

Medical Informatics Initiative

Supporting Project – Central Office of the National Steering Committee



Rules of Procedure for the National Steering Committee of the German Medical Informatics Initiative

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

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The National Steering Committee of the German Medical Informatics Initiative hereby adopts the following Rules of Procedure on the basis of the Federal Ministry of Education and Research's call for grant proposals, the voting by the evaluators, and the grant for the monitoring body and its auxiliary conditions:

Preface

The policy goal of the Medical Informatics Funding Plan from Germany's Federal Ministry of Education and Research (BMBF) is to take advantage of the opportunities presented by digitalization in the field of medicine and to improve research possibilities and patient care through the development of innovative IT solutions. The IT solutions to be developed are intended to support and drive the sharing and use of data generated from patient care, clinical research, and biomedical research above and beyond the limits of institutions and locations; as a result, existing expert knowledge and the latest research findings will be made available for everyday research activities and health care services.

The role of the National Steering Committee and of the auxiliary project during the concept phase is to harmonize the innovative IT strategies developed in the consortia with one another, paving the way for data use across locations and institutions to become a reality while preventing the emergence of isolated solutions. Moreover, intra-consortia and inter-consortia data use and sharing are also to be fostered (interoperability of the data integration centers).

The challenge for the Medical Informatics Initiative during the concept phase – a phase critical for success during which the consortia will be in competition with one another – will be achieving consensus-oriented, inter-consortia cooperation, and leading this cooperation to concrete results. It is the goal of the National Steering Committee to reach mutually agreeable decisions. By adopting these Rules of Procedure, each of the members of the National Steering Committee is undertaking the obligation to actively participate in the process to find solutions. This obligation is also laid down in the auxiliary conditions of the individual grant and is an essential component of the German Medical Informatics Initiative. The governing bodies and structures within the Medical Informatics Initiative have therefore been organized such that they depict this challenge to the greatest degree possible at the various levels of the consortium directors¹, the university locations, the various officials, the external stakeholders, etc.

The governing bodies and structures of the Medical Informatics Initiative are described below along with their duties and decision-making authority and their respective inclusion in the consensus process.

1. Governing Bodies and Structures within the Medical Informatics Initiative

The following governing bodies and structures are planned within the Medical Informatics Initiative:

- National Steering Committee
- Dialogue forum
- Working groups

¹ In the interest of improving readability, these Rules of Procedure forego the use of masculine and feminine references. Any words used to refer to individuals are intended to apply to any gender.

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- Status groups
- General Assembly
- Board of Directors and Business Office

2. National Steering Committee

a) Responsibilities and duties

- (2.1) The National Steering Committee is the upper-level governance body for the consortia benefitting from the sponsorship of the German Federal Ministry of Education and Research's Medical Informatics Initiative (BMBF MII) and its job is to monitor and guide the implementation of the funding plan. On the one hand, the members of the National Steering Committee are to bring together the requirements of the scientists in their consortia; on the other, they are to function as information disseminators, conveying the work and decisions of the National Steering Committee back to their consortia. The National Steering Committee shall work toward having the resolutions passed in committee implemented within the consortia.
- (2.2) The National Steering Committee is to facilitate harmonization efforts and stipulations extending beyond the consortia, and to resolve potential conflict situations that arise over the course of the project. These endeavors are intended to avoid the emergence of isolated solutions at individual locations, to expedite the achievement of the funding program's objectives, and to implement standards.
- (2.3) To this end, the National Steering Committee is fundamentally to discharge the following duties:
- The National Steering Committee is to identify areas/topics for which a need for coordination exists at various levels (National Steering Committee, consortia, locations), and is to stipulate when the corresponding coordination efforts are to take place. Building on this, it is to adopt a work plan and schedule with corresponding milestones. This work plan can be iteratively refined and expanded.
 - The National Steering Committee is to make decisions pursuant to the work plan regarding the number of working groups and the topics they will focus on, is to prioritize and establish the working groups (see Section 4). Where necessary, it is to make decisions that affect multiple working groups.
 - The National Steering Committee is to make decisions regarding the establishment and composition of a dialogue forum, is to appoint its spokesperson, and will be able to avail itself of this dialogue forum when making its decisions (see Section 3).
 - The National Steering Committee is to make decisions regarding cooperation across the consortia, for example concerning
 - common key issues for the data use and sharing plans of the consortia
 - common key data for the data integration centers to be set up during the setup and networking phase
 - The National Steering Committee can make recommendations, for example for the use of standards, and can advise the grantor regarding supplemental funding modules.

