	79
Figure 15: SMILE Dissemination Strategy Plan per KER 2.0.....	81

Executive Summary

This deliverable (D8.5) presents the mid-term results of SMILE's exploitation planning for its Key Exploitable Results (KERs). It consolidates the current understanding of the digital mental health ecosystem, provides a PESTLE analysis at the EU level, and integrates initial market segmentation aligned with target user groups, as well as stakeholders' unmet needs and expectations. The deliverable also establishes preliminary IP management guidelines and identifies phased exploitation pathways for each KER.

Framed within Tasks T8.3 "Tailored Business Models" and T8.4 "IPR and Exploitation Strategies," this report reflects SMILE's efforts to translate its digital mental health innovations into real-world, long-term impact. Key contributions include mapping the digital mental health ecosystem and target segments to support evidence-based exploitation strategies, conducting SWOT analyses and assessing the innovation level of each KER, defining structured KER-level exploitation frameworks, and initiating consortium-wide IP governance.

The value added by these results lies in providing a comprehensive exploitation framework, ensuring that SMILE's digital services and tools can be further developed, replicated, and integrated into innovative scientific projects or market-ready solutions. By combining market analysis, IP strategy, and KER-level exploitation planning, this deliverable provides actionable insights for both immediate project progression and longer-term uptake.

Collectively, these outputs ensure that SMILE is on track to achieve its objectives and milestones. They demonstrate progress in testing, validating, and preparing KERs for scientific, commercial, and policy applications. The results of this deliverable support replication and transfer beyond pilot sites, foster EU-wide adoption in mental health promotion, and establish post-project exploitation pathways, including commercial uptake, further research, and integration into other frameworks.

SMILE exploitation is structured through detailed KER-level strategies, including phased roll-out, IP and licensing management, and stakeholder engagement plans. These strategies ensure the KERs' scientific and commercial potential, enhancing sustainability and long-term visibility within the EU digital health ecosystem. While this is an interim framework, it provides a structured basis that will be finalised and validated in the final deliverable (D8.6).

Introduction

This deliverable marks a key step in structuring the operational foundations for the sustainable exploitation of SMILE results. It integrates the current status, preliminary findings, and methodologies to build long-term value around the tools, services, and innovations developed within SMILE. It aims to ensure that SMILE KERs extend their impact beyond the project's lifetime and supports both immediate pathways for valorisation and the mid-term ambition of launching a dedicated spin-off initiative (provisionally titled SMILE DIAG).

This mid-term version clarifies foundational and legal concepts critical for SMILE exploitation and maps the evolving ecosystem, user needs, and stakeholder priorities. It also initiates the design of tool-specific IP and business models and sets the stage for KER-by-KER exploitation plans and sustainability pathways.

Objectives of T8.3 and T8.4

Task 8.3: Tailored Business Models focuses on the design and development of flexible, inclusive, and scalable business models that reflect the diversity of actors involved in SMILE, from educational and mental health institutions to digital platform developers and public bodies. The goal is to adapt business logics and value creation mechanisms to the specific requirements of youth-oriented mental health tools and services.

Task 8.4: IPR and Exploitation Strategies ensures that the project's KERs are protected, their IPs are secured, and the innovations are translated into actionable exploitation routes. This includes mapping IP ownership, proposing suitable protection methods, and designing both partner-specific and joint exploitation paths.

Link with other WPs

While formally situated within WP8, this deliverable is intrinsically part of the broader project ecosystem. It builds upon and feeds into:

- WP2, for user segmentation, stakeholders mapping, needs analysis, requirements on the SMILE results, and benchmarking
- WP4 – WP5 – WP6, for technical developments,
- WP7, for pilot design, implementation, and user feedback loop
- WP1 – WP3, for strategic positioning, ethical compliance, and legal alignment

Structure of deliverable

This deliverable is structured to reflect a multi dimensional approach, balancing conceptual, technical, legal, and economic aspects of business planning. It includes:

- A contextual understanding of SMILE's foundational concepts used throughout the document
- A market and ecosystem landscape analysis, including a targeted market study, needs analysis, customer segmentation, and EU PESTLE assessments
- An early mapping of intellectual property and value protection, outlining protection methods suited to SMILE needs, as well as applicable protection methods per KER

- Initial exploitation strategies including SMILE KERs validation, individual exploitation plans, SWOT analysis, and innovation dimensions
- An outlook towards SMILE exploitation roadmap, including identification of risks and corresponding mitigation strategies, and considerations for transferability and replication
- The first part of the document sets the scene by presenting SMILE's strategic context with the definition and clarification of its key concepts. It also presents the project's key exploitable results, and includes comprehensive market and ecosystem analysis, through PESTLE at EU level, targeted customer segments and their needs assessment.
- The second part introduces the preliminary IP protection strategy of SMILE's assets, detailing current IP landscape, applicable protection mechanisms relevant to the project, and licensing mechanisms tool-by-tool.
- The third part sets out SMILE's exploitation framework and roadmap, exploitation strategies and planning for KERs, along with individual exploitation plans, SWOT assessment, and innovation positioning. It also includes dissemination plan for each KER.
- The fourth part addresses strategic outlooks on both sustainability and replication, including the identification of key exploitation risks and the corresponding mitigation strategies, as well as an early reflection of the transferability and replication potential of SMILE solutions across different contexts.

Methodological note

This document is based on a combination of qualitative and quantitative sources, including:

- Desk research on business models, IPR practices, and sustainability strategies in EU-funded projects
- Strategic insights and user stakeholder analyses from WP2 *“Requirements, Specifications and Engagement of Stakeholders”*, particularly within T2.1 *“Identification of Barriers, Drivers and Requirements”* and T2.2 *“Stakeholders Analysis and Mapping”*
- Internal work within WP8, coordinated by RDIUP (bilateral sessions, WP8 Monthly meetings, partner feedback forms, and surveys)

As a mid-term version, this report presents the main strategic components and frameworks positioning SMILE to responsibly scale its innovations beyond the project lifecycle. It will be completed in D8.6 due at the end of the project.

Strategic Context of Exploitation

Key concepts overview

To ensure clarity and common understanding across stakeholders and readers of this public deliverable, this section introduces several foundational concepts. These are critical for interpreting the methodology, the innovation positioning, and the strategic direction taken by SMILE in its business and exploitation planning.

Results: All results which are generated under the project, whether or not protectable. Such results may include copyright, design or patent rights, trademarks or others. Results belong to the partners who have generated them.¹

Key Exploitable Result (KER): A KER is an identified main interesting result, which has been selected and prioritised due to its high potential to be “exploited”, meaning to make use and derive benefits- downstream the value chain of a product, process, or solution, or act as an important input to policy, further research or education.²

Responsible Healthcare Innovation: Refers to digital health solutions that are inclusive, safe, ethical, and empowering, particularly for vulnerable users. It includes respecting user autonomy, ensuring accessibility, and embedding safeguards for data and well-being.

Gamification in Health: The use of game-like elements (e.g., scores, achievements, progress dashboards ...) to increase engagement, promote healthy behaviours, and sustain user motivation. In SMILE, gamification supports personalised wellbeing journeys.

Foreground IP: Foreground IP refers to intellectual property generated during the project.

Background: Tangible or intangible input (data, knowhow, information) which is held by the project partners prior to their accession to the GA and that is needed to implement the action or exploit its results.

Dissemination: Spreading knowledge to a broader audience (e.g. publications, workshops). Means through which research results are disclosed to the scientific community and more generally to the broader public (e.g., website, conferences, research papers, workshops, publications).³

Communication: Strategic outreach to engage stakeholders and the general public (e.g. website, social media).

Exploitation: Utilisation (direct/indirect) of results in research activities, which are not part of the project, as well as utilisation for further development, creation and commercialisation of a product or service.⁴

¹ European IP Helpdesk. (2022, October 19).

² European IP Helpdesk. (2022). (Bulletin No. 4 – Horizon Europe).

³ European IP Helpdesk. (2022, October 19). (Slide:20).

⁴ European IP Helpdesk. (2022, October 19). (Slide:20).

Market Segmentation and Value Chains: These terms refer to the grouping of target user domains (e.g. schools, hospitals, caregivers), and the mapping of actors who create, deliver, or benefit from value in the digital health ecosystem.

Sustainability of Results: Beyond funding periods, sustainability includes maintaining the availability, usability, and impact of project results, whether through institutional adoption, licensing, commercialisation, or open-source release.

Additionally, as a project working at the intersection of mental health, digital technologies, and youth empowerment, SMILE carries not only a responsibility to comply with regulatory frameworks, but to actively model ethical, rights-based innovation. SMILE's business and exploitation planning, both current and future, remain aligned with the project's legal, ethical, and co-design foundations. This is not just a matter of compliance, but a reflection of the project's core values and long-term trust-building strategy. SMILE operates within the regulatory framework of the GDPR, ensuring data collection and processing is lawful, transparent, and purpose-limited. However, SMILE goes beyond the legal minimum to align with data ethics in practice, especially because the project engages vulnerable populations, including minors and young adults, 10 to 24 years old. Key commitments include:

- Informed consent mechanisms adapted to age and cognitive development level;
- Data minimisation and privacy-by-design implemented at tool level;
- Ensuring data subject rights (e.g. right to be forgotten) are respected even within gamified or longitudinal features;
- Ethical review procedures within the project, involving internal and external boards;
- Future business models will include data governance provisions to maintain ethical integrity post-project.

This alignment ensures that any exploitation of project results, commercial or not, will not contradict the ethical and legal commitments of the project lifecycle. SMILE's legal strategy is not only reactive (compliance-driven), but proactive and integrated into the project's innovation pathway. SMILE ensures that ethical safeguards developed during the project (e.g., moderation, privacy, inclusive language) are carried forward into commercial use cases. Additionally, legal readiness becomes a competitive advantage for sustainability and scale-up, not a barrier to be handled post-hoc.

SMILE Key Exploitable Results

This section provides the final list of SMILE KERs, including the associated WP, KER owner and contributors. The KERs have been identified through the KER Data Collection Template developed and circulated by RDIUP.

Tableau 1: SMILE Key Exploitable Results (KERs)

Nr	WP	KER	Owner	Contributor(s)
KER 1	WP4	SMILE Game	FTK	subcontractor DTT, each SMILE partner testing, designing, or generating content for the game

KER 2	WP4	Self-Assessment and Monitoring Framework (SAMF)	UoM	-
KER 3	WP5	SMILE KM-EP deployment with Knowledge Base	FTK	each SMILE partner curating or generating content for KM-EP
KER 4	WP6	COPEN APP	RDIUP	UoM, HWU
KER 5	WP5	SMILE OKP (Open Knowledge Platform)	FTK	each SMILE partner curating or generating content for the OKP
KER 6	WP5	SMILE eXplainable Decision Support System	NION	RDIUP, UoM, UKH, HWU, UoE
KER 7	WP8	Exploitation, branding, and business strategies	RDIUP	ALL PARTNERS
KER 8	WP4	SMILE Data Models (Common Semantic Data Model for Seamless Integration of Digital Interventions into Research and Clinical Routine)	UoM	HWU, UoE, WIZ, RDIUP,
KER 9	WP5	SAPL Policy Engine	FTK	-
KER 10	WP8	EU Tracker	RDIUP	-
KER 11	WP7	Open SMILE Dataset	UoE	All SMILE evaluation pilot site leads
KER 12	WP7	SMILE Synthetic Data Generator and Dataset	UoM	UKH, IRCCS, UNIBO, CIP, SWPS, INT, HWU, UoE, UoM, NION
KER 13	WP6	Web App	RDIUP	UoE, WIZ
KER 14	WP6	FHIR server	UoM	-
KER 15	WP6	SMILE API	WIZ	RDIUP, UoM
KER 16	WP4	ESM Sigma	UoE	-

Market and Ecosystem Landscape

Market study

Mental health has become a major public health priority in the EU, particularly among children, adolescents, and young people. Suicide remains the second leading cause of death among 15-19 years of age⁵, highlighting the urgency of early intervention and prevention strategies. Beyond mortality, the broader societal and economic burden is substantial, with the annual cost of poor mental health among children and young people in the EU estimated at approximately EUR 50 billion⁶.

At the policy level, mental health is firmly embedded within European and international frameworks. The EU Charter of Fundamental Rights recognises the right of access to preventive healthcare and medical treatment, while the European Pillar of Social Rights emphasises timely access to affordable and quality healthcare services.⁷ In parallel, SMILE goals are aligned with SDG Target 3.4, Noncommunicable diseases and mental health, which aims, by 2030, to reduce premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.⁸

Despite increasing policy attention and funding initiatives, including support for best practices transfer, significant challenges persist. Mental health services across the EU remain fragmented, unevenly distributed, and often insufficiently visible to those in need. Individuals experiencing mental health issues frequently face difficulties in identifying appropriate support channels, highlighting a systemic gap between available services and effective access. The European Commission's report⁹ stresses that people experiencing mental health issues need to know where to ask for help. Today, available services and tools are scattered and vary largely across the EU. Also, they are not sufficiently visible and known to people, which needs to change.

Recent large-scale survey¹⁰ further illustrate the magnitude of the issue. The survey covered the population of EU citizens, aged 15 years and over, residents in one of the 27 Member States of the EU. Data from a Eurobarometer survey conducted in 2023 indicate that nearly half (46%) of EU citizens reported experiencing emotional or psychosocial problems, such as anxiety or depression, within the past twelve months. More than half (54%) of those affected did not receive professional help. Barriers to access include long waiting times, high costs, and lack of awareness of available services. The younger the respondents, the more likely they are to have encountered issue(s) accessing mental health services¹¹. Younger respondents are also more likely to report having experienced an emotional or psychosocial problems in the last 12 months¹².

⁵ The [State of the World's Children 2021](#): On My Mind – Promoting, protecting and caring for children's mental health, Regional brief: Europe, UNICEF, 2021.

⁶ UNICEF. (2021, October).

⁷ European Commission. (2023, June 7). (COM (2023) 298 final).

⁸ European Commission. (2023, June 7). COM (2023) 298 final).

⁹ European Commission. (2023, June 7). COM (2023) 298 final).

¹⁰ European Commission: Directorate-General for Health and Food Safety and Ipsos European Public Affairs (2023).

¹¹ From 19% for those aged 55 or above, to 32% for those aged 15-24, and 33% for those 25-39.

In addition, recent global events, including the COVID-19 pandemic, geopolitical instability, climate change, and rising living costs, have significantly impacted mental well-being, with 62% of EU citizens reporting some level of negative effect. These trends reinforce the urgency of scalable, accessible, and user-centred mental health solutions, particularly those capable of early detection and intervention in community-based settings such as schools¹³.

In response to growing demand and systemic gaps in traditional healthcare systems, the digital mental health market has experienced rapid expansion in recent years, driven by increasing demand for accessible, scalable, and cost-effective solutions. The global mental health applications market was valued at approximately USD 2.28 billion in 2024 and is projected to grow significantly, reaching nearly USD 9.80 billion by 2032, with an annual growth rate of around 20%¹⁴. This growth is driven by increasing awareness of mental health issues, rising demand for accessible care, and the scalability of digital solutions.

Currently, more than 300,000 health-related applications are available across major app platforms, with mental health applications representing one of the fastest-growing segments. Within this market, applications targeting depression and anxiety management dominate, reflecting the high prevalence of these conditions globally. Platform-wise, iOS-based applications hold a significant market share, driven by strong user adoption in key markets¹⁵.

In parallel, AI is transforming healthcare delivery. The global AI in healthcare market, valued at approximately USD 14.92 billion in 2024, is expected to grow at a compound annual growth rate of over 35%, reaching more than USD 110 billion by 2030¹⁶. AI enables advanced capabilities such as predictive analytics, personalised monitoring, and decision support systems, which are particularly relevant in the context of mental health.

Another important trend is the emergence of gamification in healthcare. The healthcare gamification market, valued at over USD 10 billion in 2022¹⁷, is projected to grow steadily, driven by its potential to enhance user engagement, motivation, and behavioural change. Gamified approaches are especially effective for younger populations, making them highly relevant for interventions targeting adolescents.

These trends collectively indicate a strong and growing market opportunity for integrated digital mental health solutions that combine accessibility, personalisation, and sustained user engagement.

Despite rapid technological advancements and market growth, several critical gaps remain in the digital mental health landscape. Existing solutions are often fragmented, lacking integration with healthcare systems, educational environments, and community-based support structures.

¹² 59% of those aged 15-24, 56% of those aged 25-39, compared to 48% of those aged 40-54, and 35% of those aged 55 and above.

¹³ According to the Eurobarometer survey, overall, 50% of respondents think mental health problems can be detected at an early stage in primary and community care. Educational settings are mentioned by 43% of respondents, while 29% select 'in the working environment'. Less than one in five respondents mention hospitals (16%) or social services (15%), and one in ten respondents (10%) refer to sport, creative or leisure activities.

¹⁴ Stellar Market Research. (2025–2032).

¹⁵ Stellar Market Research. (2025–2032).

¹⁶ MarketsandMarkets. (2025).

¹⁷ Global Market Insights. (2022, December).

Many applications operate in isolation, limiting their effectiveness in providing continuous and coordinated care. Furthermore, with a large number of digital tools available, they are not always tailored to the specific needs of adolescents. Engagement remains a challenge, as users discontinue use over time due to lack of motivation, personalisation, or perceived relevance. In addition, barriers such as limited digital literacy, privacy concerns, and insufficient trust in digital solutions continue to hinder adoption.

Another major gap lies in the limited use of co-creation¹⁸ and ecosystem-based approaches. Current solutions rarely involve multiple stakeholders in a coordinated manner. In this context SMILE addresses these unmet needs through a comprehensive, user-centred, and ecosystem-driven approach.

Key Targeted Customer Segments

SMILE operates within a multi-stakeholder ecosystem, where the distinction between end-users, customers, and partners is essential. While not all stakeholders will directly contribute to revenue generation, their role is critical in the adoption, implementation, and scaling of SMILE's solutions.

The primary customer segments, those most likely to drive procurement and funding decisions, include healthcare organisations, public authorities, educational institutions, and policymakers. These actors are central in integrating SMILE solutions into existing systems and ensuring long-term sustainability.

End-users include adolescents, who are the primary beneficiaries of the solutions, as well as legal guardians, school professionals, and healthcare professionals. Given that adolescents are often under legal age, they are not direct customers but remain the core target group in terms of impact and design.

Additional stakeholders include researchers and academia, civil society organisations, businesses, insurers, and investors, all of whom may play roles as partners, facilitators, or enablers within the broader SMILE ecosystem.

Unmet Customer Needs analysis

The needs addressed by SMILE are grounded both in market analysis and in the specific requirements identified in the project's Grant Agreement. These needs reflect technological, societal, and systemic challenges that currently limit the effectiveness of mental health interventions. Key unmet specific needs include:

- SN#1 Technological, legal and market requirements for the gamified-based approach;
- SN#2 Secure knowledge sharing that can promote the well-being via co-creation ecosystems;
- SN#3 Demonstrate the potential and business value of digitisation and virtualisation in real-world contexts;
- SN#4 User-centric tools and interaction mechanisms to lower the usage barrier and minimise skills gap for digital transformation;

¹⁸ Where multiple actors such as teenagers, parents, school professionals and health professionals, actively collaborate in the design, development and evaluation of digital tools.

