

Medical Informatics Initiative

Supporting Project – Central Office of the National Steering Committee



Joint Interoperability Key Issues Paper

Commitment statement by the consortia participating in the Medical Informatics Initiative regarding compliance with minimum requirements to be satisfied in order to achieve interoperability

Last revised: March 13, 2017
Version 1.2

Based on the revised draft of the Roadmap document from the National Steering Committee of the Medical Informatics Initiative. The wording will be further revised and updated in accordance with the guidelines set by the National Steering Committee.

DISCLAIMER: The official document has been adopted in German language.

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1 Executive Summary

Preface

This document describes the essential requirements – by the means of key issues – to be taken into account by the consortia in order to gradually achieve interoperability between the networked data integration centers at all relevant levels. Key interrelated issues for which interoperability is of significance have been identified for the concept phase as well as for the setup and networking phase. Milestones comprising minimal requirements have been defined and will be expanded on during the setup and networking phase.

Key Issues

Key issue 1: Interoperability on the basis of standards

The application of open, international standards is preferred for all levels of interoperability. Existing standards should be adjusted and/or expanded or proprietary developments implemented only when absolutely necessary. The aim is to establish close and ongoing cooperation with standardization bodies early on. The consortia are to coordinate with one another regarding the necessity of legislative guidelines for standards. An open, standard-compliant data sharing format able to be deployed between all locations will be established for metadata and data. Whenever possible, all of the tools used should be well-established and open and should also support international standards.

Key Issue 2: Interoperability via coordination and a step-by-step approach

Technical and organizational interoperability between the data integration centers will be accomplished in an iterative, step-by-step process. The consortia are to use the milestones in the Roadmap as a guideline for implementation. The key milestones will be achieved via coordinated efforts within the first four years (up to the setup and networking phase). The sequence of steps is based on the Roadmap to be adopted by the National Steering Committee. Details are provided further on in this document.

Key Issue 3: Interoperability via cooperation

As a general rule, all developments are to be informed by national and international best practices. There will be close coordination and cooperation with related initiatives and projects. Stakeholders are all to be involved on a continual basis. The intention is to create goal-oriented partnerships with industry. Results will be made available to the public and all stakeholders.

Key Issue 4: Risk management and monitoring

Efforts will be made to hold a workshop in the second half of 2017, specifically with the industry associations bvitg e.V.¹, KH-IT² and CIO-UK (formerly ALKRZ, Working Group for Managers of Clinical Research Centers at Germany's University Hospitals) in order to review the requirements of this key issues paper for feasibility, particularly as far as the timeline is concerned, to derive a rough cost estimate, and to articulate recommendations for steps to take. For each of the MII's milestones, interoperability goals will be defined based on the key issues for interoperability and geared toward consortia-spanning use cases; the consortia will then agree to specific deadlines for accomplishing

¹ <http://www.bvitg.de>

² <https://www.kh-it.de>

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these. The monitoring of compliance with the interoperability guidelines will be embedded in the implementation of the specific joint projects. Having an ongoing, active Interoperability Working Group provide expert knowledge, tools, and experts is recommended.

Roadmap

The milestones listed in the following (indicated with an “M”) are based on the Roadmap and the key issues discussed above. Start dates are defined for work on interoperability in relation to key aspects of the solutions developed in connection with the MII, which will then be continuously and iteratively expanded over the course of time.