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- The National Steering Committee must address the responses and suggestions of the governing bodies and structures within the Medical Informatics Initiative.
- The National Steering Committee and its Business Office are able to contact all of the participating locations in order to forward information or to broaden necessary coordination processes.

b) Composition

(2.4) The National Steering Committee is to consist of:

- i. The consortium directors and one further representative for each consortium receiving funding (one vote per consortium)
- ii. The general secretaries or CEOs of the Association of Medical Faculties in Germany (MFT), the Association of University Hospitals in Germany (VUD), and the Association for Technology, Methods, and Infrastructure for Networked Medical Research (TMF) (with one joint vote)
- iii. The dialogue forum spokesperson (without a vote)
- iv. One representative of the BMBF as the grantor (without a vote)
- v. One representative each for health services research project managers the DLR Project Management Agency (PT DLR) and Project Management Jülich (PT J) (without a vote)

(2.5) Regarding i:

In addition to the consortium director, each consortium is to appoint one other authorized consortium representative to the National Steering Committee. One of the two is to act as a representative for the medical informatics staff, the other is to act as a representative at the level of the board members for the participating hospital or, respectively, the dean's office. The representative for the board of directors or dean's office may be represented by a specifically designated representative of the same level. The primary employment of at least one of the two representatives must be as a member of the staff of a participating university hospital location. The representatives are to personally exercise their office. Each of the two representatives may represent the other at National Steering Committee meetings, or they may participate jointly in meetings; they are to exercise the consortium's voting right in the National Steering Committee in the form of one, joint vote. In special cases, a specifically designated proxy of the same level may act on behalf of the board of directors representative and will have the same rights and duties at meetings.

(2.6) All members of the National Steering Committee shall have a right to put forward motions and to speak. They may participate in the process to determine the committee's agenda. As a general rule, recommendations by the BMBF and the project management agency are to be taken into consideration in the agenda.

(2.7) Other guests may be invited as needed and in coordination with the Board of Directors. This is the process by which, in special cases, National Steering Committee members may bring in special experts as consultants. Consultants shall not automatically have a right to speak and shall not have the right to put forward motions.

(2.8) Balance across the consortia is to be sought for all committees and activities of the National Steering Committee and Medical Informatics Initiative.

c) Meeting and work procedures

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- (2.9) As a rule, the National Steering Committee is to meet every two months. During the intervening months, additional voting can be undertaken via telephone and web conferencing. The dates for the phase underway until December 31, 2017 are to be set in advance.
- (2.10) The National Steering Committee is to assign the development of strategies and other papers to the working groups and/or to offices that are relevant for the work of the National Steering Committee or the working groups. These submissions will be considered and decided on by the National Steering Committee – the submissions will be accepted or returned.
- (2.11) In addition to National Steering Committee members, decision papers can also be introduced to the National Steering Committee by the working groups.
- (2.12) The meeting documents are to be put together by the Business Office and sent to National Steering Committee members via e-mail no later than by one week prior to the date of the meeting. The Business Office is to take minutes of the meetings and send the minutes together with the meeting documents via e-mail for the following meeting.

d) Voting procedure

- (2.13) All decisions by the National Steering Committee are to be adopted with a qualified majority of two thirds of members with voting rights in attendance.²
- (2.14) Written voting procedures outside of meetings and voting by e-mail are permitted. In such cases, the same majority requirements apply; National Steering Committee members without a voting right are also to be included in communications in this connection.

