Federated Learning and Medical Device Regulation: Bridging Gaps in Healthcare AI Governance

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***Abstract*—The rapid advancement of artificial intelligence (AI) in healthcare has opened a new application area for federated learning (FL) platforms, which enable model training across decentralized datasets while preserving privacy and avoiding direct data sharing. Although this approach holds great potential for clinical applications, its regulatory status remains ambiguous. Under current regulatory frameworks, such as the EU Medical Device Regulation (MDR 2017/745) or the Federal Food, Drug and Cosmetic Act (FD&C Act) in US, it is unclear whether FL platforms, or the AI models they generate, qualify as medical devices, and what the associated implications might be. This paper examines the regulatory framework, beginning with an assessment of whether FL platforms may be classified as medical devices based on their functionality, intended purpose, and impact within clinical environments. It analyses key regulatory criteria, including specific medical intent, data security, trustworthiness, traceability, and usability. In addition, it also examines specific challenges related to FL, such as traceability, validation in decentralized settings, and accountability for model outputs. We perform a regulatory assessment of a real-world FL platform deployed in a healthcare context, identifying gaps and grey areas in the current legislation. This analysis aims to provide technical and regulatory insights for developers, regulators, and healthcare providers, and offers recommendations to guide future adaptations of medical device regulations for distributed AI systems.**

***Index Terms*—Federated Learning, Regulatory Framework, Medical Device.**

I. Introduction

The integration of artificial intelligence (AI) into healthcare is rapidly transforming clinical practice, offering improved diagnostic capabilities, personalized treatments, and higher operational efficiencies ([1], [2]). Among emerging AI paradigms, federated learning (FL) [3] has gained attention for its ability to train machine learning models across decentralized datasets while preserving data privacy. This feature makes FL particularly attractive in healthcare, where patient data sensitivity and regulatory constraints present major barriers to centralized model training.

Despite its technical promise, the regulatory pathway for FL platforms in healthcare remains ambiguous. Under existing frameworks, including the European Union EU Medical Device Regulation (MDR 2017/745) [4] and the United States US Federal Food, Drug, and Cosmetic Act (FD&C Act) [5], AI-based systems intended for medical purposes must comply with stringent requirements. However, the decentralized architecture of FL, the distribution of responsibilities across multiple stakeholders, and the inherent challenges in ensuring model traceability, validation, and continuous oversight introduce substantial uncertainties regarding their classification as medical devices and their regulatory approval pathway. While regulatory developments in the European Union are still evolving, the United States has shown a comparatively faster progress in adapting its frameworks to address AI-based technologies in healthcare, as will be further discussed in this paper.

Existing literature has primarily focused either on the technical development of FL systems or on general regulatory considerations for AI in healthcare, but few studies have examined the specific intersection of FL platforms and medical device regulations. This gap is critical, as misclassification or lack of compliance could hinder clinical deployment and pose risks to patient safety.

In this paper, we investigate the regulatory implications of deploying FL platforms in healthcare environments. We analyze the criteria under Medical Device Regulation MDR2017/745 and FD&C Act that determine whether a FL platform, or the models it produces, should be classified as a medical device. Furthermore, we perform a practical classification assessment of an actual FL platform used in a healthcare setting under a EU funded Project, identifying regulatory gaps and proposing recommendations to support future regulatory frameworks for distributed AI technologies in medicine.

The main contributions of this paper are:

- To present a regulatory analysis framework tailored to assess FL platforms under MDR2017/745 and FD&C Act criteria.
- To apply it to a case study evaluating a real-world FL platform against current medical device regulations.
- To provide practical recommendations to address the unique regulatory challenges posed by federated learning in healthcare.

