

KiMeKo: A Collaborative AI Platform for Medical Device Development

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Abstract—KiMeKo (*KI-Med-Kollaborationsplattform*) is a publically funded collaborative research project that develops a sustainable AI-Med ecosystem for AI-based medical device development. The project runs from July 2024 to December 2027 and joins seven Northern German research institutions. KiMeKo addresses the complete development trajectory, from concept and data acquisition to validation, regulatory evidence generation, and approval-oriented documentation. The project contributes a practical toolchain and platform capabilities for non-experts and experts, including structured innovation support, uncertainty-aware sensor-data fusion, hybrid expert-system modeling, and workflow-guided data acquisition and anonymization. This paper summarizes project objectives, expected outputs, relevance to IEEE COMPSAC 2026 themes, and current progress. In particular, KiMeKo aligns with Applied AI and Smart & Connected Health by combining AI engineering, privacy-conscious data processing, and regulation-aware medical software development.

Index Terms—AI in healthcare, medical device development, trustworthy AI, regulatory compliance, collaborative platform

I. INTRODUCTION AND PROJECT DETAILS

The increasing use of artificial intelligence in medical device development creates significant opportunities, but also imposes strict requirements regarding reliability, privacy, and compliance. KiMeKo (*KI-Med-Kollaborationsplattform*) addresses this challenge by bundling multiple R&D initiatives into one coordinated ecosystem for AI-based medical device innovation [1]. The project is funded by the German Bundesministerium für Forschung, Technologie und Raumfahrt (BMFTR) pursuant to a resolution of the Budget Committee of the German Bundestag. The core project details are summarized in Fig. 1.

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Project Details (KiMeKo)

Full name:	KI-Med-Kollaborationsplattform (KiMeKo)
Homepage:	https://kimeko.digital-hub.sh/
Project period:	07/01/2024 – 12/31/2027
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Registration no.:	01 S24056A
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Fig. 1. Project details of the KiMeKo project.

KiMeKo builds on a substantial portfolio of prior, complementary initiatives in Northern Germany. Earlier projects such as *KI-SIGS* [2] and *KI-Lab* [3] established foundational capabilities for AI engineering, collaborative platform development, and transfer between academia, clinics, and industry. Additional precursor activities, including *GAIA-X-Med* [4], *MCEA*¹, and *OR.NET* [5], contributed key technical building blocks for secure data spaces, causal and model-based reasoning, and interoperable medical-device connectivity (IEEE 11073 SDC).

However, these competencies emerged across distributed projects, institutions, and technical stacks. As a result, methods, tooling, and process artefacts were available but not yet consistently integrated into a unified lifecycle from idea to approval-oriented deployment. KiMeKo addresses this gap by consolidating these prior results into a coherent, service-oriented AI-Med collaboration platform with strong emphasis

¹<https://www.uni-luebeck.de/aktuelles/nachricht/artikel/medizinisches-expertensystem-mcea.html>

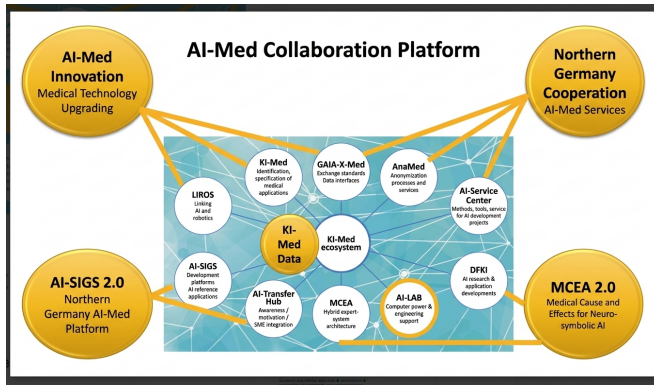


Fig. 2. Prior initiatives and competencies that form the basis of KiMeKo.

on scalability, compliance, and practical reuse. The project also contributes to developing and strengthening the AI-Med ecosystem (<https://ki-med-nord.de>) in Northern Germany. This ecosystem provides integrated support across data access, algorithm development, compute infrastructure, regulatory guidance, and clinical validation to accelerate approval-ready AI medical products and is supported by several research institutions in this region. Figure 2 illustrates the prior initiatives and competencies that form the basis of the AI-Med Ecosystem.