- SN#5 next-generation incentives Provide mechanism beyond marginal pricing;
- SN#6 Define comprehensive a decision-making process;
- SN#7 Strengthen the role of adolescents in psychological distress assessment.
- SN#8 Create modular, customisable and targeted pool of integrated services for the pilots to meet specific needs, ensure scalability and replicability of solutions and practices.

SMILE KERs are designed to directly respond to these needs, ensuring strong alignment between technological development, user expectations, and market demand. Each KER contributes to addressing one or more of these challenges, forming a coherent and integrated response to current gaps in the mental health ecosystem.

PESTLE analysis

PESTEL is a method to gather relevant knowledge on the macro environment. "PESTEL" refers to a mnemonic guideline of the domains it considers: Political, Economic, Social (or Socio-cultural), Technological, Environmental and Legal.

RDIUP developed a navigation tool that aims to identify the factors that are likely to influence, directly or indirectly, the adoption, scaling, and sustainability of SMILE KERs at the national/regional level. This analysis will help inform tailored exploitation pathways and scaling strategies at the EU-level and per country-level as well as necessary. For each factor identified, it is classified as:

- Major Opportunity
- Minor Opportunity
- Minor Barrier
- Major Barrier,

Then, described and explained, and detailed on its relevance to SMILE and how it acts as factor (including mitigation measures if any).

Tableau 2: SMILE EU-level PESTEL analysis

POLITICAL DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE (how it acts as a factor)
Rising political priority of mental health and youth well-being	Major Opportunity	Accelerated by COVID-19 impacts, increased digital exposure, and social isolation and inequalities among young people, youth mental health has now become a top political priority across the EU (EU Comprehensive Approach	SMILE strongly aligns with current EU agendas, increasing its political legitimacy and relevance, and facilitating engagement with key stakeholders.

		<i>to Mental Health, EU Youth Strategy, School Health policies).</i>	
Fragmented governance across countries and sectors	Major Barrier	<i>Responsibilities for youth mental health differ significantly between health systems, education authorities, and youth services, and vary widely across EU Member States.</i>	<i>Replication work will require adaptable governance and implementation models. SMILE addresses this through country-level institutional mapping and flexible deployment pathways rather than a single implementation model. SMILE must adopt flexible governance and implementation frameworks to adapt to diverse national landscapes and avoid one-size-fits-all models.</i>
Limited adaptation of health systems to self-assessment tools	Minor Barrier	<i>Many health systems remain oriented towards clinician-led, treatment-focused models, with limited integration of preventive, non-clinical self-assessment, or youth-driven digital tools</i>	<i>SMILE tools are positioned as complementary, non-diagnostic, and evidence-based support</i>
ECONOMIC DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE (how it acts as a factor)
Growing investment in youth mental health	Major Opportunity	<i>EU Health funding programmes increasingly invest in youth mental health solutions, recognising long-term cost savings for national health, education, and social systems.</i>	<i>This supports SMILE adoption of a mixed funding models for sustainability</i>
Expansion of digital health market	Major Opportunity	<i>Digital health and wellness ecosystems, including prevention and well-being apps, are expanding,</i>	<i>Indicates a favourable market context for exploitation once validation evidence is available, especially if SMILE</i>

		<i>driven by unmet needs and supported by EU digital health strategies and funding opportunities.</i>	<i>differentiates itself through evidence and co-design approach.</i>
Public and Private Investment	Major Opportunity	<i>EU co-funding mechanisms and PPPs support innovation and scaling of digital solutions</i>	<i>SMILE can thus leverage multi-source funding in future exploitation including public-private synergies</i>
Fragmented funding streams across EU Member States	Minor Barrier	<i>Funding mechanisms differ widely between EU countries and regions, complicating a uniform economic strategy.</i>	<i>Requires country-specific exploitation pathways and adaptable pricing models rather than a uniform pricing model.</i>
Economic disparities in access to digital solutions	Minor Barrier	<i>Socio-economic inequalities and uneven access to devices and digital services in EU countries and regions differ from groups of populations, which affect access to digital support services among young people.</i>	<i>SMILE incorporates inclusive design and accessibility measures to avoid deepening inequalities, including: apps functioning with limited or unstable internet access (most of COPEN features work offline); Multilingual interfaces; Simple UX/UI design tailored to varying levels of digital literacy; Accessibility features (e.g., readable fonts, contrast modes, simplified navigation); Deployment via schools and youth organisations, reducing reliance on individual device ownership.</i>
Lack of reimbursement frameworks for digital prevention tools	Minor Barrier	<i>Many health systems in Member States lack reimbursement frameworks for digital mental health solutions</i>	<i>Reinforces the need for SMILE to prioritise public programmes, partnerships, and institutional strategies rather than individual reimbursement too early.</i>
Economic uncertainty (e.g. inflation, budget pressure)	Minor Barrier	<i>This can limit / slow institutional uptake of new digital initiatives.</i>	<i>Highlights the importance of cost-effective evidence generation and clear value propositions to support institutional decision-making.</i>

SOCIAL DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE (how it acts as a factor)
Digital nativeness of SMILE target group	Major Opportunity	<i>Young people aged 10 – 24 experience an increase in digital learning, and are comfortable with digital tools, social media, games / gamified apps, and interactive content.</i>	<i>This supports SMILE’s use of gamification, digital engagement personalised digital design, and retention strategies tailored to youth behaviours.</i>
High and rising mental health needs among young people	Major Opportunity	<i>Anxiety, depression, stress, loneliness, and emotional distress are increasingly prevalent among young people aged 10 to 24, which underscores societal demand for supportive mental well-being tools.</i>	<i>This creates strong societal demand and relevance for SMILE tools, supports the SMILE narrative of addressing unmet needs and reinforces demand signals in future exploitation</i>
Trust and acceptance of digital mental health tools	Minor Barrier	<i>Concerns persist regarding effectiveness, safety, legitimacy of digital solutions versus traditional supports, and ethical use of digital mental health solutions.</i>	<i>SMILE must emphasise evidence, transparency, and user agency to build trust among young people and key stakeholders. SMILE actively builds trust and acceptance through: Clinical and scientific validation; Co-creation with end-users; Transparent communication on what the tools do and do not do; Clear ethical safeguards.</i>
Stigma and cultural norms around mental health	Minor Barrier	<i>Mental health stigma varies by culture, which can influence uptake and engagement.</i>	<i>Requires culturally sensitive communication, outreach, and educational components integrated into SMILE deployments.</i>
Parental and institutional perceptions of digital interventions	Minor Barrier	<i>Educators, parents, and youth workers may be cautious about adopting digital mental health solutions without clear</i>	<i>Justifies SMILE’s co-creation approach and careful messaging about complementary (not clinical</i>

		<i>evidence and safeguards.</i>	<i>replacement) roles.</i>
TECHNOLOGICAL DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE (how it acts as a factor)
Maturity of digital mental health technologies	Major Opportunity	<i>Mobile apps, data analytics, AI enabled functionalities, serious games, chatbots, and digital platforms are increasingly integrated in mental health contexts.</i>	<i>Supports SMILE's multi-tool ecosystem approach and potential scalability.</i>
Widespread access to smartphones	Major Opportunity	<i>High penetration of mobile devices among EU youth provides broad delivery capacity for digital tools.</i>	<i>Enables scalable deployment for SMILE</i>
Decreasing costs of software and hardware	Major Opportunity	<i>Lower costs reduce barriers for development and distribution of digital solutions.</i>	<i>Encourages efficient design and iteration within SMILE's R&I cycle</i>
Data protection and cybersecurity expectations	Major Barrier	<i>There is an increase in data sensitivity and cybersecurity requirements, especially on Mental health data, involving minors, which are highly sensitive and subject to strict security expectations. Which increases technical requirements for security and privacy.</i>	<i>SMILE implements privacy- and security-by-design principles, including: End-to-end encryption for sensitive data exchanges; Data minimisation strategies; Pseudonymisation/anonymisation techniques; Role-based access control for different stakeholders; Secure cloud infrastructure compliant with EU standards; Regular security audits and risk assessments; Age-appropriate consent.</i>
Concerns about algorithmic bias in AI components	Minor Barrier	<i>Use of AI features may trigger concerns about fairness, transparency, and reliability.</i>	<i>Reinforces the need for explainable, transparent AI components and careful documentation of performance</i>

			<i>and limits.</i>
Lack of interoperability standards	Minor Barrier	<i>Lack of unified interoperability standards limits seamless integration with existing digital health systems.</i>	<i>SMILE contribution to ongoing standardisation efforts and fosters integration between its modules (through the SMILE OKP platform), and design modular components ready for future interoperability frameworks.</i>

ENVIRONMENTAL DIMENSION

Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE (how it acts as a factor)
Limited direct environmental impact	Minor Opportunity	<i>Mental health digital tools generally have minimal environmental effects.</i>	<i>SMILE environmental considerations remain light and compliant with EU expectations.</i>
Lack of awareness about environmental influences on mental health	Minor Barrier	<i>Worsening climate events create indirect psychological stress</i>	<i>SMILE integrates in its trainings content focusing on awareness-raising on the link between environment and mental health, through the KM-EP</i>

LEGAL DIMENSION

Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE (how it acts as a factor)
Strong EU legal framework for data protection	Major Opportunity	<i>The EU-wide regulations (e.g., GDPR, AI Act) provides a robust and harmonised legal baseline across EU Member States.</i>	<i>This strengthens trust, legal clarity, and cross-border replication potential. SMILE embeds age-differentiated consent, data minimisation, and safeguarding mechanisms.</i>
EU Initiatives on cross-border digital health	Major Opportunity	<i>European Health Data Space (EHDS) aims to streamline cross-border</i>	<i>Alignment with EHDS principles strengthens SMILE research foundations and</i>

		<i>health data access, facilitate secondary use for research and innovation, and foster interoperability.</i>	<i>future integration potential.</i>
Liability considerations for crisis situations	Major Barrier	<i>Handling crisis related signals (e.g., self-harm risk detection) raises complex liability and responsibility legal questions.</i>	<i>This requires from SMILE clear crisis protocols, escalation mechanisms, and disclaimers embedded into tool design.</i>
Divergent national laws on digital services	Minor Barrier	<i>Member States may adopt varying standards on online protection, and digital services compliance.</i>	<i>Requires adaptive compliance strategies and monitoring of national implementation trends to avoid legal friction</i>
Lack of harmonised IP protections for AI and digital apps	Minor Barrier	<i>Variations in legal frameworks for software, algorithmic IP, and digital product rights can complicate commercial exploitation.</i>	<i>Suggests need for robust IP strategy and potential EU-level IP advisory integration within SMILE exploitation plans.</i>

Intellectual Property and Value Protection

IP Protection Landscape

In particular, our work on IP management considers: (i) the existing guide “Your Guide to IP in Horizon 2020”¹⁹, since the tips and recommendations it provides remain valid and helpful for Horizon Europe projects; (ii) the new guide “Your Guide to Intellectual Property Management in Horizon Europe”²⁰ which focuses on Horizon Europe collaborative projects; and (iii) the guide “Successful Valorisation of Knowledge and Research Results in Horizon Europe”²¹, which explains how to boost the impact of a project through effective communication, dissemination, and exploitation.

When considering IP protection, it must be noted that IP can be protected by several types of IPR, and consequently, the most appropriate protection strategy must be chosen. The selection of the most suitable form of IP protection depends on the nature and specific characteristics of the results under consideration and the objectives of the IP owner. A few key terms concerning IP protection are the following.

- Copyrights and Creative Commons licenses;
- Non-disclosure and confidentiality agreements;
- Trade and service marks;
- Trade secrets;
- Patents and utility models;
- Industrial designs

Short definitions and key elements of these terms are provided in the following subsections.

Copyright (or author’s right) is the term used to describe the rights that creators have over their literary, scientific, and artistic works²².

The Creative Commons (CC) licenses are a free, simple, and standardised way that every person and organisation in the world can use to grant copyright permissions for creative and academic works. They are free of charge and do not require creators or other rights holders to register with Creative Commons organisation to assign a CC license to their work²³. There are six different license types, listed from most to least permissive in the Annex.

Non-disclosure agreements (NDAs) are legally enforceable agreements between parties that are used to ensure that certain information will remain confidential²⁴.

¹⁹ European Commission: Executive Agency for Small and Medium-sized Enterprises. (2019).

²⁰ European Commission: European Innovation Council and SMEs Executive Agency. (2022).

²¹ European Commission: European Innovation Council and SMEs Executive Agency. (2022). European IP Helpdesk.

²² European Commission: Executive Agency for Small and Medium-sized Enterprises (2019).

²³ Creative Commons. (2023).

²⁴ Thomson Reuters. (2022, August 2).

A trademark is an exclusive right over the use of a sign concerning the goods and services for which it is registered. Trademarks consist of signs capable of distinguishing the products, for both goods and/or services, of a trader from those of others²⁵.

Trade secrets can be considered any confidential business information providing a competitive advantage to an enterprise. The information must be secret, not generally known, have commercial value due to its secrecy, and have been subject to reasonable measures to keep it secret²⁶.

A patent is an exclusive right granted to protect inventions, products or processes, that offer a new technical solution or facilitate a new way of doing something²⁷.

An industrial design is the outward appearance of the whole or part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture, and/or materials of the product itself and/or its ornamentation²⁸.

Drawing from EU-funded project experiences and official guidelines, several key insights inform SMILE's IPR approach:

- **Common IP Risks:** Consortia often face challenges related to unclear ownership, access rights, and timely protection, which can delay commercialisation.
- **Ownership Structures:** Joint IP ownership clauses, access rights for background and foreground IP, and licensing terms are clearly articulated in the CA.
- **Best Practices:** Similar EU funded initiatives demonstrate the value of establishing robust IP frameworks early, fostering open innovation while safeguarding commercial interests.
- **Resources:** The IPR Helpdesk provides essential factsheets and training materials on licensing, open source strategies, and collaborative IP management.

Applicable IP Protection Methods

SMILE aligns with principles of *FAIR data* and *open collaboration*. Therefore, IP protection does not mean locking results, but rather clarifying ownership, ensuring responsible use, and enabling tailored reuse. This section identifies suitable IP protection methods for the KERs emerging from SMILE. Given the fact that SMILE involves a mix of outputs, including software, code, user interfaces, pedagogical content, methodologies, algorithms, datasets, and branding elements, a mixed IPR strategy is recommended. The protection approach must reflect:

- Ownership and joint contribution complexity
- Exploitation intentions
- User data sensitivity
- FAIR and open science principles
- Ethical and legal compliance
- Open science / Open source ambitions

²⁵ European Commission: Executive Agency for Small and Medium-sized Enterprises (2019).

²⁶ European Commission: Executive Agency for Small and Medium-sized Enterprises (2019).

²⁷ European Commission: Executive Agency for Small and Medium-sized Enterprises (2019).

²⁸ European Commission: Executive Agency for Small and Medium-sized Enterprises (2019).

Based on the EU IPR Helpdesk²⁹ the following protection tools are considered, depending on the nature of the result:

- Copyright, for software code, UI designs, training content, and multimedia materials
- Trademark, for logos, branding elements, and service identifiers
- Design rights, particularly for the visual identity and UX/UI components
- Database rights, in case of structured collections of pseudonymised user data
- Trade secrets, when internal algorithms or know-how are best kept confidential
- Open-source licensing, applied selectively where openness increases adoption without risking business objectives

SMILE IP Mapping Process

To align with best practices and consortium goals, SMILE has conducted an IPR Collection and Mapping through a comprehensive survey to map existing background IP and identify foreground IP generated by the project. This confidential internal document is available in the project's internal cloud. The survey results are maintained confidentially and protect consortium interests without disclosing partner-specific details at this stage.

SMILE's Background IP

The CA's Attachment 1 "Background included" presents an initial list of usable Background. The Background IP as preliminary identified in attachment 1 of the CA was further elaborated during the project lifecycle through a background IP survey prepared by RDIUP and circulated to all SMILE partners. The background IP collection template is annexed to this deliverable.

The SMILE Background IP is summarised in the following table:

Tableau 3: SMILE Background IP

Partner	Name/title of IP	Product (Hardware/ Software/Algorithm/Process, etc).	Type of IP	Ownership
FTK	SAPL	Software, Algorithms	Copyright	FTK
	KM-EP	Software and Algorithms	Copyright	FTK
RDIUP	Blockchain layer	Software	Copyright	RDIUP
UoM	Symmetric Model of Interaction (SMI)	Software	Copyright	University Maribor
	Multimodal Risk Assessment And Symptom Tracking (MRAST) framework with Expressive Chatbot	Software	Copyright	University Maribor
NION	ExCare IoT and Big	Software/Algorithm	Trademark	NION

²⁹ The European IPR Helpdesk. (2017).

	Data platform			
WIZ	Middleware for multi-organization data exchange	Software	Self-owned product and service without being registered because software cannot be patented	WIZ
INT	Living Lab Methodology for Participatory Digital Mental Health Design and Validation	Process	Copyright	INT
HWU	Gamified CBT for social anxiety	Design and original software created with the University of Glasgow under a Technology Gateway grant. Elements contained within PhD. Company (Daiseye Ltd) to exploit this commercially was originally incorporated	Copyright	Mel McKendrick (solely)
UoE	ESM Sigma	Software, momentary assessment methodology including items and question logic	Copyright	University of Edinburgh Matthias Schwannauer

Regarding SMILE Foreground IP, when deciding on protection, the beneficiary must consider its own interests and the interests (especially commercial) of the other beneficiaries. Final mapping of Foreground UP, exploitation lead, and IP protection plan will be confirmed in D6.6. To effectively safeguard and exploit its KERs, SMILE proposes the following actions from now till project end, as needed:

1. **KER-by-KER IP Audit** with contributing partners (ownership, protection, licensing)
2. **Formal Registration** where applicable (e.g. trademark via EUIPO)
3. **Internal and External Licensing Documentation**
4. **Alignment with Post-Project Exploitation Strategy**
5. **Inclusion in Innovation Radar**

SMILE Exploitation Framework

SMILE partners are considering three parallel exploitation paths for the project results:

- 1) The commercial exploitation model, which implies the paid provision of the project results to the end-users, complying with a e.g. licensing scheme;
- 2) The research exploitation model, which implies the re-utilisation of the research know-how acquired in future research activities and projects; and
- 3) The technological exploitation model, which implies the re-utilisation of the technological know-how acquired for the development of innovative products and the provision of advanced services built on top of them.

Exploitation Strategy Overview

Effective exploitation of SMILE's innovations requires both tailored individual plans for each KER and a coordinated joint exploitation strategy that leverages consortium synergies. At this stage, individual exploitation plans for the KERs have been drafted, while plans for joint exploitation remain under development. Additionally, further refinement will be based on pilot results from trials, stakeholder feedback, and evolving regulatory landscapes, with the final comprehensive exploitation plan delivered at project conclusion.

Each KER has developed phased exploitation pathways. These preliminary exploitation pathways articulate how the specific result will be exploited, detailing the objective of that pathway, what happens immediately after project end, the key activities of those pathways, along with the target market and customers/users identifying precise market segments and/or end-users, and a key milestone marking the success of this phased exploitation pathway like a concrete measurable step.