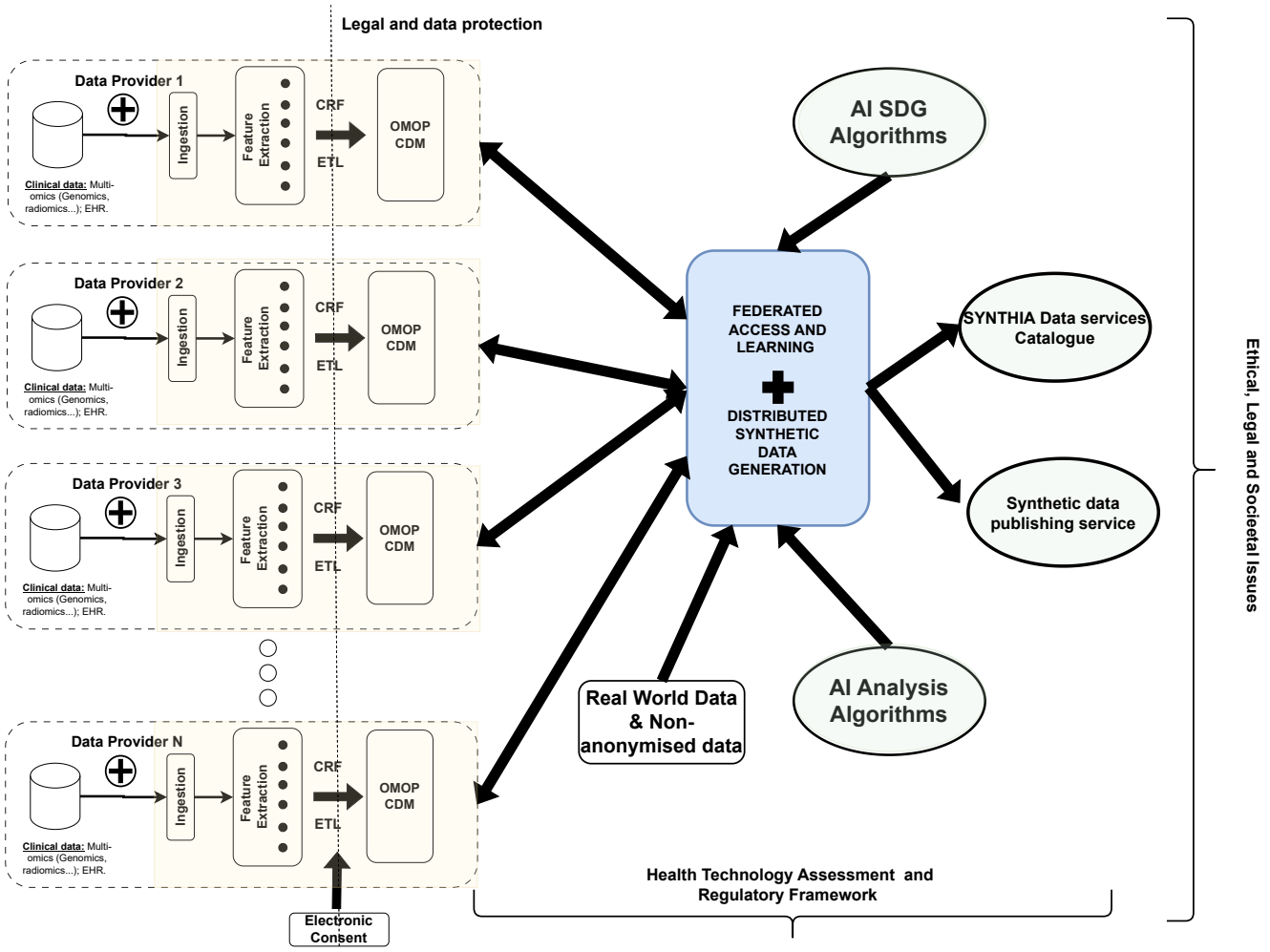

Fig. 1. General architecture of the Federated Learning Platform design for SYNTHIA project. From left to right: The representation of each data provider (e.g. hospital) with the pipeline to make available the datasets in the platform. The central light-blue represents the central orchestrator node, and the rest are added-value services.

II. Background and Related Work

A. Federated Learning in Healthcare

FL is a decentralized machine learning approach that enables model training across multiple institutions without requiring the transfer of sensitive patient data. In healthcare, FL has been proposed as a privacy-preserving solution for collaborative model development across hospitals, research centers, and clinical networks. Prior studies have demonstrated its potential in various domains, including medical imaging, electronic health records analysis, and predictive modeling for diagnosis and prognosis ([7], [8]).

By maintaining data localization and enabling collaborative learning, FL addresses critical barriers related to data privacy regulations, patient consent, and institutional data governance policies [9]. However, the operational complexity of FL systems including heterogeneity of data sources, synchronization challenges, and model aggregation strategies, raises additional concerns around reproducibility, robustness, and accountability in clinical applications.