- Standards for patient consent and the use of data
 - M 1.1a Creation of version 1.0 of a standardized consent form template
 - M 1.1b Creation of an expanded version of the consent form
 - M 1.2: Coordination with data privacy and protection officers
 - M 1.3a Creation of a standardized basic consent form in digital format
 - M 1.3b Creation of a standardized expanded consent form in digital format
- Trusted Third Parties (TTPs)
 - M 2.1 Creation of a specification for intra-consortia TTPs
 - M 2.2 Preparation of a requirements paper on the federation of TTPs
 - M 2.3 Establishment of cross-consortia identity management and record linkage for selected use cases
- Rules for use & access
 - M 3.1 Preparation of a key issues paper by the Data Sharing Working Group
 - M 3.2 Availability of technical support for use & access operations
- Data privacy and protection methods
 - M 4.1 Preparation of initial data protection plans
 - M 4.2 Enabling of authentication and authorization of users according to defined permission levels
 - M 4.3 Establishment of more extensive data protection plans
- Semantic interoperability
 - M 5.1a Reconciliation of content and terminologies for the core data set*
 - M 5.1b Availability of content and terminologies for the core data set **
 - M 5.1c Reconciliation of content and terminologies for extensions ***
 - M 5.2a Design of structures, information model, and syntax for the basic module
 - M 5.2b Design of structures, information model, and syntax for the extensions
 - M 5.3 Preparation of the metadata design (quality/availability/provenance)
 - M 5.4a Availability of services for terminologies for use by all consortia
 - M 5.4b Availability of services for metadata for use by all consortia
- Data sharing methods
 - M 6.1a Enabling of inter-consortia queries and data sharing for the basic module
 - M 6.1b Enabling of inter-consortia queries and data sharing for the extensions

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- M 6.2a Design of interoperable run-time environments for the basic module of the core data set
- M 6.2b Design of interoperable run-time environments for extensions of the core data set
- Use cases common to all consortia to demonstrate benefits
 - M 7.1 Preparation of specifications for common use cases
 - M 7.2a-b Holding “Projectathons”
- Patient empowerment
 - M 8: Workshop “Harmonizing Approaches to Patient Empowerment”
- Strengthening research, teaching, and continuing education
 - M 9a: Workshop “Conveying Digital Competence in Medical Education”
 - M 9b: Status symposium “Teaching in the Field of Medical Informatics and Medical Data Science”
- Expansion and enhancement phase

* This includes:

- Defining and adopting LOINC subset for labs (Q3 or Q4 2017)
- Mapping LOINC at the locations (by December 31, 2019 or by the data availability milestone)
- Expert workshop on UCUM & LOINC with neighboring countries (Q4 2017)

** This includes:

- OPS procedure classification-based medication available in all DICs (Q4 2018)
- Availability of LOINC subset in all DICs (starting Q1 2020)

*** This includes:

- Workshop with GBN/GBA, BBMRI.de on the biospecimen basic data set (Q1 2018)
- GBN/GBA planning project for authoritative biospecimen basic data set (extension) (start in 2018)
- Start of the preparatory project for determining the actual status and further structuring and expansion of the core data set in the “Medication” basic module (Q1 2018)
- Start of the preparatory project for PDMS extension/emergency data/intensive care data/biosignal data for coordination of a subset of data elements (preparation in 2017)
- Further planning and preparatory projects as necessary

