Leitfaden für Antragstellende der Digitalen FortschrittsHubs Gesundheit des BMBF Förderkonzeptes ‚Medizininformatik'

1. Wen kann ich bei Fragen zur Antragstellung ansprechen?

Es wird empfohlen, zur Antragsberatung Kontakt mit dem DLR Projektträger, Gesundheitsforschung aufzunehmen. Weitere Informationen und Erläuterungen sind dort erhältlich. Ansprechpartnerinnen sind:

Dr. Leonie Pothmann (digihubs@dlr.de, 0228-3821-2126)
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2. Wer kann einen Antrag für einen Digitalen FortschrittsHub stellen?

Die Förderung erfolgt in Form von Verbundvorhaben. Von den Partnern eines Verbundes ist eine Koordinatorin oder ein Koordinator zu benennen. Jeder Digitale FortschrittsHub muss mit einem oder mehreren **Datenintegrationszentren der Medizininformatik-Initiative** zusammenarbeiten. Antragsberechtigt sind staatliche und staatlich anerkannte Hochschulen, Universitätskliniken, außeruniversitäre Forschungseinrichtungen, Unternehmen der gewerblichen Wirtschaft, Einrichtungen und Träger der Gesundheitsversorgung, eingetragene Vereine und Stiftungen sowie Sozialversicherungsträger (Krankenkassen, Rentenversicherungen, etc.). Für nicht-zuwendungsfähige Partner ist die Vergabe von Unteraufträgen bzw. Teilnahme- oder Aufwandsentschädigungen (z.B. für teilnehmende Praxen) möglich.

3. Gibt es Vorgaben zum Format?

Für die Projektskizze gelten die Vorgaben der **Gliederungsvorlage** (Word Vorlage

„Template_application_DigiHub.docx“). Der Text muss in **englischer Sprache (Arial, Schriftgröße 11, Zeilenabstand 1)** verfasst sein. Zu allen Gliederungspunkten sind Angaben zu machen.

Teil A) der Gliederungsvorlage:

Das **detaillierte Konzept des FortschrittsHubs** ist in Teil A) der Vorlage darzustellen. Für jeden geplanten „**Use Case**“ (1-3) soll ein separater Gliederungspunkt 9. erstellt werden. Teil A darf einen Umfang von **35 Seiten** nicht überschreiten.

Teil B) der Gliederungsvorlage:

Jeder am FortschrittsHub beteiligte Partner muss seine Arbeiten separat entsprechend Teil B der Gliederungsvorlage beschreiben. Der Umfang pro Partner darf **4 Seiten** nicht übersteigen.

Finanzplan:

Bitte nutzen Sie die EXCEL Vorlage „Financial_Plan_DigiHub.xlsx“ für die Erstellung des Finanzplans des FortschrittsHubs.

4. Wie wird die Projektskizze eingereicht?

Die Projektskizze für den Digitalen FortschrittsHub wird von der Koordinatorin/dem Koordinator des Hubs über das Internet-Portal ptoutline (https://ptoutline.eu/app/DigiHubs_de) spätestens bis

28. Mai 2020, 12:00 Uhr

eingereicht. Weitere Informationen zur elektronischen Einreichung finden Sie im Internet-Portal. Eine Vorlage des Antrages per E-Mail oder FAX ist nicht möglich.

Ein vollständiger Verbundantrag für einen Digitalen FortschrittsHub umfasst:

- Eine in ptoutline erstellte **Übersicht** (Internet-Formular für alle Partner)
- Ein **detailliertes Gesamtkonzept** des FortschrittsHubs einschließlich aller Partner sowie Anlagen (Teile A und B der Gliederungsvorlage) als eine in ptoutline hochgeladene PDF-Datei
- Den **Finanzplan** des FortschrittsHubs als eine in ptoutline hochgeladene EXCEL Datei (Vorlage „Financial_Plan_DigiHub.xlsx“)
- Letter of support der Leiter der beteiligten Datenintegrationszentren der Medizininformatik Initiative