Several platforms have been proposed to facilitate the deployment of FL in real-world healthcare environments. One such example is the FLIP (Federated Learning Interactive Platform), which aims to lower technical barriers for healthcare institutions by enabling the configuration and management of FL networks through an intuitive web-based interface [6]. FLIP has been iteratively developed with active contributions from diverse stakeholders including AI practitioners, clinical researchers, patient representatives, system administrators, and software developers, ensuring technical robustness, clinical relevance, and ethical alignment. The platform has demonstrated high usability and offers a promising pathway to democratize the adoption of FL in medical settings. In [10], the authors present a healthcare-specific FL platform designed following the Platform-as-a-Service (PaaS) paradigm. This plat-

TABLE I
MOST IMPORTANT GDPR 2016/679 ARTICLES AND ITS IMPLICATION TO FL

Article	Topic	Relevance
Art. 2	Definitions	FL involves "processing" even if data remains local; roles of controller and processor must be clarified.
Art. 5	Principles of data processing	FL systems must ensure lawfulness, fairness, transparency, data minimization, purpose limitation, and confidentiality.
Art. 6	Lawfulness of processing	Legal basis must be established (e.g., explicit consent, public interest in healthcare).
Art. 9	Special categories of data	Processing of health data is allowed only under strict conditions (explicit consent or justified legal exception).
Art. 12-14	Transparency and information duties	Data subjects must be informed about the processing, even in decentralized systems.
Art. 15	Right of access	FL systems must ensure lawfulness, fairness, transparency, data minimization, purpose limitation, and confidentiality.
Art. 16-18	Rectification, erasure, restriction	FL systems must allow corrections or deletions of local data contributing to models.
Art. 20	Data portability	May require data to be extractable from local sources upon request.
Art. 24	Responsibility of the controller	Each institution (node) must demonstrate GDPR compliance (accountability).
Art. 25	Data protection by design and by default	FL architectures must integrate privacy-enhancing measures (e.g., differential privacy, encryption).
Art. 26	Joint controllers	If multiple entities determine the purposes jointly, a joint controller agreement is needed.
Art. 30	Records of processing activities	Each participant must document their local data processing in the FL workflow.
Art. 32	Security of processing	Robust technical safeguards must be in place (e.g., secure aggregation, encryption).
Art. 33-34	Data breach notifications	Even decentralized breaches may require timely notification to authorities and individuals.
Art. 35	Data Protection Impact Assessment (DPIA)	Mandatory for high-risk FL use cases, such as health prediction models.

form leverages the Message Queuing Telemetry Transport (MQTT) protocol to enable communication across system components, with a strong emphasis on the security of sensitive healthcare data. Additionally, the work in [11] introduces an FL platform characterized by decentralized data management, collaboration without central aggregation, adaptability across diverse healthcare environments, support for AI-based solutions, and the integration of blockchain technology to enhance data security and address implementation challenges.

B. Regulatory Frameworks for AI in Healthcare

AI-based systems intended for medical purposes are subject to strict regulatory oversight. The EU MDR2017/745 governs the conformity assessment and market approval of medical devices, explicitly recognizing certain AI software under the definition of a medical device. In the US, the Federal Food, Drug, and Cosmetic Act (FD&C Act), administered by the FDA, provides the regulatory framework, supplemented by specific guidance documents on Software as a Medical Device (SaMD) and AI/ML-based modifications.

While the regulatory environment for AI is rapidly evolving, the classification and conformity assessment of FL platforms remain particularly complex due to their decentralized architecture, the distributed nature of data and model training, and the collective responsibility among participating institutions.

C. Related Work

Previous research has explored the technical challenges and privacy benefits of FL in healthcare ([7], [8]), as well as general regulatory considerations for AI applications in medicine [12]. Some works have addressed the availability and suitability of public datasets for training AI models in specific healthcare domains, such as pediatric oncology, where a systematic review identified key datasets that could support AI development under privacy-preserving frameworks like FL [13].

However, only a few studies have specifically examined the regulatory status of FL platforms, their qualification as medical devices, and the practical implications for conformity assessment processes under the MDR and FDA frameworks. This paper addresses this gap by providing a detailed regulatory analysis of FL platforms, supported by a real-world case study, and proposing practical considerations for their governance and compliance in healthcare settings.