e) Role of the chair and presiding over meetings

- (2.15) In the phase underway until December 31, 2017, the Board of Directors members produced from among the associations TMF, MFT, and VUD (which are neutral as concerns the consortia) are to fulfill the role of the chair. The Board of Directors is also responsible for preparing and presiding over the meetings of the National Steering Committee.³

f) Communications

- (2.16) All decisions by the National Steering Committee are to be announced promptly on an internal Medical Informatics Initiative website, provided confidentiality has not been

² Note: If the number of members (in attendance) is eight (8), this means that six (6) yes votes are required for a motion to pass.

³ Note: During the concept phase, no election is to be held for one or more National Steering Committee spokesperson(s). For the setup phase, the intention is to have the National Steering Committee elect a spokesperson from among its members starting in 2018; this spokesperson will then prepare for, follow up on, and preside over the National Steering Committee meetings together with the Business Office. A corresponding proposal for rules of procedure for the National Steering Committee is to be submitted during the setup and networking phase by September 2017.

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- expressly stipulated. The Business Office is to ensure that the minutes concerning resolutions are made available on this Medical Informatics Initiative website without undue delay.
- (2.17) Furthermore, the consortium representatives in the National Steering Committee are responsible for communications between the National Steering Committee and all of the locations and partners in their consortium.
- (2.18) Other communications regarding the activities within the Medical Informatics Initiative taking place jointly with the public and partners in the national and international arena are to be handled together via the National Steering Committee and its Business Office.
- (2.19) All publications from the auxiliary project or the National Steering Committee must be coordinated with the BMBF.

3. Dialogue Forum

a) Responsibilities and duties

- (3.1) The dialogue forum is adjunct to the National Steering Committee and serves as the committee's external advisory committee. As needed, the National Steering Committee can avail itself of the entire dialogue forum or individual members thereof. The dialogue forum thus also facilitates the legitimization of the decisions of the National Steering Committee from an outside perspective; in this way, it follows through on the policy goal of being cognizant from the start of the potential application of IT solutions beyond university hospitals, and of including all prospective networking partners in the design of the funding initiative at an early stage. Furthermore, the dialogue forum can act as a communications conduit to corresponding structures and funding programs in the field of medicine and health care.

b) Appointment and composition

- (3.2) The National Steering Committee is to appoint the members of the dialogue forum during the concept phase. Later reappointments are possible.
- (3.3) Attachment A of the Rules of Procedure lists the institutions that will be invited to dispatch a representative to the dialogue forum.

c) Meeting and work procedures

- (3.4) The National Steering Committee is to designate the spokesperson for the dialogue forum prior to the forum's first meeting. The spokesperson is to preside over the dialogue forum's meetings together with the Board of Directors, and is also to participate in National Steering Committee meetings without a vote (see Section 2b).
- (3.5) One to two dialogue forum meetings are anticipated by the start of the setup and networking phase. The National Steering Committee and its Business Office are responsible for meeting notices and agendas. Pursuant to a resolution, the dialogue forum may add its own agenda items.
- (3.6) Votes in the dialogue forum are to be decided by a simple majority of members in attendance.

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- (3.7) The National Steering Committee must address the responses and suggestions from the dialogue forum.

4. Working Groups

- (4.1) In preparation for its decisions, the National Steering Committee is to set up specialist working groups, appoint their members, and designate their spokespersons. These groups are to work out recommended solutions for problems that require coordination between and/or outside of the consortia.
- (4.2) The working groups are to include not only persons in the sponsored consortia in charge of the particular subjects but also external representatives (e.g., from industry, standardization agencies, staff members in charge of IT for the German Centers for Health Research (DZG), from professional associations, clinical users, etc.). As a general rule, the working groups are also to be explicitly enabled to integrate ideas and experts from outside of the consortia receiving funding.
- (4.3) The Business Office is responsible for scheduling, sending meeting notices, inviting external experts, and for special preparatory and follow-up work.
- (4.4) The results from a working group are to be developed by consensus. If a working group is unable to reach a consensus in a given situation, alternatives for the points in contention are to be worked out and multiple variations submitted to the National Steering Committee for its decision. An outline of the of the opinions held by external experts in attendance and their recommendations are to be recorded in the minutes and thereby brought to the attention of the National Steering Committee.
- (4.5) The National Steering Committee must address the working groups' results (submissions, suggestions, and responses) in its next meeting.

