DELIVERABLE

Project Acronym: **SMASH-HCM**

Grant Agreement number: **101137115**

Project Title: **Stratification, Management, and Guidance of Hypertrophic Cardiomyopathy Patients using Hybrid Digital Twin Solutions**

D8.4 – Contact with regulatory agencies FIMEA, DEKRA

Revision: 1.0

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Project co-funded by the European Commission within HORIZON-HLTH-2023-TOOL-05-03		
Dissemination Level		
PU	Public, fully open	X
CO	Confidential, restricted under conditions set out in Model Grant Agreement	
CI	Classified, information as referred to in Commission Decision 2001/844/EC	

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Revision History, Status, Abstract, Keywords, Statement of Originality

Revision History

Revision	Date	Author	Organisation	Description
0.1	16.6.25	AK	TAU	Initial version
0.2	17.6.25	KAS	TAU	Comments
0.3	17.6.25	AK	TAU	Revisions
0.4	18.6.25	MVG	TAU	External review
1.0	18.6.25	AK	TAU	Included review edits, submitted

Date of delivery	Contractual:	30.06.2025	Actual:	18.6.2025
Status	Final ☒ / draft ☐			

Abstract (for dissemination)	This deliverable, D8.4, "Contact with regulatory agencies FIMEA, DEKRA," documents the discussions conducted with representatives of relevant regulatory organisations on the SMASH-HCM project.
Keywords	Medical Device Regulation, Digital Twins, Hypertrophic Cardiomyopathy

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Table of Content

Executive Summary

SMASH-HCM is conducting research and developing innovative technologies to improve the stratification and disease management of patients with hypertrophic cardiomyopathy.

The purpose of Deliverable D8.4, “Contact with regulatory agencies FIMEA, DEKRA,” documents the discussions conducted with representatives of relevant regulatory organisations on the SMASH-HCM project and supports regulatory engagement under Task 8.3, advancing compliance with MDR, IVDR, and AI regulations. The Finnish Medicine Agency (FIMEA) was contacted, and initial discussions took place, with an agreement to revisit them at a later stage of the project. In the case of DEKRA Finland Oy, it was considered premature to engage at this point, and it was decided to initiate contact once the project has progressed further.

Ongoing collaboration with FIMEA and DEKRA helps ensure safety, performance, and future CE marking. This work strengthens SMASH-HCM’s path towards clinical adoption and impact.

1 Introduction

The purpose of SMASH-HCM (https://smash-hcm.eu/) is to develop a human digital-twin-based platform to dramatically improve HCM stratification and disease management, both for clinicians and patients. SMASH-HCM combines clinical research, cardiology, radiology, cell biology, -omics tools, biophysical computational modelling, artificial intelligence (AI) and machine learning (ML), biomedical signal and image processing, clinical decision support software development, innovation management, and social sciences to address unmet clinical, societal and psychological needs. The result will be human digital twin driven deep phenotyping and risk stratification tools to support clinical workflows and decision making, making possible the development of effective personalised treatment and patient self-management.

The work conducted for deliverable D8.4, "Contact with regulatory agencies FIMEA, DEKRA," represents an important component of the SMASH-HCM project's Task 8.3. "Preparatory work for market access and EU Medical Device Regulation (MDR)". This task, which began in Month 6 and will continue until the end of the project, is led by TAU and is carried out in close collaboration with project partners Medtronic Bakken Research Center B.V. (MDT), Pharmatics Limited (PHARM), and InsSilicoTrials Technologies S.P.A. (IST).

The aim of this task is to initiate negotiations with the Finnish regulatory agencies Finnish Medicines Agency (FIMEA) and DEKRA Finland Oy (DEKRA) to obtain guidance on approval under the current regulatory framework for MDR and In Vitro Diagnostic MDR (IVDR). The SMASH-HCM data collection and software validations will be performed in compliance with EU (Artificial Intelligence) AI Act draft and Good Machine Learning practice (GMLP) for later CE marking application. Safety and performance requirements will be explored adhering to ISO13485 and IEC62304 standards, with guidance obtained from FIMEA.

SMASH-HCM's continued engagement with regulatory bodies supports: a) developing a framework to assess SMASH-HCM computational models, b) building a framework that supports the development of guidelines, and c) building partnerships with academic and research centers and collaborate with international partners.

2 Engagement with regulatory organisations

2.1 FIMEA

https://fimea.fi/en/frontpage
Contact persons:
Minna Kymäläinen, Head of Department / Clinical Specialist
Sami Myllymaa, Senior Specialist, Medical Devices
Mika Erjanne, Senior Specialist, Medical Devices

Fimea, the Finnish Medicines Agency is the national competent authority for regulating pharmaceuticals. As a central administrative agency operating under the Ministry of Social Affairs and Health, it promotes the health and safety of the population by regulating medicinal, medical devices, blood and tissue establishments, biobanks and by developing the pharmaceuticals sector.

In Fimea, Minna Kymäläinen, Head of Department and Clinical Specialist was contacted in spring 2025. Since SMASH-HCM is a research project with an aim to create a digital twin with already existing data, the process does not require registration in FIMEA. However, she expressed keen interest in collaboration and in advising us in the context of MDR at the later stage, for example around month 36-40, when we have specific plans for commercial applications. Further topics of discussion include, e.g., existing legislative initiatives and policy on AI in healthcare, such as the pending legislation on the European Health Data Space by DG SANTE.

2.2 DEKRA

https://www.dekra.fi/en/home/
Contact persons (TBC)

DEKRA is a globally recognised organisation specialising in technical inspections across various industrial sectors. Known for its impartiality and reliability, DEKRA ensures safety standards and regulatory compliance are consistently met. Of particular relevance to the medical sector, DEKRA is a leading Notified Body for medical devices under EU regulations (MDR and IVDR), offering expert conformity assessments to help manufacturers bring safe and effective medical technologies to market.

The initial discussions with the FIMEA indicated that we should contact DEKRA once the AI and in-silico models are at a more advanced stage. We expect to do that by month 30.

3 Conclusions

The SMASH-HCM project is a pioneering initiative that integrates advanced digital technologies and interdisciplinary expertise to revolutionize the management of hypertrophic cardiomyopathy. Task 8.3, and specifically Deliverable D8.4, plays a crucial role in laying the groundwork for successful market access and regulatory compliance under the EU Medical Device Regulation. Continued collaboration with regulatory bodies such as FIMEA and DEKRA ensures that SMASH-HCM aligns with evolving standards, supporting the development of safe, effective, and patient-centered solutions. These regulatory engagements not only advance the project's technical and clinical goals but also strengthen its foundations for long-term impact and scalability across healthcare systems.