III. CASE OF STUDY

The case of study for the present work is based on the FL platform of the SYNTHIA project. The general architecture of the FL platform is presented in figure 1. This architecture is mainly composed of three main components. *First:* A set of federated nodes, that are the entities that host the data. The data might be in one or multiple modalities and

TABLE II
MOST IMPORTANT HIPAA RULES AND ITS IMPLICATION TO FL

Rule	Topic	Relevance
Privacy Rule (45 CFR§§160, 164 Subpart E)	Use and disclosure of PHI	Training models locally on PHI constitutes a use under HIPAA, even without transmitting data externally. Any model sharing or coordination must comply with use/disclosure rules.
Security Rule (45 CFR§164 Subpart C)	Safeguards for electronic PHI (ePHI)	FL platforms must implement administrative, physical, and technical safeguards for local data and any exchanged metadata or model parameters.
Breach Notification Rule (45 CFR §164 Subpart D)	Notification obligations in case of data breaches	If model updates or gradients reveal PHI, or if FL infrastructure is compromised, breach notification obligations may be triggered.
Minimum Necessary Standard	Limitations on data usage	Even locally, FL must use only the minimum necessary PHI to achieve its training purpose (e.g., via feature selection or pseudonymization).
De-identification Standard (45 CFR §164.514)	Use of de-identified data	If data is de-identified per HIPAA standards (safe harbor or expert determination), HIPAA may not apply. However, FL often relies on partially identifiable data.
Business Associate Agreements (BAAs)	Requirements for third-party vendors	If an external FL platform provider handles PHI or facilitates its processing, a BAA is required between the covered entity and the vendor.
Access, Amendment & Accounting Rights	Individual rights over their PHI	FL participants must maintain mechanisms to honor individuals' rights to access, amend, or receive an accounting of disclosures involving their PHI.
Audit Controls and Monitoring	System oversight	FL platforms must include audit trails, logging, and mechanisms to detect unauthorized access or use, even in distributed environments.

therefore, it requires a pipeline to process this information, including:

- ingest the data
- pseudoanonymize the data
- extract features
- Extract Transform and Load (ETL) the data to be mapped into a common data model (CDM).
- label the information to make it available on the network.

Once the data set is available within the FL network, it might take place of an experiment for training.

Second: A central node, which is responsible for all the functions of AI-practitioner that involve:

- grant access to the platform and its services.
- upload AI models.
- observe the datasets to create experiments
- create experiments by adding at least 1 dataset available.
- run the experiments. By run an experiment is meant to train the model on the dataset(s) selected.
- observe the metrics of the model trained.
- download the updated model.

Third: Added value services that are on top of the FL network. These services include:

- analytics on the meta-data available.
- analytics on the models trained in the FL environment.
- investigation on synthetic (aggregate) data.
- decision support for decision making based on data generated.

A. Data protection under GDPR and HIPAA

1) General Data Protection Regulation GDPR2016/679: Although FL minimizes data transfer between institutions, it still constitutes the processing of personal data under the EU GDPR2016/679 [14], as the local data remains identifiable and contributes to model training. As such, FL systems operating in healthcare must comply with key GDPR2016/679 requirements, particularly when dealing with sensitive health data.

The table I summarizes the most relevant GDPR2016/679 articles and their implications for FL platforms:

2) Health Insurance Portability and Accountability Act HIPAA: The local training of AI models on Protected Health Information (PHI) still constitutes data processing under the U.S. HIPAA [15]. FL platforms must therefore comply with HIPAA's requirements for privacy, security, and breach notification when operated by or on behalf of covered entities or business associates. The most relevant rules that affect the deployment of such systems in the US are outlined in table II.

B. Federated Learning, Medical device or not?

To assess whether this module qualifies as a medical device, multiple aspects must be carefully considered. The applicable regulatory framework will be discussed in this section, focusing on applying the classification rules defined in Annex VIII of the MDR2017/745.

Before conducting the classification analysis, it is important to clarify a number of key terms and definitions introduced in the MDR2017/745, as they are essential for a proper understanding of the criteria that determine whether a software component falls within the scope of a medical device.