5. Status Groups

- (5.1) Status groups are discussion forums for designated officials from all of the locations. To this end, within the first four months of the funding program, the participating locations are to designate contact persons, coordinated within the respective consortium, for three status groups:
- a) Medical informatics institute directors or comparable positions
 - b) IT computer center directors or IT operations managers or comparable positions
 - c) University hospital board members or deans or comparable positions
- (5.2) The Business Office is to set up distribution lists and an electronic communication platform for the status groups. Additional meetings can be held for these status groups as needed, e.g., in connection with the General Assembly (see Section 6) or in connection with preexisting event formats (e.g., VUD member meetups, the German Association for Medical Informatics, Biometry and Epidemiology (GMDS) Conference).
- (5.3) The status groups may be consulted by the National Steering Committee and its Business Office and brought into its deliberations as needed. The National Steering Committee must address the responses from the status groups.

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6. General Assembly and Annual Conference

- (6.1) In order to facilitate a personal exchange between all locations and actively involved parties participating in the initiative, a General Assembly is to be convened once a year, to which all of the participating locations may send several representatives from various functional disciplines (and status groups, see Section 5).
- (6.2) The General Assembly is to be held in connection with a “Medical Informatics Initiative Annual Conference”, which also serves to disseminate and present the results from the working groups. The annual conference is to be held and open to guests from nonparticipant locations and other disciplines in the field of health care no later than during the setup and networking phase.
- (6.3) The National Steering Committee and its Business Office are responsible for the preparations and the agenda of the annual conference and of the General Assembly.
- (6.4) The National Steering Committee must deal with the suggestions and responses from the General Assembly at its next meeting.

7. Board of Directors and Business Office

- (7.1) The role of the Board of Directors is to be undertaken jointly by the TMF, MFT, and VUD. The TMF is to provide the staff for the Business Office.
- (7.2) In addition to the terms of its grant, the Board of Directors and Business Office must comply with all of the provisions of these Rules of Procedures and the resolutions of the National Steering Committee.
- (7.3) In particular, the duties of the Board of Directors include:
 - Preparing and presiding over the meetings of the National Steering Committee
 - Preparing and presiding over the dialogue forum jointly with the dialogue forum spokesperson
- (7.4) In particular, the duties of the Business Office include:
 - Preparing and sending invitations for all cross-consortia events organized by the Medical Informatics Initiative
 - Keeping the minutes for all working sessions of the committees
 - Communicating coordination processes and results and information to the consortia
 - Public relations for all cross-consortia aspects of the Medical Informatics Initiative (including operating a website)
 - Performing topic preliminary work and providing assistance to the National Steering Committee and working groups
- (7.5) The Board of Directors and Business Office must maintain strict neutrality toward all of the consortia and locations.
- (7.6) The National Steering Committee headquarters are located at the TMF premises in Berlin.

8. Dispute Resolution

- (8.1) All issues in dispute within the governing bodies and structures of the Medical Informatics Initiative are to be decided on by the National Steering Committee.

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- (8.2) If disputes arise for which the National Steering Committee cannot render a decision or reach a decision by qualified majority, the authority to resolve the dispute can be transferred to a third party to be selected by the grantor (BMBF).