5. Was geschieht nach der Einreichung der Projektskizzen?

Die eingegangenen Projektskizzen für einen Digitalen FortschrittsHub werden von einem unabhängigen, interdisziplinär besetzten Gremium internationaler Expertinnen und Experten nach den in der Förderrichtlinie (https://www.gesundheitsforschung-bmbf.de/de/10580.php)

unter Punkt 7.2.1 erläuterten Kriterien bewertet. Es werden sowohl das Konzept für den FortschrittsHub (Teil A) als auch die Konzepte der einzelnen Partner (Teil B) begutachtet. Auf der Grundlage der Bewertung des Gremiums werden die für eine Förderung geeigneten FortschrittsHubs ausgewählt. Das Auswahlergebnis wird den Antragstellenden schriftlich mitgeteilt.

Die Partner der ausgewählten FortschrittsHubs werden unter Angabe eines Termins aufgefordert, förmliche Förderanträge vorzulegen. Über diese Formanträge wird nach abschließender Prüfung entschieden.

Aus der Vorlage eines Antrages kann kein Rechtsanspruch auf Förderung abgeleitet werden.

6. Allgemeine Hinweise

Die Konzepte müssen die bereits getroffenen Vereinbarungen der Medizininformatik-Initiative, wie z.B. den Kerndatensatz (https://www.medizininformatik-initiative.de/), beachten. Die Antragstellenden sind darüber hinaus verpflichtet, nationale und internationale Standards zur Qualitätssicherung der Forschung sowie zur Interoperabilität und zur standardisierten Dokumentation von Daten zu beachten. Hierzu sind insbesondere die nachfolgenden Dokumente in der jeweils geltenden Fassung zu berücksichtigen (die Aufzählung ist nicht abschließend):

- Memorandum zur Sicherung der guten wissenschaftlichen Praxis (DFG) (https://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/download/empfehlung_wiss_praxis_1310.pdf),
- Memorandum III: Methoden für die Versorgungsforschung Teil 2 (https://www.thieme-connect.de/products/ejournals/abstract/10.1055/s-0030-1262858),
- Leitlinien für Gute Epidemiologische Praxis (https://www.dgepi.de/assets/Leitlinien-und-Empfehlungen/Leitlinien_fuer_Gute_Epidemiologische_Praxis_GEP_vom_September_2018.pdf),
- Gute Praxis Datenlinkage (https://www.thieme-connect.de/products/ejournals/pdf/10.1055/a-0962-9933.pdf),
- FAIR Data Principles (http://www.forschungsdaten.org/index.php/FAIR_data_principles)

Im Falle der Durchführung von klinischen Studien sind die „Grundsätze und Verantwortlichkeiten bei der Durchführung klinischer Studien“ des BMBF verpflichtend zu beachten:

http://www.dlr.de/pt/Portaldata/45/Resources/Dokumente/GF/Grundsaetze_Verantwortlichkeiten_Klinische_Studien.pdf.

Es wird empfohlen, die Dokumente und öffentlich verfügbaren Arbeitshilfen des TMF e.V. (www.tmf-ev.de/produkte) einzusehen.

Application for a
Digital Hub: Advances in Research and Health Care
of the "Medical Informatics" funding scheme

A) DETAILED CONCEPT

[max. 35 pages]

1.1 General Information

Coordinator	• First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • E-mail address
Title	
Acronym	
Funding Requested (Total)	

1.2 Members requesting funding

In Table 1, please list only partners that will request funding. Other partners, e.g. associated partners or relevant subcontractors are to be included in Table 2. Please assign a Partner-ID to each partner using continuous numbering, in accordance with Table 2 and the Financial Plan (section 14).