Below is the SMILE Exploitation roadmap updated.

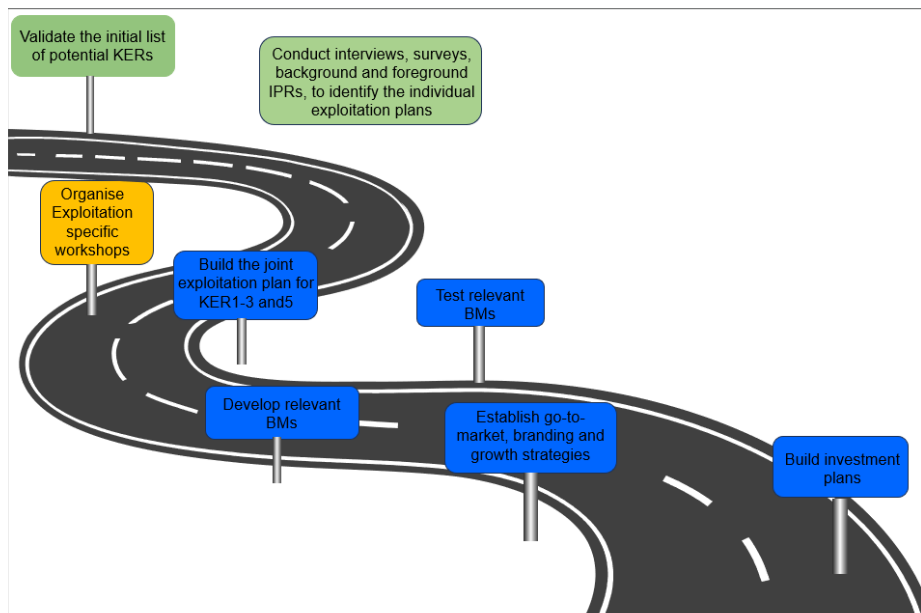


Figure 1: SMILE Exploitation Roadmap

The supporting activities to the SMILE exploitation roadmap are:

- **Regular Exploitation Reviews:** Quarterly check-ins to assess progress against roadmap milestones and address emerging challenges.
- **Stakeholder Engagement:** Continuous involvement of users, policymakers, and other external parties to validate exploitation relevance.
- **Training & Capacity Building:** Workshops and materials to enable partners and users to leverage the KERs effectively.
- **Funding & Business Development:** Identification of follow-up funding opportunities, investors, or commercial partners.

Exploitation and Innovation Analysis by KER

This section provides a comprehensive analysis of each SMILE KER, detailing its characteristics, contributors, and technical readiness, as well as its exploitation potential and innovation profile. For each KER, a structured table presents its type, KER manager and contact person, contributing partners, exploitation type, description, TRL before and after SMILE, initial exploitation vision, next steps, and related pilot or demonstration activities.

To support the adaptation of exploitation strategies to the market and potential customers, a SWOT analysis has been conducted for each KER. This identifies internal strengths and weaknesses as well as external opportunities and threats, providing a clear overview of the factors that may facilitate or hinder successful exploitation.

The innovation dimension of each KER is also assessed, highlighting what makes it novel compared to existing solutions, products, or processes. Each KER is assigned an Innovation Level, reflecting the degree of novelty and potential impact, and explaining why this innovation matters:

1. **Standard:** The KER aligns with current market or technological standards; no significant novelty, but solid and reliable.
2. **Improvement:** The KER offers enhancements or optimisations over existing solutions (e.g., better performance, cost reduction).
3. **Within Paradigm:** The KER introduces a new approach or technology within the existing innovation framework or market paradigm.
4. **Outside Paradigm:** The KER represents a breakthrough that challenges or redefines current technologies, markets, or user practices.
5. **Discovery:** The KER is a pioneering, fundamental innovation opening entirely new fields or creating new markets.

Finally, each KER is associated with phased exploitation pathways, describing stepwise plans for pilot implementation, post-project scaling, potential commercialisation, collaboration opportunities, and long-term sustainability. These pathways are first presented through a figure, then a detailed pathway is included (pathway name, objective, activities, targets, and key milestone of completion).

KER 1. SMILE Game

KER TITLE		KER Type
SMILE Game		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
FTK - Forschungsinstitut für Telekommunikation und Kooperation e. V.	Prof. Dr. Dominic Heutelbeck (dheutelbeck@ftk.de)	FTK, subcontractor DTT, each SMILE partner testing, designing, or generating content for the game
Exploitation Type: Public		

Full Description		
<p>The SMILE gaming app is a collaborative multiplayer serious game for mental health and well-being that embeds self-assessment and self-monitoring within structured, gamified intervention scenarios. Designed as a digital tool for cognitive restructuring, it engages players in interactive tasks that explicitly target negative assumptions and cognitive distortions, thereby supporting the acquisition of new skills and the systematic challenging of biased thinking patterns.</p>		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL2 - technology concept formulated	TRL5 - technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)	The SMILE Serious Game is an experience-driven gateway into adolescent mental health, translating clinically grounded cognitive restructuring and coping strategies into an accessible, narrative-based game that adolescents can engage with on their own devices.
Next Steps (Action Plan)		
<p>Building on this foundation, the Serious Game will be further extended in follow-up R&D efforts as a modular product line that can be tailored to different age groups, clinical pathways, and service settings, and, where appropriate. In the medium term, this positions the SMILE game as a candidate market-ready component for public mental health services, school-based prevention programmes, and health-research infrastructures that require robust, engaging, and ethically compliant gamified interventions.</p>		
KER and Pilot / Demonstration activities		
<p>Pilot activities comprise a Living Labs phase with around 119 adolescents participants in LL1, 105 provided feedback through the EU Survey, and a co-creation activity with 65 adolescents at an innovation fair. In LL2, 9 teenagers who participated in sequence 1 were interviewed, followed by a multi-site proof-of-concept study in seven European countries using the fully integrated apps under a harmonised protocol.</p>		

SWOT Analysis

Strengths	Weaknesses
<p>Serious Game is fully implemented, deployed via app stores, technically stable, and actively play tested by adolescents under real world pilot conditions. Through its integration with the Companion App, SAMF, and the OKP, it continuously generates high granularity engagement.</p>	<p>The game is implemented using proprietary libraries and game assets. Ownership of these assets is currently contested and further encumbered by the bankruptcy of the original developer and IP holder. This makes a permanent transfer of the codebase to a third party legally challenging and limits the feasibility of exploitation beyond the SMILE project.</p>
Opportunities	Threats

<p>The game can evolve into a collection of reusable components, as well as an R&D testbed for digital mental health interventions and open research. Its multimodal behavioural data and biomarkers generated offer a unique testbed for explainable AI, and next generation digital interventions targeting mood and anxiety in adolescents.</p>	<p>Competing platforms, regulatory changes, and uncertain post project resourcing may limit adoption and sustainable evolution. There is a risk of technical debt and obsolescence after the project's end.</p>
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Innovation Dimensions

<p>Innovation Level</p>
<p>3 - Within Paradigm: The KER introduces a new approach or technology within the existing innovation framework or market paradigm.</p>
<p>Why innovative / exploitable?</p>
<p>Through its integration with the Companion App, SAMF, and the OKP, it continuously generates high granularity engagement and behavioural signals that can be correlated with questionnaires, diary data, and digital biomarkers, providing a living testbed for ethically governed, youth friendly digital mental health interventions.</p>

Phased Exploitation Pathways



Figure 2: Exploitation Pathways (KER 1: Game)

Detailed Exploitation Pathways

Short-term exploitation pathway: Pilot Validation & Technical Consolidation

Consolidate the Serious Game following Living Labs and multi-country proof-of-concept validation.

- Analyse pilot data from deployment in seven countries
- Stabilise and optimise performance
- Consolidate integration with COPEN, SAMF, and OKP
- Document technical architecture and behavioural signal generation
- Address IP and ownership clarification constraints

Target: SMILE research partners & pilot sites, Living Labs environments, internal R&D teams

Key Step: Consolidated & Documented Pilot-Validated Version

Mid-term exploitation pathway: Modular R&D Extension & Adaptation

Extend the Serious Game as a modular intervention framework adaptable to new contexts.

- Develop modular extensions for different age groups
- Adapt for different clinical pathways and service settings
- Maintain role as R&D testbed for digital biomarkers and explainable AI
- Refine integration with digital mental health infrastructures

Target: Research consortia, public mental health services, school-based prevention programmes, health-research infrastructures

Key Step: Modular Version Ready for Context-Specific Adaptation

Long-term exploitation pathway: Candidate Component for Public & Research Ecosystems

Position the Serious Game as a validated gamified intervention component within structured digital mental health ecosystems.

- Integration into broader digital intervention frameworks
- Reuse as research-grade gamified intervention backbone
- Continued evolution as ethically governed youth mental health tool
- Alignment with future R&D projects and service infrastructures

Target: Public mental health services, school-based prevention systems, research infrastructures, digital mental health ecosystems

Key Step: Adoption As Reusable Gamified Intervention Component

KER 2. Self-Assessment and Monitoring Framework (SAMF)

KER Title	KER Type
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Self Assessment and Monitoring Framework (SAMF)		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
UM	izidor.mlakar@um.si	
Exploitation Type: Public		
Full Description		
<p>The SAMF framework in SMILE is a Self-Assessment and Monitoring Framework that processes adolescents' weekly video diary recordings to extract structured, non-identifiable "digital cues" for mental health analysis. It uses a Python/Java pipeline to derive multimodal features from each recording, including linguistic markers from the transcript, paraverbal speech features, and visual facial/gaze cues, which are stored as JSON for later use by analytics and decision-support tools, while the original videos are discarded to protect privacy. In practice, SAMF sits in the OKP data-processing layer alongside the DSS and FHIR server, turning rich, narrative diary content into standardized digital biomarkers that can be correlated with questionnaire scores and in-game measures to track symptoms and risk over time in a secure, interoperable way.</p>		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL3 - experimental proof of concept	TRL5 - technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)	<p>The SAMF Sk will be further developed through targeted R&D that extends its multimodal digital biomarkers, adapts it to new cohorts and care settings, and investigates (X)AI models with clinically usable explainability (e.g. transparent risk estimates and feature-based rationales for decisions). SAMF will be published under a CC-BY license, supported by open documentation and reference integrations, to maximize reuse in future projects and for other populations. In parallel, the HUMADEx team will work with our associated start-up to move SAMF closer to market, as a pre-screening tool and backend service for digital mental health products, validating it in real-world pilots, while keeping the core framework openly available.</p>
Next Steps (Action Plan)		
<p>Define and finalise the XAI design for SAMF by specifying target use cases, explanation types (feature importance, prototypes, counterfactuals), and required clinical narrative outputs for clinicians. Implement the selected XAI methods on top of SAMF features and DSS models, ensuring they are technically integrated into the existing OKP / FHIR-based pipeline. Finalise and publish the SAMF code and documentation in a public repository under the CC-BY license, including clear versioning and</p>		

<p>citation guidelines. Set up a dedicated co-development agreement with the HUMADEx-linked start-up, defining roles for hardening SAMF into a deployable backend service. Launch a small-scale clinician-focused usability and explainability study (mock dashboards, case vignettes) to test XAI outputs derived from SAMF features in collaboration with HE CERTAIN project.</p>
<p>KER and Pilot / Demonstration activities</p>
<p>SAMF will be tested and demonstrated primarily in the SMILE pilots, where it is integrated in the OKP processing layer to transform adolescents' diary recordings and related inputs into multimodal digital biomarkers that feed FHIR, DSS, and clinician-facing dashboards for screening, longitudinal monitoring, and extension of traditional clinical interviews with real-world data. In parallel, HE CERTAIN Pilot 2 – Health (https://certain-project.eu/) will extend and deploy the SAMF-based AI components with a focus on AI certification, using CERTAIN's guidelines and tools to evaluate transparency, bias, robustness, and privacy, and to generate the documentation and XAI artefacts needed to position SAMF as a certifiable backend analytics service for healthcare applications beyond SMILE.</p>

SWOT Analysis

Strengths	Weaknesses
<p>multimodal, multilingual, privacy-preserving pipeline with structured outputs usable for downstream analytics.</p> <p>strong interoperability and deployment via API/FHIR-based architecture, which supports integration with dashboards and decision-support workflows.</p> <p>already has a use-case, integrated in a broader ecosystem (i.e. the OKP) that supports collection and transformation of heterogeneous youth mental health data the development is carried out by a multi-partner consortium combining technical teams (apps, security, interoperability, analytics) and clinical staff</p>	<p>clinical validity, performance and generalisability depend on cross-site evaluation, since performance can vary across languages, cohorts, and recording conditions</p> <p>explainability requirements can be demanding in clinical environments, and the current need to develop/validate (X)AI layers adds complexity before routine adoption</p> <p>operational overhead (MLOps, data governance, security controls, pilot-centric access policies, training and ongoing maintenance), when moving from pilots to routine service delivery.</p> <p>many platforms bundle content, coaching/therapy, and “always-on” user experiences, which can look more complete to buyers than a specialised biomarker-extraction component unless the clinical value is very clear</p>
Opportunities	Threats
<p>fast-growing market: the global mental health apps market is expanding quickly (e.g., estimated USD 7.48B in 2024 with projected ~14.6% CAGR 2025–2030)</p> <p>large unmet need in youth mental healthcare access: digital approaches are increasingly seen as a way to reduce persistent barriers (time, cost, system capacity) and improve reach/uptake for young people</p> <p>emerging need for real-world, longitudinal</p>	<p>AI used in medical contexts with increasing obligations around data governance, transparency, human oversight, and post-market monitoring</p> <p>navigating both AI-specific rules and medical-device frameworks can create additional compliance workload and potential timing risk for roll-out</p> <p>mental health apps have been under public scrutiny for privacy and potential</p>

<p>measurement: health systems are moving toward continuous, ecologically valid monitoring (beyond episodic clinical interviews)</p> <p>growing stakeholder concern about privacy, security, and trust in digital mental health tools increases the value of SAMF’s privacy-preserving processing plus CERTAIN-style certification and transparency work</p> <p>few direct competitors for multimodal, standards-ready components: many products focus on content/therapy delivery, while fewer offer interoperable (FHIR/API-ready) multimodal biomarker pipelines</p>	<p>harm/ineffectiveness, so reputational risk can rise quickly</p> <p>broader public awareness of sensitive-data misuse (including enforcement actions discussed in policy commentary) can make participants, parents, and institutions more cautious about adoption</p> <p>well-funded commercial platforms may outpace adoption via established distribution (payers/employers) and faster product packaging, even if the underlying biomarker pipeline is less advanced</p> <p>some young users prefer the option to contact a health professional and may disengage from “tool-only” experiences, which can limit acceptance if human-in-the-loop support is not available</p>
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Innovation Dimensions

<p>Innovation Level</p>
<p>5 - Discovery: The KER is a pioneering, fundamental innovation opening entirely new fields or creating new markets.</p>
<p>Why innovative / exploitable?</p>
<p>End-to-end pipeline from adolescent video diary recordings to standardized multimodal digital biomarkers (linguistic, speech, facial features) ready for clinical analytics and clinical DSS integration. Combining SAMF features with questionnaire scores and serious-game digital biomarkers, the solution enables advanced data fusion for early risk detection and personalised monitoring</p> <p>Enables continuous, remote collection of rich data in real-world settings, supporting both screening and routine clinical follow-up and thereby extending traditional time-limited clinical interviews with longitudinal, ecologically valid information.</p> <p>Built to interface with FHIR and modern API-based infrastructures, SAMF can be rapidly embedded into existing telehealth, EHR, and digital therapeutics platforms, increasing its market potential as a plug-in backend service.</p>

Phased Exploitation Pathways



Figure 3: Exploitation Pathways (KER 2: SAMF)

Detailed Exploitation Pathways

Short-term exploitation pathway: Open Release & XAI Integration

Further develop SAMF through targeted R&D and explainable AI integration:

- Define and implement XAI models with clinically usable explainability
- Integrate XAI methods into the OKP / FHIR pipeline
- Extend multimodal digital biomarkers
- Finalise and publish SAMF under CC-BY license
- Provide open documentation and reference integrations

Target (validation & research reuse phase): Research partners, EU-funded research project, digital health researchers, clinical research teams

Key Step: Public Cc-By Release of SAMF + Xai-Integrated Version

Mid-term exploitation pathway: Backend Service Co-Development

Move SAMF closer to market in collaboration with HUMADEx-linked start-up:

- Establish co-development agreement
- Harden SAMF into deployable backend service
- Position as pre-screening tool for digital mental health products
- Validate in real-world pilots
- Conduct clinician-focused usability & explainability study

Target: Digital mental health product developers, telehealth platforms, EHR-integrated digital tools, clinical pilot environments

Key Step: First Real-World Pilot as Backend Service

Long-term exploitation pathway: Certifiable Healthcare Analytics Component

Position SAMF as a standards-ready, certifiable backend analytics solution:

- Deploy multimodal biomarker extraction as interoperable FHIR/API component
- Align with AI transparency and certification frameworks (via HE CERTAIN collaboration)
- Generate required documentation and XAI artefacts
- Enable embedding in healthcare applications beyond SMILE

Target: Healthcare system integrators, digital therapeutics platforms, telehealth providers, health IT vendors

Key Step: Certification-Ready Deployable SAMF Service

KER 3. SMILE KM-EP

KER Title		KER Type
SMILE KM-EP deployment with Knowledge Base		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
FTK	Prof. Dr.-Ing. Matthias Hemmje (mhemmje@ftk.de)	FTK, each SMILE partner curating or generating content for the SMILE KM-EP deployment with Knowledge Base
Exploitation Type: Public		
Full Description		
A central digital hub aggregating, managing, and disseminating SMILE's tools, datasets, and resources for stakeholders including adolescents, parents, teachers, clinicians, and policymakers. It integrates content management, eLearning tools, and decision support systems.		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL7 - system prototype demonstration in operational environment	TRL8 - system complete and qualified	The SMILE KM-EP deployment with Knowledge Base is an informational gateway into SMILE's outcomes and a living demonstrator for FAIR, open, and participatory digital mental health innovation. It offers contextualised, curated resources for diverse stakeholder groups and generates empirical insights into how discoverable, interpretable, and reusable digital mental health assets can best be provided. Building on this

		foundation, the SMILE KM-EP deployment with Knowledge Base will be further extended through future R&D follow-up projects building on the current state to mature into a market-ready product for the public health and health research sector.
Next Steps (Action Plan)		
Next steps for the SMILE KM-EP deployment with Knowledge Base focus on deepening curated content, strengthening governance, and preparing for post-project sustainability and exploitation. The Knowledge Base will be continuously enriched and curated following a participatory design approach.		
KER and Pilot / Demonstration activities		
The SMILE KM-EP deployment with Knowledge Base is already fully deployed as a technically stable portal under the SMILE project domain and is integrated into the project's infrastructure. It is being demonstrated and iteratively refined.		