- **Medical Device** means any software *intended* by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
  - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

TABLE III
REGULATORY ASSESSMENT OF THE MODULES IN THE SYNTHIA FEDERATED LEARNING PLATFORM UNDER MDR 2017/745

Module / Block	**Main Function**	**MDR Classification**	**Justification**
Federated Node: Pre-processing pipeline (ingestion, pseudonymization, feature extraction, ETL, labeling)	Local handling and transformation of health data	Not a medical device	Performs preparatory tasks without direct clinical purpose. May be considered an accessory under Art. 2(2).
Central Node: AI practitioner interface (access, model upload, experiment creation)	Manages experiments and FL orchestration	Potentially a medical device	If the module influences the development of a clinical model, it contributes to the function of the medical device (Art. 2(1), Rule 11).
Model training execution	Trains models on distributed datasets	Likely part of a medical device	Integral to generating an AI model used for diagnosis or treatment. Covered by Rule 11 (Annex VIII).
Model visualization and download interface	Allows viewing metrics and retrieving models	Possibly MD or accessory	If used for clinical insight or workflow, it may qualify as part of or accessory to the MD.
Metadata analytics	Technical/statistical system insight	Not a medical device	No direct medical intent or output.
Analytics on trained models	Analyze performance and explainability of trained models	Possibly MD or accessory	Contributes to performance evaluation (Art. 61, Annex XIV), especially if linked to clinical validation.
Synthetic data exploration	Aggregated data analysis	Not a medical device	Unless used to support clinical decisions, this function is not regulated.
Decision support tools	Clinical decision-making based on trained models	Medical device (Class IIa or higher)	Falls under Rule 11: software that supports diagnosis or therapy is a medical device.

- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means.

- **Active Device** means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Software shall be deemed to be an active device;
- **Accessory** for a medical device means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

Compliance with a certified Quality Management System (QMS) is a mandatory requirement for all companies placing a medical device on the market under the MDR2017/745. The applicable standard for establishing and maintaining such a system is ISO13485:2016 [16], which defines the requirements for a comprehensive QMS specifically tailored to the medical device industry. ISO13485:2016 governs all stages of the device lifecycle, including key processes such as Design and Development, which are particularly critical for software components.

In the case of software that is classified as a medical device, design and development activities must also comply with the requirements of IEC62304:2006 (and its amendment A1:2015) [17], the international standard that provides a framework for the lifecycle processes of medical device software. IEC62304:2006 specifies the processes, activities, and tasks necessary for the safe design, development, maintenance, and risk management of software intended for medical purposes, and is fully aligned with the principles of ISO13485:2016.

When applied to FL platforms, this regulatory context introduces a key challenge: FL is not, by default, a medical device. From a general perspective, federated learning provides a technical infrastructure to enable the distributed training of AI models, agnostic to both the specific nature of the data and the intended clinical or non-clinical purpose of the resulting models. However, the training strategy, model orchestration, and data aggregation protocols are defined and implemented within the FL platform itself. This means the FL platform actively influences the development process and final behavior of AI algorithms, including those intended for diagnostic, therapeutic, or clinical decision support purposes.

Under this premise, the FL platform may fall within the scope of the MDR2017/745, particularly if its output (the AI model) is intended for a medical purpose and

the platform plays a role in ensuring its performance and reliability. Given this context, a modular assessment becomes necessary.

To properly evaluate its regulatory status, the FL platform should be interpreted as a system composed of multiple functional modules, each of which may (or may not) qualify independently as a medical device or accessory. This modular approach is aligned with MDR2017/745 Articles 2, 22, and 23, which distinguish between full systems, parts, and accessories. Each module (e.g., the orchestrator, the local training engine, the aggregation component, or the visualization interface) must therefore be analyzed individually based on its intended function within the system. These assessments can then be combined to support a consistent overall classification.

In the following section, we apply this rationale to the FL platform presented in this study, leveraging the functional decomposition previously introduced to determine the regulatory status of each module and of the system as a whole.

1) Assessment under MDR2017/745: In order to determine the regulatory classification of the SYNTHIA platform components under MDR2017/745, a modular assessment has been conducted based on each module's functionality, interaction with clinical data, and potential influence on medical decisions. As defined in Article 2(1) of the MDR, a product qualifies as a medical device if it is intended for a medical purpose, such as diagnosis, prevention, or treatment of disease. Furthermore, Rule 11 in Annex VIII provides specific guidance for software, stating that any software that provides information used to take decisions with medical purposes must be classified at least as Class IIa.

The SYNTHIA FL platform comprises distinct modules with varying purposes and levels of clinical impact. Modules performing pre-processing functions, such as data ingestion, pseudonymization, and ETL, do not serve a medical purpose on their own and are therefore not considered medical devices. However, they may be regarded as accessories under Article 2(2) if they support the functioning of a regulated system.