Table 1. *Note: PI = Principal Investigator, DIC = Data Integration Centre of the Medical Informatics Initiative.*

Partner-ID	Partner / Institution	PI	Role in the consortium	DIC	Requested funding [EURO]
P1	e.g. University Hospital	Academic title, first + last name, department	e.g. coordinator, partner	Yes/ No	
P2					
P3					
…					

2 Summary

Please provide a summary of the overall strategy of the hub, the main goals and methodological approaches of the project (max. 1800 characters, including spaces). The summary should provide the reviewers with a quick overview of the cornerstones of the project.

3 Overall Objectives

Please delineate the objectives of the hub in relation to the background of the funding concept. Describe your strategies for enabling the multi-directional use and access of patient care data within the hub and the transfer of results and (IT-) solutions to health care providers. Also address long-term benefits for research and health care, e.g. how this approach can be exemplary for a research-compatible electronic Health Record.

4 Structure and Integration of Partners

4.1 Structure

Please describe the structure and organization of the planned hub, the integration of existing networks or collaborations, relevant (IT- & data-) infrastructures and technologies, data availability, management and exchange as well as knowledge and communication/information flow. Wherever possible, existing structures (IT, data, collaborations) should be utilized.

Use Table 2 for the planned collaborative structure (between research partners or research networks, with health care institutions, self-help organizations or patient advocacy groups, companies or IT partners, owners of routine data sets such as health insurance companies or public entities). Include all stakeholders and occupational groups relevant for the hub focus. Please include an additional organizational chart for visualization.

Note that a detailed description of each partner's contribution is requested in part B.

4.2 Integration, Motivation and Benefit of Partners

Please address interdisciplinary, multi-professional and cross-sectoral collaborations in the hub. Explain your strategy for integrating the partners into the hub and their respective added value. In turn, please also comment on the added value for the partners by differentiating between the expected benefits in different sectors in the health care system (e.g. IT solutions in ambulant/routine care, clinical practice). Describe how issues of feasibility as well as motivation and interests of all relevant stakeholders will be addressed or evaluated (if applicable, as specific work packages of the project).

Table 2. *In Table 2, please use the same numbering as in Table 1. Additional partners (e.g. partners that do not request funding) can be included by assigning continuous numbers.*

Partner -ID	**Type of partner**	**Unit, address, Head/Stakeholder**	**Specific role / contribution** *(examples)*
P1 P2 …	Scientific collaboration partners		*DIC or university hospital with data-resources/data management* *practice-based research network* *further academic partners / e.g. evaluation of benefits*
P5 P7 …	Health care institutions		*hospitals and other health care service providers*
P6 P8 …	Self-help groups / (Patient) organizations		*Resp. Organization / participatory research approaches beyond mere consulting (please see 9)*

P10 …	Companies / relevant subcontractors		*development and application of IT interfaces*
P11 …	Other providers of routine data		*e.g. secondary analysis of health care insurance data/data access & contribution*

5 Governance

Depict the governance structures (include a figure to visualize governance structures). Describe how partners will maintain an active role in the hub and how the decision making process will take place. Comment on planned seeking of external perspectives, expert advice or monitoring.

6 Relation to the Medical Informatics Initiative (MII)

Please describe the collaboration with Data Integration Centres and other members / bodies of the MII. Please describe how agreements and standards of the MII will be implemented in the hub.

7 Technical, Organizational and Legal Considerations for Cross-sectoral Data Use and Access

Please note that a succinct Data Management Plan (DMP) will be requested in section 8 / Table 3. Where applicable refer to the DMP.

Describe your concept for achieving a cross-sectoral use of patient care data within the hub and indicate the principles for achieving and granting data access. Depict the nature and extent of the data to be included. Describe how the data will be processed, stored and managed. Comment on critical interfaces between different care sectors and affordances of interactions with existing IT systems particularly in ambulant/routine care. Describe how interoperability will be achieved and how it will go beyond mere compatibility. Which relevant standards will be met?

Please delineate how interests of the different partners will be considered in the technical development of the hub as well as in further IT developments/applications.