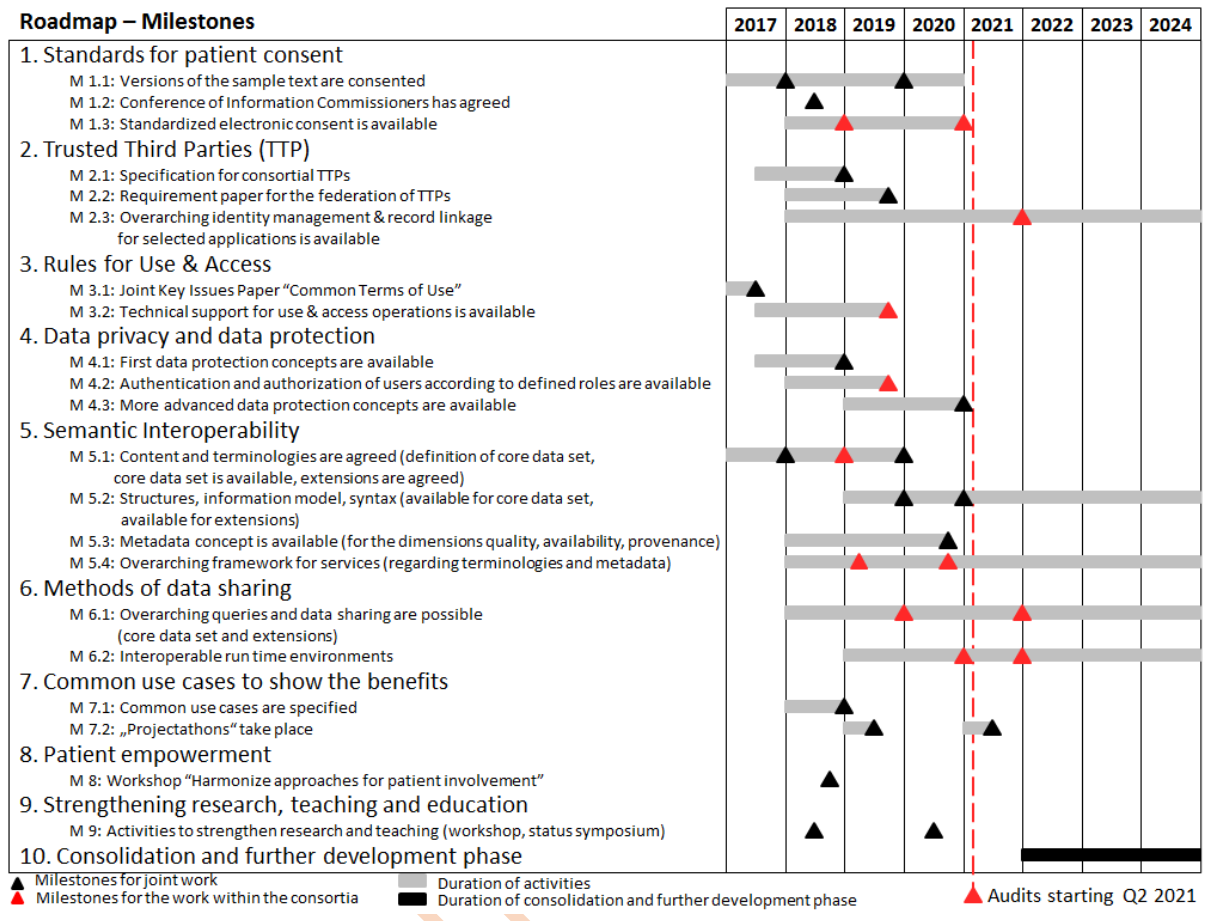
(The content of planning and preparatory projects still needs to be detailed in the Interoperability Working Group)

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MI-I | NSG | Last update: March 31st, 2017

Roadmap – Milestones



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2 Introduction

This document describes the essential requirements – by the means of milestones and key issues – that are to be achieved by the consortia in order to ensure interoperability. The consortia have to agree about interoperability between their data integration centers. The milestones to be achieved for this purpose were defined based on the Roadmap.

“Interoperability” refers to the ability of various systems, technologies, processes, or organizations to work together. Normally this requires compliance with common standards and rules.

Interoperability is the ability of independent, heterogeneous systems to interact in the most seamless way possible in order to efficiently exchange and present data to the user in a way that allows use of the data without this process requiring separate dialogs between the systems.³

The prerequisites and milestones for achieving interoperability are described on the following pages. The wording will be further revised and updated in accordance with the guidelines set by the National Steering Committee of the Medical Informatics Initiative.

³ Definition based on the German Wikipedia entry: <https://de.wikipedia.org/wiki/Interoperabilit%C3%A4t>

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3 International standards are to be applied