By contrast, modules that contribute directly to the development, training, or deployment of AI models used in clinical decision-making such as the orchestration interface, model training components, and decision support services may fall under the scope of the MDR2017/45. Their classification depends on their intended purpose and the degree to which they affect the safety and performance of a resulting medical device, particularly in the context of AI-based software.

As shown in Table III, each module must be evaluated individually. In this assessment, components such as the model training process and decision support tools are likely to be classified as medical device software, while other modules may be non-regulated or accessories, depending on their integration and claims.

2) Assessment under US FDA Framework: In this context, the classification of each module is determined by its functionality and by whether it contributes to a product intended to diagnose, treat, or mitigate disease. The intended use of the software remains the most important determinant of classification, rather than its internal architecture or whether the data remain local.

Modules involved in data preparation, such as ingestion, pseudonymization, ETL, and feature extraction, are considered general-purpose IT components and fall outside the scope of device regulation unless they directly influence the clinical functionality of a regulated SaMD. Similarly, modules used solely for system-level analytics or synthetic data visualization are not regulated unless their outputs are directly used for clinical purposes. The overall evaluation of the FL modules according to US FDA framework are outlined in table IV.

IV. Conclusions and Future Work

The regulatory classification of the SYNTHIA FL platform modules varies between the EU and the US, reflecting differences in how each jurisdiction defines medical devices and software components.

Under the EU Medical Device Regulation (MDR 2017/745), classification is based on the intended purpose of each module, its role in supporting diagnosis or therapy, and its functional independence. Software that provides information used to make clinical decisions falls under Rule 11 of Annex VIII, and is generally classified as Class IIa or higher, depending on risk. Modules that do not have a direct medical function, such as ETL pipelines or synthetic data tools, are typically excluded from MDR scope unless they are considered accessories (Art. 2.2).

In contrast, the US Food and Drug Administration (FDA) defines a medical device under 21 USC § 321(h), and software that meets this definition is regulated either through 510(k), De Novo, or Premarket Approval (PMA) pathways. The FDA follows the Software as a Medical Device (SaMD) framework developed by the International Medical Device Regulation Forum IMDRF, and focuses on the functionality and clinical impact of the software, rather than its architecture. Components like model orchestration, training pipelines, or explainability dashboards may not be regulated independently, but can still be subject to Quality System Regulation (21 CFR Part 820) if they are part of the SaMD lifecycle.

In both jurisdictions, components such as decision support tools and model training engines for clinical models are subject to regulation, while pre-processing or analytics layers are generally excluded unless they influence clinical outputs. However, the FDA offers greater flexibility in terms of system-level classification, while the MDR 2017/745tends to apply stricter modular criteria.

Additionally, the establishment of the European Health Data Space (EHDS) aims to facilitate secure, standardized, and interoperable access to health data for both primary

TABLE IV
REGULATORY ASSESSMENT OF THE SYNTHIA FL PLATFORM MODULES UNDER US FDA FRAMEWORK

Module / Block	**Main Function**	**FDA Classification**	**Justification**
Federated Node: Preprocessing pipeline (ETL, pseudonymization, labeling)	Data handling prior to training	Not a device	Does not perform or influence medical decisions. Considered general-purpose IT.
Central Node: AI practitioner interface	Manages access, orchestration, and training setup	Potentially part of a regulated system	If contributes to development of SaMD, may be considered part of its lifecycle under QSR.
Model training component	Trains AI models on PHI for clinical use	Likely part of SaMD	Core to the creation of a regulated software function if intended to support diagnosis/treatment.
Model metrics and download	Provides performance insight and access to final model	May be device component or accessory	If used for interpretability or deployment in clinical settings.
Metadata analytics	System usage and logs	Not a device	No clinical intent or function.
Model analytics (explainability, auditability)	Supports performance evaluation	Likely required under QSR/SaMD lifecycle	Contributes to risk management and validation; covered in SaMD clinical evaluation guidance.
Synthetic data tools	Aggregate data analysis	Not a device (unless used in clinical decisions)	Only regulated if synthetic output is used for diagnostic/therapeutic support.
Decision support tools	Support to decision making based on model output	SaMD (Class II or III)	Directly supports diagnosis or treatment decisions; clearly regulated.