Present your concept of data security, data protection and consent management for personal data and compare it with the respective status quo at the partner sites in different care sectors.

Please indicate in how far the FAIR principles[1] are incorporated and by which technical, organizational and legal means these are ensured.

Challenges and Risks

Describe challenges and risks for the success of the hub according to the topics in sections 4-7. Discuss intended solutions and possible alternatives. Present appropriate measures to deal with these risks and challenges (risk mitigation measures).

Example:

[1] http://www.forschungsdaten.org/index.php/FAIR_data_principles

Description of risk (indicate level of likelihood: low/medium/high)	Proposed risk-mitigation measure
4.1 Structure of the Hub:	
4.2. Integration, Motivation and Benefit of Partners:	
…	

8 Data Management Plan

Clearly describe your data management plan (DMP) using Table 3. Highlight differences between partners by pasting rows for each partner when necessary. In the same manner, use case(s) can be specified. This may particularly apply to sections DMP_2 and DMP_4.

The DMP has to ensure data management, maintenance and long-term accessibility for future reuse of your results. To ensure that your research data are soundly managed please follow the principles of FAIR data. Please use existing international standards and data repositories which allow publishing of FAIR data. Data management costs are eligible for funding during the period of funding.

Table 3. Data Management Plan

DMP_1	**General information**	
1.1	Acronym	
1.2.	Responsibilities: • data management • metadata creation • data security • quality assurance of data	*Apart from the PI: who is responsible*
1.3.	DM support office:	*Is there a DM support office in your institution?* ☐ Yes ☐ No *If yes, have you contacted it for support?*
DMP_2	**Description of data set**	
2.1.	Data to be collected / generated:	*Describe the data that will be collected / generated within the project.*
2.2	Type and format of data:	*Specify the type, and format of the data.*
DMP_3	**Standards and metadata**	
3.1	Documentation of data: MII standards: Metadata standard:	*How will the data be documented?* *Which standards of the MII will be implemented and how?* *What metadata standard will be used to make the data accessible and reusable? If no standard exists please outline how a suitable metadata structure will be developed.*
DMP_4	**Data storage**	
	During the funding period	
4.1	Volume of data and site of storage:	*What is the volume of the data and where will the data be stored?*
4.2	Storage capacity during the project	*Is there sufficient storage capacity during the project?* ☐ Yes ☐ No

	Data back-up and responsibility:	*Will the data be backed-up regularly during the project?* ☐ Yes ☐ No *Who is responsible for this?*
	After the funding period	
4.3	Trusted Repository, FAIR principles and MII standards	*Specify in which trusted repository the data will be stored after the project[2].* *If the data will not be stored in a trusted repository: how will the data be made* *- findable,* *- accessible and* *- reusable?* *Specify how this relates to the agreements and standards of the MII*
4.4	Persistent identifier:	*Will a persistent identifier be used to make the data findable?* ☐ Yes ☐ No
4.5	Storage of confidential, privacy-sensitive or competition-sensitive data:	*How will confidential, privacy-sensitive or competition-sensitive data be stored?*
4.6	Duration of archiving:	*For how long will the data be archived?*
DMP_5	**Making data available**	
5.1	Availability / reuse of the data:	*Are the data available for reuse apart from the use case?* ☐ Yes, immediately ☐ Yes, after ....months/years ☐ No *If not, please explain why the data are not suitable and/or available for reuse.*
5.2	Limited availability of data?	*If data are only made available after a certain period then please state the reason for this.* *If part of the data cannot be made (directly) available then please state the part concerned.*
5.3	Conditions for the reuse of the data:	*Please specify, also with regard to the agreements and standards of the MII*

9 Use Case(s)

9.x. Use Case [name of use case]

Please fill in x. for each use case separately (1-3 use cases).