Contributors. The project team consists of roughly 40 scientists guided by the principal investigators including Martin Leucker, Alexander Schlaefer, Frank Ueckert, Christoph Lueth, Philipp Rostalski, Nihat Ay, Thomas Kirste, Stefan Fischer, and Lars Kaderali. The presenting author is Martin Leucker.

II. OBJECTIVES AND EXPECTED OUTPUTS

KiMeKo aims to build-up and provide an economically and scientifically sustainable AI-Med ecosystem supporting the complete path from idea to approval-oriented implementation. The project objectives are operationalized by five tightly connected work packages:

- **WP1 – AI-Med Services Center:** standardized services and tools for scalable AI-based medical device development, with explicit support for non-expert users.
- **WP2 – Northern German AI-Med Platform:** structured platform functions such as innovation assessments, implementation blueprints, and regulatory checklists.
- **WP3 – Fusion of measurement and monitoring data:** uncertainty-aware sensor-fusion algorithms and modular model structures for interoperability.
- **WP4 – Modeling and data integration for hybrid expert systems:** evaluation of LLM-based support for quantitative and qualitative causal model construction.
- **WP5 – Data acquisition process tool:** workflow-guided path from data request and anonymization to compliant data usage.

Expected tangible outputs include (i) a reusable platform/toolchain for AI-Med development, (ii) process templates and regulatory evidence artifacts, (iii) validated algorithmic

components for data fusion and hybrid reasoning, and (iv) a transferable collaboration model for multi-institutional medical AI innovation.

III. DETAILS OF THE PROJECT

Let us describe the work packages in detail.

a) **WP1 – AI-Med Services Center:** WP1 develops a service-oriented development platform for AI-based medical applications. As a shared operational foundation, it provides a cloud collaboration space accessible at <https://www.digital-hub.sh>, secured through single sign-on, and equipped with standard project-management and development tools such as Nextcloud, GitLab, and a Matrix server. A Kubernetes-based framework enables the composition and scheduling of complex AI workflows, ensuring efficient utilisation of GPU infrastructure. Integration with GAIA-X-conformant data spaces provides authenticated, contract-governed access to medical datasets. Dedicated validation and verification services support systematic quality assurance of machine-learning artefacts, including MDR-conformant documentation suitable for regulatory submissions. Deployment services, building on ONNX-based model transformation, target both cloud and on-site edge environments as required in clinical settings. The platform further offers domain-adapted neural network architectures, a library of pre-structured models for common clinical scenarios, alignment services for adapting Foundation Models to medical domains, and services for probabilistic graphical models (PGMs), enabling uncertainty-aware inference across diverse application contexts.

A central research challenge in WP1 is to design the platform and its services so they are accessible and usable for non-expert users, such as clinicians and medical researchers, while still providing the depth and flexibility required by AI developers. Although many individual tools and methods are available, the heterogeneity of existing solutions makes their integration challenging.

b) **WP2 – Northern German AI-Med Platform:** WP2 establishes platform capabilities that synchronise the development paradigms of clinicians, AI developers, and industry stakeholders throughout the innovation lifecycle. We roughly follow the AI clinical pathway (<https://clinicalai.eu/clinical-ai-pathway-guide/>). A dedicated *IdeasLab* supports structured innovation assessment, evaluating medical-AI concepts for clinical relevance, technical feasibility, and economic viability. A complementary *TestLab* enables the evaluation of AI-Med applications under realistic clinical conditions, with particular emphasis on user-interface design and integration into existing care workflows. Though not covered in this project, the long term goal is to upgrade and enhance this TestLab to an AI Sandbox in the sense of the EU AI Act. Two to three blueprint applications are developed end-to-end to serve as transparent reference implementations. The work package further produces training materials to enable both technical and medical stakeholders, a regulatory roadmap covering the Medical Device Regulation (MDR), the EU AI Act, ISO 13485, and IEC 62304, as well as actionable quality

checklists that accelerate certification preparation, especially for SMEs.