SWOT Analysis

Strengths	Weaknesses
SMILE KM-EP deployment with Knowledge Base is fully deployed and technically stable, offering an editorially curated portal tightly integrated with SMILE's infrastructure.	The game is implemented using proprietary libraries and game assets. Ownership of these assets is currently contested and further encumbered by the bankruptcy of the original developer and IP holder. This makes a permanent transfer of the codebase to a third party legally challenging and limits the feasibility of exploitation beyond the SMILE project.
Opportunities	Threats
The platform can evolve into a reusable hosted service, as well as an R&D testbed for mental health information services and open research.	Competing platforms, regulatory changes, and uncertain post-project resourcing may limit adoption, data sharing, and sustainable evolution.

Innovation Dimensions

Innovation Level
3 - Within Paradigm: The KER introduces a new approach or technology within the existing innovation framework or market paradigm.
Why innovative / exploitable?
The SMILE KM-EP deployment with Knowledge Base is innovative as a taxonomy enabled knowledge portal that represents a stakeholder- oriented ecosystem. It serves as a reusable blueprint for similar mental- health and public- -health platforms. It is exploitable as a fully operational, branded asset that can be further developed into a marketable product and service, for example as a configurable hosted dissemination service for institutions, and a R&D testbed for public mental health information solutions.

Phased Exploitation Pathways

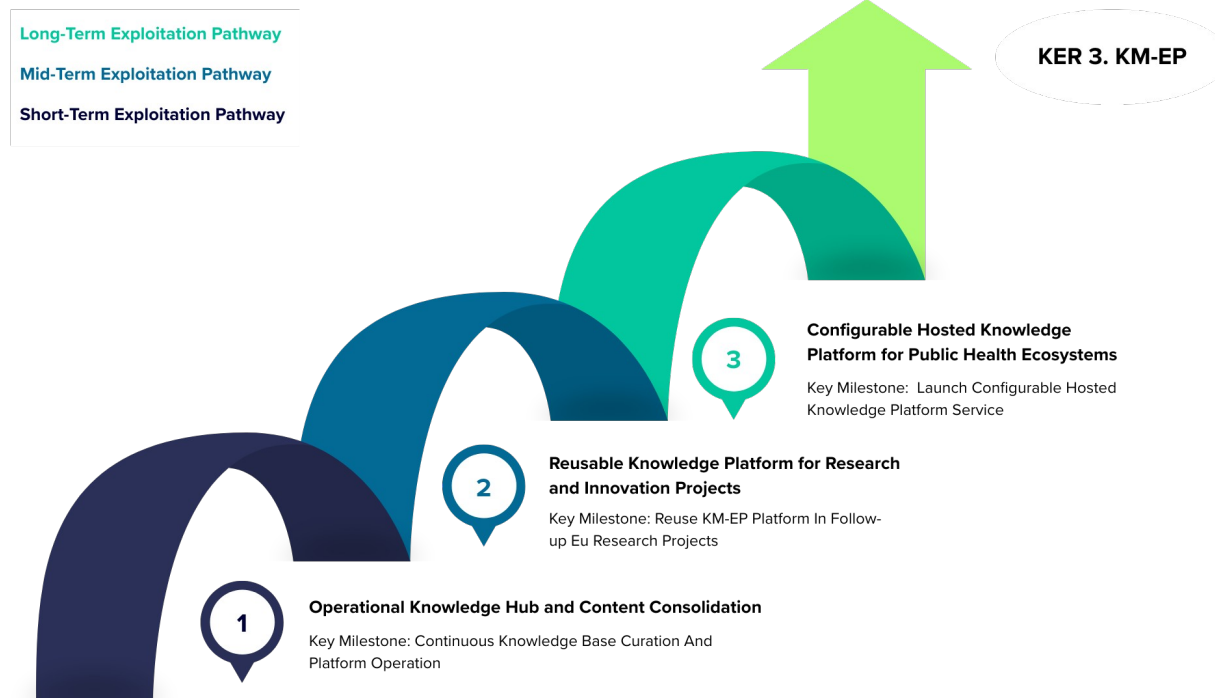


Figure 4: Exploitation Pathways (KER 3: KM-EP)

Detailed Exploitation Pathways

Short-term exploitation pathway: Operational Knowledge Hub and Content Consolidation

Maintain the KM-EP deployment with Knowledge Base as the central digital hub for SMILE outcomes, aggregating tools, datasets, and curated resources.

- Maintain the platform as the official gateway to SMILE tools, datasets, and resources
- Continue content curation and enrichment of the Knowledge Base through participatory design
- Generate insights on how digital mental health assets can be discovered, interpreted, and reused
- Maintain integration with the SMILE project infrastructure

Target: Adolescents, Parents, Teachers, Clinicians, Policymakers, SMILE research partners

Key Step: Continuous Knowledge Base Curation and Platform Operation

Mid-term exploitation pathway: Reusable Knowledge Platform for Research and Innovation Projects

Position the KM-EP deployment as a reusable blueprint for digital mental health knowledge ecosystems in future research initiatives.

- Reuse the KM-EP platform architecture in future EU research and innovation projects

- Use the platform as an R&D testbed for digital mental health information services
- Support experimentation on discoverability and reuse of digital mental-health assets
- Extend curated resources and platform functionality through follow-up research projects

Target: EU research consortia, Research institutions, Digital mental-health research initiatives, Public health innovation programmes

Key Step: Reuse KM-EP Platform in Follow-up EU Research Projects

Long-term exploitation pathway: Configurable Hosted Knowledge Platform for Public Health Ecosystems

Develop the KM-EP deployment into a market-ready digital knowledge platform for public health and research infrastructures.

- Transform the platform into a configurable hosted knowledge portal for institutions
- Offer the platform as a knowledge dissemination and management service
- Support public health information services and research knowledge ecosystems
- Enable organisations to deploy similar curated digital health knowledge hubs

Target: Public health organisations, Universities and research centres, Health research infrastructures, Public health innovation programmes

Key Step: Launch Configurable Hosted Knowledge Platform Service

KER 4. COPEN APP & KER 13. WebAPP

KER Title		KER Type
COPEN		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
RDIUP	Habib Nasser (habib.nasser@rdiup.com)	UoM, HWU, UoE
Exploitation Type: Commercial		
Full Description		
COPEN is a mobile application designed to support youth mental health by combining data collection with interactive engagement. Its main features include the administration of standardized questionnaires (PHQ9, GAD7) and real-time surveys via the ESM (Experience Sampling Methodology) method, complemented by a weekly video diary where the user interacts with a companion bot. To encourage consistency, the app integrates gamification mechanisms such as reward systems (badges, levels, "Smiles" virtual currency), while offering personalized visual feedback on user progress and a multilingual interface adapted to notification preferences.		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL1 - basic principles observed	TRL6 - technology demonstrated in relevant environment (industrially)	RDIUP and UoE will collaborate on a new proposal to refine both the Experience Sampling

	relevant environment in the case of key enabling technologies)	Method (ESM) design and the COPEN app. This initiative will focus on increasing operational efficiency and boosting user engagement to ensure high-quality data collection.
Next Steps (Action Plan)		
Improvement of the APP under new proposal and commercialisation of mental health screening tool with the clinician web		
KER and Pilot / Demonstration activities		
<p>The COPEN App has undergone rigorous iterative development to ensure it meets both technical and clinical standards: Living Lab Validation: Initial usability testing was conducted in a controlled "Living Lab" environment to refine the interface. Longitudinal Pilot Testing: The platform underwent two distinct pilot sequences over several months. User-Centric Refinement: Insights from seven dedicated pilot users were used to debug and optimize the data collection methodology, ensuring the app is "field-ready" for large-scale deployment.</p> <p>Pilot activities comprise a Living Labs phase with around 119 adolescents participants in LL1, 105 provided feedback through the EU Survey, and a co-creation activity with 65 adolescents at an innovation fair. In LL2, 9 teenagers who participated in sequence 1 were interviewed, followed by a multi-site proof-of-concept study in seven European countries using the fully integrated apps under a harmonised protocol.</p>		

KER Title		KER Type
Web APP		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
RDIUP	Habib Nasser (habib.nasser@rdiup.com)	UoE
Exploitation Type: Commercial		
Full Description		
<p>The Web APP is a centralized management platform designed for researchers and healthcare professionals to oversee studies and participant. It serves as a "command center" where operators can remotely configure study parameters without updating the mobile app. The interface provides real-time view to monitor relevant information. In the future researchers can use this app to manage participant enrolment. The platform streamlines the research workflow by offering secure, one-click data exports for advanced statistical analysis in tools like SPSS or R. By implementing role-based access control, the web app ensures that sensitive health data is only accessible to authorized clinical or research personnel. Ultimately, the Web App transforms raw mobile data into actionable clinical insights, enabling rapid intervention and highly efficient study management.</p>		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision

TRL1 - basic principles observed	TRL6 - technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)	RDIUP will refine the Web App to improve administrative efficiency. The vision is to create a "Command Center" where a single researcher/administrator can manage hundreds of participants with automated flagging systems, reducing the human labour required for data cleaning and participant follow-up.
Next Steps (Action Plan)		
Improvement of the APP under new proposal and commercialisation of mental health screening tool with the clinician web		
KER and Pilot / Demonstration activities		
Web APP Stability: The web portal has been stress-tested alongside the mobile app during the living lab and the 02 piloting sequence to ensure it seamless integration with the COPEN APP and other SMILE tools. User Hierarchy: Implementation of role-based access (Admin, Researcher, Clinician) ensures that sensitive participant data is only seen by authorised personnel.		

KER 4. COPEN: SWOT Analysis

<p>Strengths</p> <p>Comprehensive Data Collection: Combines "Gold Standard" validated scales (PHQ9, GAD7) with high-frequency Experience Sampling Methods (ESM) for deep longitudinal insights.</p> <p>Multimodal Inputs: The use of video recordings and voice calls alongside text provides a richer data set than standard survey apps.</p> <p>User Engagement: Gamification and educational content on lifestyle/nutrition help prevent "survey fatigue," which is a common hurdle in clinical studies.</p> <p>Peer Support: Built-in P2P chat and voice calls provide immediate social value to the user, moving the app from a "tracking tool" to a "support community."</p>	<p>Weaknesses</p> <p>Participant Burden: Asking for five daily ESM questionnaires plus weekly video diaries is a high "ask." There is a risk of high attrition rates if users feel overwhelmed.</p> <p>Privacy Complexities: While the P2P system is secure, managing a community of participants (especially in a mental health context) requires intense moderation to prevent misinformation or toxic interactions.</p> <p>Hardware Dependency: Relying on personal devices means data quality may vary based on the user's camera/mic quality or OS version.</p>
<p>Opportunities</p> <p>Decentralized Clinical Trials (DCTs): As the industry moves away from site-based visits, COPEN is perfectly positioned to serve as a primary tool for remote data collection.</p> <p>AI Integration: The video and voice recordings could eventually be analysed via affective computing (AI sentiment analysis) to detect vocal biomarkers of depression or anxiety.</p>	<p>Threats</p> <p>Data Privacy Regulations: Strict adherence to GDPR, HIPAA, or local health data laws is mandatory; any breach in the P2P system would be a major liability.</p> <p>Market Saturation: The "Mental Health & Wellness" app space is crowded. COPEN must clearly differentiate its "research-grade" accuracy from generic mood trackers.</p>

Scaling to Corporate Wellness: Beyond clinical studies, the app's focus on "mental health literacy" and nutrition could be marketed as a B2B employee wellness solution.	Digital Divide: Potential participants with lower digital literacy or older devices may be inadvertently excluded from studies, leading to demographic bias in the data.
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KER 13. Web APP: SWOT Analysis

Strengths	Weaknesses
End-to-End Integration: Direct pipeline from participant data (ESM/PHQ9 etc.) to researcher dashboard. Granular Control: Researchers can remotely configure study parameters without app updates.	Interface Complexity: Managing high-frequency data for many participants requires a very intuitive UI to avoid "data overload" for clinicians.
Opportunities	Threats
Clinical Support: Using the back office to flag "at-risk" participants automatically based on collected data and evidence based assessment. SaaS Potential: Selling the platform as a solution for research/medical organisation.	Cybersecurity: A web-based back office increases the "attack surface" for sensitive health data, requiring bank-level encryption (SOC2/HIPAA).

KER 4. COPEN: Innovation Dimensions

Innovation Level
3 - Within Paradigm: The KER introduces a new approach or technology within the existing innovation framework or market paradigm.
Why innovative / exploitable?
The COPEN App revolutionizes mental health research by replacing retrospective "recalled" data, which is often prone to memory bias, with near real-time data collection. High-Fidelity Insights: By capturing data in the user's natural environment, providers gain a precise "biopsychosocial" map of a patient's daily life. Empowerment: It bridges the gap between researchers and participants, providing clinicians with actionable, real-time data while empowering users through self-awareness and gamified literacy. Market Readiness: The modular design allows it to be licensed to pharmaceutical companies, academic institutions, or healthcare providers as a "Study-in-a-Box" solution.

KER 13. Web APP: Innovation Dimensions

Innovation Level
3 - Within Paradigm: The KER introduces a new approach or technology within the existing innovation framework or market paradigm.
Why innovative / exploitable?
Real-Time Intervention: Unlike traditional studies where data is analysed after the trial, the Web APP

allows professionals to monitor participant in real-time .
Dynamic Research Design: Researchers will be empower to adjust questionnaire frequency or educational content via the web portal, making the study "adaptive" to participant behaviour.
Dual-Purpose Utility: The platform serves two distinct markets: Academic Research (longitudinal studies) and Clinical Practice (remote patient monitoring) in the long term.

Joint Phased Exploitation Pathways



Figure 5: Exploitation Pathways (KER 4: COPEN & KER 13: WebApp)

Detailed Joint Exploitation Pathways

Short-term exploitation Pathway 1: V1 Stabilisation & IP Consolidation

- UX/UI refinement and technical hardening
- Extended post-SMILE validation
- Positioning in EU innovation calls

Target: SMILE pilot institutions, research partners, schools, youth NGOs, municipal youth services, EU project consortia.

Key Step: Copyright Application + Stable Version Release (Copen V1.1)

Short-Term Exploitation Pathway 2: V2 Mental Health Monitoring Service

- Screening questionnaires, tracking, personalised feedback & dashboards
- SaaS model: B2B subscription, tiered institutional plans, token-based peer-support

B2B targets: schools, youth centres, municipalities, NGOs

B2C targets: Young users (10–24 years) and parents.

Key Step: First Paid Organisational Contract

Mis-Term Exploitation Pathway 1: V3 Academic & Research Platform

- Research-oriented version: study design, validated questionnaires, longitudinal analysis, recruitment via registered volunteer base, etc.
- Integration into EU research proposals

Target: Universities, PhD researchers, clinical research groups, Horizon Europe consortia, public health bodies.

Key Step: First Academic Licensing Agreement

Mid-Term Exploitation Pathway 2: V4 Cross-Domain Platform

- Extend COPEN beyond mental health: education, employment, skills tracking, social services, community evaluation
- Enterprise licensing model with configuration & onboarding services

Target: Ministries of Education, regional authorities, large NGOs, corporate HR, foundations, workforce agencies.

Key Step: First Non-Mental Health Enterprise Deployment

Long-term exploitation pathway: V5 Scalable Digital Well-being Ecosystem

- Platform Expansion: Cross-organisational benchmarking, advanced analytics, API-based interoperability with third-party platforms, and multi-country SaaS deployment framework.
- Revenue Resilience: Strengthen recurring revenue through multi-tenant SaaS architecture and long-term institutional contracts at national and pan-European level.
- European Infrastructure: Position COPEN as a recognised European digital infrastructure for structured well-being and behavioural monitoring, serving national authorities and international NGOs.

Target: National public authorities, pan-European youth organisations, international NGOs, cross-country education networks.

Key Step: Multi-Country Saas Deployment Beyond SMILE Partners

KER 6. SMILE eXplainable Decision Support System

KER Title		KER Type
SMILE eXplainable Decision Support System		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
NVision Systems and Technologies SL	Zouhair Haddi (zouhair.haddi@nvision.es)	RDIUP, UoM, UKH, HWU, UoE

Exploitation Type: Commercial		
Full Description		
<p>SMILE XDSS is an interactive tool designed to a) aggregate and explore data related collected from young users (10-24) of SMILE Open Knowledge Platform and b) model data and return results interpretation with statistical and eXplainable AI (XAI) methods. A co-design approach was adopted to develop the XDSS tools in line with principles of AI trustworthiness and clinical expectations. Through its 6-functionalities, the XDSS can assist clinical psychologists, pilot investigators, and researchers in inspecting and analysing digital biomarkers to acquire insights as a support to mental health monitoring, assessment and intervention.</p>		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL3 - experimental proof of concept	TRL5 - technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)	<p>The initial exploitation of the SMILE XDSS is primarily development-focused, aiming to consolidate the tool through further R&D, scientific publications, and validation on real-world pilot data. Next steps include refining statistical and explainable AI models, improving performance and trustworthiness metrics, and strengthening clinical usability and evidence. The XDSS is tightly integrated within the SMILE OKP, co-developed by multiple partners; therefore, exploitation will likely follow a collaborative model. While commercialization is a possible longer-term pathway, concrete objectives, pricing models, and contractual arrangements are not yet defined. Potential target users are clinical professionals, who would access the XDSS through its integration in the SMILE digital ecosystem. Overall, the current strategy prioritizes development and validation, laying the groundwork for future commercialization once sufficient evidence and regulatory clarity are achieved.</p>
Next Steps (Action Plan)		
<p>Availability of pilot study data will enable training and optimization of XAI models on real-world data, improving performance along with explainability and trustworthiness metrics. This optimisation positions the SMILE xDSS as a pioneering digital biomarker-driven decision support system in youth mental health research. Evidence generated through the SMILE pilot study, together with future clinical validation, will support progression toward medical device classification and integration into routine care, laying a solid foundation for eventual commercialisation.</p>		
KER and Pilot / Demonstration activities		
<p>Within SMILE, pilot activities were designed to generate real-world data, which is a prerequisite for the XDSS. The current version of the system requires training and optimization of its statistical and explainable AI (XAI) models on pilot data before it can be meaningfully tested or demonstrated. As a result, the XDSS itself was not evaluated during the pilot study, since its performance, explainability, and trustworthiness depend on models trained with the collected data. The SMILE pilot therefore serves as an enabling step, providing the necessary data foundation for subsequent testing, validation,</p>		

and demonstration of the XDSS in relevant real-world settings beyond the project.