9.x.1 Rationale of the Use Case

[2] *See for example: https://www.publisso.de/open-access-publizieren/forschungsdaten/forschungsdatenrepositorien/*

Give a detailed description of the intended specific application ('use case') that shall demonstrate the added value of the cross-sectoral use and access of patient care data in the hub and beyond. Provide a rationale for choosing the use case.

9.x.2 Relevance and Benefit of the Use Case

Define users/stakeholders and the process to identify their needs. Describe how the views of individuals, groups or organizations that could benefit from the use case are taken into account. Differentiate between e.g. health care providers, patients, representatives of clinical practice in different sectors.

As follows,

- *describe the benefits of the use case for health care providers*
- *substantiate the relevance of the use case for improving patient care*
- *comment on how this approach may be exemplary for a research-compatible electronic Health Record*
- *outline strategies and measures to disseminate the results within the German health care system and potential economic benefits*

9.x.3 IT Solutions

Describe in detail the IT- and technological strategies of the use case. Explain the necessary R&D activities to realise the IT solutions in both directions. Present the data to be included, data routes, data processing and potentially required data use agreements. Describe how the IT solutions can match with the existing systems. Outline how they can be transferred into different health care settings and applied by the respective stakeholders. Also address how this relates to the agreements and standards of the MII.

9.x.4 Challenges and Risks

Specify the implementation challenges for the use case. Discuss alternative approaches and solutions (risk mitigation measures).

Example:

Description of risk (indicate level of likelihood: low/medium/high)	Proposed risk-mitigation measure

9.x.5 Key Performance Indicators

Please describe tangible key performance indicators for the functional performance of the use case (reachable within the funding period).

10 Patient Involvement

Please describe your participatory research approaches. Explain how patients and other relevant parties (for instance relatives, representatives or citizens) will be involved[3]. Please address how their needs, goals, concerns and preferences will be considered, and in how far engagement is planned e.g. as specific work packages. Patient involvement can be implemented in different stages of the project and to a different extent. Please justify why your concept is adequate for the planned project.

11 Gender, Diversity and Minorities

Please identify whether and in how far gender, diversity and minority issues are relevant for the planned hub including the use case(s). If not relevant, please provide a short explanation. Aspects of (in-)equality, for instance regarding accessibility or utilization of health care services, can be addressed with different scopes, also as specific work packages in the project. If applicable, please describe strategies to reduce the influence of biases.

12 Sustainability of the Digital Hub

Provide a realistic provisional plan for the continued operation and long-term sustainability of the Digital Hub after the funding period. Please address how the motivation for a substantial collaboration will be sustained. Also comment on how further collaboration partners can be integrated into the hub.

Please comment on current and future funding of existing structures.

13 Work Plan, Milestones and Time Lines

Provide one comprehensive work plan including work packages and define time lines and milestones/deliverables for the implementation of your concept. Work plan and milestones should reflect collaboration and common targets. Work packages (WPs) can include one or more partners. Please organize the plan in relevant sections, e.g. Data Use and Access, Use Cases, Benefit and acceptance for different stakeholders, Governance/Structure. Depending on your concept, additional WPs can be included where necessary. Indicate the contribution of each partner by referring to the Partner-ID. Also sum up the information in a table or diagram as the example below.

