

# AISYM4MED POLICY BRIEF

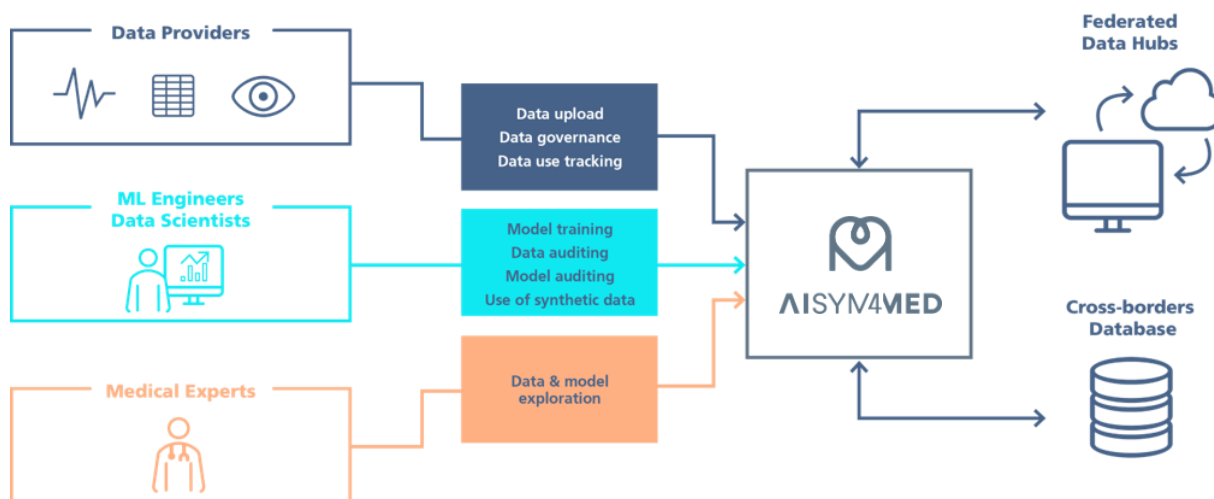
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## EXECUTIVE SUMMARY

The AISym4MED project is developing a secure and trustworthy platform to accelerate the development of robust AI solutions in healthcare. By enabling secure data sharing, synthetic data generation, and comprehensive data/model auditing, AISym4MED aims to improve medical research, enhance patient outcomes, and contribute to European leadership in AI-driven healthcare innovation. A key early project output is pyMDMA<sup>1</sup>, an open-source Python library that provides a comprehensive suite of metrics for evaluating both real and synthetic data. This makes it particularly valuable for assessing the reliability of synthetic data, which is increasingly used to address privacy concerns and data scarcity in healthcare.

## PROJECT OVERVIEW

The difficulty in accessing and utilizing healthcare data hinders AI innovation in Europe. AISym4MED addresses this challenge by building a platform that facilitates secure data sharing and provides researchers with high-quality data, including synthetic data, for developing and validating AI models. This platform will adhere to European data protection standards and promote ethical AI development.



## PROGRESS AND ACHIEVEMENTS

AISym4MED has made significant progress across its core objectives:

- **Secure Data Infrastructure:** A distributed architecture for secure data access, analysis, and sharing is being developed. This includes standardized data formats, a de-identification module, and ongoing work on a Data Protection Impact Assessment (DPIA) and transparency solutions.
- **Synthetic Data Generation:** Advanced techniques are being developed to generate realistic and privacy-preserving synthetic medical data, including time series (e.g. ECG, EEG), images, and tabular data. These efforts leverage state-of-the-art generative models and transfer learning strategies, with new metrics for evaluating synthetic data quality. The project has released the pyMDMA Python library implementing several data auditing metrics and is conducting focus groups with the aim of discussing a process for evaluation of synthetic data by clinical experts.
- **Data Privacy and Trustworthiness:** Data privacy and security are prioritized through a dedicated architecture, encryption, distributed computation, federated learning, and a standalone de-identification module. A comprehensive DPIA is being developed to address compliance and security risks.
- **End-User Validation:** Clinicians, researchers, AI developers and hospital managers are actively involved in co-creation workshops and pilot testing to ensure the platform meets real-world needs.
- **Scalability and Exploitation:** A comprehensive dissemination and communication strategy is in place, including publications, conference participation, and the HEALTHDATA4EU Cluster. The exploitation strategy is also under development to ensure the platform's long-term sustainability and widespread adoption.

<sup>1</sup> fraunhoferportugal/pymdma: pymdma

AISym4MED has laid the groundwork for a platform that can significantly impact healthcare data management, AI development, and policy decisions related to data governance and AI regulation.

## IMPACT AND POLICY IMPLICATIONS

AISym4MED is poised to have a significant impact on the European healthcare landscape:

- **Scientific Advancement:** The project contributes to advancements in responsible AI, data privacy, synthetic data generation, and data and model auditing.
- **Technological Development:** The platform will provide researchers and innovators with the tools and data necessary to accelerate the development of AI-driven healthcare solutions.
- **Economic Benefits:** By facilitating data access and promoting innovation, AISym4MED will boost the competitiveness of the European health industry and contribute to economic growth.
- **Societal Benefits:** The project will ultimately lead to improved healthcare outcomes through the development of more robust, reliable and fairer AI models.
- **Policy implications are particularly relevant in the following areas:**
- **Data Governance and Privacy:** AISym4MED's focus on data privacy and security aligns with GDPR principles and can inform guidelines related to ethical data access frameworks.
- **AI Regulation in Healthcare:** The project's data and model auditing functionalities facilitate the implementation of the AI act and medical device regulation requirements and compliance demonstration. The work on responsible AI, particularly on synthetic data and federated learning, may contribute to the development of technical standards and guidelines for trustworthy AI in healthcare.
- **Healthcare Innovation:** AISym4MED's platform can serve as a model for promoting the use of AI and synthetic data for better healthcare delivery.

## NEXT STEPS AND FUTURE PLANS

In the next reporting period, AISym4MED will focus on:

- Completing the DPIA, transparency and model auditing solutions.
- Refining and expanding synthetic data generation capabilities.
- Conducting pilot studies with end-users to gather feedback and improve the platform.
- Continuing dissemination and engagement activities to foster wider adoption.

By continuing to advance its core objectives, AISym4MED will contribute to a future where AI is seamlessly integrated into healthcare, leading to improved patient care and a more efficient healthcare system.

Moreover, we will launch the **“Health Data Synergy for Robust Medical AI”** community of practice, aiming to bring together experts and entities from different fields to improve secure health data processing and the robustness of medical AI solutions.

### Main goals

- Shape the global conversation on breaking health data silos for the development of robust medical AI solutions.
- Build expertise on AI model assessment for medical applications.
- Foster the development of synthetic health data generation.
- Advance the knowledge on effective evaluation and usage of synthetic health data.

### Main lines of action

1. Establish consensus guidelines on clinical evaluation of synthetic data.
2. Generate policy recommendations about research and innovation on health data in the EU.
3. Advance the EU knowledge on health data synthesis and medical AI auditing.
4. Disseminate the scientific and technical advances in the area.
5. Guide the development of the AISym4MED platform.

The full calendar of planned activities can be found at [aisym4med.eu/aisym4med-community-of-practice](https://aisym4med.eu/aisym4med-community-of-practice) including a focus group session with policy makers and policy implementation representatives.

## CONTACT

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