SWOT Analysis

Strengths	Weaknesses
<ul style="list-style-type: none"> • Co-designed XDSS aligned with clinical needs • Integration within the SMILE Open Knowledge Platform, enabling access to rich, longitudinal, real-world data • Scalable architecture that supports further development, validation, and future clinical integration • Use of statistical and eXplainable AI methods, supporting transparency, interpretability, and informed clinical decision-making • Built within a multidisciplinary consortium combining expertise in AI, digital health, psychology, and ethics 	<ul style="list-style-type: none"> • Dependence on pilot study data availability, with XDSS performance directly linked to the number and diversity of participating young users • Limited data volume at early stages, constraining model robustness and generalizability • Strong dependency on data collected through the SMILE Open Knowledge Platform apps, limiting standalone operation • Resource and infrastructure constraints, as the XDSS is not deployed in a cloud environment, reducing ease of external access and scalability
Opportunities	Threats
<ul style="list-style-type: none"> • Addresses a high-impact and under-served population by targeting youth mental wellbeing through digital biomarkers • Responds to a rapidly growing global need, as mental health challenges among young people are increasing and projected to become one of the leading health burdens worldwide by 2030 • Fills a clear market and research gap, as there are currently very limited integrated platforms combining digital interventions, real-world data collection, and an explainable decision support system for mental health • Limited direct competition in the area of clinically oriented, explainable XDSS tools for youth mental health, creating space for leadership and standard-setting • Benefits from increasing policy, funding, and institutional focus on preventive, data-driven, and personalized mental health care 	<ul style="list-style-type: none"> • Risk of insufficient or unbalanced pilot data, as XDSS performance and generalizability are highly dependent on the volume and diversity of participating young users, potentially limiting robustness and external validity. • Evolving regulatory requirements, particularly under the EU AI Act, may introduce additional compliance burdens if the XDSS progresses from research to commercialization • Competitive landscape crowded with digital mental health apps and solutions, many of which have strong market visibility despite limited scientific or clinical validation • Risk of market confusion or skepticism due to the proliferation of low-evidence digital mental health tools • Dependence on sustained institutional and clinical adoption, which may be slowed by conservative attitudes toward AI-driven decision support in mental health settings

Innovation Dimensions

Innovation Level
3 - Within Paradigm: The KER introduces a new approach or technology within the existing innovation framework or market paradigm.
Why innovative / exploitable?
The co-created SMILE XDSS is expected to evolve into a standard tool for personalized mental

wellbeing monitoring and assessment in young people. Its data-driven design, fully integrated within the SMILE digital ecosystem, has the potential to reduce disparities in access to timely mental health insights and support. Through this integration, the XDSS aims to narrow the gap between technological innovation and clinical practice by providing explainable, trustworthy, and interactive tools that reinforce informed decision making in mental health care.

Phased Exploitation Pathways



Figure 6: Exploitation Pathways (KER 6: xDSS)

Detailed Exploitation Pathways

Short-term exploitation pathway: Scientific Validation & Research Dissemination

Advance the XDSS from synthetic-data validation to real-world validation using SMILE pilot datasets.

- Exploit the validated multimodal data model, statistical & XAI methodology, digital biomarkers evidence, and trustworthiness metrics
- Activities include:
 - Model training on pilot data
 - Performance and robustness assessment
 - Clinical relevance evaluation
 - Peer-reviewed scientific publications
 - Methodological dissemination
- In parallel, XDSS will be reused and leveraged in future EU proposals and R&D projects

Target: Researchers, academics, clinical research communities

Key Step: First Peer-Reviewed Publication Based on Real Pilot Data

Mid-term Exploitation Pathway: Statistical-Based Commercial Entry

Focus exclusively on non-interventional, non-recommendation-based components of the XDSS to enable earlier, lower-risk market entry.

- Exploit:
 - Statistical analysis modules
 - Data aggregation & visualisation tools
 - Monitoring dashboards
 - Descriptive & exploratory analytics on multimodal behavioural data
- Commercialisation routes:
 - Licensed analytical software modules
 - Integration into research or wellbeing platforms
 - B2B contracts for monitoring, reporting & research analytics

Target: Research organisations, public health bodies, digital wellbeing platforms

Key Step: First Commercial Analytics Contract

Long-term Exploitation Pathway: Full Decision-Support System Deployment (Conditional)

- Subject to:
 - Availability of sufficient real-world clinical data
 - Clinical validation and evidence generation
 - Regulatory clarity (including EU AI Act compliance)
 - IP consolidation among partners
 - Migration to scalable cloud-based architecture
- Exploit the full XDSS, including statistical models and XAI interpretation layers.
- Commercialisation model:
 - Licensed software or SaaS
 - B2B / B2G contracts with healthcare providers and institutions

Target: Clinics, hospitals, public mental health institutions

Key Step: Cloud-Based xDSS Beta Deployment In Clinical Environment

KER 7. Exploitation, branding, and business strategies

KER Title		KER Type
SMILE Exploitation, branding, and business strategies		4. Other Intangible Results
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
RDIUP	habib.nasser@rdiup.com	All SMILE partners

Exploitation Type: Public		
Full Description		
<p>The SMILE Exploitation, branding, and business strategies, is a structured methodological framework developed within the project to ensure the long-term sustainability, scalability, and strategic positioning of SMILE KERs. This KER include: Business Model development (including BMC refinement), SWOT and PESTEL strategic analysis, IP and ownership clarification pathways, Market positioning and branding guidance, Exploitation roadmap definition (short-, mid-, and long-term), Post-project sustainability planning (thanks to EU Tracker's post-project AI powered tool for impact pathways assessment)</p>		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL3 - experimental proof of concept	TRL6 - technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)	<p>The primary objective is knowledge consolidation, reuse, and dissemination. Primary Pathway – Internal Strategic Reuse: Reuse in future EU-funded projects, Integration into proposal preparation and exploitation work packages, Application as structured exploitation governance model in new consortia.</p> <p>Secondary Pathway – Structured Dissemination and Valorisation: Publication as an open strategic guideline or methodological contribution, Integration into training and capacity-building activities for EU project stakeholders through SMILE training KER.</p> <p>This KER is not designed for direct commercialisation as a standalone product, but as a strategic methodological asset strengthening exploitation governance capacity.</p>
Next Steps (Action Plan)		
<p>Its exploitability lies in its transferability: can be reused, adapted, and embedded in future EU projects, improving exploitation maturity and impact readiness across research consortia. Consolidate the framework based on full SMILE KER validation. Formalise structured guidelines and templates derived from its application. Document best practices and lessons learned. Integrate the framework into future proposal preparation activities (SMILE follow up project) Disseminate methodological insights through project deliverables, workshops, and relevant events.</p>		
KER and Pilot / Demonstration activities		
<p>Within SMILE, the framework has been: Applied across multiple KERs Used to structure BMC development Used to conduct SWOT and PESTEL analyses Integrated into exploitation deliverables Validated through partner workshops, bilateral meetings, and exploitation specific meeting The framework has therefore been demonstrated in a real operational multi-partner EU project environment.</p>		

SWOT Analysis

Strengths	Weaknesses
<p>Validated across multiple KERs within SMILE. Structured and replicable methodology. Aligns directly with EC impact expectations. Integrates strategic, business, and branding dimensions. Enhances exploitation maturity across the consortium. Transferable to other EU projects</p>	<p>Requires expertise and facilitation to implement effectively. Still in consolidation phase.</p>
Opportunities	Threats
<p>Increasing EC emphasis on measurable impact and sustainability. Growing demand for structured exploitation governance in EU projects.</p>	<p>Risk of being perceived as a standard exploitation template if not properly communicated. Limited visibility beyond project networks.</p>

Innovation Dimensions

<p>Innovation Level</p>
<p>2 - Improvement: The KER offers enhancements or optimisations over existing solutions (e.g., better performance, cost reduction).</p>
<p>Why innovative / exploitable?</p>
<p>It Moves beyond static deliverables toward operational decision-support tools.</p> <p>Integrates branding, market positioning, IP structuring, and sustainability pathways within a single coherent model.</p> <p>Ensures systematic alignment with European Commission impact and sustainability expectations.</p> <p>Provides a replicable structure.</p> <p>Include an AI-powered structure for post-project impact pathways assessment through EU Tracker.</p> <p>Its exploitability lies in its transferability: can be reused, adapted, and embedded in future EU projects, improving exploitation maturity and impact readiness across research consortia.</p>

Phased Exploitation Pathways

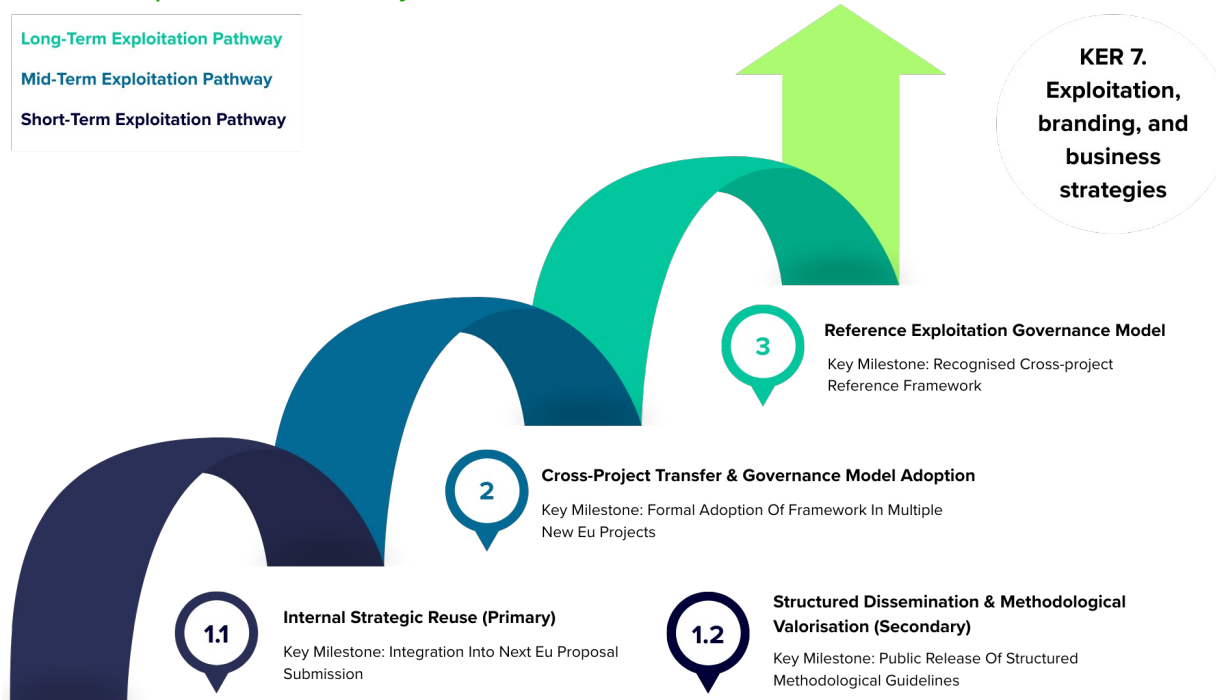


Figure 7: Exploitation Pathways (KER 7: Exploitation, branding, and business strategies)

Detailed Exploitation Pathways

Short-Term Exploitation Pathway 1: Internal Strategic Reuse (Primary)

Consolidate and operationalise the SMILE exploitation governance framework: finalise guidelines, document lessons learned, and integrate into follow-up EU proposal and consortia

Target: SMILE partners, proposal development teams, exploitation WP leaders

Key Step: Integration Into Next Eu Proposal Submission

Short-Term Exploitation Pathway 2: Structured Dissemination & Methodological Valorisation (Secondary)

Disseminate the framework as a transferable methodological contribution: publish as open strategic guideline, present at workshops, and build capacity for EU project stakeholders.

Target: EU project coordinators, exploitation managers, research support offices

Key Step: Public Release Of Structured Methodological Guidelines

Mid-term Exploitation Pathway: Cross-Project Transfer & Governance Model Adoption

Position the framework as a reusable exploitation governance model across EU projects, embedding structured BMC, SWOT, and PESTEL approaches aligned with EC sustainability expectations.

- Embed in new EU projects

- Align roadmaps with EC expectations
- Deploy EU Tracker AI post-project impact pathway assessment as structured support

Target: Multi-partner EU consortia, research-performing organisations, innovation agencies

Key Step: Formal Adoption of Framework in Multiple New Eu Projects

Long-term Exploitation Pathway: Reference Exploitation Governance Model

Establish the SMILE framework as a recognized, structured approach for exploitation maturity across the EU R&I ecosystem.

- Consolidate Evidence: Cross-project impact data to substantiate methodology's effectiveness
- Strengthen Branding: Position framework as a replicable impact governance structure with visible identity
- Expand Visibility: Reach stakeholders beyond the SMILE network into the broader EU R&I ecosystem

Target: EU R&I ecosystem stakeholders, coordinators of large collaborative projects, institutions seeking structured impact governance

Key Step: Recognised Cross-Project Reference Framework

KER 8. SMILE Data Models

KER Title		KER Type
Common Semantic Data Model for Seamless Integration of Digital Interventions into Research and Clinical Routine		2. Scientific or Technological R&D Result including ICT Hardware
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
UM	izidor.mlakar@um.si	HWU, UoE, WIZ, RDIUP
Exploitation Type: Public		
Full Description		
The model ensures that each intervention step, i.e. from automated task scheduling to serious game sessions, ESM prompts, video diaries, and subsequent analytics, remains consistently linked to its study context, clinical workflow, measurements, and evidence, enabling FAIR, interoperable, and semantically rich data flows across the Companion App, Game App, DSS, OKP and external healthcare and research systems.		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL1 - basic principles observed	TRL4 - technology validated in lab	The initial exploitation vision is to continue R&D on interoperable mental-health data models, digital biomarkers, and digital interventions within SMILE and within new research proposals. We will validate

		<p>and stress-test the framework in SMILE pilots, publish at least one joint research paper and open the model under CC-BY specifications and guidelines. We intend to keep the model itself public while protecting brand and implementation know-how where needed and enable knowledge transfer and future commercialisation by integrating refined framework components into HUMADEx's start-up company and its products and services for clinical routine.</p>
<p>Next Steps (Action Plan)</p>		
<p>Finalise and publish the CC BY public specification of the semantic model, data flows, and reference implementation patterns (OKP, FHIR, SAMF, DSS) as part of SMILE public outputs. Co-author and submit at least one joint research paper (SMILE partners + DITA/HUMadex) showcasing the framework and pilot evidence, targeting a digital mental health or medical informatics venue. Package a minimal "integration toolkit" (profiles, example APIs, deployment recipes) to support reuse in new research projects and Living Labs beyond SMILE.</p>		
<p>KER and Pilot / Demonstration activities</p>		
<p>We have already moved the common semantic data model from conceptual design to demonstration and piloting. It was iteratively refined in SMILE Living Labs and is being used in the SMILE multi-country pilots to orchestrate Companion App, Serious Game and DSS activities, manage cluster-randomised protocols, and link digital interventions with their corresponding measurements and outcomes. As a next exploitation step, a modified version of the model is being prepared for reuse in HE CERTAIN (https://certain-project.eu/) pilots, allowing adaptation to new clinical and research contexts while preserving the same FHIR-based semantics, FAIR data principles, and interoperability patterns proven in SMILE.</p>		

SWOT Analysis

Strengths	Weaknesses
<p>Capability to generate and exchange "knowledge" among stakeholders by collecting data, transforming it into digital biomarkers.</p> <p>FHIR-based common semantic data model that standardises representation of participants, protocols, activities, and outcomes, supporting consistent data capture across components.</p> <p>Structured support for complex study operations (e.g., cluster-based protocols and automated orchestration of activities through Plan Definition/Care Plan/Task patterns).</p>	<p>The landscape already includes digital mental health solutions (e.g., SPARX, Thymia, Alien Health Game), meaning SMILE must differentiate clearly and prove superiority beyond existing, recognisable products.</p> <p>Some public release and reuse can be constrained by external instrument licensing (e.g., public release of questionnaire chatbots depends on the license of the underlying PRO instrument), which can slow dissemination compared with competitors using fully proprietary instruments.</p> <p>Detailed logging is noted as resource-intensive ("consumes a lot of resources") and planned to be reduced later, which signals a trade-off between observability and performance/cost.</p> <p>Dependence on a FHIR-centric means there is</p>

	<p>potential misalignment with the main regulatory observational-data ecosystem, where competitors natively working in OMOP can plug in more easily to DARWIN EU and future EHDS nodes.</p> <p>Additional ETL and maintenance overhead will be required to interoperate, which can be framed as a resource and time disadvantage.</p>
<p>Opportunities</p>	<p>Threats</p>
<p>EU initiatives like the European Health Data Space and national digital health strategies are creating demand for interoperable, standard-based platforms that can reuse real-world data and support cross-border research.</p> <p>Regulatory bodies are explicitly looking for high-quality, standardised data and decision-support tools to strengthen real world evidence, opening room for platforms that can bridge care, research, and youth services.</p> <p>Few competitors combine serious gaming, multimodal biomarker extraction, explainable DSS, and a full research grade data infrastructure targeted specifically to adolescents and young adults.</p> <p>HL7 FHIR is increasingly promoted as the interoperability layer for European health data exchange, with new HL7 Europe FHIR Implementation Guides explicitly designed to support the European Health Data Space.</p> <p>FHIR is optimised for flexible, real-time, API driven interactions with apps and devices, making it ideal for patient facing and clinician facing applications. Namely, most OMOP-focused competitors are strong on retrospective analytics but weaker on interactive workflows.</p>	<p>The EHDS framework will require strict governance for secondary use (data permits, HDAB review, transparency obligations), and failure to meet emerging interoperability and security expectations could restrict access to secondary use data markets.</p> <p>European infrastructures for secondary use are converging on hybrid FHIR/OMOP expectations, with some documents explicitly recommending OMOP for semantic interoperability.</p> <p>EU and national regulators are increasing oversight on health and mental health apps (MDR, AI Act, DSA, child protection rules), increasing the cost and complexity of compliance.</p>

Innovation Dimensions

<p>Innovation Level</p>
<p>3 - Within Paradigm: The KER introduces a new approach or technology within the existing innovation framework or market paradigm.</p>
<p>Why innovative / exploitable?</p>
<p>Integrates a FHIR based semantic model, ontology, digital interventions (Companion App, Serious Game, DSS workflows) and multimodal digital biomarkers (self-reports, game behaviour, diary cues) into one end to end, pilot validated pipeline for youth mental health. Is openly specified (CC-BY) yet production-grade, enabling direct reuse of both standardized interven-</p>

tions and data flows as a backbone for new research studies, clinical pilots, and commercial products

Phased Exploitation Pathways

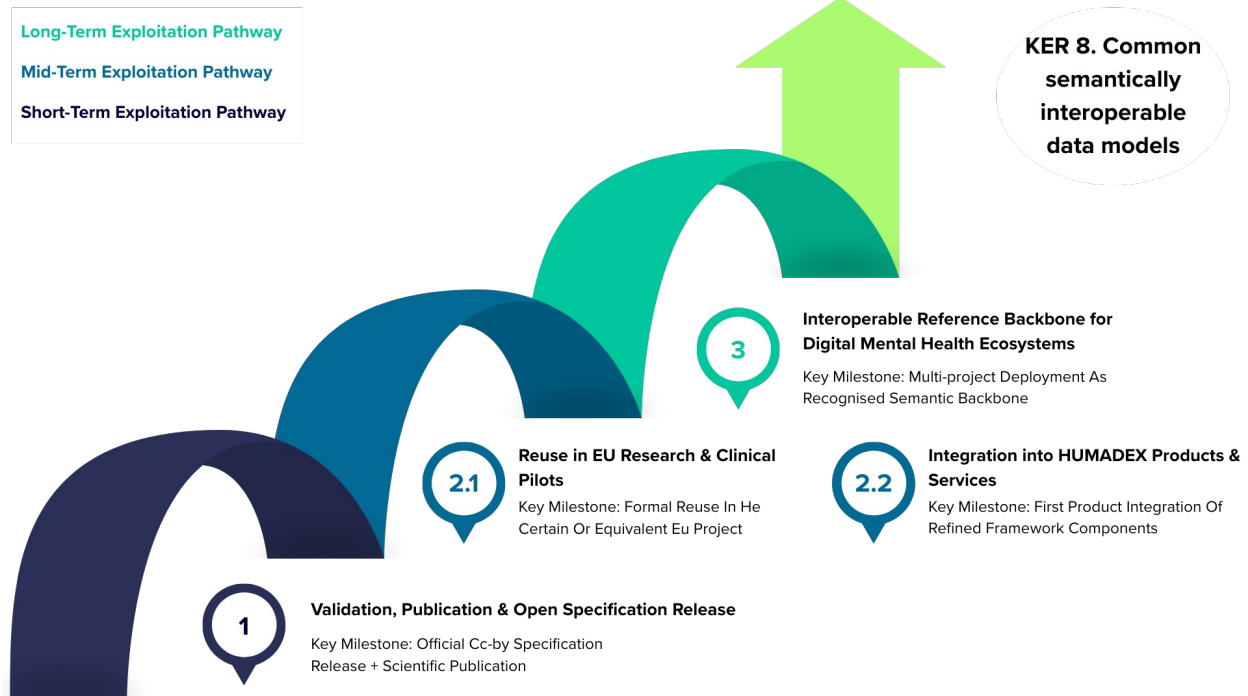


Figure 8: Exploitation Pathways (KER 8: Data Models)

Detailed Exploitation Pathways

Short-term exploitation pathway: Validation, Publication & Open Specification Release

Consolidate and publish the FHIR-based semantic framework validated in SMILE pilots.