- a. Existing and, wherever possible, open and internationally supported standards for data, metadata, and communications processes are to be applied.
- b. Using this basis, common standards and/or specifications will be coordinated and locked in for
 - Identity management (users, patients, study subjects) (e.g., IHE XUA or PIX/PDQ)
 - Informed consent information sheets (including communication of changes when patients revoke) (e.g., IHE APPC)
 - Communications processes
 - Terminology servers (e.g., HL7, CTS2)
 - Metadata repositories (e.g. ISO 11179, openEHR, ISO 13606, and CIMI)
 - Semantics
 - Standards will be set for individual medical documentation areas (e.g., LOINC for lab values, etc.)
 - SNOMED CT is recommended as reference terminology and it is assumed that national licensing will be obtained at some point
 - There will be guardrails regarding later adjustments and evaluations will be performed regularly
 - Syntax (see Connecting Health and Care for the Nation - A Shared Nationwide Interoperability Roadmap, p. 24, and the [NHS' Interoperability Handbook](#))
 - Selected medical data elements and metadata, in particular from the MII core data set
 - Based on examples of best practices for common data models
 - Based on other national and international initiatives/projects (see gematik)
 - Recommendation: Regular evaluations by the Interoperability Working Group (as a monitoring body, long-term funding required)
- c. Furthermore, common standards will be considered and sought for
 - Query language and process (check existing)
 - Federated authentication processes
- d. Coordination with other projects and undertakings will be a goal where their results can be applied or refined by the MII.
- e. Over the course of the MII, these configurations will be regularly evaluated by the Interoperability Working Group
- f. Agencies/standardization
 - The MII aims to have influence with the agencies that revise standards, e.g., for IHE profiles, by formulating and communicating the MII's requirements
 - If there are no standards that are an exact match, the standards that are most suitable are to be refined
 - If necessary, national extensions will be developed and harmonized for international standards or profiles

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- Cooperation with gematik:
 - The MII will contribute recommendations for the interoperability index in an appropriate manner
 - Further topics will be coordinated within the Interoperability Working Group
- g. The consortia are to coordinate with one another regarding the necessity of legislative guidelines for standards (example: regulations in Austria)

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4 Roadmap Milestones for Achieving Interoperability

4.1 Roadmap: Development of common standards for patient consent to the use of patient data

4.1.1 Milestones: Creation of a standardized consent form (template versions)

Consent Working Group milestones of relevance for the Interoperability Working Group

- a. Creation of version 1.0 of a standardized consent form template by **June 30, 2017**
A metadata model is to be coordinated (based on the coordinated content of the consent form).
Each of the standardized patient consent forms is to be deployed in the initial configuration.
- b. Creation of an expanded version of the consent form by **December 31, 2019**

4.1.2 Coordination with data privacy and protection officers

Consent Working Group milestone of relevance for the Interoperability Working Group

After preliminary consultations, the Data Privacy and Protection Working Group should have coordination efforts with the relevant data privacy officers concluded **by June 30, 2018**.

4.1.3 Milestones: Creation of a standardized basic consent form in digital format

- a. Creation of a standardized basic consent form in digital format **by December 31, 2018**
A digital version of the patient consent form is to be made available as standardized documentation.
- b. Creation of a standardized expanded consent form in digital format **by December 31, 2020**
The digital version is to be updated based on the continuing work of the Consent Working Group.

4.2 Roadmap: Establishment of Trusted Third Parties (TTPs)

4.2.1 Milestone: Creation of specifications for intra-consortia TTPs

The specifications for the processes, tools, and data elements used by the intra-consortia TTPs are to be developed and made available **by December 31, 2018**

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4.2.2 Milestone: Preparation of requirements paper on the federation of TTPs

Owing to the requirements arising from use cases, in addition to the preparation of specifications for intra-consortia TTPs, expanded specifications for the consortia-spanning federation of TTPs are to be prepared by **September 30, 2019**.

4.2.3 Milestone: Establishment of cross-consortia identity management and record linkage for selected use cases

Functional solutions for cross-consortia record linkage for individual use cases are to be developed based on the specifications by **December 31, 2021**

4.3 Roadmap: Definition of uniform rules for shared use of data (use & access)

4.3.1 Milestone: Preparation of a key issues paper by the Data Sharing Working Group

Data Sharing Working Group milestones of relevance for the Interoperability Working Group
Submission of version 1.0 of a jointly coordinated use and access policy specimen (Data Sharing Working Group key issues paper) by **June 30, 2017**

This is to be refined later as necessary based on expanded requirements (data classes and types, for example patient empowerment, etc.).