A central research challenge in WP2 is to derive from existing projects blue prints that serve as the basis for both manual development and automated design and implementation, especially, the blue prints should be the basis for building proactive, agentic AI support for developers and clinicians, guiding them through the complex landscape of technical and regulatory requirements.

c) *WP3 – Fusion of Measurement and Monitoring Data:* WP3 addresses the linking and fusion of heterogeneous medical-device measurement data toward a partial *Digital Twin* of the patient. The modelling follows the MCEA (Medical Cause and Effect Analysis) methodology, structuring organ systems by anatomy, physiology, and pathology at multiple levels of abstraction [6]. Factor-graph-based probabilistic models serve as the mathematical backbone, enabling modular message-passing inference algorithms that naturally accommodate measurement uncertainties and distributed computation. Device connectivity is realised through the IEEE 11073 SDC (Service-oriented Device Connectivity) standard [7], allowing manufacturer-independent data exchange. Two clinical use cases—selected for depth and generalisability—guide the entire development. A reference implementation is deployed at the Lübeck Innovation Hub for Robotic Surgery (LIROS), integrating SDC-networked medical devices with a dedicated edge-PC node for real-time sensor fusion. The work package concludes with systematic evaluation and comprehensive documentation of the fusion workflow and toolbox.

A central research challenge in WP3 is to design modular, uncertainty-aware fusion algorithms that can effectively integrate heterogeneous data sources while respecting the constraints of real-time clinical environments and the interoperability requirements of medical devices.

d) *WP4 – Modeling and Data Integration for Hybrid Expert Systems:* WP4 lays the foundations for hybrid AI systems that combine symbolic reasoning over causal knowledge models with sub-symbolic learning, in particular Large Language Models (LLMs). One research strand develops methods for LLM-based extraction of causal models from medical guidelines, textbooks, and clinical studies, progressing from qualitative cause–effect relations through quantitative probabilistic models to complex predicate-logic representations. A complementary strand investigates *alignment* methods that constrain LLM outputs to remain consistent with a given causal background theory, thereby improving reliability and explainability in clinical contexts. Three demonstrators of increasing complexity are produced, each accompanied by dedicated evaluation suites constructed with domain experts. A user interface enables medical professionals to interact with, review, and refine the extracted models. The complete toolchain is released as open-source software.

A central research challenge in WP4 is to develop effective methods for extracting and aligning causal models from unstructured medical texts, ensuring that the resulting hybrid expert systems are both accurate and interpretable for clinical

users.

e) *WP5 – Data Acquisition Process Tool:* WP5 develops a cross-state, cross-clinic workflow management tool that standardises the entire lifecycle of medical data reuse—from initial data requirements and ethics-board approval through anonymisation to compliant storage and utilisation. The work-package addresses especially the data repositories of the Medical Informatics Initiative (MII, [8]) and the National University Medicine (NUM) network, which are key data sources for AI-Med development in Germany. The tool provides a unified interface for requesting data access, tracking approval processes across multiple institutions, and orchestrating anonymisation and pseudonymisation services. By embedding regulatory requirements and best practices into the workflow, the tool ensures that data handling complies with site-specific data-protection regulations and ethical standards. Integration with existing clinical data infrastructures and regulatory resource catalogues further streamlines the process, reducing administrative overhead and accelerating access to high-quality datasets for AI development. The workflow is modelled in BPMN (Business Process Model and Notation) and executed on an open-source engine such as Camunda, chosen for its flexibility, standards compliance, and process-automation capabilities. Individual workflow steps are encapsulated as SOA components providing access to clinical data sources via MII Data Integration Centres, anonymisation and pseudonymisation services respecting site-specific data-protection regulations, ethics-commission portals, and regulatory-resource catalogues. A web-based portal guides users through the complete data-request lifecycle. The tool integrates is accompanied by a training programme and rollout plan targeting the broader Northern German AI-Med ecosystem.