- Finalise CC-BY public specification
- Publish semantic model, data flows, and reference patterns
- Co-author and submit at least one joint scientific publication
- Package minimal integration toolkit (profiles, APIs, deployment recipes)

Target: Research institutions, digital mental health researchers, EU project consortia, living Labs and pilot sites

Key Step: Official Cc-By Specification Release + Scientific Publication

Mid-Term Exploitation Pathway 1: Reuse in EU Research & Clinical Pilots

Extend the semantic model into new research and clinical contexts.

- Reuse in HE CERTAIN pilots
- Adaptation to new cohorts and study designs
- Continued R&D on digital biomarkers and interoperable mental-health data models
- Validation under new operational environments

Target: Horizon Europe projects, clinical research infrastructures, hospitals conducting digital intervention studies, cross-border research initiatives

Key Step: Formal Reuse in HE Certain or Equivalent EU Project

Mid-Term Exploitation Pathway 2: Integration into HUMADEx Products & Services

Enable future commercialisation through integration of refined components into start-up offerings.

- Embed semantic framework elements into HUMADEx products
- Integrate into clinical routine services
- Transfer implementation know-how
- Protect brand and implementation expertise where needed

Target: Clinical service providers, digital health product users, healthcare organisations adopting HUMADEx services

Key Step: First Product Integration of Refined Framework Components

Long-term Exploitation Pathway: Interoperable Reference Backbone for Digital Mental Health Ecosystems

Position the model as a reusable semantic backbone aligned with European interoperability initiatives.

- Alignment with EHDS and FHIR implementation guides
- Expansion beyond youth mental health
- Continued refinement for cross-border research and care integration
- Structured interoperability with hybrid FHIR/OMOP ecosystems

Target: European digital health infrastructures, research–care integrated ecosystems, large-scale interoperability initiatives, regulatory-aligned digital health platforms

Key Step: Multi-Project Deployment as Recognised Semantic Backbone

KER 9. SAPL Policy Engine

KER Title		KER Type
SAPL Policy Engine		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
FTK e.V.	Dominic Heutelbeck dheutelbeck@ftk.de	FTK e.V. (sole developer)
Exploitation Type: Commercial + Public (both apply — open-source with follow-up R&D and potential commercial support)		
Full Description		

<p>SAPL is an open-source Attribute Stream-Based Access Control (ASBAC) policy engine and domain-specific language. Unlike traditional request-response authorization (XACML, OPA, Cedar), SAPL uses a publish-subscribe model where authorization decisions are continuously streamed and updated in real-time when attributes or policies change. Built on Java 21 and Project Reactor, it integrates natively with Spring Boot/Spring Security and supports ABAC, RBAC, and data filtering/transformation within policies.</p>		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
<p>TRL6 - technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)</p>	<p>TRL7 - system prototype demonstration in operational environment</p>	<p>FTK e.V. will exploit SAPL through a dual-track open-core model. The policy engine core remains open source (Apache 2.0) on Maven Central, targeting Java/Spring developers building access control for healthcare, IoT, and enterprise applications. Commercial exploitation focuses on enterprise tooling (policy administration, monitoring, audit dashboards) and professional consulting/integration services offered directly by FTK. Target customers are European enterprises and public sector organisations requiring fine-grained, real-time authorization — particularly in regulated domains (healthcare, energy, public administration). Academic exploitation continues through publications and knowledge transfer at universities (FernUniversität in Hagen). Further EU-funded R&D projects will be pursued to extend SAPL into new domains. Launch of commercial offerings is planned to follow the SAPL 4.0 release and the SMILE project conclusion.</p>
<p>Next Steps (Action Plan)</p>		
<p>Release of 4.0.0 completing the SMILE development cycle of the engine. Attendance of industry events for dissemination. Development of a commercial enterprise-oriented tooling. Development of a business plan for the consulting business.</p>		
<p>KER and Pilot / Demonstration activities</p>		
<p>Within SMILE, SAPL was deployed as the authorisation infrastructure for the project's mental health platform in a pilot deployment across multiple European partner sites. SAPL enforces real-time, attribute-based access policies over the platform's clinical data APIs, decision support tools, gamified self-assessments, and AI services.</p> <p>The deployment spans the full SMILE consortium (14 partners, 7 EU countries plus the UK) over the project duration (September 2023 to October 2026). Key outcomes include validation of ASBAC streaming authorisation in a sensitive healthcare context with multi-tenant, cross-organisational data access requirements, and demonstration that fine-grained policy changes propagate in real-time without session interruption. Prior to SMILE, SAPL was also demonstrated in the VPP4ISLANDS project (Horizon 2020) protecting virtual power plant APIs for European island energy systems.</p>		

SWOT Analysis

Strengths	Weaknesses
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<p>Unique streaming authorisation paradigm (ASBAC) with no direct competitor. Deep Spring ecosystem integration. Modern Java 21 stack. Comprehensive tooling (Servers, LSP, playground, testing framework, Maven plugin). Academic foundation, Apache 2.0 open-source. Validated in multiple EU projects.</p>	<p>Small community (limited GitHub adoption). Java/JVM-only — no Go, Rust, or Python runtime (however support for SAPL Style PEPs for JS, PHP, C#, Python). Limited adoption compared to OPA. Reliance on EU project funding cycles.</p>
<p>Opportunities</p>	<p>Threats</p>
<p>Growing demand for real-time authorisation in IoT, healthcare, and Industry 4.0. EU Digital Sovereignty initiatives favouring European open-source solutions. Increasing adoption of reactive/streaming architectures. Potential for standardisation of ASBAC model.</p>	<p>Dominant competitors with major backing (OPA/CNCF, Cedar/AWS). Risk of remaining niche if streaming authorisation need isn't broadly recognized. Funding dependency on EU project cycles. Fast-moving cloud-native ecosystem may favour Go/Rust-based solutions. Current focus of development geared more towards no-code low-code solutions.</p>

Innovation Dimensions

<p>Innovation Level</p>
<p>3 - Within Paradigm: The KER introduces a new approach or technology within the existing innovation framework or market paradigm.</p>
<p>Why innovative / exploitable?</p>
<p>SAPL is the only policy engine offering native streaming authorization decisions (ASBAC). No competitor (OPA, Cedar, Casbin, XACML) supports continuous, reactive policy evaluation. This addresses a real gap for IoT, healthcare, and session-based applications where permissions must update in real-time. The JSON-native DSL is significantly more readable than XACML. Published at ACM SACMAT, the approach has academic validation. Apache 2.0 licensing enables unrestricted commercial and public exploitation.</p>

Phased Exploitation Pathways



Figure 9: Exploitation Pathways (KER 9: SAPL)

Detailed Exploitation Pathways

Short-Term Exploitation Pathway 1: SAPL 4.0 Release and IP Consolidation

- Complete the SAPL 4.0 development cycle incorporating SMILE-driven enhancements (healthcare authorization patterns, multi-tenant policy management).
- Publish on Maven Central.
- Consolidate IP position through trademark registration of "SAPL" and "ASBAC."

Target: Software developers, research projects requiring advanced ABAC, technology integrators

Key Step: SAPL 4.0 Stable Release + Trademark Registration

Short-Term Exploitation Pathway 2: Academic Exploitation and Standardisation Groundwork

- Publish SMILE results at ACM SACMAT / IEEE venues, demonstrating ASBAC validation in healthcare.
- Submit ASBAC as a candidate model to relevant standardisation bodies (e.g., OASIS, IETF).
- Build academic adoption through university course integration (FernUniversitat in Hagen).

Target: Standardisation bodies, universities and higher education institutions, PhD students and research groups

Key Step: Peer-Reviewed Publication of SMILE Authorisation Architecture

Mid-Term Exploitation Pathway 1: Commercial Enterprise Tooling (SAPL Enterprise)

- Develop and launch commercial enterprise add-ons:
 - policy administration dashboard
 - real-time audit and compliance monitoring
 - visual policy editor
 - multi-PDP cluster management.
- Offer as subscription-based enterprise product alongside the open-source core (open-core model).

Target: Large enterprises, Regulated industries (healthcare, energy, finance), SaaS providers, DevOps and platform engineering teams

Key Step: Launch Of SAPL Enterprise Product

Mid-Term Exploitation Pathway 2: Professional Services and Consulting

- Establish FTK as the go-to consultancy for streaming authorisation architecture.
- Offer integration services, training, and certification programmes targeting regulated industries (healthcare, energy, finance, public administration)
- Leverage SMILE and VPP4Islands as reference deployments

Target: Organisations from regulated industries, government IT departments

Key Step: First Commercial Consulting Engagement Outside EU-Funded Projects

Long-term exploitation pathway: Authorization-as-a-Service (SAPL Cloud or On-Premise)

- Launch a managed cloud authorization service (SaaS) providing SAPL PDP-as-a-Service with streaming decision endpoints.
- Target organisations that need real-time ABAC without operating their own infrastructure.
- Position against Auth0/Permit.io/OPA in the emerging cloud authorization market.

Target: SaaS startups, scale-ups, platform providers

Key Step: SAPL Cloud Beta Launch

KER 10. EU Tracker

KER Title		KER Type
EU Tracker		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
RDIUP	habib.nasser@rdiup.com	-
Exploitation Type: Commercial		

Full Description		
<p>EU Tracker is an all-in-one AI-powered web platform designed to manage, track and maximise the impact of EU-funded projects. The platform integrates: (a) Communication, Dissemination & Exploitation tracking dashboards, (b) KPI visualisation aligned with European Commission logic, (c) Automated data scraping for EU portal reporting, (d) AI-powered proposal impact generation (I-Gen), (e) AI agent for post-project impact tracking beyond project lifetime, (f) Deliverable tracking and review preparation tools.</p> <p>Unlike generic project management tools, EU Tracker is fully aligned with EU funding programme structures (Horizon Europe, Erasmus+, CSA, RIA), evaluation criteria, and reporting requirements.</p>		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL4 - technology validated in lab	TRL8 - system complete and qualified	<p>RDIUP will exploit EU Tracker through a SaaS freemium model.</p> <p>1. Freemium model:</p> <p>Basic (Free) – limited DC tracking entries. Silver – advanced KPI dashboards, scraping. Gold – full impact management + post-project tracking. I-Gen AI module sold via credit-based system (separate monetisation layer).</p> <p>2. Target customers: Project coordinators, WP Leaders (Communication, Dissemination, Exploitation), Universities, SMEs, Research centres, NGOs, Public bodies managing EU projects.</p> <p>3. Business model:</p> <p>Subscription per project duration. Subscription per organisation. Add-ons: Training & onboarding, Proposal preparation support, White-label integration, SSO integration for large institutions.</p>
Next Steps (Action Plan)		
<p>Short-term (post-SMILE consolidation phase):</p> <ul style="list-style-type: none"> • Consolidate and stabilise EU Tracker features validated within SMILE. • Integrate structured feedback from SMILE partners and other early users. • Finalise commercial packaging: Pricing model (completed), Onboarding process (completed), Training materials and documentation (ongoing refinement). • Continue UX improvements and minor feature optimisation (non-blocking refinements). • Ensure regulatory vigilance regarding AI usage, data scraping, and privacy compliance. <p>Mid-term (market scaling phase):</p> <ul style="list-style-type: none"> • Identify and onboard early adopters among ongoing and upcoming EU-funded projects. • Launch targeted dissemination and exploitation actions post-SMILE (direct outreach to coordinators, WP leaders, research support offices). • Expand I-Gen modules (e.g., extended business planning, IP mapping, advanced impact 		

<p>analytics).</p> <ul style="list-style-type: none"> • Scale SaaS subscriptions per project and per organisation. • Develop white-label and SSO integration options for large universities and research institutions. <p>Long-term (strategic growth phase):</p> <ul style="list-style-type: none"> • Strengthen market validation through cross-project evidence. • Explore structural scaling options, including potential dedicated legal structuring if adoption reaches critical mass. • Position EU Tracker as a reference AI-enabled impact management platform in the EU R&I ecosystem.
<p>KER and Pilot / Demonstration activities</p>
<p>Within SMILE, EU Tracker is fully integrated into WP8. And is used to: Report DC activities of the partners, visualise KPIs progress, enable structured partner input and consolidation of data. The tool is demonstrated through real SMILE KPIs and targets, validating its relevance and usability in a live Horizon Europe project context.</p>

SWOT Analysis

Strengths	Weaknesses
<p>Strong alignment with EU funding programme logic and evaluation criteria.</p> <p>Direct compliance with Horizon Europe impact, exploitation, and monitoring requirements.</p> <p>Developed by RDIUP, an experienced EU R&I SME with consolidated expertise in EU projects, dissemination, exploitation, impact pathways, KPIs, reporting logic, and proposal drafting.</p> <p>Integrates technical tool + methodological expertise in a single ecosystem.</p> <p>All-in-one impact governance platform (DCE, KERs, IP, deliverables, post-project tracking, AI generation).</p> <p>Flexible, modular, and adaptable across projects, sectors, and programme types.</p> <p>High reuse and scalability potential across multiple EU projects.</p> <p>Cross-project validation already underway.</p> <p>High readiness level and immediate commercial exploitability.</p>	<p>Requires ongoing marketing and visibility efforts to reach coordinators and research offices.</p> <p>Requires continuous monitoring of AI and data scraping regulatory frameworks.</p> <p>Scaling speed dependent on available human and financial resources.</p>
Opportunities	Threats
<p>Increasing European Commission pressure on real impact, exploitation, and measurable outcomes.</p> <p>Growing number of EU-funded projects requiring structured impact support.</p> <p>Lack of comparable specialised impact management tools on the market.</p>	<p>Competition from generic project management platforms</p> <p>Budget constraints in some EU projects.</p> <p>Resistance to change from established project management practices.</p> <p>Potential regulatory tightening related to AI usage</p>

<p>Increasing digitalisation of research management and reporting processes. Potential integration with consulting, training, and capacity-building services. Expanding adoption of AI in proposal drafting and strategic planning.</p>	<p>or automated data scraping.</p>
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Innovation Dimensions

<p>Innovation Level</p>
<p>4 - Outside Paradigm: The KER represents a breakthrough that challenges or redefines current technologies, markets, or user practices.</p>
<p>Why innovative / exploitable?</p>
<p>EU Tracker introduces a structured, operational, and longitudinal approach to Communication, Dissemination, and Exploitation (DCE) management in EU-funded projects, going beyond conventional static templates and fragmented spreadsheets. It addresses a clear and recurring structural pain point in EU projects: weak follow-up of DCE activities, fragmented KPI monitoring, and poor post-project sustainability tracking. Unlike generic project management tools, EU Tracker: Transforms impact from a reporting obligation into a continuous strategic process. Integrates KER reporting, IP tracking, DCE monitoring, deliverable review preparation, post-project impact pathways, and AI-generated impact sections into a single, coherent platform. Aligns natively with European Commission evaluation logic, impact pathways, and reporting/monitoring guidelines (Horizon Europe and other EU programmes). Extends impact tracking beyond project lifetime through an AI-powered post-project monitoring agent. Combines structured compliance logic with AI-assisted generation (I-Gen), enabling high-quality and consistent impact section drafting for proposals. It demonstrates strong replicability potential across EU programmes (RIA, IA, CSA, Erasmus+), project sizes, and thematic domains, making it a scalable and transferable solution for the broader EU R&I ecosystem.</p>

Phased Exploitation Pathways



Figure 10: Exploitation Pathways (KER 10: EUTRACKER)

Detailed Exploitation Pathways

Short-term exploitation pathway: Validation & R&D expansion

Consolidate and refine EU Tracker based on SMILE use cases and early user feedback building a stable, validated foundation for broader deployment.

- Cross-project validation across additional EU projects
- Feature refinement for diverse project types (RIA, CSA, Erasmus+)
- Knowledge generation and best-practice consolidation
- Integration in future RDIUP projects and proposals

Target: Early adopters, project coordinators and WP leaders testing the tool.

Key Step: Consolidate & Stabilise Current EU Tracker Version

Mid-Term Exploitation Pathway 1: Commercial SaaS

- Monetise EU Tracker as a subscription-based SaaS per project or per organization, with freemium tiers:
 - Basic (free)
 - Silver (advanced dashboards)
 - Gold (full impact management + post-project tracking)
 - I-Gen AI module via credit-based system
 - Add-ons: training & onboarding, consulting, proposal support, white-label, SSO

Target: Project coordinators & WP leaders (C/D/E/Impact), across universities, research centres, SMEs, NGOs, public bodies

KEY STEP: Launch SaaS Subscriptions & Onboarding

Mid-Term Exploitation Pathway 2: Training & Support Services (complementary)

Accelerate adoption of EU Tracker and monetise RDIUP's methodological expertise.