4.3.2 Milestone: Availability of technical support for use & access operations

Technical solutions for the support of the respective processes in the individual consortia are to be implemented based on the Data Sharing Working Group's key issues paper by **September 30, 2019**

4.4 Roadmap: Definition of data privacy and protection methods

4.4.1 Milestone: Preparation of initial data protection plans

The consortia-spanning data privacy and protection aspects are to be coordinated in the Data Privacy Working Group.

The data protection plans for the consortia developed on the basis of TMF's generic data protection guidelines are to be prepared by **December 31, 2018**.

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4.4.2 Milestone: Enabling of authentication and authorization of users⁴

Joint decisions on how data users are to be authenticated are to be made by **September 30, 2019**. Data users should be able to complete a prospective registration, for example via a portal shared by the consortia (alternatively: federated portals). The coordination efforts required for this are to be organized early on.

The consortia will determine together how to achieve functional reliability.

Furthermore, query options are to correspond with progress in the area of semantic interoperability. For instance, at the beginning it will be possible to make inquiries over the phone, while at the end of development it should be possible to send queries through a query portal.

4.4.3 Milestone: Establishment of more extensive data protection plans

Establishment of more detailed methodologies, e.g., privacy-preserving record linkage and anonymization, by **December 31, 2020**

Permission levels (model) for the use of various data categories are to be stipulated. The requirements to be met by users will be less stringent for the retrieval of metadata than for the retrieval of aggregated or specific data.

4.5 Semantic interoperability

4.5.1 Milestones: Content, terminologies

- a. Coordination of core data set by **December 31, 2017**

See the attachment “Core Data Set” in this regard

Creation of core data set with basic module and extensions by **December 31, 2017**

- b. Availability of core data set with basic module and extensions by **December 31, 2018**.

The core data set will be made available for queries in the consortia.

Semantic harmonization of data from the basic module of the core data set (mapping of local data)

- c. **Coordination** of prioritized extensions **by December 31, 2019**
 - Semantic harmonization of data (mapping of local data) from each of the relevant extensions of the core data set by **December 31, 2020**

⁴ MII: Uniform Use and Access Policy Key Issues Paper from the Data Sharing Working Group, p. 2

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- Formulation of requirements for the standardized collection of data (joint working group with medical associations)
- Following discussion with the medical associations, presentation of the positive effects of structured and standardized documentation by **December 31, 2019**

4.5.2 Milestones: Structures, information model

- a. Design of structures, information model, and syntax for the basic module **by December 31, 2019**
 - An initial information model will be developed as a reference, which the DICs will be required to use to map data for cross-consortia data transfer.
 - This will be based on published information models and examples of best practices.
 - The information model is to be revised at regular intervals.
 - The data sharing interfaces are to be defined.
 - Reconciled data are to be mapped for data sharing by the consortia or, as the case may be, the DICs, to an optimized (TBD) sharing model.
 - The consortia are to develop a common set of use case descriptions for cross-DIC data use scenarios.
 - Coordination with existing projects and initiatives is to be actively sought.
 - Fundamentally, efforts are also to be made toward the parallel development (including ongoing adjustments in accordance with medical requirements) of a common data model; initially the information model will be implemented only as a reference sharing model.
- b. Design of structures, information model, and syntax for the extensions **by December 31, 2020**

Subsequently, structures, information model, and syntax are to be harmonized internationally (**by December 31, 2021**).

4.5.3 Milestone: Preparation of the metadata design (availability/quality/provenance)

See the “Metadata on Availability” attachment

- Data sources, data extraction, and data transformation are to be documented in standardized format by December 31, 2019.
- Submission of a metadata design for the description of the quality, availability, and provenance of data by **December 31, 2019**
- Transparent and trackable data provenance can be demonstrated.
- The metadata on the available data should be made transparent (FAIR principles).⁵

⁵ For example, see [Wilkinson, et al., The FAIR Guiding Principles for scientific data management and stewardship](#) and [Ragan et al., Characterizing Provenance in Visualization and Data Analysis: An Organizational Framework of Provenance Types and Purposes](#)

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- Recommendation: The MII will require cross-consortia collaboration on the development of solutions for data provenance. This can be accomplished by way of an auxiliary project.