A central research challenge in WP5 is to design a workflow management tool that effectively coordinates the complex, heterogeneous multi-institutional processes involved in medical data acquisition and reuse, while ensuring compliance with diverse regulatory requirements and minimizing administrative burden for users.

IV. RELEVANCE TO COMPSAC SYMPOSIA AND THEME

The COMPSAC 2026 Research Projects Exhibition requires a clear alignment of projects with conference themes and symposia [9], [10]. KiMeKo strongly aligns with:

- **Applied Artificial Intelligence (AAI):** AI engineering methods, LLM-assisted modeling, trustworthy and explainable AI, and deployment-oriented tooling in health-care.
- **Smart & Connected Health (SCH):** intelligent health-data processing, privacy-aware analytics, and AI-enabled support functions in regulated clinical contexts.
- **Security, Privacy, and Trust (SEPT):** process support for anonymization and compliance-centered workflows.

KiMeKo also matches the COMPSAC 2026 theme “Agentic AI” by combining proactive workflow support (WP5), model-driven decision preparation (WP4), and lifecycle-oriented orchestration of development artifacts across institutions.

V. CURRENT STATUS AND INTERMEDIATE RESULTS

KiMeKo is currently in an active implementation phase. Initial platform and tooling concepts are established, and work-package level developments are progressing in parallel across the consortium. Public-facing milestones include presentations of the broader “KI-Med-Oekosystem Nord” initiative in Berlin (parliamentary event) and at DMEA 2026, demonstrating project visibility and stakeholder engagement [1].

a) *WP1 – AI-Med Services Center:* WP1 has established a valid, stakeholder-driven overall concept that provides a stable basis for the service center. Progress includes GAIA-X-conformant building blocks for SSI and interoperability, an initial validation workflow with first tools such as QUEST and CREST, early deployment prototypes on Kubernetes and in the LIROS use case, and a broad model library including modern Foundation Models such as MedSAM.

b) *WP2 – Northern German AI-Med Platform:* WP2 has nearly completed its innovation assessment framework, which now serves as a central steering instrument for the platform design. In parallel, regulatory requirements are being integrated early in a compliance-by-design manner, creating a strong foundation for blueprint applications and a strategic advantage through the close coupling of technical development and regulatory preparation. For supporting the overall development process, agentic AI support is currently under development.

c) *WP3 – Fusion of Measurement and Monitoring Data:* WP3 has made very solid progress toward a digital twin, both at qualitative and quantitative levels. Successful SDC analysis, first implementations, and initial sensor-fusion prototypes on edge devices such as Raspberry Pi systems show that the work package is technically stable and fully on schedule, while also preparing the ground for more advanced probabilistic models.

d) *WP4 – Modeling and Data Integration for Hybrid Expert Systems:* WP4 has developed a functioning pipeline for extracting causal models and has advanced the training and comparison of modern LLM architectures. The emerging hybrid approach, combining LLMs with causal inference systems, together with progress on alignment and system architecture, provides a strong basis for quantitative causal modeling.

e) *WP5 – Data Acquisition Process Tool:* WP5 has already established a functioning workflow for medical data use, including integration with MII, NUM, and FDPG-related structures. First productive data access across Greifswald, Lübeck, and a federated setup with UKE, together with progress on the user portal, strong treatment of privacy and regulation, and good cross-site harmonization, demonstrate substantial implementation maturity.

VI. CONCLUSION

KiMeKo establishes a coordinated, regulation-aware AI-Med collaboration platform that addresses technical, methodological, and organizational barriers in medical AI innovation. Through its five work packages, the project delivers practical tools and methods from data handling to approval-oriented

development support. Its direct relevance to COMPSAC symposia and the 2026 “Agentic AI” theme makes KiMeKo a strong candidate for the Research Projects Exhibition track.

USE OF GENERATIVE AI

The authors used generative AI tools solely to support English language polishing and readability improvements. All technical content, interpretations, and conclusions were created and verified by the authors, who take full responsibility for the final manuscript.

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