- Workshops, onboarding & personalised guidance
- Training on impact planning, KPI monitoring & EC-aligned reporting
- Integration in consulting & EU project support services

Target: Project coordinators, WP leaders, proposal writers

Key Step: Launch Structured Training and Support Offer

Long-term exploitation pathway: Strategic Growth & Market Scaling

- Critical Mass Threshold: Market scaling through a dedicated legal entity once adoption reaches critical mass
- Cross-Project Validation: Broader promotion through validated evidence across diverse EU project types and consortia
- Reference Platform Status: Establish EU Tracker as the go-to solution for structured, AI-enabled impact management in EU-funded projects

Target: All EU project stakeholders seeking structured, AI-enabled impact management

Key Step: Position EU Tracker as Reference Platform And Scale SaaS Adoption

KER 11. Open SMILE Dataset

KER Title		KER Type
KER 11. Open SMILE Dataset		4. Other Intangible Results
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
University of Edinburgh	Matthias Schwannauer (m.schwannauer@ed.ac.uk)	all SMILE evaluation Pilot site leads
Exploitation Type: Public		
Full Description		
SMILE has agreed to the use of open science principles. One year following the end of the trial the full anonymised research dataset will be made available under curated access for the research community. The data will be published in the form of a comprehensive data dictionary. Access will be curated and permitted for scientific and non-commercial use, following approval of an abstract and data analysis plan.		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision

n/a	n/a	We will share a curated dataset in line with the FAIR principles, making it Findable, Accessible, Interoperable and Reusable, thus increasing the transparency and reproducibility of our research, reducing duplication and wasteful repetition of research results, and ultimately increasing trust in science.
Next Steps (Action Plan)		
After completion of the SMILE project, the dataset will be shared for the research community in the form of a comprehensive data dictionary. The dataset will be available upon request for scientific, non-commercial use, following approval of an abstract and data analysis plan. Linking the dataset to articles published by the SMILE consortium will enable more researchers to explore, validate and build on our work, strengthening credibility and generating impact beyond the lifecycle of the SMILE project.		
KER and Pilot / Demonstration activities		
It has been demonstrated across a range of research fields that sharing open and curated datasets helps advance discovery by making research more transparent, more robust, and by accelerating research progress, and that the number of researchers who share data is steadily growing.		

Innovation Dimensions

Innovation Level
1 - Standard: The KER aligns with current market or technological standards; no significant novelty, but solid and reliable.
Why innovative / exploitable?
This KER will enable the research community to access the breadth of data collected during the SMILE proof-of-concept study, making the most of the efforts placed in the study and enabling new insights beyond the lifecycle of the project.

Phased Exploitation Pathways

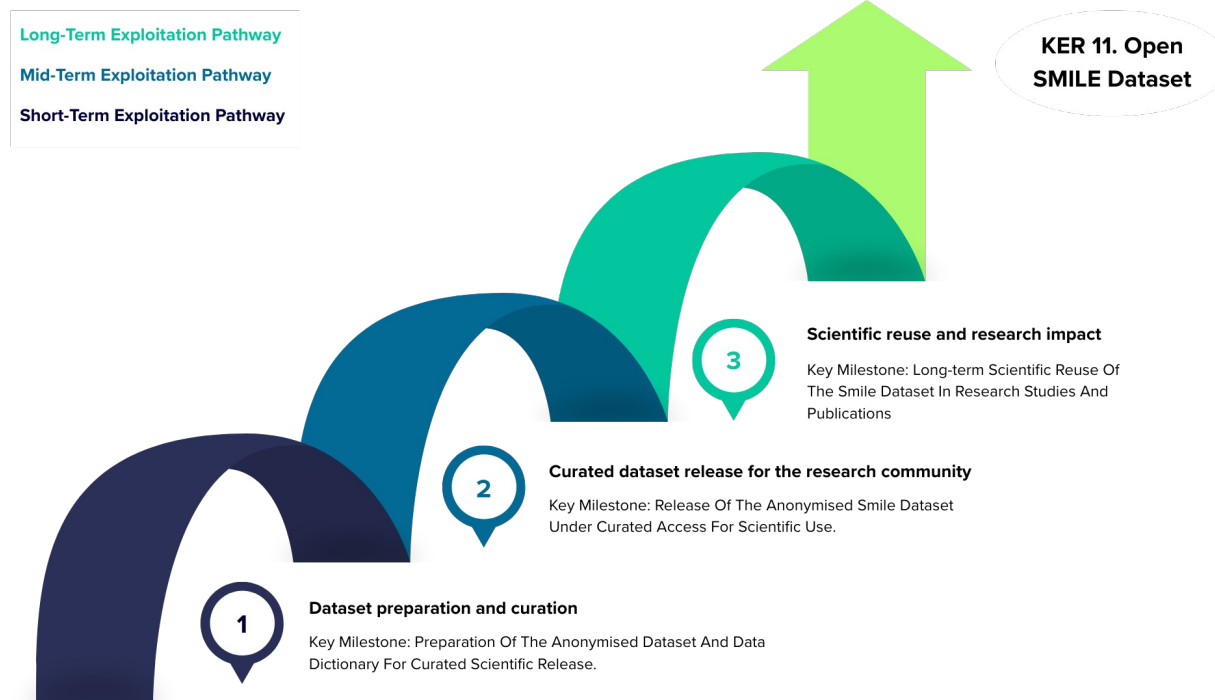


Figure 11: Exploitation Pathways (KER 11: Open SMILE Datasets)

Detailed Exploitation Pathways

Short-term exploitation pathway: Dataset preparation and curation

Following Open Science principles, the SMILE consortium prepares the pilot data for release as an open dataset. Activities focus on ensuring that the dataset is properly anonymised, structured and documented for future scientific reuse.

- Prepare and curate the anonymised SMILE research dataset.
- Ensure compliance with FAIR principles (Findable, Accessible, Interoperable, Reusable).
- Develop a comprehensive data dictionary describing variables and dataset structure.
- Prepare documentation supporting transparency, reproducibility and research trust.

Target: Research community (universities, research centres, health data scientists).

Key Step: Preparation of the Anonymised Dataset and Data Dictionary for Curated Scientific Release.

Mid-term Exploitation Pathway: Curated dataset release for the research community

The curated dataset will be released following the agreed timeline and made available to the scientific community under controlled access conditions.

- Share the full anonymised SMILE research dataset one year after the end of the trial.
- Provide the accompanying data dictionary to support dataset interpretation and reuse.

Project Number : 101080923

Project Acronym: SMILE

- Establish a curated access process allowing researchers to submit an abstract, data analysis plan and variable request.
- Provide dataset access for scientific and non-commercial use only.

Target: Research community (universities, research centres, health data scientists).

Key Step: Release of the Anonymised Smile Dataset Under Curated Access for Scientific Use.

Long-term Exploitation Pathway: Scientific reuse and research impact

The dataset contributes to continued scientific research and supports validation and extension of the SMILE findings beyond the project lifecycle.

- Enable researchers to reuse the dataset for secondary analyses and new research questions.
- Support scientific publications and collaborations building on SMILE results.
- Increase transparency and reproducibility in digital mental health research.

Target: Academic researchers and mental health research networks

Key Step: Long-Term Scientific Reuse of the Smile Dataset in Research Studies and Publications.

KER 14. FHIR server

KER Title		KER Type
SMILE FHIR Server		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
UM	izidor.mlakar@um.si, valentino.safran@um.si	-
Exploitation Type: Public		
Full Description		
The SMILE FHIR server is a HL7 FHIR platform, built on the HAPI FHIR server and implemented as a set of containerized microservices that expose a secure, scalable REST API for storing and querying SMILE study resources. It represents the production implementation of the SMILE Common Semantic Data Model. The server sits at the center of a broader ecosystem that includes a Spring Boot REST layer, multilingual Rasa chatbots, and a FHIR dashboard, all communicating over a Docker virtual network and persisting data to the FHIR server as JSON FHIR resources. Security is enforced through Keycloak-based authentication and authorization (JWT tokens, role-based access control, TLS, VPN, firewall rules, and API keys for service-to-service calls).		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL2 - technology concept formulated	TRL4 - technology validated in lab	"The SMILE FHIR based platform is designed as reusable standards-compliant open core (CC-BY licensing) for secure, scalable digital health solutions beyond the SMILE project itself. The current phase

		<p>focuses on evaluation within SMILE pilots. Results from the pilots will be used to improve and refine the platform (performance tuning, security and IAM refinements, UX improvements). In the mid-term, the platform will be repurposed as a generic HL7 FHIR/Keycloak/Rasa stack for other EU funded projects, as a managed research infrastructure for multi-site trials and digital interventions. Other commercialization paths include: white-label FHIR backend for digital health products, reference architecture plus expertise package for FHIR compliant ecosystems."</p>
<p>Next Steps (Action Plan)</p>		
<p>"Finalise and document the release package of the SMILE FHIR platform. Improve the current deployment during SMILE pilots by monitoring logs and metrics, fixing issues found in real world use. Proactively identify and approach candidate EU projects and consortia, where UM is already a partner, where the platform can be reused and re-utilized on different cohorts/settings. Carry out exploitation through HUMADDEX's start-up company with integration of the FHIR stack as a managed service integrated into digital health solutions."</p>		
<p>KER and Pilot / Demonstration activities</p>		
<p>"Platform is being tested end to end across seven pilots. Pilot administrators and clinicians use the Clinician Web App and DSS to monitor onboarding, assign activities, visualise mood, anxiety and depression risk, inspect DSS and diary-analysis outputs, and export data for further analysis, demonstrating the KER's ability to support real-world care workflows and research endpoints. The KER will be reused as the core FHIR stack in the Horizon Europe AI4HOPE project, extending its exploitation beyond SMILE into the dementia care domain. The KER will be reused and demonstrated in the Horizon Europe CERTAIN project's pilots, where the FHIR-based platform is utilised for pre-screening and screening workflows in routine clinical settings."</p>		

SWOT Analysis

Strengths	Weaknesses
<p>Production grade HL7 FHIR stack with HAPI FHIR and containerised microservices.</p> <p>Direct implementation of the SMILE Common Semantic Data Model.</p> <p>Multi-layer security (JWT, RBAC, TLS, VPN, firewalls, policy-based access, audit logging).</p> <p>Complete software stack connected to the implementation, including Companion App, Serious Game, Clinician Portal, DSS, SAMF, API, FHIR dashboard, etc.</p> <p>CC BY release lowers adoption barriers while HUMADDEX's start up provides a concrete commercialization channel</p>	<p>FHIR stack has only a one real world deployment</p> <p>Requires a trained DevOps, security, and informatics capacity to operate and maintain</p> <p>EHR vendors and cloud providers (with managed FHIR services and strong sales channels) may be perceived as lower risk choices by conservative hospitals.</p> <p>Core technical documentation exists, however, installer packages, admin tooling, and non-technical documentation are still being consolidated.</p>

Opportunities	Threats
<p>Growing demand for interoperable and standardised digital health backends due to increased use of telemonitoring and digital therapeutics.</p> <p>Many initiatives struggle to move from raw app data and proprietary models to standardised, analysable FHIR resources</p> <p>Increasing regulatory pressure on security, auditability, and explainability.</p>	<p>Major EHR vendors and hyperscale clouds increasingly offer managed FHIR services with strong integration into existing hospital ecosystems.</p> <p>Hospitals and public institutions often prefer established vendors, long contracts, and “single vendor” solutions.</p> <p>Changes in EU or national regulations on data protection, AI in healthcare, or medical device classification can increase compliance overhead</p> <p>High profile breaches or negative press around digital health systems, even unrelated ones</p> <p>Changing national profiles, local FHIR extensions, or competing standards (e.g. OpenEHR and OMOP).</p>

Innovation Dimensions

Innovation Level
3 - Within Paradigm: The KER introduces a new approach or technology within the existing innovation framework or market paradigm.
Why innovative / exploitable?
<p>HL7 FHIR, microservices, containerization, and Keycloak into a single, production tested reference architecture that goes beyond minimal FHIR server setups for GDPR-compliant, PHI-grade deployments in hospitals and research infrastructures.</p> <p>Directly implements the SMILE Common Semantic Data Model (research, care planning, and PRO workflows) as live FHIR resources</p>

Phased Exploitation Pathways



Figure 12: Exploitation Pathways (KER 14: FHIR)

Detailed Exploitation Pathways

Short-term exploitation pathway: Pilot Consolidation & Open-Core Release

Validate and harden the SMILE FHIR stack within SMILE pilots.

- Performance monitoring and tuning
- Security and IAM refinements (Keycloak, RBAC, JWT, TLS)
- Bug fixing based on real-world pilot deployment
- Consolidation of documentation and release package
- Preparation of CC-BY open-core publication

Target (validation phase): SMILE pilot administrators and clinicians, internal technical teams (DSS, SAMF, WebApp integration), early research collaborators

Key Step: Stable Release Package + Documented Cc-By Open-Core Publication

Mid-Term Exploitation Pathway 1: Reuse as Research Infrastructure (EU Projects)

Repurpose the SMILE FHIR stack as a reusable, standards-compliant backend for EU-funded projects and multi-site trials.

- Deployment in AI4HOPE and CERTAIN projects
- Adaptation to new cohorts and clinical domains
- Positioning as managed research infrastructure for Horizon Europe projects

- Reuse in telemonitoring and digital intervention pilots

Target: Horizon Europe consortia, clinical research infrastructures, universities and hospitals running multi-site studies, EU-funded digital health projects

Key Step: First Formal Reuse in a New EU Project as Core FHIR Infrastructure

Mid-Term Exploitation Pathway 2: Managed FHIR Backend via HUMADEx Start-up

Exploit the FHIR stack commercially as a white-label backend and managed service.

- Integration of the FHIR stack into digital health products
- Managed hosting and secure deployment services
- Reference architecture + expertise package
- Technical integration support

Target: Digital health SMEs, start-ups building telehealth or digital therapeutics, research-to-market spin-offs, healthcare solution providers requiring FHIR compliance

Key Step: First Commercial Deployment Via Humadex-Linked Start-Up

Long-term exploitation pathway: Reference Architecture for Secure FHIR Ecosystems

Position the SMILE FHIR platform as a production-tested reference architecture for GDPR-compliant, interoperable digital health ecosystems.

- Scaling across multiple domains beyond youth mental health
- Continuous security and compliance upgrades
- Expansion of interoperability layers
- Strengthening integration with standardised semantic data models

Target: Hospitals and healthcare networks, national digital health infrastructures, large-scale EU research platforms, health data interoperability initiatives

Key Step: Multi-Project Deployment as Recognised FHIR Reference Stack

KER 15. SMILE API

KER Title		KER Type
SMILE API		3. ICT Software Digital solution
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
WIZ	alex@butean.com	RDIUP, UoM, FTK
Exploitation Type: Commercial		
Full Description		
The SMILE API is the component that ensures communication, dataflow, data structure translations and storage. As a high-demand data transit component, the SMILE API forwards the requests between		

<p>all the SMILE tools and makes sure that the data access rights are implemented directly into the technical requests. The SMILE API has a swagger interface, a user interface that describes, implements, and provides examples for all data endpoints. The SMILE API is the communication and data hub in the SMILE project.</p>		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL5 - technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)	TRL7 - system prototype demonstration in operational environment	The SMILE API is designed as a modular technical component. The initial exploitation vision is to include this component into other research projects and commercial solutions.
Next Steps (Action Plan)		
Adapt and include SMILE API into future projects and commercial solutions.		
KER and Pilot / Demonstration activities		
SMILE API played a central role in the piloting and demonstration activities. The tool is the backbone of the communication between all the other tools. All data endpoints started with templates and examples, and they have evolved into active pass-through components. The SMILE API was used alongside all 7 pilots and in all piloting activities.		

SWOT Analysis

Strengths	Weaknesses
Provides a central data hub to any multi-organisation data exchange systems. It is easily adaptive and can be deployed within days.	Most of the data end points come with precise descriptions and data structure. If any of the connected trusted systems are compromised (security) and they are flooding the main API, this could cause an availability problem.
Opportunities	Threats
Extremely adaptive to new systems due to interoperability by design.	Once such a system is actively integrated in environments and once its logic is transparent to the other systems, competitors might mimic his behaviour and force for a replacement.

Innovation Dimensions

Innovation Level
2 - Improvement: The KER offers enhancements or optimisations over existing solutions (e.g., better performance, cost reduction).
Why innovative / exploitable?
Every decentralised multi-organisation data exchange requires a translation security and data layer. The SMILE API is built for SMILE but can be extended, reinitialised for different domains or generalised. It is exploitable because it is highly adaptable to systems since it was designed and

built with interoperability as the core requirement.

Phased Exploitation Pathways

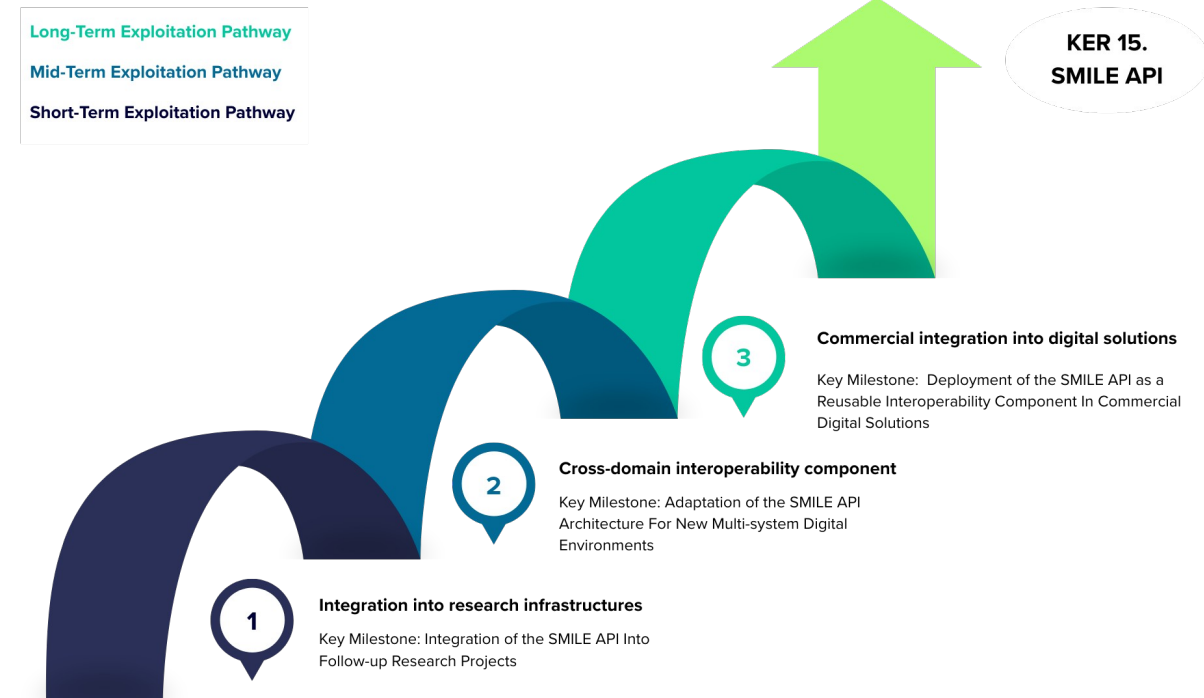


Figure 13: Exploitation Pathways (KER 5: SMILE API)

Detailed Exploitation Pathways

Short-term exploitation pathway: Integration into research infrastructures

Use the SMILE API as a modular communication and data exchange component in future research projects requiring secure data interoperability.

- Adapt the API for new research projects
- Reuse the data communication and access control architecture
- Integrate with additional tools requiring secure data exchange
- Use the Swagger interface to support rapid deployment and integration

Target: Research projects

Key Step: Integration of the SMILE API Into Follow-Up Research Projects

Mid-term Exploitation Pathway: Cross-domain interoperability component

Extend the SMILE API architecture for multi-organisation digital ecosystems beyond the SMILE project.