4.5.4 Milestones: Availability of services (terminologies, metadata) for use by all consortia

- a. Services for terminologies are to be available for use by all consortia **by March 31, 2019**.
 - Requirements analysis on consortia-spanning terminology services based on international projects
 - A chart describing which data are concerned (including information on reference models, archetypes, how many are in operation) is to be developed.
 - Recommendation: This can be realized by way of an auxiliary project.
 - Terminologies are to be useable by all of the various institutions.

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- b. Services for metadata are to be available for use by all consortia by **September 30, 2020**.
- A chart describing the relevant data (including information on reference models, archetypes, how many are in operation) is to be developed.
 - Recommendation: This can be realized by way of an auxiliary project.
 - Metadata are to be transparently documented and made useable by all of the various institutions (and DICs), for example by means of a central or federated portal.
 - Perspectively, metadata elements are to be reconciled with one another
 - There will be a standardized metadata description for the interfaces between the DICs.
 - Uniform recommendations are to be made regarding how metadata are to be described (auxiliary project).
 - The consortia will reach agreements on governance structures and policies.
 - Coordination with existing projects and initiatives is to be actively sought.

4.6 Roadmap: Development of data sharing methods and general parameters

4.6.1 Milestone: Enabling of inter-consortia queries and data sharing (basic module, extensions)

- a. Creation of a standardized query interface for the basic module of the core data set by **December 31, 2019**

An established solution with open specification is to be used.

- b. Creation of a standardized query interface for extensions of the core data set by **December 31, 2021**

4.6.2 Milestones: Design of interoperable run-time environments

- a. Design of interoperable run-time environments for the basic module of the core data set by **December 31, 2020**

- b. Design of interoperable run-time environments for extensions of the core data set by **December 31, 2021**

Vision: Data analysis train: A containerized algorithm moves from location to location attaching itself to local data sets without being able to remove them, results of the analysis are integrated at the source DIC.

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4.7 Roadmap: Use cases common to all consortia to demonstrate benefits

4.7.1 Milestone: Preparation of specifications for common use cases

The use cases utilize patient and subject data from several locations **until December 31, 2018**.

- The use cases are based on the employment and refinement of methods: medical informatics, bioinformatics, mathematical modeling of biological systems, medical statistics and biometry, clinical epidemiology.
- Efficient and time-saving performance of studies, verification of the feasibility of studies, definition of specific cohort descriptions (phenotyping), recruitment of large cohorts
- The results will be made available to the public and all stakeholders and will be used on a wide scale.

4.7.2 Milestones: Holding “Projectathons”

The current status of solutions found for the common use cases is to be tested and presented in so-called “projectathons”, which are to be held with the participation of the relevant consortia and external partners.

- a. First projectathon to be held **by mid-2019**
Determination of deficiencies
- b. Second projectathon to be held **by mid-2021**
Response to new findings using an iterative procedure

4.8 Roadmap: Patient empowerment

Detailing of interoperability aspects relating to the Consent Working Group’s milestones

Milestone: Workshop “Harmonizing Approaches to Patient Empowerment”

Development of a plan for the inclusion of patients in the dialog in connection with a cross-consortia workshop by **September 30, 2018**

4.9 Activities to strengthen research, teaching, and continuing education

Also see the Roadmap, “Strengthening research, teaching, and continuing education”

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Milestone: Strengthening research, teaching, and continuing education

- a. Workshops “Conveying Digital Competence in Medical Education” to be held by June 30, 2018
- b. Status symposium “Teaching in the Field of Medical Informatics and Medical Data Science” to be held by June 30, 2020

4.10 Roadmap: Achieving interoperability in the expansion and enhancement phase

At this time, milestones for interoperability in the expansion and enhancement phase have not yet been formulated.

Recommendation: Since interoperability is an ongoing topic of interest, it should be continuously monitored by the Interoperability Working Group.

