

AIQNET

Medical Data Ecosystem

Integrated. Interoperable. Automated.

Many companies from the health sector – a shared vision

The consortium of 16 established companies from the fields of medical technology, pharmaceutical industry and healthcare provision grouped together under the acronym “KIKS” and won the competition for projects of artificial intelligence for clinical studies run by the Federal Government in 2019. The partners have been developing the technical infrastructure and applications based on it as part of a project which has been running with the financial support of the Federal Ministry of Economic Affairs since January 2020.

The focus lies on the data protection-compliant, anonymised provision of structured medical data for process automation, studies, research and product development. A special feature of the project is the close cooperation between industry, research and healthcare provision institutions.



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Become part of our vision

Cooperative development of a digital ecosystem for data-based medical applications. Our aim is 100 applications and 1,000 connected clinics within the next 5 years.

Please contact us if you would like any further information.

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AIQNET makes **medical data** smarter

A platform that ensures the legally compliant and automated use of medical data for research, development studies and evidence-based medicine



Advancing innovations in a data-based and automated manner

For technological developments in healthcare it will be critical that high-quality medical and clinical data are provided in an exchangeable format that retains the context of the data – a format from which data protection-compliant access can be realised for the various stakeholders such as clinics, researchers, medical technology and pharmacy.

AIQNET provides access to clinical data from laboratories, radiology, case history, diagnosis and treatment via one system. The legal and ethical requirements for the processing of medical data for research purposes are met in full by means of a governance framework and patients are given a comprehensive range of options for controlling the use of their data.

More efficient implementation of regulatory requirements for medical products

AIQNET benefits medical technology companies that are obliged by legal regulations (MDR) to

conduct a continuous clinical assessment of their products. This includes post market surveillance (PMS) as well as the clinical observation after bringing a product to market (post market clinical follow-up, PMCF). Class II and III products (e.g. implants) must also be subjected to an initial clinical test.

To meet the legal requirements for the assessment of performance and safety more and more frequently requires evaluation of the corresponding data from routine treatments. The AIQNET ecosystem provides access to the data storage systems of the clinics, and unstructured data such as images or lab reports are made available in a way that they can be evaluated, converted into a universally exchangeable format (FHIR) and, depending on requirements, made available for access in pseudonymous or anonymous form. This means that data from routine treatments can, in a data protection compliant manner, be generated for the designated offices to check safety and performance of medical products.

Challenges for the medical technology and pharmaceutical industries

The analysis of health datasets has the potential for bringing about major advances in medical research and product development. However, before this can happen the huge challenge of providing legally secure and interoperable access to the clinical data required must be overcome. In addition, the MDR requirements for the clinical assessment of medical products have changed. Such assessments must be documented, e.g. by continuous monitoring (PMCF) after market launch with regard to clinical performance and safety.



AIQNET creates an **ecosystem for the wide-ranging use of health data for research, development, clinical studies and evidence-based medicine in compliance with international legal regulations.**

AIQNET supports you in clinical trials and studies

AIQNET enables the use of structured clinical data, regardless of system, interface and organisation, that simplifies the planning and implementation of clinical trials and studies. The ecosystem provides the technological infrastructure for big data analyses, access to real world data, and can therefore also cover the requirements for the development of AI applications. Together with the Clinical Trial Management System that is already available, comprehensive analysis and evaluation functions, e-mail notifications, risk-based monitoring and intuitive dashboards can be automated inexpensively, transparently and efficiently and also planned, monitored and analysed while involving all stakeholders.

Reduction of integration and development work for new clinical applications

Operating AIQNET allows you to make a wide number of applications available on the platform without requiring any additional integration work. Software manufacturers and the manufacturers of digital health applications (DIGAs) can use the platform, which has been independently audited with regard to data security and protection, to implement their application. The aim is to advance the digitalisation process without integration barriers on the basis of the FHIR standard. Access to compatible applications from third-party providers is implemented via a market place and gives pharmaceutical companies and medical technology manufacturers the possibility of developing highly specialised applications for e.g. data-based diagnostic processes considerably faster as well as integrating them in clinical workflows and also in the application.

The AIQNET platform provides the prerequisites for the legally secure use of medical data



Legal certainty for all stakeholders

- Data pertaining to patients is subject to strict data protection requirements under the terms of GDPR. The AIQNET platform provides clinics with a controlled data governance framework for making data available for research and development in a manner compliant with data protection laws.

- Implementation of the prohibition with reservation of authorisation: From taking account of patient permission to regulations as to possible usage purposes.

- Definition of the necessary technical and organisational requirements of a data recipient to ensure data protection.

- Assurance of adequate pseudonymisation and anonymisation levels of patient data.

Data integration

- AIQNET processes unstructured and structured information from different medical systems and applications such as KIS, LIS, RIS, PACS. The connection is made via an integration server that functions with the HL7 v2, v3, CDA, SDC, FHIR and DICOM protocols.

- Medical and clinical data that is available as unstructured texts, PDF files and radiography images are structured and analysed by third-party applications and made available for interoperable use.

- The extracted health data can be used by clinics to support and automate internal processes and also made available for research applications and developments of external partners and organisations.