(clinical) and secondary (research, innovation) uses. This new framework will have a significant impact on federated learning platforms, particularly in relation to data access rights, cross-border data flows, and technical requirements for data interoperability.

Future work should also provide additional technical detail regarding the internal mechanisms of federated learning platforms, including the specific federated averaging strategies, lifecycle management of models, and privacy-preserving techniques applied. While this study has focused on the SYNTHIA platform, a comparative discussion with other federated or AI-based healthcare platforms, and how they have addressed regulatory classification, would offer a broader and more comprehensive perspective.

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REFERENCES

[1] S. Mangairkarasi, T. Venkata Ramana, R. Vaishnavi, S. Agalya, V. Sathya, and R. Sıva Subramanıan, "Advancing Healthcare Through Artificial Intelligence," Advances in healthcare information systems and administration book series, pp. 113–134, Dec. 2024, doi: 10.4018/979-8-3693-6294-5.ch005.

[2] I. A. Bhagat, K. G. Wankhede, N. A. Kopawar, and D. A. Sananse, "Artificial Intelligence in Healthcare: A Review," International journal of scientific research in science, engineering and technology, vol. 11, no. 4, pp. 133–138, Jul. 2024, doi: 10.32628/ijsrset24114107.

[3] Q. Yang, Y. Liu, T. Chen, and Y. Tong, "Federated machine learning: Concept and applications," ACM Transactions on Intelligent Systems and Technology, vol. 10, pp. 1–19, 2019.

[4] European Parliament and Council, Regulation (EU) 2017/745 on medical devices, Official Journal of the European Union, L117, 5 May 2017, pp. 1–175.

[5] United States Congress, *Federal Food, Drug, and Cosmetic Act (FD&C Act)* 21 USC. § 301 et seq., 1938.

[6] B. A. Galende, S. U. Mayoral, F. M. García, y S. B. Lottmann, "FLIP: A New Approach for Easing the Use of Federated Learning", Applied Sciences, vol. 13, n.o 6, Art. n.o 6, ene. 2023, doi: 10.3390/app13063446.

[7] S. Mishra, R. Tondon, and N. P. S. Rathore, "Revolutionizing Healthcare with Federated Learning: A Comprehensive Review" pp. 1–5, Sep. 2024, doi: 10.1109/acroset62108.2024.10743932.

[8] M. Joshi, A. Pal, and M. Sankarasubbu,"Federated Learning for Healthcare Domain - Pipeline, Applications and Challenges" ACM transactions on computing for healthcare, vol. 3, no. 4, pp. 1–36, May 2022, doi: 10.1145/3533708.

[9] M. Aggarwal, V. Khullar, and N. Goyal, "A comprehensive review of federated learning: Methods, applications, and challenges in privacy-preserving collaborative model training," Informa, 2024, pp. 570–575. doi: 10.1201/9781003471059-73.

[10] D. Santos et al., "A Federated Learning Platform as a Service for Advancing Stroke Management in European Clinical Centers," Oct. 2024, doi: 10.48550/arxiv.2410.13869.

[11] K. Rai and C. Kaushal, "Federated Deep Learning System for Application of Healthcare in Pandemic Situation," pp. 131–142, Jul. 2024, doi: 10.1201/9781032694870-10.

[12] V. S. Bortolini, W. Engelmann, and A. de S. Garcia, "Artificial Intelligence in Medicine" Brazilian Journal of Law, Technology and Innovation, vol. 2, no. 2, pp. 1–18, Oct. 2024, doi: 10.59224/bjlti.v2i2.1-18.

[13] Hernández-Peñaloza, G. Et al. General context and relevant public datasets available for improving pathways in Paediatric Cancer applying Artificial Intelligence. A review, EJC Paediatric Oncology, 2024, https://doi.org/10.1016/j.ejcped.2024.100196.

[14] European Parliament and Council, Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation),4 May 2016, pp. 1–88.

[15] U.S. Congress, "Health Insurance Portability and Accountability Act of 1996 (HIPAA)", Public Law 104-191, Aug. 21, 1996.

[16] International Organization for Standardization, "ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes", ISO, Geneva, Switzerland, 2016.

[17] International Electrotechnical Commission, "IEC 62304:2006 – Medical device software – Software life cycle processes", IEC, Geneva, Switzerland, 2006.