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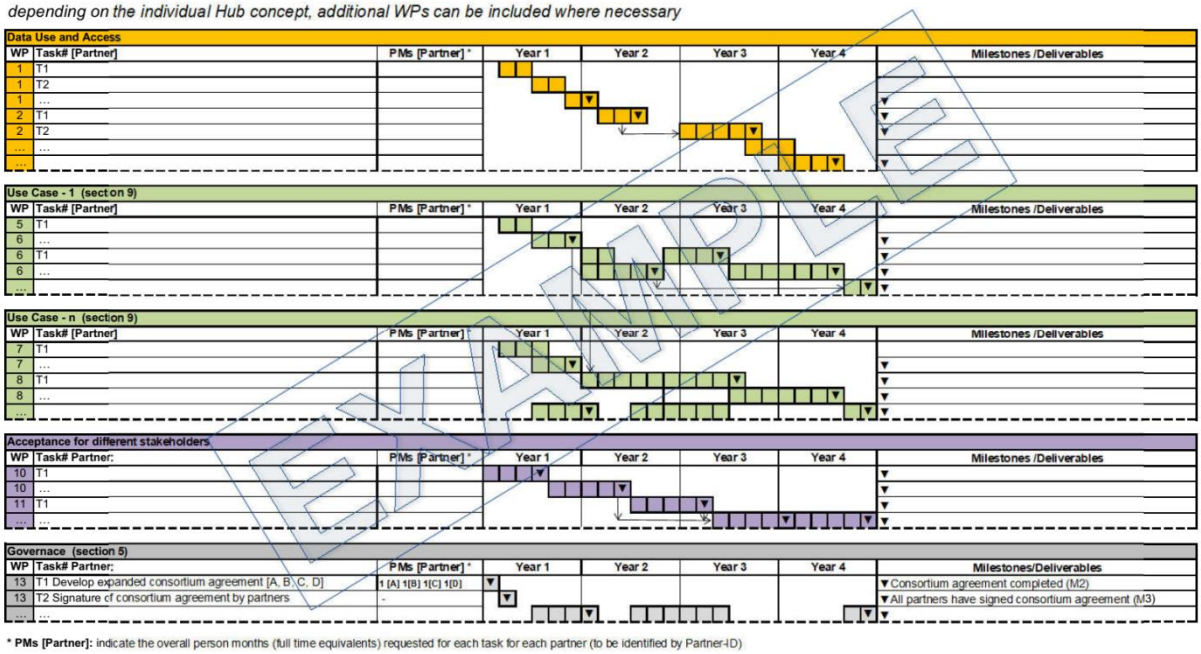
[3] *Please see the „Briefing note for Researchers" by INVOLVE of the British National Institute for Health Research (NHS): http://www.invo.org.uk/resource-centre/resource-for-researchers/*

13. Work Plan, Milestones and Time Lines

please number WPs continuously and in accordance with the Financial Plan

depending on the individual Hub concept, additional WPs can be included where necessary



Data Use and Access							
WP	Task# [Partner]	PMs [Partner] *	Year 1	Year 2	Year 3	Year 4	Milestones /Deliverables
1	T1						
1	T2						
1	…						
2	T1						
2	T2						
…	…						
…							

Use Case - 1 (section 9)							
WP	Task# [Partner]	PMs [Partner] *	Year 1	Year 2	Year 3	Year 4	Milestones /Deliverables
5	T1						
6	…						
6	T1						
6	…						
…							

Use Case - n (section 9)							
WP	Task# [Partner]	PMs [Partner] *	Year 1	Year 2	Year 3	Year 4	Milestones /Deliverables
7	T1						
7	…						
8	T1						
8	…						
…							

Acceptance for different stakeholders							
WP	Task# Partner:	PMs [Partner] *	Year 1	Year 2	Year 3	Year 4	Milestones /Deliverables
10	T1						
10	…						
11	T1						
…	…						

Governace (section 5)							
WP	Task# Partner:	PMs [Partner] *	Year 1	Year 2	Year 3	Year 4	Milestones/Deliverables
13	T1 Develop expanded consortium agreement [A, B, C, D]	1 [A] 1[B] 1[C] 1[D]					Consortium agreement completed (M2)
13	T2 Signature of consortium agreement by partners	-					All partners have signed consortium agreement (M3)
…	…						

*** PMs [Partner]:** indicate the overall person months (full time equivalents) requested for each task for each partner (to be identified by Partner-ID)

14 Financial Plan

Justify the required resources of the detailed financial plan itemized according to the work packages specified in section 13. Also indicate the respective partners involved. Use the provided EXCEL file "Financial_Plan_DigiHub" as a template for the detailed financial plan.