9. Reimbursement of Expenses

- (9.1) Travel expenses will be reimbursed by the TMF from the funds provided through the MI monitoring body project up to a maximum of the amount approved by and available through that project. Subject to the foregoing, the following travel expenses are generally reimbursable:
- a) For the attendance of two representatives per consortium at National Steering Committee meetings
 - b) For dialogue forum participants
 - c) For working group meeting participants
- (9.2) TMF's board of directors is to make the decisions concerning the reimbursement of travel expenses for experts or additional consultants.
- (9.3) Actions deviating from these rules may be taken in special cases where doing so is justified and the Board of Directors has passed a corresponding resolution.
- (9.4) The reimbursement of travel expenses is to be guided by the German Travel Expenses Act (BRKG) and TMF's Travel Expense Policy, which is based on this act and takes into account the limits of the grant.
- (9.5) Unless otherwise provided in these Rules of Procedure or other arrangements are made individually, the costs for arranging meetings, events, and telephone and web conferencing are the responsibility of the Business Office, provided this is taken into account in the TMF's grant award notification.
- (9.6) Costs for awarding contracts to third parties that are approved by the National Steering Committee can be financed from the funds provided through the MI monitoring body project provided there are still sufficient funds available (financing restriction) and the purpose for the contract is in line with the project application and grant award notification.

10. Effective Date and Updating

- (10.1) These Rules of Procedure are to be put to a vote and adopted by the National Steering Committee, if necessary in modified form. Once adopted, the Rules of Procedure shall take effect immediately and shall remain in full force and effect initially until December 31, 2017.
- (10.2) The Rules of Procedure may be modified, amended, and refined by the National Steering Committee at any time in connection with its consultations and voting. These Rules of Procedure and any modifications thereto are governed by the terms of the respective grant award notifications and are subject to review of their content by the BMBF. The TMF is required to indicate to the grantor any discrepancies between the Rules of Procedure and the grant award notification.
- (10.3) Rules of Procedure adapted for the setup and networking phase (planned to start January 1, 2018) are to be developed and submitted no later than September 2017.

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ATTACHMENT A

The following institutions were appointed to the dialogue forum by the National Steering Committee on October 6, 2016 pursuant to Section 3.2 of the MII National Steering Committee Rules of Procedure:

- Representatives of German ministries:
 - BMBF (Federal Ministry of Education and Research)
 - BMG (Federal Ministry of Health)
 - BMWi (Federal Ministry for Economic Affairs and Energy)
- DFG (German Research Foundation)
- Office of the Innovation Fund for the Federal Joint Committee (G-BA)
- IT industry:
 - bvitg (National Association of Health Care IT Providers)
 - ZVEI (German Electrical and Electronic Manufacturers' Association)
 - BITKOM (Federal Association for Information Technology)
 - Cerner (individual company)
 - Agfa (individual company)
 - SAP (individual company)
- Other industry:
 - BDI (Federation of German Industries) – Health Care Sector Digitalization Working Group
- Standardization agencies:
 - HL7 Deutschland e.V.
 - IHE Deutschland e.V.
- DKG (German Hospital Federation)
- KBV (National Association of Statutory Health Insurance Physicians)
- BÄK (German Medical Association)
- National Association of Statutory Health Insurance Funds
- Patient representatives in the Federal Joint Committee
- APS e.V. (German Coalition for Patient Safety)
- Task Force on Research by State and Federal Data Protection Officers
- Task Force on Health of State and Federal Data Protection Officers
- RfII (German Council for Scientific Information Infrastructures)
- Subcommittee for Medical Studies at Institutions of Higher Education of the KMK (Standing Conference of the Ministers of Education and Cultural Affairs)
- Medical Committee of the WR (Council of Science and Humanities)
- National headquarters of the four non-university research institutions:
 - MPG (Max Planck Society)
 - FhG (Fraunhofer Society)
 - HGF (Helmholtz Association of German Research Centers)
 - WGL (Gottfried Wilhelm Leibniz Scientific Association)
- NaKo (German National Cohort)
- DZG (German Centers for Health Research, one joint representative)
- AWMF (Association of Scientific Medical Societies)