5 Cooperative Efforts are to be Undertaken to Achieve MII’s Goals

- a. Patients’ representatives are to be brought into the process early on.
- b. Stakeholders are all to be brought into the process.
- c. Professional associations are to be brought into the process (see GMDS, GI, etc.).
- d. Marketing (portrayal of added value) is to be coordinated.
- e. The approach for evaluations (audits) is to be coordinated.
- f. Providers should be persuaded by the MII’s presentations.
- g. Goal-oriented partnerships with industry should be established.
- h. There should be close coordination and cooperation with parallel initiatives (e.g., Fraunhofer, Helmholtz).
- i. Recommendation: Establish close and ongoing cooperation with standardization agencies early on.
- j. All consortia are to participate regularly in “projectathons” in order to achieve and provide proof of interoperability.
- k. An iterative approach is to be coordinated.

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6 Risks to Interoperability are to be Inventoried and Monitored

Risk	Countermeasures
Technical risks	
Faulty implementation/following of standards and guidelines	<ul style="list-style-type: none"> • Systematic conformity tests “Projectathons”
Incompatibility due to divergence	<ul style="list-style-type: none"> • With advancements, the focus should be on backward compatibility • Versioning • Development of extensions and profiles should always be narrow in scope and only be performed when absolutely necessary • Cues should be taken from international projects and approaches <p>Precise, continually updated documentation and communication of implemented standards, specifications, and tools</p>
Faulty data transmission due to human error	Regular training sessions for employees tasked with data sharing activities, prompt communication of changes to existing procedures, reduction of mindless, manual work, e.g., via automation
Management/governance risks	
Selection of inappropriate standards or tools, which had appeared to be promising at the start of the funding period, are replaced with new and different standards	Critical identification of relevant standards and tools based on the goals and use cases; continual coordination process that documents the emergence of new standards and recommends these where applicable, including migration path (change management)
Shortcomings in the implementation of the data sharing standards show up during operation, e.g., with regard to reliability, the functionality range, or usability	Ensure the high quality of the software as early as the development phase as well as continuously while in operation (iterative)
A deficient definition and/or interpretation of the metadata leads to a faulty data transmission/synchronization	Tests conducted by both recipient and sender for data integrity and consistency, use of metadata index even as data is extracted from the source systems, changes to be entered promptly there
Faulty or missing digital record of information leads to a faulty interpretation of the data (e.g., observational bias)	List of areas in the metadata index that have not yet been developed but which are suspected of containing medically relevant knowledge (“documented gaps”), also includes known gaps due to local documentation practice
Local standards (“forks”) arise that are no longer compatible with all consortia	Quick and transparent coordination of change and feature requests by a central coordinating committee representing all of the consortia and

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	the MII
Dependency between individual work packages; the availability of the data sharing interfaces is limited with regard to either timing or performance (e.g., throughput)	The delay of a work package (e.g., coordinated consent form design or information model) leads to timing roadblocks at other locations. Sufficient validation of the IT systems to be deployed (e.g., in accordance with GAMP), selection of a suitable operator (e.g., university computer center), and preparation of an operating plan
External risks (legislation, etc.)	
Planned technical data sharing processes can be put into operation only after a delay or not at all due to lack of approval	Timely involvement of the relevant offices (e.g., data protection, information security, ethics, technical operations) in order to allow their responses to be incorporated into the operating plans

Index of Abbreviations

CTS2	Common Terminology Services 2
HL7	Health Level 7
MII	Medical Informatics Initiative
CDM	Common data model
CMI	Clinical Information Modeling Initiative
AWMF	Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V.
DIC	Data integration centers

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Drafting Group Members and Contributors

Philipp Bruland
Johannes Drepper
Thomas Ganslandt
Birger Haarbrandt
Andreas Henkel
Josef Ingenerf
Matthias Löbe
Mathias Kaspar
Robert Krock
Fabian Prasser
Ulrich Sax (Leader, Minimum Requirements Key Issues Paper Drafting Group)
Björn Schreiweis

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