- Adapt the API to support other domains requiring secure data interoperability

- Reinitialise the component for different digital platforms and infrastructures
- Enhance interoperability features for multi-system environments
- Support integration of heterogeneous tools through standardised API endpoints

Target: Digital platform developers, Technology integrators, Research infrastructures

Key Step: Adaptation of the SMILE API Architecture for New Multi-System Digital Environments

Long-term exploitation pathway: Commercial integration into digital solutions

Develop the SMILE API as a commercially exploitable backend interoperability component for digital platforms requiring secure data exchange.

- Integrate the API into commercial digital solutions and software ecosystems
- Offer the component as a backend interoperability layer for multi-tool platforms
- Support scalable data exchange between distributed systems
- Enable organisations to deploy interoperable data infrastructures

Target: Technology companies, Enterprise software developers

Key Step: Deployment of the SMILE API as a Reusable Interoperability Component in Commercial Digital Solutions

KER 16. ESM Sigma

KER Title		KER Type
ESM Sigma UK		2. Scientific or Technological R&D Result including ICT Hardware
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
University of Edinburgh	Matthias Schwannauer (m.schwannauer@ed.ac.uk)	-
Exploitation Type: Public		
Full Description		
As part of the Companion App, SMILE implemented Experience Sampling Technology for the contextual assessment and monitoring of SMILE participants. The technology comprises a set of prompts or validated questions and methodology of how these questions are presented and what their underlying question logic is. Use of this technology is restricted to SMILE only; no partner, including the Companion App developers, is permitted to use this technology in full or in part without a written agreement with the University of Edinburgh, the manager of this KER.		
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision
TRL6 - technology demonstrated in relevant environment (industrially relevant	TRL6 - technology demonstrated in relevant environment (industrially relevant environment in the	Prior to SMILE, this technology was iteratively tested and refined by the KER Manager to capture the contextual determinants of mental health across a

environment in the case of key enabling technologies)	case of key enabling technologies)	range of populations.
Next Steps (Action Plan)		
Continued refinement and use of the technology in a research context, focusing on studies investigating the contextual determinants of mental health.		
KER and Pilot / Demonstration activities		
The KER is part of the SMILE proof-of-concept study, enabling collection of mood, well-being, and contextual data across children and young people aged 10-24 years old, across 7 European countries. Data collected with this technology will enable evaluation of the SMILE gamified platform and form part of the SMILE Open Dataset (KER 11).		

Innovation Dimensions

Innovation Level
1 - Standard: The KER aligns with current market or technological standards; no significant novelty, but solid and reliable.
Why innovative / exploitable?
This technology provides a scientifically validated adjunct or alternative to standardised patient-reported outcome measures. The technology enables capturing in-the-moment mental states and how they fluctuate across different contexts, enabling more ecologically valid, in-depth assessment compared to standardised patient-reported outcome measures.

Phased Exploitation Pathways



Figure 14: Exploitation Pathways (KER 16: ESM Sigma)

Detailed Exploitation Pathways

Short-term exploitation pathway: Continued Scientific Use and Methodological Refinement

The ESM Sigma methodology continues to be used and refined in academic research contexts led by the University of Edinburgh.

- Continued refinement of the Experience Sampling methodology and question logic
- Use of the technology in ongoing SMILE research activities
- Contribution of collected data to the SMILE Open Dataset (KER 11)
- Scientific dissemination through research publications

Target: Academic researchers studying adolescent mental health, SMILE consortium research teams

Key Step: Continued Application and Refinement of the ESM Sigma Methodology In SMILE-Related Research

Mid-term exploitation pathway: Integration in future research projects

The validated methodology is used in future academic research projects investigating contextual determinants of mental health.

- Integration of the methodology into future research projects led by the University of Edinburgh

Project Number : 101080923

Project Acronym: SMILE

- Use of ESM Sigma to investigate contextual determinants of mental health across populations
- Expansion of datasets supporting contextual monitoring of well-being

Target: Academic researchers, mental health research groups

Key Step: Integration of ESM Sigma Methodology into Future Research Projects.

Long term Exploitation Pathway: Development of validated ESM app-based tool for future research and implementation

Further development of the ESM methodology validated in SMILE may support the development of new research tools for contextual mental health monitoring.

- Explore further development of ESM-based tools building on the SMILE validation results.
- Support future studies investigating contextual determinants of mental health.
- Enable continued methodological innovation in ecological momentary assessment research.

Target: Academic researchers studying adolescent mental health, Research groups investigating contextual determinants of mood and well-being

Key Step: Support Future Contextual Mental Health Research Based on ESM Methodology

Dissemination Plan per KER

The following figure presents the dissemination plan for all SMILE KERs, illustrating the timeline of activities for 2026, from the current stage until the end of the project in November 2026. Each KER is represented along the vertical axis, with planned dissemination actions mapped across the horizontal timeline. Completed actions are highlighted in green, activities currently in progress are shown in orange, and upcoming or planned actions are marked in blue.

This visual is a living document that is updated regularly to allow an at-a-glance understanding of the dissemination progress, enabling the consortium to track achievements, monitor ongoing efforts, and anticipate forthcoming activities. It also supports the strategic alignment of dissemination with exploitation and innovation plans for each KER.



Figure 15: SMILE Dissemination Strategy Plan per KER 2.0

Sustainability, Risks, and Next steps

Transferability and Replication Potential

By documenting effectiveness and engaging continuously with educators, clinicians, and local authorities, SMILE’s services and tools are positioned for broader uptake beyond the pilot sites. Transferability is supported through structured guidelines, modular toolkits, and training materials, available via KM-EP, enabling adoption by other institutions, communities, and Member States. Replication potential is further reinforced through collaboration with EU-level networks and complementary initiatives, including the cluster of seven sister projects, ensuring knowledge exchange and visibility across the mental health innovation ecosystem.

Several KERs, such as the gamification platform, COPEN App, and SMILE API, already integrate considerations for transferability within their phased exploitation pathways, reflecting their adaptability to other projects and contexts.

SMILE outputs are aligned with existing EU and national frameworks for digital mental health, enhancing the likelihood of adoption and integration into routine practice. This alignment, along with evidence from pilot activities, will be further emphasised in the upcoming SMILE policy brief

Exploitation Risks and Mitigation Measures

To support SMILE’s exploitation strategy, potential risks and associated mitigation measures have been identified across technical, market, regulatory, and IP dimensions. The table below consolidates these risks with their impact level and mitigation approaches.

Tableau 4: SMILE Exploitation Risks and Mitigation strategies

Risk	Impact Level	Mitigation Strategy
Delayed KER finalisation	Medium	Active project management Buffer time
IP disputes among partners	High	Early and transparent IP agreements Legal External support
Regulatory or ethical barriers	Medium	Continuous compliance monitoring Expert External advice
Low market uptake or interest	Medium	Targeted outreach User involvement Co-design feedback
Resource constraints for scaling	Medium	Identifying additional funding sources Build additional partnerships
Evolving healthcare regulations	Medium	Early consultation with regulators
Data protection and privacy challenges	High	GDPR-compliant processes Consent management Secure data handling
Ethical Considerations	Medium	Ongoing stakeholder engagement Adherence to ethical standards
Behavioural barriers to adoption	Medium	Training Awareness campaigns

		User-friendly design
Sustaining user engagement	Medium	Continuous innovation in incentives Gamified content updates
Interoperability issues	Medium	Integration testing
Scalability and performance	Medium	Platform stress testing Cloud infrastructure
Rapid technological changes	Medium	Continuous monitoring Agile updates Iterative improvements
Funding Gaps	Medium	Explore additional funding Investor engagement Partnerships
Resource Allocation	Medium	Consortium commitment agreements Prioritisation planning
Licensing and Spin-Off Challenges	Medium	Strategic IP management Legal review Commercialisation roadmap

These identified risks and challenges will be regularly reviewed and updated in the final deliverable (M42) to reflect project progress and market evolution, ensuring a resilient and adaptable exploitation strategy.

Conclusion

This mid-term deliverable marks a significant milestone in the strategic business and exploitation planning of the SMILE project. To date, we have developed a comprehensive understanding of the digital mental health ecosystem, conducted a market study and a PESTLE analysis at EU, mapping the complex ecosystem landscape integrating public data, developed an initial market segmentation aligned with target user groups.

In terms of SMILE KERs exploitation, we conducted a thorough SWOT analysis at KER level, innovation dimension assessment, and we built a phased exploitation pathway for each KER. Regarding IP, we established a baseline for PR management within the consortium, by initiating a rigorous literature review and benchmarking of relevant IP protection methods. Overall, 16 KERs have been identified, TRL progression reflects both incremental improvements and novel innovations in SMILE implementation.

While significant progress has been made, several critical components remain under development and will be deepened in the final deliverable, including results from ongoing trials and comprehensive user feedback, detailed financial analyses and elaborated Business Model Canvas components, as well as finalised exploitation agreements and governance frameworks.

Looking forward, the consortium commits to continuous monitoring and iterative refinement of the exploitation report, ensuring alignment with emerging market trends, regulatory frameworks, and technological advancements. Regular updates will integrate feedback from pilot sites, stakeholders, and external experts. A collaborative review process will be maintained to finalise the strategic IP roadmap and the joint exploitation plan, fostering sustainability beyond the project lifetime.

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Project Acronym: SMILE

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Annex

Annex 1. Background IP Template

1. Who is the designated point of contact for IPRs within your organisation?

[Acronym]	
Full name:	
Title:	
Function:	
Email:	

Section 1 - Background IP Questionnaire

1. Does your organisation own any existing background IPs potentially to be used in the SMILE project? (Yes/No)

→

If yes, please complete the Table 2 for each IP. If there is more than one IP, please copy the table and paste in a new page and fill one table per IP.

Questions	Answers
General	
Name/title of IP	
Description of IP	
Number of updates (latest version number)	
IPR number (e.g. patent number, trademark number, etc.)	
Product (Hardware/ Software/Algorithm/Process, etc)	
Type of IP (e.g. patent, trademark, copyright, secrecy, utility model, design registration)	
IP condition (submitted, granted, etc.) and application date, date granted, and expiry date	
Affiliation of IP granting organisation	
Geographic area where IP applies (e.g. France, EU, Worldwide, etc.)	
What is the relevance of your organisation's IP to the SMILE project? E.g., what challenges are expected if the IP is not accessible/useable in the SMILE project?	
TRL at start of project / expected TRL at end of project	
Ownership of IP	

Ownership (please indicate all parties)	
If the IP is co-owned, which other organisations are currently using the IP and how is ownership shared?	
Specific limitations for implementation and exploitation (e.g. exclusive license).	
Is the IP previously transferred from a third party to your organisation? If yes, please indicate the original owner of the IP and the year the ownership is transferred.	
Access rights and usage of IP	
Are any other access rights, e.g. third-party licenses, needed for the utilisation of the existing IP in the SMILE project?	
Are there any financial and/or technical constraints to access and/or use the existing IP in the SMILE project?	
Are any of the IP prevented to be exploited in the industry, and for what reason (e.g. because of implications to human health, ethical issues, or potential ecological damage)?	
Additional information	
Please provide any additional links, descriptions and/or other publicly available information of your background IP	
Is there any additional information regarding your background IPR that SMILE exploitation leaders should be aware of?	
Additional comments (e.g. challenged claims, risk of IP infringements and litigated patents)	

Please complete the checklist below

I've indicated all applicable background IPs	
I've identified all applicable co-owners of background IPs	
I've supplied all applicable documentation/links to background IPs	
I've identified all applicable third-party licenses required to use IPs	

Annex 2. Foreground IP Template

Section 2 - Foreground IP Questionnaire

2. Does your organisation expect to develop any IPs that will be generated within the SMILE project (foreground IP)? (Yes/No).

→

If yes, please complete the Table 4 for each IP. If there is more than one IP, please copy the table and paste in a new page and fill one table per IP.


Questions	Answers
General	
Description of expected IP	
Product (Hardware/ Software/ Process, etc)	
Expected type of IP (e.g. patent, trademark, copyright, secrecy, utility model, design registration)	
Development of IP	
What are your R&D needs and expectations for the development of the IP?	
Background IP required for the development of this IP?	
Any third-party licenses required to develop the IP?	
How important are your organisation's foreground IP for the SMILE project? E.g. what challenges are expected if the IP is not accessible/useable in the SMILE project, or when development is unsuccessful?	
Do you plan or need additional governmental funds for the R&D and/or IP development? If so, what is/are the organisation(s) and the status of obtaining the funds?	
What is your organisation's expected timeline and general sense of milestones for bringing this IP to the market?	
Ownership of IP	
Will the IP be developed alone or with other consortium partners?	
Will the IP be exclusively owned or include other consortium partners?	

What is your organisation's commercialisation decision process for the development of this IP?	
Additional information	
Is there any additional information regarding your foreground IP that SMILE exploitation leaders should be aware of?	
Would you require additional support or internal workshops on IPR strategies during the project?	

Please Complete the Checklist below:

I've indicated all applicable foreground IPs	
I've identified all applicable licenses required for development of foreground IPs	
I've identified all applicable partners required for development of foreground IPs	
I've identified all applicable financial and technical constraints for development of foreground IPs	

Annex 3. KER Data Collection Template

		
KER GENERAL INFORMATION		
KER Title		KER Type
KER Manager (organisation)	KER contact person (email)	KER Contributors (if any)
Exploitation Type		
Full Description		
EXPLOITATION DETAILS		EXPLOITATION VISION
TRL Before SMILE	TRL After SMILE	Initial Exploitation Vision (development / commercial / what happens next?) [What do you plan to do ? R&D ? Publications ? IP Protection ? Testing ? Commercialisation ? Knowledge transfer ?]
Innovation Level		
Why innovative / exploitable?		

<i>[Explain novelty or market potential]</i>	Next Steps (Action Plan) <i>[Outline immediate next actions to exploit the KER]</i>
KER and Pilot / Demonstration activities <i>[Describe testing / demonstration in project's pilots]</i>	
SWOT ANALYSIS	
Strengths <i>[Internal advantages, unique qualities, skilled staff, IP, assets ...]</i>	Weaknesses <i>[Gaps, competitor advantages, resource limits ...]</i>
Opportunities <i>[External favorable conditions or markets, unmet needs, emerging needs, few competitors ...]</i>	Threats <i>[External risks, competition, regulations, negative press, changing attitudes ...]</i>

Annex 4. PESTEL Analysis Template

PESTEL Analysis – Pilot Country: [Insert Country Name]

PESTEL is a method to gather relevant knowledge on the macro environment. "PESTEL" refers to a mnemonic guideline of the domains it considers: Political, Economic, Social (or Socio-cultural), Technological, Environmental and Legal.

The navigation tool below aims to identify the factors that are likely to influence, directly or indirectly, the adoption, scaling, and sustainability of SMILE KERs at the national/regional level

Please complete the following with as much detail as possible. Focus on aspects that may impact SMILE KERs. Use supporting data, references to policies, or examples where relevant. This input will help inform tailored exploitation pathways and scaling strategies per pilot country.

For each factor you identify, please classify it as a:

- Major Opportunity
- Minor Opportunity
- Minor Barrier
- Major Barrier

POLITICAL DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE <i>(how it acts as a factor)</i>
	Major Opportunity		
	Minor Opportunity		
	Major Barrier		
	Minor Barrier		
<i>(Add rows as needed for each dimension)</i>			
ECONOMIC DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE <i>(how it acts as a factor)</i>
	Major Opportunity		
	Minor Opportunity		
	Major Barrier		
	Minor Barrier		
<i>(Add rows as needed for each dimension)</i>			

SOCIAL DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE <i>(how it acts as a factor)</i>
	Major Opportunity		
	Minor Opportunity		
	Major Barrier		
	Minor Barrier		
<i>(Add rows as needed for each dimension)</i>			
TECHNOLOGICAL DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE <i>(how it acts as a factor)</i>
	Major Opportunity		
	Minor Opportunity		
	Major Barrier		
	Minor Barrier		
<i>(Add rows as needed for each dimension)</i>			

ENVIRONMENTAL DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE <i>(how it acts as a factor)</i>
	Major Opportunity		
	Minor Opportunity		
	Major Barrier		
	Minor Barrier		
<i>(Add rows as needed for each dimension)</i>			
LEGAL DIMENSION			
Factor	Classification	DESCRIPTION / EXPLANATION	RELEVANCE TO SMILE <i>(how it acts as a factor)</i>
	Major Opportunity		
	Minor Opportunity		
	Major Barrier		
	Minor Barrier		
<i>(Add rows as needed for each dimension)</i>			



PESTEL Factors Explained:³⁰

POLITICAL DIMENSION
<p>Refers to the political systems in term of state structure, governance and policy-making process, both formal and informal. Some factors to be analysed could be:</p> <ul style="list-style-type: none">• Type, of state (i.e. centralized vs federal) and regime (i.e democratic vs authoritarian)• Role and organizational shape of the state• Electoral processes• Power sharing between tier of the state, or between the state and other non-state actors;• Public Policy analysis (policy framework, policy relevance and credibility);• Coherence of existing policies both with internal and international commitments
ECONOMIC DIMENSION
<p>Refers to the economic structure of the country, both formal and informal. Some factors to be analysed could be:</p> <ul style="list-style-type: none">• Respective role of state and private sector• Market typology• Formal vs informal and illegal economy• Relation and relative weight of local, national and international economy• Banking system...
SOCIAL (or SOCIO-CULTURAL) DIMENSION
<p>Refers to the social characteristic of the country, including traditional values and attitudes. Gender focused analysis are particularly relevant for EUD, as gender mainstreaming is requested in all interventions. Some factors to be analysed could be:</p> <ul style="list-style-type: none">• Demographic composition• Social structure• Migration trend• Ethnic composition• Cultural diversity• Religious diversity• Typology of existing social institutions
TECHNOLOGICAL DIMENSION
<p>Refers to the availability of technology in the country, both in term of hard and soft competencies. This may include:</p>

³⁰ <https://wikis.ec.europa.eu/spaces/ExactExternalWiki/pages/50109048/Context+analysis+%E2%80%93+PESTEL>

<ul style="list-style-type: none"> • Available technology (per sector, at local, national or regional level) • Conformity with intervention quality standard • Accessibility of technology by population • Dissemination and access to new technologies • Engagement in development and research • Performance of higher education • State investment in technological development and dissemination
ENVIRONMENTAL DIMENSION
<p>Refers to environmental issues both at local and global level (i.e. climate change); it is particular relevant for EUD as environmental assessment is mandatory for all interventions. It may include:</p> <ul style="list-style-type: none"> • Geography (regional, national and local level) • Weather trend (regional, national or local level) • International commitment an national regulation • Implementation of existing regulation (willingness, capacity, credibility)...
LEGAL DIMENSION
<p>Refers to the legal framework in place. It is particularly relevant for EUD as commitment to Human Rights is intrinsically connected to all EUD interventions through the Right Based Approach. It may include:</p> <ul style="list-style-type: none"> • Commitment to international convention / treaties • National legislation • Alternative sources of legislation (customary law) • Coherence between national legislation and adherence to international commitments • Implementation willingness / capacity • Ethical issues (i.e. privacy)

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