15 Other Funding

In case you have already submitted parts of this proposal to other institutions, funding organizations or the BMBF, please mention this here. If this is not the case please declare:

"A request for funding this project has not been submitted to any other addressee. In case I submit such a request I will inform the Federal Ministry of Education and Research immediately".

In case third parties provide funds, free services or other resources for the hub (including DICs), please specify the contribution. Attach corresponding letters of intent (Annex C.5).

B) DESCRIPTION OF PARTNER [name]

[max. 4 pages per partner]

Each partner applying for funds has to provide a project description as specified below. Wherever possible, a network of institutions should be represented by one partner institution, e.g. an existing network of health care providers or a practice-based research network.

Partner-ID	Partner / Institution	Head / Stakeholder / PI	Requested funding [EURO]
P1	e.g. University Hospital	Academic title, first + last name, department, address	

1. Role of the Partner in the Hub

Delineate shortly your role and contribution for achieving the project objectives

2. Expertise – Basic Settings – Status Quo ante

Please describe the status quo ante in terms of organizational, structural and technical settings (e.g. governance, information flow, processes/SOPs, infrastructures, standards, data availability and routes). Is a basic governance and consent management already in place?

Illustrate relevant expertise and experiences. Please include CVs or bio-sketches of up to three key persons in annex C.6.

3. Objectives and Approach

Please describe your specific objectives and approaches with respect to the overall work plan and milestones referring to section A.13. Describe your tasks and authorities.

3.1 Partner integration, data use and access

Depending on your role in section 1 (one or more may apply – the list below is not exhaustive), please address your strategy for:

- *Data contribution and access: data protection, data security, data access and availability, patient consent, data quality control. Interoperability with existing data collections and IT solutions in Germany and abroad.*
  Point out correlations and clarify – if applicable – partner specific differences in comparison to the hub or host consortium. Comment on data routes and interfaces for multi-directional data use and access, particularly concerning interfaces to local IT systems
- *Scientific collaboration: description of the research project; relevance and aims; own preliminary work; research methods and work programme, data handling and statistical analyses, dissemination of results*
- *Health care providers: integration of (IT) solutions into local structures and routine processes*
- *Companies: research & development e.g. for services, interfaces and solutions*
- *Patient organizations etc.: type, means, time and scope of involvement*

3.2 Use Case

If applicable, describe how you will participate in a hub use case. Describe the primary end points planned to reach within the funding period. If applicable, please also address how you will gain specific expertise (e.g. training in electronic medical documentation).

3.3 Other specific Work Packages

Other specific work packages can address benefit and acceptance of stakeholders, legal or health economic aspects, gender aspects or other relevant issues for the success of the Digital Hub in concordance with the common aims and work plan.

Signatures

(Hub coordinator, Head/PI of the partner)

C) ANNEX

0. Overview of the Annex

Please include a table of contents with page numbers

1. References

For a list of relevant publications of partners see Annex, section 6.

2. Abbreviations

3. List of Commitments of all Hub Partners

Please present a list of the binding commitments of all participating hub partners (ordered by hub partner, as in Table 1 of part A). The corresponding letters – preferably in English - must be signed by the authorized representatives of the respective institution. Please attach the letters in Annex A.4. The following commitments are to be submitted; further documents may be appended:

- *willingness to collaborate with the MII and its working groups on relevant issues (e.g. interoperability, data privacy) and to implement achieved agreements*
- *confirmation of own contributions (e.g. continued operation of data integration solutions, continued collaboration after the funding period to ensure sustainability of the Digital Hub)*
- *willingness of all data providing hub partners to continuously provide all partners with the data access necessary for the use cases*

4. Commitments of Hub Partners

5. Commitments of Third Parties

6. CVs/Bio-sketches for each Partner

Include CVs or bio-sketches along with the 5 most important publications with regard to the hub concept (1 page/person). Additionally, in case of patent applications relevant to the project aims, please indicate patent number/issue date or application serial number/application date, ideally with a link to the respective data base.